



Health Evidence Review Commission's Value-based Benefits Subcommittee

November 18, 2021

8:00 AM - 1:00 PM

Online Meeting

[Join online meeting here](#)

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Section 1.0

Call to Order

AGENDA
VALUE-BASED BENEFITS SUBCOMMITTEE
11/18/2021

8:00am - 1:00pm

[Virtual Meeting](#)

All times are approximate

Note: public testimony on specific agenda topics will be taken at the time that agenda item is discussed

- | | | |
|-------------|--|-----------------|
| I. | Call to Order, Roll Call, Approval of Minutes – Kevin Olson | 8:00 AM |
| II. | Staff report – staff | 8:05 AM |
| | A. Errata | |
| III. | Straightforward/Consent agenda – Ariel Smits | 8:15 AM |
| | A. Consent table | |
| | B. Straightforward guideline note changes | |
| IV. | COVID-19 Coding Updates | 8:20 AM |
| | A. New COVID-19 codes | |
| V. | Advisory Panel Reports | 8:30 AM |
| | A. GAP | |
| | A. Expanded carrier screening | |
| | 1. Updates to the prenatal and non-prenatal genetic testing guidelines | |
| | B. Whole genome sequencing | |
| | C. Updates to the Hereditary Cancer Genetic Testing Guideline | |
| | B. OHAP | |
| | A. 2022 CDT code placements | |
| | B. Porcelain crowns | |
| | C. Non-restorative caries treatment | |
| | D. Orthodontia for handicapping malocclusion | |
| | E. D0190 dental screening | |
| | C. BHAP | |
| | A. Nightmare disorder | |
| | B. SUD waiver HCPCS review | |
| | C. Selective mutism | |
| | BREAK | |
| VI. | 2022 Coding Placements | 10:15 AM |
| | A. 2022 CPT codes | |

- A. Straightforward code placements
- B. Codes requiring minimal discussion
- C. Left atrial appendage exclusion
- D. Cerebral embolic protection devices
- E. Drug induced sleep endoscopy
- F. Peroral endoscopic myotomy (POEM)
- G. Periurethral transperineal adjustable balloon continence device
- H. Laser interstitial thermal therapy (LITT)
 - I. Hypoglossal nerve stimulator
 - J. Thermal destruction of intraosseous basivertebral nerve
- K. Drug-eluting lacrimal canaliculus stents
- L. Trabecular bone score
- M. Genetics related code
- N. Laboratory studies
- O. New vaccine codes
- P. Remote therapeutic monitoring
- B. 2022 HCPCS codes**

BREAK

- | | | |
|--------------|--|-----------------|
| VII. | New Discussion Topics <ul style="list-style-type: none"> A. Deletion of duplicate angioedema line B. Platelet rich plasma C. Radiofrequency ablation and cryotherapy for select renal cell cancers D. Pelvic congestion syndrome E. Cyanoacrylate vein ablation F. Breast reconstruction after lumpectomy G. Breast MRI guidelines H. Modify SO14 to add childhood growth and development | 11:45 AM |
| VIII. | Public comment | 12:55 PM |
| IX. | Adjournment – Kevin Olson | 1:00 PM |

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on October 7, 2021

For specific coding recommendations and guideline wording, please see the text of the 10/7/2021 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Add several new COVID-related vaccine and treatment codes to covered lines
- Add codes to the preventive services line to allow falls prevention services
- Add several diagnosis and procedure codes to a covered line to allow treatment of acquired penile anomalies
- Add the procedure code for neurectomy for wrist arthritis to a covered line
- Add the diagnosis code for vitiligo to a covered line
- Make various straightforward coding changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- No change in current non-coverage of wireless capsule endoscopy for esophageal or gastrointestinal motility indications
- No expansion of current coverage of continuous glucose monitoring was recommended
- No change in the current limitations on diabetic test strips was recommended
- No changes were made to lack of coverage of cranial electrical stimulation
- No change was made to lack of coverage for minimally invasive lumbar decompression for spinal stenosis
- No change was made to lack of coverage for interspinous/interlaminar process spacer devices
- No changes were made to lack of coverage of various interventions for treatment of acute and chronic pain

RECOMMENDED GUIDELINE CHANGES (changes to the 1/1/22 Prioritized List unless otherwise noted)

- Edit the neuropsychological testing guideline to specify that patients being considered for epilepsy surgery could be tested as part of their pre-operative work up to determine surgical candidacy
- Edit the preventive services guideline to specify coverage of falls prevention programs
- Edit the penile anomalies guideline to specify coverage for acquired anomalies after surgeries if specific criteria are met
- Add a new guideline regarding when neurectomy for wrist arthritis is covered
- Edit the severe inflammatory skin disease guideline to include vitiligo
- Edit the guideline on kyphoplasty and vertebroplasty to specify how long a patient needed to be treated with conservative management
- Make several straightforward guideline changes

VALUE-BASED BENEFITS SUBCOMMITTEE

Online meeting

October 7, 2021

8:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair (arrived 8:30 AM); Holly Jo Hodges, MD, MBA, Vice-chair; Cris Pinzon, MPH, BSN, BS, RN; Kathryn Schabel, MD; Brian Duty, MD (arrived 9:00 AM); Mike Collins; Adriane Irwin, PharmD.

Members Absent: Regina Dehen, ND, Lac.

Staff Present: Ariel Smits, MD, MPH; Jason Gingerich; Liz Walker, PhD, MPH; Daphne Peck.

Also Attending: Bethany Godlewski (OHSU Center for Evidence-based Policy); Brandon Fair; Chris Tanaka (DEXCOM); Christine Fallabel; Cindy Seger; Dave Inbody (Oregon Health Authority) Jay Halaj; Josh Briley; Julie Dhossche (OHSU); Liz Custer; Paul Konovodoff; Renee Taylor; Sabra Leitenberger; Scott Bowen; Vishal Khemlani; YJ Shukla; Elena Burns.

➤ Roll Call/Minutes Approval/Staff Report

The meeting was called to order at 8:05 am and roll was called. A quorum of members was present at the meeting. Minutes from the August 12, 2021 VbBS meeting were reviewed and approved.

Gingerich reported to the VBBS that staff had conducted a claims analysis to determine whether select elective procedures reduced due to the smoking cessation and elective procedures ancillary guideline and found no major changes after guideline implementation.

Gingerich announced several open positions on HERC and its subcommittees and asked members to let colleagues and contacts know about the vacancies and encourage applications.

Gingerich clarified current coverage on breast electrolysis for gender dysphoria. He also reported on the pending new conflicts-of-interest rule from September's rules advisory committee.

David Inbody, Oregon Health Authority (OHA)'s CCO Operations Manager, gave a presentation on In Lieu of Services (ILOS). Members had a robust discussion of the Prioritized List's role in helping CCOs decide which ILOS to pursue. Inbody clarified that this new option will be available to CCOs beginning in 2022.

There were no errata to report.

➤ **Topic: Straightforward/Consent Agenda**

Discussion: There was no discussion about the consent agenda items.

Recommended Actions:

- 1) Remove CPT 64792 (Excision of neurofibroma or neurolemmoma; extensive) from lines 207 DEEP OPEN WOUND, WITH OR WITHOUT TENDON OR NERVE INVOLVEMENT and 528 DEFORMITIES OF UPPER BODY AND ALL LIMBS
 - a. Add 64792 to line 199 CANCER OF SOFT TISSUE
- 2) Add CPT 45800 (Closure of rectovesical fistula) to line 230 URINARY FISTULA
- 3) Add CPT 95873 (Electrical stimulation for guidance in conjunction with chemodenervation) and 95874 (Needle electromyography for guidance in conjunction with chemodenervation) to line 410 MIGRAINE HEADACHES
- 4) Modify Ancillary Guideline A4 as shown in Appendix A
- 5) Modify Guideline Note 173 as shown in Appendix A
- 6) Add CPT 30520 (Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft) to line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
- 7) Add ICD-10-CM Q67.4 (Other congenital deformities of skull, face and jaw) to line 577 DEVIATED NASAL SEPTUM, ACQUIRED DEFORMITY OF NOSE, OTHER DISEASES OF UPPER RESPIRATORY TRACT
- 8) Modify Guideline Note 118 as shown in Appendix A

MOTION: To approve the recommendations stated in the consent agenda. **CARRIES 6-0.** (*Absent: Duty*)

➤ **Topic: COVID-19 Coding Updates**

Discussion: Smits reviewed the summary document. There was no discussion.

Recommended Actions:

- 1) Add CPT 0013A (IMM ADMN SARSCOV2 100 MCG/0.5 ML 3RD DOSE) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 2) Add HCPCS M0240 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring, subsequent repeat doses) and M0241 (Intravenous infusion or subcutaneous injection, casirivimab and imdevimab includes infusion or injection, and post administration monitoring in the home or residence, this includes a beneficiary's home that has been made provider-based to the hospital during the covid-19 public health emergency, subsequent repeat doses) to line 399 INFLUENZA, COVID-19 AND OTHER NOVEL RESPIRATORY VIRAL ILLNESS
- 3) Add CDT D0606 (molecular testing for a public health-related pathogen, including coronavirus) to the Diagnostic Procedure File
- 4) Add the following CDT codes to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
 - a. D1701 Pfizer-BioNTech COVID-19 vaccine administration — first dose
 - b. D1702 Pfizer-BioNTech COVID-19 vaccine administration — second dose
 - c. D1703 Moderna COVID-19 vaccine administration — first dose

- d. D1704 Moderna COVID-19 vaccine administration — second dose
- e. D1705 AstraZeneca COVID-19 vaccine administration — first dose
- f. D1706 AstraZeneca COVID-19 vaccine administration — second dose
- g. D1707 Janssen COVID-19 vaccine administration

MOTION: To recommend the code changes as presented. CARRIES 6-0. (Absent: Duty)

➤ **Topic: Clarification of when neuropsychological testing is covered prior to epilepsy surgery**

Discussion: Smits reviewed the summary document. There was minimal discussion on this topic.

Recommended Actions:

- 1) Modify Diagnostic Guideline D26 as shown in Appendix A

MOTION: To recommend the guideline note change as presented. CARRIES 7-0.

➤ **Topic: Fall prevention programs**

Discussion: Smits reviewed the summary document. The discussion centered around the fact that people younger than age 65 can be at risk for falls due to medication or other reasons. There are standardized tools such as the STEADI that can identify people at risk for falls, or providers can identify patients based on their specific disease, having a facility fracture, or by other means. The group requested that the guideline wording be expanded to include patients younger than 65 at increased risk of falls.

Recommended Actions:

- 1) Add HCPCS S9451 (Exercise classes, non-physician provider, per session) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
- 2) Modify Guideline Note 106 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as amended. CARRIES 7-0.

➤ **Topic: Continuous glucose monitoring**

Discussion: Smits reviewed the summary document. Smits noted that after the meeting materials had been sent out, there was a CCO request to clarify the continuous glucose monitoring (CGM) guideline to specify that CGM is not covered for type 2 diabetes or gestational diabetes; the group felt that this change was appropriate. There was discussion about whether CGMs could be covered in certain clinical situations; Hodges replied that medical directors can look at case by case requests and approve by exception if medically justified.

Recommended Actions:

- 1) Modify Guideline Note 108 as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 7-0.

➤ **Topic: Limits on diabetic test strips**

Discussion: Smits reviewed the summary document. Olson noted that OHP is more limiting on test strips than Medicare. No change to current limitations on diabetic test strips was recommended.

➤ **Topic: Treatment of acquired penile anomalies**

Discussion: Smits reviewed the summary document. Duty noted that the guideline would apply to adults as well as children who meet criteria. This was felt to be appropriate.

Recommended Actions:

- 1) Add to line 424 COMPLICATIONS OF A PROCEDURE USUALLY REQUIRING TREATMENT
 - a. CPT 54162 (Lysis or excision of penile post-circumcision adhesions)
 - b. ICD-10-CM N48.89 (Other specified disorders of penis)
 - c. ICD-10-CM T81.9XXA (Unspecified complication of procedure, initial encounter)
 - d. ICD-10-CM N48.83 (Acquired buried penis)
- 2) Modify Guideline Note 73 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. **CARRIES 7-0.**

➤ **Topic: Neurectomy for wrist arthritis**

Discussion: Smits reviewed the summary document. There was a question about whether this service is available in Oregon. Schabel reported that it is widely done by hand surgeons as an alternative to wrist fusion.

Recommended Actions:

- 1) Add CPT 64772 (Transection or avulsion of other spinal nerve, extradural) to line 356 RHEUMATOID ARTHRITIS, OSTEOARTHRITIS, OSTEOCHONDritis DISSEANS, AND ASEPTIC NECROSIS OF BONE Treatment: ARTHROPLASTY/ RECONSTRUCTION
- 2) Add a new guideline to line 356 as shown in Appendix B

MOTION: To recommend the code and guideline note changes as presented. **CARRIES 7-0.**

➤ **Topic: Cranial electrical stimulation**

Discussion: Smits reviewed the summary document.

Public testimony

- 1) Josh Briley, PhD, Science and Education Director for EPI (manufacturer), clinical psychologist: Dr. Briley testified regarding his experience using Alpha Stim to treat thousands of patients. He noted that the HERC staff literature reviewed included only a small portion of the literature on Alpha Stim. He personally has seen clinically significant improvement in depression, anxiety and insomnia. User surveys show very significant improvement in symptoms as well. Alpha Stim is

very safe, side effect rate is <1% and are mild and self-limiting. This technology is also less expensive than extensive therapy and has fewer side effects than medications. It also works faster than therapy.

- 2) Jay Halaj, PhD, Senior Consultant for Allevia Health (manufacturer): Dr. Halaj testified that the Portland VA and other VAs cover Alpha Stim. Hundreds of practitioners use this device and thousands of patients are using it. After about 20 minutes of using the device, patients have a response and are able to push through barriers in processing trauma. It brings on a sense of calm and reduces arousal. Device use can avoid costly emergency visits for situations like panic attacks. It's also especially useful in addition treatment as a non-chemical way to reduce anxiety and insomnia from treatment in that population.

Pinzon asked the presenters if the VA has done studies on the outcomes of Alpha Stim. The response was that the VA has only done small pilot studies. The group felt that larger studies were feasible and needed before this technology should be considered for adoption to the Prioritized List.

Recommended Actions:

- 1) Modify Guideline Note 173 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 6-0. (Abstained: Pinzon)

➤ **Topic: Minimally invasive lumbar decompression for spinal stenosis**

Discussion: Smits reviewed the summary document.

Public Testimony

- 1) Vishal Khemlani, MD, anesthesiologist, Vertos Medical affiliate (manufacturer): Dr. Khemlani gave a brief presentation of the MILD procedure and said he has done over 150 procedures. His presentation gave an overview of the procedure's effectiveness and included patient success stories.
- 2) Paul Konovodoff, Director for Market Access, Vertos Medical (manufacturer): Mr. Konovodoff began his testimony by addressing cost of the MILD procedure, stating the procedure has a Medicare cost of \$4,000 for an ambulatory surgical center, or \$6200 for hospitals charges and \$600-700 cost for the physician fee. He said that the MILD procedure is covered for 92 million lives, including many commercial lives. He said 41,000 procedures have been done nationwide and 1500 certified providers are currently doing this procedure, 15 or 20 of which are in Oregon. Ohio and Illinois Medicaid have recently added coverage. MILD has been FDA approved since 2005.

The subcommittee discussed whether there are active trials ongoing, and the testifiers indicated there are ongoing trials. Schabel asked about the risk of needing spine surgery after the 5 years the patients were observed in the studies. Khemlani stated that the effects seemed to last in his experience. He noted that the Cleveland Clinic study included in the staff review was following

patients who were initially in the MIDAS study, and so may have been followed for more than 5 years.

Schabel expressed concern that this procedure was being introduced into a patient care area in which there is no current surgical interventions. The patients that were studied for MILD were probably not candidates for fusion, and their only other options would be conservative therapy and epidural steroid injections. This makes MILD a new treatment paradigm, which may introduce more care than these patients needed.

Olson expressed concern that the patient sample sizes were small.

Schabel asked Konovodoff when he expected a non-experimental CPT or HCPCS code for the procedure to be issued; Konovodoff stated that his company is not pursuing a Category 1 CPT code designation.

Recommended Actions:

- 1) Add CPT 0275T and HCPCS G0276 to Line 662
- 2) Modify Guideline Note 173 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

➤ **Topic: Interspinous/interlaminar process spacer devices**

Discussion: Smits reviewed the summary document. There was no significant discussion on this topic.

Recommended Actions:

- 1) Modify Guideline Note 173 as shown in Appendix A

MOTION: To recommend the guideline note changes as presented. CARRIES 7-0.

➤ **Topic: Vitiligo**

Discussion: Smits reviewed the summary document.

Public testimony

Drs. Julie Dhossche and Sara Leitenberger, OHSU pediatric dermatology: Dr. Dhossche began the brief invited presentation by declaring no conflicts of interest. She gave an overview on vitiligo, current therapies for repigmentation, and maintenance therapies.

The subcommittee discussed whether any step therapy requirements would be appropriate. The group decided since the only medications currently used are topical/oral steroids and tacrolimus, it was felt that step therapy would not need to be spelled out. There was also discussion about this condition being an equity issue, as it affect persons with more pigmented/darker skin to a higher degree. There was discussion about if a patient only receives partial remission with therapy, if that would be enough to reduce anxiety, depression or other negative consequences. The experts stated that in their experience, even some reduction in depigmentation can have a large effect on

psychological outcomes. Leitenberger stated that reduction of depigmentation to a small area allows the use of cosmetics or other products to cover up the area.

Recommended Actions:

- 1) Add ICD-10 L80 (Vitiligo) to line 426 SEVERE INFLAMMATORY SKIN DISEASE
- 2) Modify Guideline Note 21 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0. (*Absent: Duty*)

➤ **Topic: Interventional therapies for treatment of acute and chronic pain**

Discussion: Smits reviewed the summary documents. There was no discussion of the treatments with no evidence of effectiveness.

For the kyphoplasty and vertebroplasty summary, Hodges noted that NICE, AAOS and other groups require a 4-to-6-week trial of conservative management prior to kyphoplasty and vertebroplasty. The group agreed to add this requirement to the guideline.

There was minimal discussion regarding radiofrequency denervation for sacroiliac pain.

Recommended Actions:

- 1) Add CPT 64555 (Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)) to line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
- 2) Modify Guideline Note 173 as shown in Appendix A
- 3) Modify Guideline Note 37 as shown in Appendix A
- 4) Modify Guideline Note 109 as shown in Appendix A

MOTION: To recommend the guideline note changes as amended. CARRIES 7-0.

➤ **Public Comment:**

No additional public comment was received.

➤ **Next meeting:**

November 18, 2021 as a virtual meeting

➤ **Adjournment:**

The meeting adjourned at 1:05 PM.

Appendix A

Revised Guideline Notes

ANCILLARY GUIDELINE A4, SMOKING CESSATION AND ELECTIVE SURGICAL PROCEDURES

Surgical consultation is covered for patients who actively smoke and who are referred for surgical consultations; if elective surgery is recommended based on a consultation, the requirements of this guideline note apply.

Smoking cessation is required prior to elective surgical procedures for active tobacco users. Cessation is required for at least 4 weeks prior to the procedure and requires objective evidence of abstinence from smoking prior to the procedure.

Elective surgical procedures in this guideline are defined as surgical procedures which are flexible in their scheduling because they do not pose an imminent threat nor require immediate attention within 1 month. Procedures for contraceptive/sterilization purposes, procedures targeted to active cancers (i.e. when a delay in the procedure could lead to cancer progression), and diagnostic procedures, and bloodless surgery (e.g. cataract surgery, certain skin procedures) are not subject to the limitations in this guideline note. This guideline applies regardless of procedure location and anesthesia type.

The well-studied tests for confirmation of smoking cessation include cotinine levels and exhaled carbon monoxide testing. However, cotinine levels may be positive in nicotine replacement therapy (NRT) users, smokeless tobacco and e-cigarette users (which are not contraindications to elective surgery coverage). In patients using nicotine products aside from combustible cigarettes the following alternatives to urine cotinine to demonstrate smoking cessation may be considered:

- Exhaled carbon monoxide testing
- Anabasine or anatabine testing (NRT or vaping)

Certain procedures, such as lung volume reduction surgery, bariatric surgery, erectile dysfunction surgery, and spinal fusion have 6 month tobacco abstinence requirements. See Guideline Notes 8, 100, 112 and 159.

DIAGNOSTIC GUIDELINE D26, NEUROBEHAVIORAL STATUS EXAMS AND NEUROPSYCHOLOGICAL TESTING

Neurobehavioral status exams (CPT 96116 and 96121) and neuropsychological testing services (CPT 96132 and 96133) are only covered when all of the following are met:

- A) Symptoms are not explained by an existing diagnosis; AND
- B) When the results of such testing will be used to develop a care plan.

OR when neuropsychological testing is done as part of the pre-operative evaluation prior to epilepsy surgery as part of the process to determine if the patient is an appropriate surgical candidate or post-operative follow up after epilepsy surgery.

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 426,482,504,532,541,656

Inflammatory skin conditions included in this guideline are:

Appendix A

- A) Psoriasis
- B) Atopic dermatitis
- C) Lichen planus
- D) Darier disease
- E) Pityriasis rubra pilaris
- F) Discoid lupus
- G) [Viteligo](#)

The conditions above are included on Line 426 if severe, defined as having functional impairment as indicated by Dermatology Life Quality Index (DLQI) ≥ 11 or Children's Dermatology Life Quality Index (CDLQI) ≥ 13 (or severe score on other validated tool) AND one or more of the following:

- A) At least 10% of body surface area involved
- B) Hand, foot, [face](#), or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 482, 504, 532, 541 and 656.

For severe psoriasis, first line agents include topical agents, phototherapy and methotrexate. Second line agents include other systemic agents and oral retinoids and should be limited to those who fail, or have contraindications to, or do not have access to first line agents. Biologics are included on this line only for the indication of severe plaque psoriasis; after documented failure of first line agents and failure of (or contraindications to) a second line agent.

For severe atopic dermatitis/eczema, first-line agents include topical moderate- to high- potency corticosteroids and narrowband UVB. Second line agents include topical calcineurin inhibitors (e.g. pimecrolimus, tacrolimus), topical phosphodiesterase (PDE)-4 inhibitors (e.g. crisaborole), and oral immunomodulatory therapy (e.g. cyclosporine, methotrexate, azathioprine, mycophenolate mofetil, or oral corticosteroids). Use of the topical second line agents (e.g. calcineurin inhibitors and phosphodiesterase (PDE)-4 inhibitors) should be limited to those who fail or have contraindications to first line agents. Biologic agents are included on this line for atopic dermatitis only after failure of or contraindications to at least one agent from each of the following three classes: 1) moderate to high potency topical corticosteroids, 2) topical calcineurin inhibitors or topical phosphodiesterase (PDE)-4 inhibitors, and 3) oral immunomodulator therapy.

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,529

Spine surgery is included on Line 346 only in the following circumstances:

- A) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
 - 1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND
 - 2) Has neurogenic claudication OR
 - 3) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
 - a) Markedly abnormal reflexes
 - b) Segmental muscle weakness
 - c) Segmental sensory loss

Appendix A

- d) EMG or NCV evidence of nerve root impingement
- e) Cauda equina syndrome
- f) Neurogenic bowel or bladder
- g) Long tract abnormalities

Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.

- B) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
- 1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
 - 2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
 - 3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation
- corticosteroid injections for cervical pain
- [intradiscal injections, including platelet rich plasma, stem cells, methylene blue, or ozone](#)

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

The development of this guideline note was informed by HERC coverage guidances on [Percutaneous Interventions for Low Back Pain](#), [Percutaneous Interventions for Cervical Spine Pain](#), [Low Back Pain: Corticosteroid Injections](#) and [Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions](#). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

GUIDELINE NOTE 73, PENILE ANOMALIES

Lines [424](#), [433](#), [571](#), [658](#)

[Congenital a](#)nomalies of the penis (ICD-10-CM Q54.4, Q55.5 and Q55.6) are included on Line 433 only when they

- A. Are associated with hypospadias, OR

Appendix A

- B. Result in documented urinary retention, OR
 - C. Result in repeated urinary tract infections, OR
 - D. Result in recurrent infections such as meatitis or balanitis, OR
 - E. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
 - F. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion, OR
 - G. Involve aplasia/congenital absence of the penis.
- Otherwise, these diagnoses are included on Line 658

Acquired anomalies of the penis (ICD-10-CM N48.83, N48.89 or T81.9XXA) are included on line 424 only when they are the result of a prior penile procedure AND either

- A. Result in a skin bridge. OR
- B. Result in a buried penis; OR
- C. Are associated with hypospadias, OR
- D. Result in documented urinary retention, OR
- E. Result in repeated urinary tract infections, OR
- F. Result in recurrent infections such as meatitis or balanitis, OR
- G. Involve 35 degrees of curvature or greater for conditions resulting in lateral or ventral curvature, OR
- H. Involve 60 degrees of rotation or greater for conditions resulting in penile torsion.

Otherwise, these diagnoses are included on line 571 or 658.

GUIDELINE NOTE 106, PREVENTIVE SERVICES

Lines 3,622

Included on Line 3 are the following preventive services:

- A) US Preventive Services Task Force (USPSTF) “A” and “B” Recommendations in effect and issued prior to January 1, ~~2021~~ 2020.
 - 1) <http://www.uspreventiveservicestaskforce.org/Page/Name/uspstf-a-and-b-recommendations/>
 - a) Treatment of falls prevention with exercise interventions is included on Line 292.
 - 2) USPSTF “D” recommendations are not included on this line or any other line of the Prioritized List.
- B) American Academy of Pediatrics (AAP) Bright Futures Guidelines:
 - 1) <http://brightfutures.aap.org>. Periodicity schedule available at [http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity Schedule FINAL.pdf](http://www.aap.org/en-us/professional-resources/practice-support/Periodicity/Periodicity%20Schedule_FINAL.pdf).
 - a) Bright Futures is the periodicity schedule for screening for EPSDT for the Oregon Health Plan.
 - 2) Screening for lead levels is defined as blood lead level testing and is indicated for Medicaid populations at 12 and 24 months. In addition, blood lead level screening of any child between ages 24 and 72 months with no record of a previous blood lead screening test is indicated.
- C) Health Resources and Services Administration (HRSA) Women’s Preventive Services-Required Health Plan Coverage Guidelines as updated by HRSA in December 2019. Available at <https://www.hrsa.gov/womens-guidelines-2019> as of September 4, 2020.

Appendix A

- D) Immunizations as recommended by the Advisory Committee on Immunization Practices (ACIP): <http://www.cdc.gov/vaccines/schedules/hcp/index.html> or approved for the Oregon Immunization Program: <https://public.health.oregon.gov/PreventionWellness/VaccinesImmunization/ImmunizationProviderResources/Documents/DMApVactable.pdf>

- 1) COVID-19 vaccines are intended to be included on this line even if the specific administration code(s) do not yet appear on the line when the vaccine has both 1) FDA approval or FDA emergency use authorization (EUA) and 2) ACIP recommendation.

Colorectal cancer screening is included on Line 3 for average-risk adults aged 45 to 75, using one of the following screening programs:

- A) Colonoscopy every 10 years
- B) Flexible sigmoidoscopy every 5 years
- C) Fecal immunochemical test (FIT) every year
- D) Guaiac-based fecal occult blood test (gFOBT) every year

CT colonography CPT 74263), FIT-DNA (CPT 81528) and mSEPT9 (HCPCS G0327) are included on line 502 CONDITIONS FOR WHICH INTERVENTIONS RESULT IN MARGINAL CLINICAL BENEFIT OR LOW COST-EFFECTIVENESS.

Colorectal cancer screening for average-risk adults aged 76 to 85 is covered only after informed decision making between patients and clinicians which includes consideration of the patient's overall health, prior screening history, and preferences.

Supervised evidence-based exercise programs for fall prevention for persons age 65 and older OR younger patients who are at increased risk of falls are included on line 3 using CPT 98961 or 98962 or HCPCS S9451. HCPCS S9451 is only included on Line 3 for the provision of supervised exercise therapy for fall prevention. Programs should be culturally tailored/culturally appropriate when feasible.

Note: CPT code 96110 (Developmental screening (eg, developmental milestone survey, speech and language delay screen), with scoring and documentation, per standardized instrument) can be billed in addition to other CPT codes, such as evaluation and management (E&M) codes or preventive visit codes.

The development of this guideline note was informed by a HERC [coverage guidance](https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

GUIDELINE NOTE 108, CONTINUOUS GLUCOSE MONITORING

Line [1](#), [8](#), [27](#)

Real-time (personal) continuous glucose monitoring (CGM) is included on Line 8 for:

- A) Adults with type 1 diabetes mellitus not on insulin pump management:
 - 1) Who have received or will receive diabetes education specific to the use of CGM AND
 - 2) Who have used the device for at least 50% of the time at their first follow-up visit AND
 - 3) Who have baseline HbA1c levels greater than or equal to 8.0%, frequent or severe hypoglycemia, or impaired awareness of hypoglycemia (including presence of these conditions prior to initiation of CGM).
- B) Adults with type 1 diabetes on insulin pump management (including the CGM-enabled insulin pump):

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- 1) Who have received or will receive diabetes education specific to the use of CGM AND
- 2) Who have used the device for at least 50% of the time at their first follow-up visit.
- C) Women with type 1 diabetes who are pregnant or who plan to become pregnant within six months without regard to HbA1c levels.
- D) Children and adolescents under age 21 with type 1 diabetes:
 - 1) Who have received or will receive diabetes education specific to the use of CGM AND
 - 2) Who have used the device for at least 50% of the time at their first follow-up visit.

CPT 95250 and 95251 (Ambulatory continuous glucose monitoring) are included on this line for services related to real-time continuous glucose monitoring but not retrospective (professional) continuous glucose monitoring.

[Continuous glucose monitors are not covered for people with type 2 diabetes or gestational diabetes.](#)

The development of this guideline note was informed by a HERC [coverage guidance](#). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

GUIDELINE NOTE 109, VERTEBROPLASTY, KYPHOPLASTY, AND SACROPLASTY

Line 478

Vertebroplasty and kyphoplasty are not included on this line (or any other line) for the treatment of routine osteoporotic compression fractures.

Vertebroplasty and kyphoplasty are only included on this line for the treatment of vertebral osteoporotic compression fractures when they are considered non-routine and meet all of the following conditions:

- A) The patient is hospitalized under inpatient status due to pain that is primarily related to a well-documented acute fracture, and
- B) The severity of the pain prevents unassisted ambulation, and
- C) The pain is not adequately controlled with oral or transcutaneous medication, and
- D) The patient must have failed an appropriate [4-to-6 week](#) trial of conservative management.

Sacroplasty is not included on these or any lines of the Prioritized List for coverage consideration.

The development of this guideline note was informed by a HERC [coverage guidance](#). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

GUIDELINE NOTE 118 SEPTOPLASTY

Lines 42,119,246,287,465,506,525,[577](#)

Septoplasty is included on these lines when

- A) The septoplasty is done to address symptomatic septal deviation or deformity which
 - 1) Fails to respond to a minimum 6 week trial of conservative management (e.g. nasal corticosteroids, decongestants, antibiotics); AND
 - 2) Results in one or more of the following:
 - a. Persistent or recurrent epistaxis, OR

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- b. Documented recurrent sinusitis felt to be due to a deviated septum and the patient meets criteria for sinus surgery in Guideline Note 35, SINUS SURGERY;
OR
 - c. Nasal obstruction with documented absence of other causes of obstruction likely to be responsible for the symptoms (for example, nasal polyps, tumor, etc.) [note: this indication is included only on line ~~506~~577]; OR
- B) Septoplasty is performed in association with cleft lip or cleft palate repair or repair of other congenital craniofacial anomalies; OR
- C) Septoplasty is performed as part of a surgery for a neoplasm or facial trauma involving the nose.

Septoplasty is not covered for obstructive sleep apnea.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
0275T	Percutaneous laminotomy/laminectomy (interlaminar approach) for decompression of neural elements (with or without ligamentous resection, discectomy, facetectomy and/or foraminotomy), any method under indirect image guidance (eg, fluoroscopic, CT), single or multiple levels, unilateral or bilateral; lumbar	Insufficient evidence of effectiveness	October 2021
G0276	Blinded procedure for lumbar stenosis, PILD, or placebo control, performed in an approved coverage with evidence development (CED) clinical trial		
22867-22870	Insertion of interlaminar/ interspinous process stabilization/ distraction device, without fusion, including image guidance when performed, with open decompression, lumbar	Insufficient evidence of effectiveness	November, 2016 October 2021
C1821	Interspinous process distraction device (implantable)		

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Procedure Code	Intervention Description	Rationale	Last Review
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve)	Insufficient evidence of effectiveness	October 2021
64625	Anesthetic or steroid injection and/or radiofrequency ablation, nerves innervating the sacroiliac joint, with image guidance	Insufficient evidence of effectiveness	November 2019 October 2021
64633-64634	Radiofrequency ablation of the cervical and thoracic spine	Insufficient evidence of benefit	March, 2015 October 2021
64635-64636 C9752, C9753	Radiofrequency ablation of the lumbar and sacral spine	Insufficient evidence of benefit	November, 2014 Coverage guidance October 2021
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	March 2020 October 2021
90875-90876 90901	Individual psychophysiological therapy incorporating biofeedback training by any modality Biofeedback training by any modality	Insufficient evidence of effectiveness	January 2021
91111	Capsule endoscopy, esophagus	No Insufficient evidence of effectiveness	December, 2012 October 2021
91112	Gastrointestinal transit and pressure measurement	Insufficient evidence of effectiveness	December, 2012 October 2021
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; Scrambler therapy; all similar transcutaneous electrical neurostimulation therapies	Insufficient evidence of effectiveness for chronic pain and all other indications	January 2020 for TENS October 2021 for cranial electrical stimulation

Appendix A

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Appendix B

New Guideline Notes

GUIDELINE NOTE XXX PARTIAL WRIST NEURECTOMY

Line 356

CPT 64772 is only included on this line for partial wrist neurectomy and is only covered when the alternative is wrist arthrodesis.

DRAFT

Section 2.0

Consent Agenda-

Straightforward Items

Errata
November 2021

1) On October 27, 2021, two corrections were made to line titles:

- a. Restored correct name for two hernia lines
 - i. Line 168 COMPLICATED HERNIAS; UNCOMPLICATED INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER; PERSISTENT HYDROCELE.
 - ii. Line 524 UNCOMPLICATED HERNIA AND VENTRAL HERNIA (OTHER THAN INGUINAL HERNIA IN CHILDREN AGE 18 AND UNDER OR DIAPHRAGMATIC HERNIA)

(The line titles that appeared were based on a biennial review change regarding inguinal and femoral hernia coverage; those descriptions will appear on the 1/1/2022 Prioritized List.

Consent Agenda Issues—November 2021

Code	Code Description	Line(s) Involved	Issue	Recommendation(s)
20680	Removal of implant; deep (eg, buried wire, pin, screw, metal band, nail, rod or plate)	359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS	20680 is currently on multiple lines. HSD is requesting it be added to line 359 to allow removal of acromial clavicular hook plate	Add 20680 to line 359

November 2021
Straightforward Guideline Note Changes

We received a request to clarify whether patients who are being considered for an artificial disc in Guideline Note 101 need to meet the criteria for fusion surgery in Guideline Note 37. Guideline Note 101 currently states that “Artificial disc replacement (CPT 22856-22865) is included on Line 346 as an alternative to fusion.” Guideline Note 37 contains all the criteria for qualifying for a fusion. Per GN37: “Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met: 1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR 2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR 3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)”. A CCO asked for clarification on how these two guidelines relate to one another.

As part of this review, HERC staff noted that GN37 could be clarified to improve its usability

- 1) HERC staff recommendations:
 - a. Modify GN 101 as shown below
 - b. Modify GN37 as shown below

GUIDELINE NOTE 101, ARTIFICIAL DISC REPLACEMENT

Lines 346,529

Artificial disc replacement (CPT 22856-22865) is included on Line 346 as an alternative to fusion [for patients who meet criteria for spinal fusion procedures as defined in Guideline Note 37](#) only when all of the following criteria are met:

Lumbar artificial disc replacement

- A) Patients must first complete a structured, intensive, multi-disciplinary program for management of pain, if covered by the agency;
- B) Patients must be 60 years or under;
- C) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
 - Failure of at least six months of conservative treatment
 - Skeletally mature patient
 - Replacement of a single disc for degenerative disc disease at one level confirmed by patient history and imaging

Cervical artificial disc replacement

- D) Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:
 - Skeletally mature patient
 - Reconstruction of a single disc following single level discectomy for intractable symptomatic cervical disc disease (radiculopathy or myelopathy) confirmed by patient findings and imaging.

Otherwise, artificial disc replacement is included on Line 529.

Artificial disc replacement combined with fusion in a single procedure (hybrid procedure) is not covered.

November 2021
Straightforward Guideline Note Changes

The development of this guideline note was informed by a HERC [coverage guidance](https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

GUIDELINE NOTE 37, SURGICAL INTERVENTIONS FOR CONDITIONS OF THE BACK AND SPINE OTHER THAN SCOLIOSIS

Lines 346,529

Spine surgery is included on Line 346 only in the following circumstances:

- 1) Decompressive surgery is included on Line 346 to treat debilitating symptoms due to central or foraminal spinal stenosis, and only when the patient meets the following criteria:
 - 1) Has MRI evidence of moderate or severe central or foraminal spinal stenosis AND [either](#)
 - [a\)](#) Has neurogenic claudication OR
 - [b\)](#) Has objective neurologic impairment consistent with the MRI findings. Neurologic impairment is defined as objective evidence of one or more of the following:
 - [i\)](#) Markedly abnormal reflexes
 - [ii\)](#) Segmental muscle weakness
 - [iii\)](#) Segmental sensory loss
 - [iv\)](#) EMG or NCV evidence of nerve root impingement
 - [v\)](#) Cauda equina syndrome
 - [vi\)](#) Neurogenic bowel or bladder
 - [vii\)](#) Long tract abnormalities
- Foraminal or central spinal stenosis causing only radiating pain (e.g. radiculopathic pain) is included only on Line 529.
- 2) Spinal fusion procedures are included on Line 346 for patients with MRI evidence of moderate or severe central spinal stenosis only when one of the following conditions are met:
 - 1) spinal stenosis in the cervical spine (with or without spondylolisthesis) which results in objective neurologic impairment as defined above OR
 - 2) spinal stenosis in the thoracic or lumbar spine caused by spondylolisthesis resulting in signs and symptoms of neurogenic claudication and which correlate with xray flexion/extension films showing at least a 5 mm translation OR
 - 3) pre-existing or expected post-surgical spinal instability (e.g. degenerative scoliosis >10 deg, >50% of facet joints per level expected to be resected)

For all other indications, spine surgery is included on Line 529.

The following interventions are not included on these lines due to lack of evidence of effectiveness for the treatment of conditions on these lines, including cervical, thoracic, lumbar, and sacral conditions:

- local injections (including ozone therapy injections)
- botulinum toxin injection
- intradiscal electrothermal therapy
- therapeutic medial branch block
- coblation nucleoplasty
- percutaneous intradiscal radiofrequency thermocoagulation
- percutaneous laser disc decompression
- radiofrequency denervation

November 2021
Straightforward Guideline Note Changes

- corticosteroid injections for cervical pain

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529. Diagnostic anesthetic injections for selective nerve root blocks are included on Line 529 for lumbar or sacral symptoms.

The development of this guideline note was informed by HERC coverage guidances on [Percutaneous Interventions for Low Back Pain](#), [Percutaneous Interventions for Cervical Spine Pain](#), [Low Back Pain: Corticosteroid Injections](#) and [Low Back Pain: Minimally Invasive and Non-Corticosteroid Percutaneous Interventions](#). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>

Section 3.0

Covid coding

COVID-19 Related Codes

November 2021

Issues:

- 1) Multiple new codes were added for COVID vaccines effective September 3, 2021, October 6, 2021, or October 20, 2021. These codes are for booster shots for Pfizer (standard dose), Moderna (low dose), Janssen (J&J) vaccines, a new formulation of the Pfizer vaccine (tris-sucrose), and lower dose pediatric Pfizer (age 5-11) vaccines. These codes will become active with FDA EUA or approval.

HERC staff recommendations:

CPT Code	Code Description	Recommended Placement
0004A	Pfizer-Biontech Covid-19 Vaccine Administration – Booster	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
91307	Pfizer COVID-19 vaccine pediatric (age 5-11) dosage	3
0071A	Pfizer COVID-19 vaccine pediatric dosage 1 ST dose	3
0072A	Pfizer COVID-19 vaccine pediatric dosage 2 ND dose	3
91305	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) tris-sucrose formulation	3
0051A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - First dose	3
0052A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation - Second dose	3
0053A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – third dose	3
0054A	Pfizer-Biontech Covid-19 Vaccine (Ready to Use) Administration tris-sucrose formulation – Booster	3
91306	Moderna Covid-19 Vaccine (Low Dose) –Booster dose	3
0064A	Moderna Covid-19 Vaccine (Low Dose) Administration – Booster dose	3
0034A	Janssen Covid-19 Vaccine (Low Dose) Administration - Booster dose	3

Section 4.0

New Discussion Items

Prenatal/Preconception Genetic Testing GAP 2021

Issues:

- 1) The prenatal genetic testing guideline has been criticized as being not equitable due to requirements for patients to know their family history to qualify for certain screening tests. In January 2021, HERC removed the requirement to be of Ashkenazi Jewish heritage to get related disease screening, due to the lack of knowledge of ethnic background in some patients. In March 2021, HERC made additional revisions to guideline note D17, removing duplicate language for Tay-Sachs carrier status and removing the requirements related to personal and family history for fragile X conditions as well as the limitation limiting screening hemoglobinopathies to those from high-risk ethnic groups. These changes appear on the October 1, 2021 Prioritized List.
- 2) Similar changes to remove requirements for family/ethnic history need to be made to the non-prenatal genetic testing guideline for pre-conception testing. Other changes need to be made, specifically:
 - a. The preconception testing clauses are spread throughout this guideline, and need to be brought together for clarity.
 - b. Several tests are included in the prenatal genetic testing guideline that should be added to the preconception testing section created above (Fragile X and hemoglobinopathies)
 - c. GAP input: the GAP members recommended striking the “once in a lifetime” limit for preconception/carrier screening as it is difficult to operationalize and new testing techniques and treatments frequently require repeat testing.

GAP recommended changes to the non-prenatal genetic testing guideline are shown below after the initial discussion of this topic. Final recommended changes are shown in the expanded carrier screening topic summary.

HERC staff/GAP recommendations:

There are no recommendations in this summary. Please see the expanded carrier screening summary for final recommendations on modifications to Diagnostic Guideline D1. The changes shown below are reflective of the discussion on this topic at GAP prior to the expanded carrier screening discussion.

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

- A) Genetic tests are covered as diagnostic, unless they are listed below in section E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
 - 1) Change treatment,
 - 2) Change health monitoring,
 - 3) Provide prognosis, or
 - 4) Provide information needed for genetic counseling for patient; or patient’s parents, siblings, or children
- B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.

**Prenatal/Preconception Genetic Testing
GAP 2021**

- 1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.
- D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index < 70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
 - 1) CPT 81228 and 81229, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
 - 2) CPT 81243, 81244, 81171, 81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 3) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- E) Related to preconception testing/carrier screening:
 - 1) The following tests are covered for a pregnant patient or patient contemplating pregnancy. They are covered for the male reproductive partner only if the female partner is found to be a carrier.
 - a) CPT 81220-81224, Carrier testing for cystic fibrosis: CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics*
 - b) CPT 81243, 81244, 81171, 81172 Fragile X carrier screening
 - c) CPT 81248, G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
 - d) CPT 81329, Screening for spinal muscular atrophy.
 - e) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255). Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
 - f) CPT 83020, 83021 Screening for hemoglobinopathies
- F) Related to other tests with specific CPT codes:
 - 1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS

**Prenatal/Preconception Genetic Testing
GAP 2021**

- 2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
- a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
 - i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - ~~c) Carrier testing for cystic fibrosis~~
 - ~~i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.~~
 - d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg, cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg, male infertility): Covered only after genetic counseling.
 - e) CPT 81225-81227, 81230-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding medications when not required in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).
 - f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
 - g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
 - h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
 - i) After G6PD enzyme activity testing is done and found to be normal; AND either
 - (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
 - (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.

**Prenatal/Preconception Genetic Testing
GAP 2021**

- i) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
- j) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
 - i) after G6PD enzyme activity has been tested, and
 - ii) the requirements under CPT 81247 above have been met, and
 - iii) common variants (CPT 81247) have been tested for and not found.
- k) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
- m) ~~CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier~~
- n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
- o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
- p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
- q) ~~CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.~~

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 7/2018 and found at <http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf>

Expanded Carrier Screening

VBBS November 2021

Question: Should expanded carrier screening be readdressed by HERC for coverage?

Question source: PowersLaw, Inc/Access to Equitable Carrier Screening Coalition

Issue: Coverage of expanded carrier screening was discussed by GAP at their 2018 and 2020 meetings. The GAP recommended that it be covered at both of these prior meetings. Subsequently, VBBS/HERC review resulted in continued non-coverage. The major concerns of VBBS/HERC included:

- 1) Coverage for partners. Partners should only be tested for the few genes that mom tested positive for.
- 2) There was general concern about how to interpret the results. The VBBS members felt that the interpretation would be difficult for most maternity care providers, and that patients should have genetic counseling with this test, which is a limited resource. There was discussion about unintended harm of too much genetic information being given to patients with an unclear idea of how to deal with this information.
- 3) There was concern over interventions that might be done that might not be needed, or additional testing done that might not be needed. Medicaid is a vulnerable population and needs protections in place.
- 4) There was also concern about how to control the quality of which genes are included in the panel, to ensure that all include genes are recommended by ACOG guidelines.
- 5) At the 2020 and 2021 discussion of expanded carrier screening, various maternity care providers were surveyed. General obstetricians and certified nurse midwives indicated that they did not want to provide expanded carrier screening as they felt uncomfortable interpreting the test results. In contrast, high-risk OBs and geneticists felt that expanded carrier screening was desirable.

Of note, expanded carrier screening was reviewed in 2014 as part of a coverage guidance on prenatal testing. It received a weak recommendation for non-coverage.

Based on the 2020/2021 VBBS and HERC discussions on this topic, multiple changes were made to the prenatal and the non-prenatal genetic testing guidelines to remove ethnicity requirements for carrier screening, partially as a response to the concerns raised by the Access to Expanded Carrier Screening Coalition (not the Access to Equitable Carrier Screening Coalition).

The PowersLaw firm and the Access to Equitable Carrier Screening Coalition have requested a re-review of the VBBS/HERC decisions from 2018 and 2020/2021. This group notes:

“Since the October 2020 GAP meeting and the 2021 VbBS and HERC meetings, the American College of Medical Genetics and Genomics (ACMG) released their updated Practice Resource on carrier screening for autosomal recessive and X-linked conditions. ACMG guidance specifically no longer recommends an initial approach to carrier screening focused solely on cystic fibrosis, spinal muscular atrophy, or ethnicity because it does not provide equitable evaluation. Instead, ACMG recommends all pregnant patients and those planning pregnancy should be offered carrier screening for conditions with a carrier frequency of $>1/200$, which encompasses 100+ inheritable autosomal recessive and X-linked conditions, and that payers should provide coverage for this level of carrier screening. This recommendation replaces ACMG’s previous guidance and position statements on prenatal/preconception expanded carrier screening from more than a decade ago.”

Expanded Carrier Screening

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Current Prioritized List status:

CPT **81443** (Genetic testing for severe inherited conditions (eg, cystic fibrosis, Ashkenazi Jewish-associated disorders [eg, Bloom syndrome, Canavan disease, Fanconi anemia type C, mucopolipidosis type VI, Gaucher disease, Tay-Sachs disease], beta hemoglobinopathies, phenylketonuria, galactosemia), genomic sequence analysis panel, must include sequencing of at least 15 genes)

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
81443	Expanded carrier screening	Insufficient evidence of effectiveness	November, 2018

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

- A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
- B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- C) Validated questionnaire to assess genetic risk in all pregnant women
- D) Screening for hemoglobinopathies (CPT 83020, 83021)
- E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, -81510, 81511, 81420, 81507, 81512, 82105, 82677,84163)
- F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
- G) CVS or amniocentesis (CPT 59000, 59015, 76945,76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289,88291) for a positive aneuploidy screen, maternal age >34, fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.
- H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.
- I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- J) Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)
- K) Screening for fragile X status (CPT 81243, 81244, 81171. 81172) once in a lifetime
- L) Screening for spinal muscular atrophy (CPT 81329) once in a lifetime
- M) Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412)

Expanded Carrier Screening

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is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.

N) Expanded carrier screening only for those genetic conditions identified above

The following genetic screening tests are not covered:

A) Serum triple screen

B) Expanded carrier screening which includes results for conditions not explicitly recommended for coverage

The development of this guideline note was informed by a HERC [coverage guidance](https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>.

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Expert guidelines

- 1) **ACMG 2021** Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics
 - a. Carrier screening enables those screened to consider their reproductive risks, reproductive options, and to make informed decisions.
 - b. Published evidence supports clinical utility for carrier screening of multiple conditions simultaneously
 - c. Carrier screening paradigms should be ethnic and population neutral and more inclusive of diverse populations to promote equity and inclusion
 - d. All pregnant patients and those planning a pregnancy should be offered Tier 3 carrier screening.
 - i. Tier 3 screening includes testing for all genes with $\geq 1/200$ carrier frequency including X-linked conditions
 - e. ACMG does not recommend: Offering Tier 1 [cystic fibrosis and spinal muscle atrophy and risk based screening] and/or Tier 2 screening [$\geq 1/100$ carrier frequency], because these do not provide equitable evaluation of all racial/ethnic groups.
 - f. All pregnant patients and those planning a pregnancy should be offered Tier 3 carrier screening for autosomal recessive and X-linked conditions.
 - g. Reproductive partners of pregnant patients and those planning a pregnancy may be offered Tier 3 carrier screening for autosomal recessive conditions when carrier screening is performed simultaneously with their partner.
 - h. Regarding variants of uncertain significant (VUS)
 - i. Only pathogenic and likely pathogenic variants should be routinely reported
 - ii. The reporting of a VUS only in the partners of identified carriers and only with consent of the patient.
 - i. Education and counseling are critical in carrier screening. Informed decision making with carrier screening is complex and ideally should be a part of preconception care to allow any of the reproductive decision-making options. Health-care professionals should inform patients of the risks, benefits, and consequences of carrier screening. Carrier screening counseling should be provided by knowledgeable and appropriately trained health-care professionals and should be performed pre- and post-test.
- 2) **ACOG 2017** committee opinion **690** (reaffirmed in 2020) <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co690.pdf?dmc=1&ts=20181029T1555151910>
 - a. Ethnic-specific, panethnic, and expanded carrier screening are acceptable strategies for prepregnancy and prenatal carrier screening.
 - b. The disorders selected for inclusion should meet several of the following consensus-determined criteria: have a carrier frequency of 1 in 100 or greater, have well-defined phenotype, have a detrimental effect on quality of life, cause cognitive or physical impairment, require surgical or medical intervention, or have an onset early in life. Additionally, screened conditions should be able to be diagnosed prenatally and may afford opportunities for antenatal intervention to improve outcomes, changes to delivery management to optimize newborn and infant outcomes, and education of the parents about special needs after birth.
 - c. Carrier screening panels should not include conditions primarily associated with a disease of adult onset
 - d. Carrier screening panels have largely replaced more specific screening because of its efficacy and economy

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3) **ACOG 2017 committee opinion 691** <https://www.acog.org/-/media/Committee-Opinions/Committee-on-Genetics/co691.pdf?dmc=1&ts=20170808T1020526802>

- a. The cost of carrier screening for an individual condition may be higher than the cost of testing through commercially available expanded carrier screening panels

Other carrier policies

1) Cigna 2021

1. A multigene reproductive carrier screening panel with ≥ 15 genes to predict the risk of severe inherited disease is considered not medically necessary.

2) MODA 2021

1. Pregnancy related (or those planning to become pregnant, as applicable) for 1 or more of the following (a, b, or c):
 - a) Pregnant woman or couples planning pregnancy with a personal or family history of genetic disorder;
 - b) Pregnant woman or couples planning pregnancy with ancestry with high risk of genetic disorder that meet the specific criteria for the test (refer to Clinical Care Guidelines for specific conditions);
 - c) Testing of both parents (i.e. chromosome analysis, karyotype) after previous unexplained stillbirth, repeated (two or more) first trimester miscarriages, or previous child with abnormality.
 - d) Testing for Cystic Fibrosis (CF) and Spinal Muscular Atrophy (SMA) will be covered as part of standard care
 - e) The requested procedure or services are considered investigational if they are requested in a quantity or panel of services that may be individually proven but when performed as a group or panel, the evidence-based literature does not support the requested procedures or services.

GAP discussion:

GAP members felt strongly that expanded carrier screening should be covered. They recommended covering panels with genes with a carrier frequency of >1 in 200, which aligns with ACMG guidelines. The difference between panels covering genes with a carrier frequency of >1 in 100 vs 1 in 200 includes many genes/conditions that have effective treatments and have severe consequences if untreated, such as many metabolic syndromes. Members noted that expanded carrier screening can be more cost effective in many cases than looking for gene panels that contain the smaller numbers of genes that are currently allowed in the prenatal testing guideline. There was discussion that providers can order the panel size or individual tests that they are comfortable with. Coverage of expanded carrier screening would not require a provider who is uncomfortable with this type of testing to order this test. Variants of uncertain significance are rarely reported out by companies according to several of the genetic counselors on GAP. The group also suggested changing the staff suggested wording regarding genetic counseling “is required” to “must be offered” as more in line with ACMG and ACOG guidelines and that requiring testing would be too great a strain on the current genetic counselor workforce. It was also pointed out that it would be operationally difficult to determine if genetic counseling had been done prior to authorizing the test.

The group also discussed the structure of the rest of the prenatal genetic testing guideline. The current layout of the guideline puts the covered genetic tests in various areas. The group suggested putting

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them together in one section. It was also pointed out that the current coverage is the minimum testing that ACOG requires. The panel suggested that the section with the individual tests be labeled “ACOG required screening” or similar. The grouping should be mirrored in the non-prenatal genetic testing guideline preconception/carrier screening section.

GAP members requested striking the “once in a lifetime” requirement for testing similar to their request for this change with the preconception testing section of the non-prenatal genetic testing guideline. The group noted that the male partner should not have testing limited to just the genes that the female partner is found to carry. Such a limitation is impractical and could actually increase costs as panel testing is typically much less expensive than testing for individual genes.

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HERC staff summary

Since the January 2021 VBBS/HERC review, the American College of Medical Genetics has come out with an updated guideline which recommends expanded carrier screening. The guideline recommends pre- and post-test genetic counseling, which can be done by any appropriately trained health care professional. The guideline also recommends against reporting variants of uncertain significance. ACOG recommends ECS as one screening option, with inclusion only of genes with significant childhood disease potential. Private insurers with policies that could be identified by HERC staff do not cover expanded carrier screening; however, GAP members noted that most carriers in Oregon are actually covering this test.

HERC staff/GAP recommendation

- 1) Add expanded carrier screening (CPT 81443) with a requirement to offer for pre- and posttest genetic counseling.
 - a) Add CPT 81443 to the Diagnostic Procedures File and remove from line 662/GN173
 - b) Modify the prenatal and non-prenatal genetic testing guidelines as shown below

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
81443	Expanded carrier screening	Insufficient evidence of effectiveness	<u>November, 2018</u>

DIAGNOSTIC GUIDELINE D17, PRENATAL GENETIC TESTING

The following types of prenatal genetic testing and genetic counseling are covered for pregnant women:

- A) Genetic counseling (CPT 96040, HPCPS S0265) for high-risk women who have family history of inheritable disorder or carrier state, ultrasound abnormality, previous pregnancy with aneuploidy, or elevated risk of neural tube defect.
- B) Genetic counseling (CPT 96040, HPCPS S0265) prior to consideration of chorionic villus sampling (CVS), amniocentesis, microarray testing, Fragile X, and spinal muscular atrophy screening
- C) Validated questionnaire to assess genetic risk in all pregnant women
- D) ~~Screening for hemoglobinopathies (CPT 83020, 83021)~~
- E) Screening for aneuploidy with any of six screening strategies [first trimester (nuchal translucency, beta-HCG and PAPP-A), integrated, serum integrated, stepwise sequential, contingency, and cell free fetal DNA testing] (CPT 76813, 76814, 81508, -81510, 81511, 81420, 81507, 81512, 82105, 82677, 84163)
- F) Ultrasound for structural anomalies between 18 and 20 weeks gestation (CPT 76811, 76812)
- G) CVS or amniocentesis (CPT 59000, 59015, 76945, 76946, 82106, 88235, 88261-88264, 88267, 88269, 88280, 88283, 88285, 88289, 88291) for a positive aneuploidy screen, maternal age >34,

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fetal structural anomalies, family history of inheritable chromosomal disorder or elevated risk of neural tube defect.

- H) Array CGH (CPT 81228, 81229) when major fetal congenital anomalies are apparent on imaging, or with normal imaging when array CGH would replace karyotyping performed with CVS or amniocentesis in (H) above.
- I) FISH testing (CPT 88271, 88272, 88274, 88275, 81171, 81172) only if karyotyping is not possible due a need for rapid turnaround for reasons of reproductive decision-making (i.e. at 22w4d gestation or beyond)
- J) ~~Screening for cystic fibrosis carrier status once in a lifetime (CPT 81220-81224)~~
- K) ~~Screening for fragile X status (CPT 81243, 81244, 81171, 81172) once in a lifetime~~
- L) ~~Screening for spinal muscular atrophy (CPT 81329) once in a lifetime~~
- M) ~~Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay Sachs carrier status (CPT 81255) once in a lifetime. Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.~~
- N) Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
 - a. Screening for cystic fibrosis carrier status (CPT 81220-81224)
 - b. Screening for fragile X status (CPT 81243, 81244, 81171, 81172)
 - c. Screening for spinal muscular atrophy (CPT 81329)
 - d. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)- Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
 - e. Screening for hemoglobinopathies (CPT 83020, 83021)
- O) Expanded carrier screening (CPT 81443): ~~for those genetic conditions identified above~~ A genetic counseling/geneticist consultation must be offered prior to ordering test and after results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
 - a. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
 - b. the included genes have well-defined phenotype, AND
 - c. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
 - d. the included genes result in conditions have an onset early in life, AND
 - e. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.

The following genetic screening tests are not covered:

- A) Serum triple screen
- B) ~~Expanded carrier screening which includes results for conditions not explicitly recommended for coverage~~

The development of this guideline note was informed by a HERC [coverage guidance](https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx). See <https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx>.

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DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

- A) Genetic tests are covered as diagnostic, unless they are listed below in section E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:
 - 1) Change treatment,
 - 2) Change health monitoring,
 - 3) Provide prognosis, or
 - 4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children
- B) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
 - 1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- C) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.
- D) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index < 70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
 - 1) CPT 81228 and 81229, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
 - 2) CPT 81243, 81244, 81171, 81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 3) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- E) Related to preconception testing/carrier screening:
 - 1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
 - i. Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
 - 1. Screening for cystic fibrosis carrier status (CPT 81220-81224)
 - 2. Screening for fragile X status (CPT 81243, 81244, 81171, 81172)
 - 3. Screening for spinal muscular atrophy (CPT 81329)

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4. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255)- Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace and would be of similar or lower cost than individual gene testing including CF carrier testing.
 5. Screening for hemoglobinopathies (CPT 83020, 83021)
 - i. Expanded carrier screening (CPT 81443): A genetic counseling/geneticist consultation must be offered prior to ordering test and after test results are reported. Expanded carrier testing is ONLY covered when all of the following are met:
 1. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
 2. the included genes have well-defined phenotype, AND
 3. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
 4. the included genes result in conditions have an onset early in life, AND
 5. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.
- F) Related to other tests with specific CPT codes:
- 1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
 - 2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
 - a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
 - i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - ~~c) Carrier testing for cystic fibrosis~~
 - ~~i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.~~

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- d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.
- e) CPT 81225-81227, 81230-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labelling for that medication. These tests have unproven clinical utility for decisions regarding medications when not required in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).
- f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
 - i) After G6PD enzyme activity testing is done and found to be normal; AND either
 - (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
 - (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme Lyonization.
- i) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
- j) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
 - i) after G6PD enzyme activity has been tested, and
 - ii) the requirements under CPT 81247 above have been met, and
 - iii) common variants (CPT 81247) have been tested for and not found.
- k) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the anpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
- ~~m) CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier~~

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- n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test
- o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
- p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
- q) ~~CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.~~

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 7/2018 and found at <http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf>



ACMG PRACTICE RESOURCE

Screening for autosomal recessive and X-linked conditions during pregnancy and preconception: a practice resource of the American College of Medical Genetics and Genomics (ACMG)

Anthony R. Gregg¹, Mahmoud Aarabi^{2,3}, Susan Klugman⁴, Natalia T. Leach⁵, Michael T. Bashford⁶, Tamar Goldwaser^{7,8}, Emily Chen⁹, Teresa N. Sparks^{10,11}, Honey V. Reddi^{12,13}, Aleksandar Rajkovic^{10,11,14}, Jeffrey S. Dungan¹⁵ and ACMG Professional Practice and Guidelines Committee^{16*}

Disclaimer: This practice resource is designed primarily as an educational resource for medical geneticists and other clinicians to help them provide quality medical services. Adherence to this practice resource is completely voluntary and does not necessarily assure a successful medical outcome. This practice resource should not be considered inclusive of all proper procedures and tests or exclusive of other procedures and tests that are reasonably directed to obtaining the same results. In determining the propriety of any specific procedure or test, the clinician should apply his or her own professional judgment to the specific clinical circumstances presented by the individual patient or specimen.

Clinicians are encouraged to document the reasons for the use of a particular procedure or test, whether or not it is in conformance with this practice resource. Clinicians also are advised to take notice of the date this practice resource was adopted, and to consider other medical and scientific information that becomes available after that date. It also would be prudent to consider whether intellectual property interests may restrict the performance of certain tests and other procedures.

Carrier screening began 50 years ago with screening for conditions that have a high prevalence in defined racial/ethnic groups (e.g., Tay–Sachs disease in the Ashkenazi Jewish population; sickle cell disease in Black individuals). Cystic fibrosis was the first medical condition for which panethnic screening was recommended, followed by spinal muscular atrophy. Next-generation sequencing allows low cost and high throughput identification of sequence variants across many genes simultaneously. Since the phrase “expanded carrier screening” is nonspecific, there is a need to define carrier screening processes in a way that will allow equitable opportunity for patients to learn their reproductive risks using next-generation sequencing technology. An improved understanding of this risk allows patients to make informed reproductive decisions. Reproductive decision making is the established metric for clinical utility of population-based carrier screening. Furthermore, standardization of the screening approach will facilitate testing consistency. This practice resource reviews the current status of carrier screening, provides answers to some of the emerging questions, and recommends a consistent and equitable approach for offering carrier screening to all individuals during pregnancy or preconception.

Genetics in Medicine; <https://doi.org/10.1038/s41436-021-01203-z>

INTRODUCTION

Carrier screening is used to identify individuals or couples that are at risk to have a child with an autosomal recessive or X-linked genetic disorder. Throughout this document, the term “carrier” specifically refers to individuals who are heterozygous for a pathogenic or likely pathogenic variant in an autosomal recessive

or X-linked condition. Once identified, carriers of these disorders can become educated about their risks and consider a range of reproductive options. Historically, criteria for screening have included: phenotype severity that may impact decision making,^{1,2} high prevalence of carriers in the screened population,² established analytic validity of screening methods,^{2,3} predictable

¹Department of Obstetrics and Gynecology, Prisma Health, Columbia, SC, USA. ²Department of Laboratory Medicine and Pathobiology, University of Toronto, Toronto, ON, Canada. ³Genetics Program, North York General Hospital, Toronto, ON, Canada. ⁴Department of Obstetrics & Gynecology and Women’s Health, Montefiore Medical Center/Albert Einstein College of Medicine, Bronx, NY, USA. ⁵Laboratory Corporation of America, Westborough, MA, USA. ⁶Department of Obstetrics, Gynecology, and Reproductive Science, University of Pittsburgh Medical Center, Pittsburgh, PA, USA. ⁷Department of Obstetrics, Gynecology, and Reproductive Science, Mount Sinai School of Medicine, New York, NY, USA. ⁸Mount Sinai Hospital, New York, NY, USA. ⁹Department of Genetics, Kaiser Permanente Medical Center, San Francisco, CA, USA. ¹⁰Department of Obstetrics, Gynecology, & Reproductive Sciences, University of California, San Francisco, CA, USA. ¹¹Institute of Human Genetics, University of California, San Francisco, CA, USA. ¹²Department of Pathology and Laboratory Medicine and Surgery, Medical College of Wisconsin, Milwaukee, WI, USA. ¹³Genomic Sciences and Precision Medicine Center, Medical College of Wisconsin, Milwaukee, WI, USA. ¹⁴Department of Pathology, University of California, San Francisco, CA, USA. ¹⁵Department of Obstetrics and Gynecology, Northwestern University Feinberg School of Medicine, Chicago, IL, USA. ¹⁶American College of Medical Genetics and Genomics, Bethesda, MD, USA. *The Board of Directors of the American College of Medical Genetics and Genomics approved this practice resource on 12 April 2021. ✉email: documents@acmg.net

Whole Genome Sequencing
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Question: Should whole genome sequencing (WGS) be covered for testing children with clinical genetic abnormalities with no specific diagnosis?

Question source: Jim Gajewsky, MD; Illumina

Issue: Whole genome sequencing (WGS) is a laboratory test utilized to determine the arrangement (sequence) of an individual's entire genome at a single time. WGS allows the identification of mutations in the genome without having to target a gene or chromosome region based upon an individual's personal or family history. WGS is an alternative to whole exome sequencing (WES), in which only the part of the genome that codes for known transcribed genes is done. WES is currently covered as long as genetic counseling is done prior to testing.

Recently, Illumina contacted HERC staff to request a review of coverage of WGS. The company noted that WGS had not been reviewed since 2014, the science has advanced, and the costs have fallen over the past 7 years.

HERC history

Whole genome sequencing (CPT 81425-81427) was first reviewed as new CPT codes in 2014. At that time, GAP recommended placing on the Excluded List (later GN173) as the test was expensive and its clinical utility had not been established

Current Prioritized List status

CPT 81425 (Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis) and 81426 (Genome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (eg, parents, siblings) (List separately in addition to code for primary procedure)) are on line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS.

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
81425-81427	Genome sequence analysis	Insufficient evidence of effectiveness	November, 2014

Evidence

- 1) **ACMG 2021**, Systematic Evidence Review on whole exome (WES) and whole genome sequencing (WGS)
 - a. N=167 studies
 - i. Majority of studies were case reports or case series with small populations (N<20 patients)
 - ii. N=36 studies with sample size >20 patients (N ranged from 22 to 278)
 1. 27 studies on WES
 2. 7 studies on WGS
 3. 2 studies used both WES and WGS
 - b. Of the 167 included studies, 95% reported a change to patient or family clinical management
 - c. included studies documented a change in clinical management as a result of ES/GS, including change in medications, procedures, or referral to specialists. When considering the types of medical management decisions, more than half of patients experienced a reported clinical impact related to the ES/GS diagnosis. Likewise, more than half of larger included studies reported an impact of ES/ GS relating to the reproductive planning or decisions of patients' families, further expanding the usefulness of ES/GS beyond the patient. However, few studies describe beneficial health outcomes or improved quality of life resulting from ES/ GS for patients... Nonetheless, despite little direct evidence that ES/GS improved mortality or ameliorated morbidity, the studies included in this review provide indirect evidence of the clinical and personal utility of ES/GS for patients and their family members.
- 2) **MED 2018**, rapid review of whole genome sequencing
 - a. Clinical Validity and Utility
 - i. A good methodological quality systematic review concluded that there is no evidence on the clinical utility of WGS.
 1. No study compared health outcomes in patients who received WGS to patients who received other genetic testing or no testing
 - ii. A poor methodological quality study compared the diagnostic yield of WGS to other genetic testing methods in 103 children with symptoms suggestive of a chromosomal disorder but no genetic diagnosis.
 - iii. WGS identified diagnostic variants in 41% of children vs. 24% with conventional testing (p = .01).
 - iv. WGS also detected all variants detected by other methods, including whole exome sequencing (WES).
 - b. Harms
 - i. Center researchers identified no studies of the harms of WGS, but incidental or secondary findings (i.e., genetic variants unrelated or of unknown significance to the condition under suspicion) are a major concern.
 - c. Policies and Reimbursement
 - i. None of the private or public payer policies allowed coverage for WGS. CMS has not listed or provided guidance on a reimbursement rate for CPT code 81425.
- 2) **Costain 2020**, cohort study of whole genome sequencing for children with unexplained medical necessity
 - a. N=49 families with children with complex medical needs

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- b. Genome sequencing detected all genomic variation previously identified by conventional genetic testing. A total of 15 probands (30.6%; 95%CI 19.5%-44.6%) received a new primary molecular genetic diagnosis after genome sequencing. Three individuals had novel diseases and an additional 9 had either ultrarare genetic conditions or rare genetic conditions with atypical features. At least 11 families received diagnostic information that had clinical management implications beyond genetic and reproductive counseling
- c. The median number of conventional genetic tests per proband was 4 (range, 1-13), and a total of 232 tests were performed in this patient cohort
 - i. All 49 patients had had chromosomal microarray testing and 33 (67.3%) had undergone whole exome sequencing
- d. Trio genome-wide sequencing is associated with a higher diagnostic yield than only the proband undergoing sequencing
- a. Conclusions: Genome sequencing is a potentially first-tier genetic test for complex medical children

Other payer policies

Private payers (Cigna 2021, Wellmark BCBS 2021, Aetna 2021) did not cover WGS

Other Medicaid policies identified for WGS

1) **Michigan Medicaid** (August 2021 policy change)

- a. The Medicaid program covers medically necessary rapid whole genome sequencing (rWGS) for the evaluation of critically ill infants up to one year of age admitted to an inpatient intensive care unit including, but not limited to, a neonatal/pediatric intensive care unit (NICU/PICU), with a complex illness of unknown etiology.
- b. rWGS is medically necessary when **all** the following apply:
 - i. The beneficiary's signs or symptoms suggest a rare genetic condition that cannot be diagnosed by a standard clinical work-up;
 - ii. The beneficiary's signs and symptoms suggest a broad, differential diagnosis that could require multiple genetic tests if rWGS was not performed;
 - iii. Timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS results will guide the treatment and/or management of the beneficiary's condition; and
 - iv. At least **one** of the following clinical criteria apply to the beneficiary:
 - 1. Multiple congenital anomalies,
 - 2. Specific malformations highly suggestive of a genetic etiology
 - 3. An abnormal laboratory test suggests the presence of a genetic disease or complex metabolic phenotype (e.g., abnormal newborn screen, hyperammonemia, or lactic acidosis not due to poor perfusion),
 - 4. Refractory or severe hypoglycemia,
 - 5. Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems,
 - 6. Severe hypotonia,
 - 7. Refractory seizures,

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8. A high-risk stratification on evaluation for a Brief Resolved Unexplained Event (BRUE) with any of the following features:
 - a. Recurrent events without respiratory infection,
 - b. Recurrent witnessed seizure-like events, or
 - c. Required cardiopulmonary resuscitation (CPR),
 9. Abnormal chemistry levels (e.g., electrolytes, bicarbonate, lactic acid, venous blood gas, glucose) suggestive of inborn error of metabolism,
 10. Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease, or
 11. Family genetic history related to beneficiary's condition.
- c. rWGS must be ordered by the beneficiary's treating physician. Prior to ordering rWGS, the beneficiary must be evaluated by a medical geneticist or other physician sub-specialist including, but not limited to, a neonatologist or pediatric Intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered. The consultation must be documented in the beneficiary's medical record and if performed via telemedicine, should follow all the requirements specified in Medicaid's telemedicine policy.
- d. Pre- and post-test genetic counseling by an appropriate provider is also recommended.
- 2) **California Medicaid** **note: this is a bill from the California Legislature** December 2020
- a. Whole Genome Sequencing Pilot Project
 - i. Rapid Whole Genome Sequencing, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, is a covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit

GAP discussion

GAP members unanimously felt that some coverage of WGS should be allowed. It was noted that the cost of WGS has fallen dramatically, and is now similar to whole exome sequencing (WES) which is currently covered. Harding noted that WGS replaces microarray and whole exome testing, and allows much more rapid diagnosis. This is particularly important for critically ill newborns in the NICU.

It was pointed out by GAP members that WGS should be at least as effective as WES, as WGS includes all of WES as well as additional genetic material. Therefore, the lack of published studies on WGS does not mean it is not effective—its effectiveness can be extrapolated from the effectiveness of WES.

The group felt that WGS should be covered with a diagnostic guideline that allowed coverage for 1) critically ill newborns with likely genetic conditions and 2) older children if the test replaces whole exome sequencing or if the child had whole exome sequencing done at least 5 years ago that was non-diagnostic. Staff was directed to work with Stevens and Harding on actual wording of such a guideline.

Staff from Illumina, the company what does WGS, offered to forward other state Medicaid coverage policies to HERC staff.

After the meeting, staff obtained Medicaid coverage criteria for Michigan and California. Based on an email follow up exchange, the decision was to recommend coverage only for critically ill children under the age of 1 in the NICU/PICU.

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HERC staff summary

A recent MED review did not find evidence to support the use of whole genome sequencing. One small cohort study not included in the MED review found that 30% of medically complex children received a diagnosis using WGS when no diagnosis had been reached with chromosomal microarray testing or, in many cases, with whole exome sequencing. No private payer surveyed covered WGS.

The GAP was unanimously in favor of coverage of WGS in certain situations. GAP members felt the efficacy could be extrapolated from findings from WES, and that WGS had better diagnostic ability in certain circumstances. Two other state Medicaid programs were found that cover WGS, both of which limit coverage to critically ill children under the age of 1. This is the group that GAP felt most strongly about covering for this benefit.

HERC staff/GAP recommendation

- 1) Add coverage for whole genome sequencing (CPT 81425-81427)
 - a. Remove CPT 81425-81427 from line 662 and delete the entry from GN173
 - b. Add CPT 81425-81427 to DIAGNOSTIC PROCEDURES file
 - c. Add a clause to the non-prenatal genetic testing guideline as shown below
 - i. The clause alone is shown first for review; the entire guideline is shown second for completeness. Wording in purple is from changes suggested in the expanded carrier screening topic

GUIDELINE NOTE 173, INTERVENTIONS THAT ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS

Line 662

The following Interventions are prioritized on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS:

Procedure Code	Intervention Description	Rationale	Last Review
81425-81427	Genome sequence analysis	Insufficient evidence of effectiveness	November, 2014

Added clause to Diagnostic Guideline D1

- a) CPT 81425-81427, whole genome sequencing: testing is only covered when:
 - i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND
 - ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered

DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE

- B) Genetic tests are covered as diagnostic, unless they are listed below in section E1 as excluded or have other restrictions listed in this guideline. To be covered, initial screening (e.g. physical

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exam, medical history, family history, laboratory studies, imaging studies) must indicate that the chance of genetic abnormality is > 10% and results would do at least one of the following:

- 1) Change treatment,
 - 2) Change health monitoring,
 - 3) Provide prognosis, or
 - 4) Provide information needed for genetic counseling for patient; or patient's parents, siblings, or children
- C) Pretest and posttest genetic counseling is required for presymptomatic and predisposition genetic testing. Pretest and posttest genetic evaluation (which includes genetic counseling) is covered when provided by a suitable trained health professional with expertise and experience in genetics.
- 1) "Suitably trained" is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- D) A more expensive genetic test (generally one with a wider scope or more detailed testing) is not covered if a cheaper (smaller scope) test is available and has, in this clinical context, a substantially similar sensitivity. For example, do not cover CFTR gene sequencing as the first test in a person of Northern European Caucasian ancestry because the gene panels are less expensive and provide substantially similar sensitivity in that context.
- E) Related to diagnostic evaluation of individuals with intellectual disability (defined as a full scale or verbal IQ < 70 in an individual > age 5), developmental delay (defined as a cognitive index < 70 on a standardized test appropriate for children < 5 years of age), Autism Spectrum Disorder, or multiple congenital anomalies:
- 1) CPT 81228 and 81229, Cytogenomic constitutional microarray analysis: Cover for diagnostic evaluation of individuals with intellectual disability/developmental delay; multiple congenital anomalies; or, Autism Spectrum Disorder accompanied by at least one of the following: dysmorphic features including macro or microcephaly, congenital anomalies, or intellectual disability/developmental delay in addition to those required to diagnose Autism Spectrum Disorder.
 - 2) CPT 81243, 81244, 81171, 81172 Fragile X genetic testing is covered for individuals with intellectual disability/developmental delay. Although the yield of Fragile X is 3.5-10%, this is included because of additional reproductive implications.
 - 3) A visit with the appropriate specialist (often genetics, developmental pediatrics, or child neurology), including physical exam, medical history, and family history is covered. Physical exam, medical history, and family history by the appropriate specialist, prior to any genetic testing is often the most cost-effective strategy and is encouraged.
- F) Related to preconception testing/carrier screening:
- 1) The following tests are covered for a pregnant patient or patient contemplating pregnancy as well as the male reproductive partner:
 - i. Screening for genetic carrier status with the minimum testing recommended by the American College of Obstetrics and Gynecology:
 1. Screening for cystic fibrosis carrier status (CPT 81220-81224)
 2. Screening for fragile X status (CPT 81243, 81244, 81171, 81172)
 3. Screening for spinal muscular atrophy (CPT 81329)
 4. Screening for Canavan disease (CPT 81200), familial dysautonomia (CPT 81260), and Tay-Sachs carrier status (CPT 81255): Ashkenazi Jewish carrier panel testing (CPT 81412) is covered if the panel would replace

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and would be of similar or lower cost than individual gene testing including CF carrier testing.

5. Screening for hemoglobinopathies (CPT 83020, 83021)

- i. Expanded carrier screening (CPT 81443): A genetic counseling/geneticist consultation must be offered prior to ordering test and after test results are reported. Expanded carrier testing is ONLY covered when all of the following are met:

1. the panel includes only genes with a carrier frequency of ≥ 1 in 200 or greater, AND
2. the included genes have well-defined phenotype, AND
3. the included genes result in conditions have a detrimental effect on quality of life OR cause cognitive or physical impairment OR require surgical or medical intervention, AND
4. the included genes result in conditions have an onset early in life, AND
5. the included genes result in conditions that must be diagnosable prenatally to inform antenatal interventions and/or changes in delivery management and/or education of parents about special needs after birth.

G) Related to other tests with specific CPT codes:

- 1) Certain genetic tests have not been found to have proven clinical benefit. These tests are listed in Guideline Note 173, INTERVENTIONS THAT HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS FOR CERTAIN CONDITIONS; UNPROVEN INTERVENTIONS
- 2) The following tests are covered only if they meet the criteria in section A above AND the specified situations:
 - a) CPT 81205, BCKDHB (branched-chain keto acid dehydrogenase E1, beta polypeptide) (eg, Maple syrup urine disease) gene analysis, common variants (eg, R183P, G278S, E422X): Cover only when the newborn screening test is abnormal and serum amino acids are normal
 - b) Diagnostic testing for cystic fibrosis (CF)
 - i) CFTR, cystic fibrosis transmembrane conductance regulator tests. CPT 81220, 81221, 81222, 81223: For infants with a positive newborn screen for cystic fibrosis or who are symptomatic for cystic fibrosis, or for clients that have previously been diagnosed with cystic fibrosis but have not had genetic testing, CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220) is covered. If two mutations are not identified, CFTR full gene sequencing (CPT 81223) is covered. If two mutations are still not identified, duplication/deletion testing (CPT 81222) is covered. These tests may be ordered as reflex testing on the same specimen.
 - ~~c) Carrier testing for cystic fibrosis~~
 - ~~i) CFTR gene analysis of a panel containing at least the mutations recommended by the American College of Medical Genetics* (CPT 81220-81224) is covered once in a lifetime.~~
 - d) CPT 81224, CFTR (cystic fibrosis transmembrane conductance regulator) (eg. cystic fibrosis) gene analysis; introm 8 poly-T analysis (eg. male infertility): Covered only after genetic counseling.

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- e) CPT 81225-81227, 81230-81231 (cytochrome P450). Covered only for determining eligibility for medication therapy if required or recommended in the FDA labeling for that medication. These tests have unproven clinical utility for decisions regarding medications when not required in the FDA labeling (e.g. psychiatric, anticoagulant, opioids).
- f) CPT 81240. F2 (prothrombin, coagulation factor II) (eg, hereditary hypercoagulability) gene analysis, 20210G>A variant: Factor 2 20210G>A testing should not be covered for adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- g) CPT 81241. F5 (coagulation Factor V) (eg, hereditary hypercoagulability) gene analysis, Leiden variant: Factor V Leiden testing should not be covered for: adults with idiopathic venous thromboembolism; for asymptomatic family members of patients with venous thromboembolism and a Factor V Leiden or Prothrombin 20210G>A mutation; or for determining the etiology of recurrent fetal loss or placental abruption.
- h) CPT 81247. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; common variant(s) (eg, A, A-) should only be covered
 - i) After G6PD enzyme activity testing is done and found to be normal; AND either
 - (a) There is an urgent clinical reason to know if a deficiency is present, e.g. in a case of acute hemolysis; OR
 - (b) In situations where the enzyme activity could be unreliable, e.g. female carrier with extreme lyonization.
- i) CPT 81248. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; known familial variant(s) is only covered when the information is required for genetic counseling.
- j) CPT 81249. G6PD (glucose-6-phosphate dehydrogenase) (eg, hemolytic anemia, jaundice), gene analysis; full gene sequence is only covered
 - i) after G6PD enzyme activity has been tested, and
 - ii) the requirements under CPT 81247 above have been met, and
 - iii) common variants (CPT 81247) have been tested for and not found.
- k) CPT 81256, HFE (hemochromatosis) (eg, hereditary hemochromatosis) gene analysis, common variants (eg, C282Y, H63D): Covered for diagnostic testing of patients with elevated transferrin saturation or ferritin levels. Covered for predictive testing ONLY when a first degree family member has treatable iron overload from HFE.
- l) CPT 81332, SERPINA1 (serpin peptidase inhibitor, clade A, alpha-1 antiproteinase, antitrypsin, member 1) (eg, alpha-1-antitrypsin deficiency), gene analysis, common variants (eg, *S and *Z): The alpha-1-antitrypsin protein level should be the first line test for a suspected diagnosis of AAT deficiency in symptomatic individuals with unexplained liver disease or obstructive lung disease that is not asthma or in a middle age individual with unexplained dyspnea. Genetic testing of the alpha-1 phenotype test is appropriate if the protein test is abnormal or borderline. The genetic test is appropriate for siblings of people with AAT deficiency regardless of the AAT protein test results.
- ~~m) CPT 81329, Screening for spinal muscular atrophy: is covered once in a lifetime for preconception testing or testing of the male partner of a pregnant female carrier~~
- n) CPT 81415-81416, exome testing: A genetic counseling/geneticist consultation is required prior to ordering test

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- o) CPT 81430-81431, Hearing loss (eg, nonsyndromic hearing loss, Usher syndrome, Pendred syndrome); genomic sequence analysis panel: Testing for mutations in GJB2 and GJB6 need to be done first and be negative in non-syndromic patients prior to panel testing.
- p) CPT 81440, 81460, 81465, mitochondrial genome testing: A genetic counseling/geneticist or metabolic consultation is required prior to ordering test.
- q) ~~CPT 81412 Ashkenazi Jewish carrier testing panel: panel testing is only covered when the panel would replace and would be similar or lower cost than individual gene testing including CF carrier testing.~~
- r) CPT 81425-81427, whole genome sequencing: testing is only covered when:
 - i) The testing is for a critically ill infant up to one year of age admitted to an inpatient intensive care unit (NICU/PICU) with a complex illness of unknown etiology; AND
 - ii) Whole genome sequencing is recommended by a medical geneticist or other physician sub-specialist, including but not limited to a neonatologist or pediatric Intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered.

* American College of Medical Genetics Standards and Guidelines for Clinical Genetics Laboratories. 2008 Edition, Revised 7/2018 and found at <http://www.acmg.net/PDFLibrary/Cystic-Fibrosis-Population-Based-Carrier-Screening-Standards.pdf>



Original Investigation | Genetics and Genomics

Genome Sequencing as a Diagnostic Test in Children With Unexplained Medical Complexity

Gregory Costain, MD, PhD; Susan Walker, PhD; Maria Marano, MD; Danielle Veenma, MD, PhD; Meaghan Snell, MS; Meredith Curtis, BSc; Stephanie Luca, MA; Jason Buera; Danielle Arje, MSc; Miriam S. Reuter, MD; Bhooma Thiruvahindrapuram, MSc; Brett Trost, PhD; Wilson W. L. Sung, MSc; Ryan K. C. Yuen, PhD; David Chitayat, MD; Roberto Mendoza-Londono, MD; D. James Stavropoulos, PhD; Stephen W. Scherer, PhD; Christian R. Marshall, PhD; Ronald D. Cohn, MD; Eyal Cohen, MD; Julia Orkin, MD, MSc; M. Stephen Meyn, MD, PhD; Robin Z. Hayeems, PhD

Abstract

IMPORTANCE Children with medical complexity (CMC) represent a growing population in the pediatric health care system, with high resource use and associated health care costs. A genetic diagnosis can inform prognosis, anticipatory care, management, and reproductive planning. Conventional genetic testing strategies for CMC are often costly, time consuming, and ultimately unsuccessful.

OBJECTIVE To evaluate the analytical and clinical validity of genome sequencing as a comprehensive diagnostic genetic test for CMC.

DESIGN, SETTING, AND PARTICIPANTS In this cohort study of the prospective use of genome sequencing and comparison with standard-of-care genetic testing, CMC were recruited from May 1, 2017, to November 30, 2018, from a structured complex care program based at a tertiary care pediatric hospital in Toronto, Canada. Recruited CMC had at least 1 chronic condition, technology dependence (child is dependent at least part of each day on mechanical ventilators, and/or child requires prolonged intravenous administration of nutritional substances or drugs, and/or child is expected to have prolonged dependence on other device-based support), multiple subspecialist involvement, and substantial health care use. Review of the care plans for 545 CMC identified 143 suspected of having an undiagnosed genetic condition. Fifty-four families met inclusion criteria and were interested in participating, and 49 completed the study. Probands, similarly affected siblings, and biological parents were eligible for genome sequencing.

EXPOSURES Genome sequencing was performed using blood-derived DNA from probands and family members using established methods and a bioinformatics pipeline for clinical genome annotation.

MAIN OUTCOMES AND MEASURES The primary study outcome was the diagnostic yield of genome sequencing (proportion of CMC for whom the test result yielded a new diagnosis).

RESULTS Genome sequencing was performed for 138 individuals from 49 families of CMC (29 male and 20 female probands; mean [SD] age, 7.0 [4.5] years). Genome sequencing detected all genomic variation previously identified by conventional genetic testing. A total of 15 probands (30.6%; 95% CI 19.5%-44.6%) received a new primary molecular genetic diagnosis after genome sequencing. Three individuals had novel diseases and an additional 9 had either ultrarare genetic conditions or rare genetic conditions with atypical features. At least 11 families received diagnostic information that had clinical management implications beyond genetic and reproductive counseling.

(continued)

Key Points

Question What is the diagnostic yield of genome sequencing in children with unexplained medical complexity and prior negative results of genetic testing?

Findings In this cohort study that included 138 individuals from 49 families, genome sequencing detected all genomic variation previously identified by conventional genetic testing and resulted in a new diagnosis for 31% of patients.

Meaning This study suggests that, because of its high yield, comprehensive nature, and increasingly competitive costs, genome sequencing is a potentially first-tier genetic test for children with unexplained medical complexity.

+ Supplemental content

Author affiliations and article information are listed at the end of this article.

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Bulletin Number: MSA 21-33

Distribution: Hospitals, Laboratories, Medicaid Health Plans

Issued: August 17, 2021

Subject: Coverage of Rapid Whole Genome Sequencing (rWGS) Testing

Effective: As Indicated

Programs Affected: Medicaid, Healthy Michigan Plan, MICHild, Children's Special Health Care Services (CSHCS)

Note: Implementation of this policy is contingent upon approval of a State Plan Amendment (SPA) by the Centers for Medicare & Medicaid Services (CMS).

This bulletin establishes Medicaid coverage of Rapid Whole Genome Sequencing (rWGS) testing and provides a hospital reimbursement separate from the Diagnosis Related Group (DRG) payment. Effective for dates of service on or after September 1, 2021, separate reimbursement will be available for rWGS when clinical and authorization criteria are met. These changes are in response to Michigan Department of Health and Human Services (MDHHS) Fiscal Year budget appropriations in Public Act 166 of 2020, Section 1907, which provides rWGS for critically ill infants who meet established criteria. rWGS aims to assist clinicians with rapidly determining a diagnosis and limiting the number of unnecessary procedures performed on beneficiaries.

rWGS Coverage

The Medicaid program covers medically necessary rWGS for the evaluation of critically ill infants up to one year of age admitted to an inpatient intensive care unit including, but not limited to, a neonatal/pediatric intensive care unit (NICU/PICU), with a complex illness of unknown etiology.

rWGS is medically necessary when **all** the following apply:

- The beneficiary's signs or symptoms suggest a rare genetic condition that cannot be diagnosed by a standard clinical work-up;
- The beneficiary's signs and symptoms suggest a broad, differential diagnosis that could require multiple genetic tests if rWGS was not performed;
- Timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS results will guide the treatment and/or management of the beneficiary's condition; and
- At least **one** of the following clinical criteria apply to the beneficiary:
 - Multiple congenital anomalies,
 - Specific malformations highly suggestive of a genetic etiology,

- An abnormal laboratory test suggests the presence of a genetic disease or complex metabolic phenotype (e.g., abnormal newborn screen, hyperammonemia, or lactic acidosis not due to poor perfusion),
- Refractory or severe hypoglycemia,
- Abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems,
- Severe hypotonia,
- Refractory seizures,
- A high-risk stratification on evaluation for a Brief Resolved Unexplained Event (BRUE) with any of the following features:
 - Recurrent events without respiratory infection,
 - Recurrent witnessed seizure-like events, or
 - Required cardiopulmonary resuscitation (CPR),
- Abnormal chemistry levels (e.g., electrolytes, bicarbonate, lactic acid, venous blood gas, glucose) suggestive of inborn error of metabolism,
- Abnormal cardiac diagnostic testing results suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease, or
- Family genetic history related to beneficiary's condition.

Non-Covered rWGS

rWGS is not covered when one of the following reasons explains the beneficiary's admission:

- An infection or sepsis with normal response to therapy,
- Confirmed prenatal/postnatal genetic diagnosis consistent with the beneficiary's condition,
- Hypoxic-Ischemic Encephalopathy (HIE) with a clear precipitating event,
- Isolated prematurity,
- Isolated Transient Tachypnea of the Newborn (TTN),
- Isolated unconjugated hyperbilirubinemia,
- Nonviable neonates,
- Trauma, or
- Meconium aspiration.

Provider Requirements

rWGS must be ordered by the beneficiary's treating physician. Prior to ordering rWGS, the beneficiary must be evaluated by a medical geneticist or other physician sub-specialist including, but not limited to, a neonatologist or pediatric Intensivist with expertise in the conditions and/or genetic disorder for which testing is being considered. The consultation must be documented in the beneficiary's medical record and if performed via telemedicine, should follow all the requirements specified in Medicaid's telemedicine policy.

Pre- and post-test genetic counseling by an appropriate provider is also recommended.

Test Results

The purpose of rWGS is to identify a molecular diagnosis in a timely manner to directly support medical or surgical management and outcomes. In general, a preliminary test report from the performing laboratory should be provided to the beneficiary's ordering physician in less than seven days and a final report in less than 14 days. Hospitals should utilize laboratories whose average expected turnaround time for rWGS processing meets these established time frames.

Reference Laboratories

In the instance the hospital refers the beneficiary's specimen to a reference laboratory for rWGS testing, the hospital is required to bill Medicaid for rWGS services provided by the reference laboratory. The reference laboratory must hold the required Clinical Laboratory Improvement Amendments (CLIA) certification required to perform the test. The hospital and the reference laboratory must also have an agreement (as defined as "arrangement" in section 1861(w)(1) of the Social Security Act) to provide such services. The referring hospital is responsible for reimbursing the reference laboratory for the services.

Authorization

Authorization of rWGS is required for separate reimbursement. Authorization requests must be submitted to MDHHS within 30 days of the date of service using the Genetic and Molecular Laboratory Test Authorization Request form (MSA-2081), which can be accessed on the MDHHS website at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms >> Forms. Supporting clinical documentation must accompany the MSA-2081 and should clearly detail the medical necessity of the rWGS as defined in this policy. Providers should refer to the Authorization Requirements and Documentation subsection in the Laboratory Chapter of the [MDHHS Medicaid Provider Manual](#) for complete submission instructions. rWGS authorization requests received more than 30 days after the date of service or requests not approved by MDHHS will not be eligible for separate Medicaid reimbursement.

Hospitals must report the authorization number in the applicable form locator or loop for the claim to be paid. The information (e.g., authorization number, procedure code, modifier, and quantity) that was approved on the authorization should match the information on the claim form.

Billing and Reimbursement

Effective for dates of service on or after September 1, 2021, MDHHS will establish a separate payment methodology to reimburse hospitals for costs associated with rWGS testing when the test is provided in an inpatient hospital setting prior to discharge, clinical criteria are met, and MDHHS authorization is obtained.

To receive reimbursement for rWGS, the facility will be required to submit a separate invoice using the 837P or CMS-1500 Professional claim format. The hospital's National Provider Identifier (NPI) must be reported as the billing provider with place of service 21 (Inpatient Hospital) reported in the service location field/loop. The beneficiary's inpatient hospital

attending provider should be entered in the rendering provider form locator or loop, and the rWGS ordering provider should be reported in the ordering/referring provider locator or loop. If the applicable attending and ordering/referring provider information is not reported on the claim, or if these providers are not enrolled in the Michigan Medicaid program, the claim cannot be paid.

When billing for rWGS, the provider must use the following Current Procedural Terminology (CPT) procedure codes:

81425 - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis

81426 - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator genome (e.g., parents, siblings) (List separately in addition to code for primary procedure.)

0094U - Genome (e.g., unexplained constitutional or heritable disorder or syndrome); rapid sequence analysis Rady Children's Institute for Genomic Medicine (RCIGM) laboratories)

Payment for rWGS will be made in accordance with the Medicaid fee schedule in effect on the date-of-service for the procedure code(s) billed. Laboratory fee schedules are available on the MDHHS website at www.michigan.gov/medicaidproviders >> Billing & Reimbursement >> Provider Specific Information >> Laboratory.

Medicaid Health Plan (MHP) Carve Out

MHPs are not responsible for the additional rWGS payment. MDHHS will reimburse hospitals separately for rWGS for both Fee-For-Service (FFS) and MHP beneficiaries. Hospitals must request rWGS authorization and submit claims directly to the Community Health Automated Medicaid Processing System (CHAMPS) for both FFS and MHP beneficiaries. This policy does not change existing MHP payment liability.

Manual Maintenance

Retain this bulletin until the information is incorporated into the MDHHS Medicaid Provider Manual.

Questions

Any questions regarding this bulletin should be directed to Provider Inquiry, Department of Health and Human Services, P.O. Box 30731, Lansing, Michigan 48909-8231, or e-mailed to ProviderSupport@michigan.gov. When you submit an e-mail, be sure to include your name, affiliation, NPI number, and phone number so you may be contacted if necessary. Typical Providers may phone toll-free 1-800-292-2550. Atypical Providers may phone toll-free 1-800-979-4662.

An electronic version of this document is available at www.michigan.gov/medicaidproviders >> Policy, Letters & Forms.

Approved

A handwritten signature in black ink, appearing to read 'K. Massey', followed by a horizontal line.

Kate Massey, Director
Medical Services Administration



Systematic evidence-based review: outcomes from exome and genome sequencing for pediatric patients with congenital anomalies or intellectual disability

A full list of authors and affiliations appears at the end of the paper.

Disclaimer: The ACMG has recruited expert panels, chosen for their scientific and clinical expertise, to conduct systematic evidence reviews (SERs) to support the development of clinical practice guidelines. An SER focuses on a specific scientific question and then identifies, analyzes and summarizes the findings of relevant studies. ACMG SERs are provided primarily as educational resources for medical geneticists and other clinicians to help them provide quality medical services. They should not be considered inclusive of all relevant information on the topic reviewed.

Reliance on this SER is completely voluntary and does not necessarily assure a successful medical outcome. In determining the propriety of any specific procedure or test, the clinician should apply his or her own professional judgment to the specific clinical circumstances presented by the individual patient or specimen. Clinicians are encouraged to document the reasons for the use of a particular procedure or test, whether or not it is in conformance with this SER. Clinicians also are advised to take notice of the date this SER was published, and to consider other medical and scientific information that becomes available after that date.

Purpose: Exome and genome sequencing (ES/GS) are performed frequently in patients with congenital anomalies, developmental delay, or intellectual disability (CA/DD/ID), but the impact of results from ES/GS on clinical management and patient outcomes is not well characterized. A systematic evidence review (SER) can support future evidence-based guideline development for use of ES/GS in this patient population.

Methods: We undertook an SER to identify primary literature from January 2007 to March 2019 describing health, clinical, reproductive, and psychosocial outcomes resulting from ES/GS in patients with CA/DD/ID. A narrative synthesis of results was performed.

Results: We retrieved 2654 publications for full-text review from 7178 articles. Only 167 articles met our inclusion criteria, and these were primarily case reports or small case series of fewer than 20 patients. The most frequently reported outcomes from ES/GS were

changes to clinical management or reproductive decision-making. Two studies reported on the reduction of mortality or morbidity or impact on quality of life following ES/GS.

Conclusion: There is evidence that ES/GS for patients with CA/DD/ID informs clinical and reproductive decision-making, which could lead to improved outcomes for patients and their family members. Further research is needed to generate evidence regarding health outcomes to inform robust guidelines regarding ES/GS in the care of patients with CA/DD/ID.

Genetics in Medicine (2020) 22:986–1004; <https://doi.org/10.1038/s41436-020-0771-z>

Keywords: clinical genetics; exome sequencing; systematic evidence review; congenital anomalies; intellectual disability

INTRODUCTION

Exome and genome sequencing (ES/GS) are relatively new clinical diagnostic genetic testing platforms for identifying a genetic etiology among individuals with congenital anomalies (CA), developmental delay (DD), or intellectual disability (ID). CAs are structural or functional abnormalities usually evident at birth, or shortly thereafter, and can be consequential to an individual's life expectancy, health status, physical or social functioning, and typically require medical intervention. DD/ID are common features of a wide variety of genetic syndromes, or they could be isolated findings. Due to

phenotypic and genetic heterogeneity associated with CA/DD/ID, establishing a syndromic diagnosis based on clinical signs and symptoms can be challenging, particularly in the newborn period. Furthermore, some CAs may not be easily diagnosed in the newborn period but could contribute to a lifelong burden to affected children and families. Clinical genetic testing can assist clinicians in confirming or establishing a clinical diagnosis that may lead to changes in clinical management, obviate the need for further testing, or end the diagnostic odyssey, which may improve outcomes for the patient and family.

Correspondence: ACMG (documents@acmg.net)

These authors contributed equally: Jennifer Malinowski, David T. Miller

These authors contributed equally: Scott E. Hickey, Jun Shen

The Board of Directors of the American College of Medical Genetics and Genomics approved this systematic evidence review on 27 January 2020.

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NCCN Updates to the Hereditary Cancer Genetic Guideline

Issue: The NCCN references need to be updated in the hereditary cancer genetic testing guideline and the high risk breast cancer treatment guideline.

HERC staff recommendations:

- 1) Update the NCCN references as shown below in Guideline Note 3 and Diagnostic Guideline D25

GUIDELINE NOTE 3, PROPHYLACTIC TREATMENT FOR PREVENTION OF BREAST CANCER IN HIGH-RISK WOMEN

Line 191

Bilateral prophylactic breast removal and/or salpingo-oophorectomy are included on Line 191 for women without a personal history of invasive breast cancer who meet the criteria in the NCCN Clinical Practice Guidelines in Oncology. [Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic V1.2022 \(8/11/21\)](#) ~~Breast Cancer Risk Reduction, V.1.2020 (12/4/19)~~. www.nccn.org. Prior to surgery, women without a personal history of breast cancer must have a genetics consultation as defined in section A2 of the DIAGNOSTIC GUIDELINE D1, NON-PRENATAL GENETIC TESTING GUIDELINE.

Contralateral prophylactic mastectomy is included on Line 191 for women with a personal history of breast cancer.

Hysterectomy is only included on Line 191 for women with a BRCA1 pathogenic/likely pathogenic variant who undergo the procedure at the time of risk reducing salpingo-oophorectomy.

DIAGNOSTIC GUIDELINE D25, HEREDITARY CANCER GENETIC TESTING

Related to genetic testing for patients with breast/ovarian and colon/endometrial cancer or other related cancers suspected to be hereditary, or patients at increased risk to due to family history, services are provided according to the Comprehensive Cancer Network Guidelines.

- A) Lynch syndrome (hereditary colorectal, endometrial and other cancers associated with Lynch syndrome) services (CPT 81288, 81292-81300, 81317-81319, 81435, 81436) and familial adenomatous polyposis (FAP) services (CPT 81201-81203) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Colorectal [V1.2021 \(5/11/21\)](#) ~~V1.2020 (7/21/20)~~. www.nccn.org.
- B) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217) for patients without a personal history of breast, ovarian and other associated cancers should be provided to high-risk patients as defined by the US Preventive Services Task Force or according to the NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic [V1.2022 \(8/11/21\)](#) ~~V1.2021 (9/8/20)~~ www.nccn.org.
- C) Breast and ovarian cancer syndrome genetic testing services (CPT 81162-81167, 81212, 81215-81217)) for women with a personal history of breast, ovarian, or other associated cancers and for men with breast or other associated cancers should be provided according to the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Breast, Ovarian and Pancreatic [V1.2022 \(8/11/21\)](#) ~~V1.2021 (9/8/20)~~ www.nccn.org.
- D) PTEN (Cowden syndrome) services (CPT 81321-81323) should be provided as defined by the NCCN Clinical Practice Guidelines in Oncology. Genetic/Familial High-Risk Assessment: Ovarian and Pancreatic. [V1.2022 \(8/11/21\)](#) ~~V1.2021 (9/8/20)~~ or Genetic/Familial High-Risk Assessment: Colorectal [V1.2021 \(5/11/21\)](#) ~~V1.2020 (7/21/20)~~. www.nccn.org.

NCCN Updates to the Hereditary Cancer Genetic Guideline

Genetic counseling should precede genetic testing for hereditary cancer whenever possible.

- A) Pre and post-test genetic counseling should be covered when provided by a suitable trained health professional with expertise and experience in cancer genetics. Genetic counseling is recommended for cancer survivors when test results would affect cancer screening.
 - 1) “Suitably trained” is defined as board certified or active candidate status from the American Board of Medical Genetics, American Board of Genetic Counseling, or Genetic Nursing Credentialing Commission.
- B) If timely pre-test genetic counseling is not possible for time-sensitive cases, appropriate genetic testing accompanied by pre- and post- test informed consent and post-test disclosure performed by a board-certified physician with experience in cancer genetics should be covered.
 - 1) Post-test genetic counseling should be performed as soon as is practical.

If the mutation in the family is known, only the test for that mutation is covered. For example, if a mutation for BRCA 1 has been identified in a family, a single site mutation analysis for that mutation is covered (CPT 81215), while a full sequence BRCA 1 and 2 (CPT 81163) analyses is not. There is one exception, for individuals of Ashkenazi Jewish ancestry with a known mutation in the family, the panel for Ashkenazi Jewish BRCA mutations is covered (CPT 81212).

Costs for rush genetic testing for hereditary breast/ovarian and colon/endometrial cancer is not covered.

Hereditary breast cancer-related disorders genomic sequence analysis panels (CPT 81432, 81433, 81479) are only included for patients meeting the criteria for hereditary cancer syndrome testing per NCCN guidelines.

2022 CDT CODE REVIEW

CDT code	Code Description	Suggested Placements	Comments
D3911	intraorifice barrier	<p>384 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY)</p> <p>411 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY)</p> <p>444 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: BASIC ENDODONTICS (I.E., ROOT CANAL THERAPY)</p> <p>456 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT ANTERIOR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY)</p> <p>507 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT BICUSPID/PREMOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY)</p> <p>538 DENTAL CONDITIONS (E.G., PULPAL PATHOLOGY, PERMANENT MOLAR TOOTH) Treatment: ADVANCED ENDODONTICS (E.G., RETREATMENT OF PREVIOUS ROOT CANAL THERAPY)</p>	<p>From the American Association of Endodontics: A permanent restorative material is placed over the root canal obturation material... A temporary restoration is subsequently placed over the intraorifice barrier. The intraorifice barrier prevents ingress of bacterial contaminants into the canal if the coronal temporary restoration is dislodged or placement of the permanent restoration is delayed. The intraorifice barrier does not take the place of the final restoration.</p> <p>All lines with root canal therapy are suggested for placements.</p>
D3921	decoronation or submergence of an erupted tooth	<p>384, 411, 444, 456, 507, 538</p> <p>See proposed new guideline below</p>	<p>From the American Association of Endodontics: The requested endodontic code will address the intentional removal of the coronal tooth structure when preserving the root will facilitate maintenance or continued development of the bone around ankylosed or fractured teeth. Decoronation is also used following endodontic treatment when extraction is contraindicated</p>
D4322	splint – intra-coronal; natural teeth or prosthetic crowns	<p>492 DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)</p>	<p>Replacing D4321 (Provisional splinting-extracoronar) which was on line 492</p>

2022 CDT CODE REVIEW

CDT code	Code Description	Suggested Placements	Comments
D4323	splint – extra-coronal; natural teeth or prosthetic crowns	492 DENTAL CONDITIONS (E.G., PERIODONTAL DISEASE) Treatment: ADVANCED PERIODONTICS (E.G., SURGICAL PROCEDURES AND SPLINTING)	Replacing D4321 (Provisional splinting-extracoronaral) which was on line 492
D5227	immediate maxillary partial denture - flexible base (including any clasps, rests and teeth)	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES	Other flexible base dentures (D5225, D5226) are on line 646
D5228	immediate mandibular partial denture - flexible base (including any clasps, rests and teeth)	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: ELECTIVE DENTAL SERVICES	Other flexible base dentures (D5225, D5226) are on line 646
D5725	rebase hybrid prosthesis	619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Related to dental implants, which are on line 619
D5765	soft liner for complete or partial removable denture – indirect	454 DENTAL CONDITIONS (E.G., MISSING TEETH, PROSTHESIS FAILURE) Treatment: REMOVABLE PROSTHODONTICS (E.G., FULL AND PARTIAL DENTURES, RELINES)	Note from DCO dental directors: should be covered with same limitations as other liners
D6198	remove interim implant component	619 DENTAL CONDITIONS (E.G., MISSING TEETH) Treatment: IMPLANTS (I.E., IMPLANT PLACEMENT AND ASSOCIATED CROWN OR PROSTHESIS)	Related to dental implants, which are on line 619
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMITIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA	Orthodontics related. Orthodontics are currently on lines 42,256,300,618.
D7299	removal of temporary anchorage device, requiring flap	42,256,300,618	See D7298
D7300	removal of temporary anchorage device without flap	42,256,300,618	See D7298
D9912	pre-visit patient screening	Diagnostic Procedure File	From the ADA: Capture and documentation of a patient's health status prior to or on the scheduled

2022 CDT CODE REVIEW

CDT code	Code Description	Suggested Placements	Comments
			<p>date of service to evaluate risk of infectious disease transmission if the patient is to be treated within the dental practice.</p> <p>This is a COVID related screening code. The DCO group felt that this code should be bundled with the visit code</p>
D9947	custom sleep apnea appliance fabrication and placement	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	From the sleep apnea guideline: Mandibular advancement devices (oral appliances) are covered for those for whom CPAP fails or is contraindicated.
D9948	adjustment of custom sleep apnea appliance	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	See D9947
D9949	repair of custom sleep apnea appliance	202 SLEEP APNEA, NARCOLEPSY AND REM BEHAVIORAL DISORDER	See D9947

Proposed new guideline

GUIDELINE NOTE XXX DECORONATION OR SUBMERGENCE OF AN ERUPTED TOOTH

Lines 384, 411, 444, 456, 507, 538

Decoronation or submergence of an erupted tooth (CDT D3921) is only included on these lines for teeth that would otherwise qualify for endodontic services included on these lines but for which endodontics cannot be performed due to high-risk circumstances (e.g. certain medications or radiation related osteonecrosis).

Porcelain Crowns

Question: Should porcelain crowns (CDT D2740) be moved to a covered line?

Question source: OHA Dental Rules Advisory Committee (RAC)

Issue: Currently porcelain crowns (D2740) are on line 592 ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS). Currently, by OAR, crowns are limited to children and pregnant women and the type of crown is limited to porcelain fused to metal (CDT D2751 and D2752). D2751 (Crown-porcelain fused to predominantly base metal) and D2752 (Crown-porcelain fused to noble metal) are on line 469 ADVANCED RESTORATIVE (I.E., BASIC CROWNS). The RAC also suggested consideration of moving D2928 (Prefabricated porcelain/ceramic crown – permanent tooth) from line 592 to line 469.

From Gary Allen, OHAP and dental RAC member

When this limitation was decided years ago, porcelain fused to metal crowns were less expensive but technology has changed and porcelain crowns (D2740) are now more widely used. RAC members suggested this also be referred to OHAP to discuss moving code D2740 to Line 468. RAC members would also like to reconsider placement of code D2928 which was a new code discussed last year. It was recommended for addition to Line 591.

From Kaz Rafia, OHA dental director

Zirconia crowns are significantly less costly to manufacture, are clinically a better fit, and with a longer lifespan.

D2928 belongs to Line 592, should not be covered.

OHAP discussion: no significant discussion

HERC staff/OHAP recommendation:

- 1) Add CDT D2740 (Crown - porcelain/ceramic) to line 469 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE (I.E., BASIC CROWNS)
 - a. Remove CDT D2740 from line 592 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: ADVANCED RESTORATIVE-ELECTIVE (INLAYS, ONLAYS, GOLD FOIL AND HIGH NOBLE METAL RESTORATIONS)

Non-Restorative Caries Treatment

Question: Should a new guideline be adopted regarding non-restorative caries treatment?

Question source: Gary Allen, DMD

Issue: Most early dental decay is treated with invasive treatment such as drillings and fillings. Such invasive treatment can lead to future problems with the tooth. There are alternative treatments supported by the American Dental Association for non-restorative treatment of caries lesions. Such treatment can consist of fluoride varnish, fluoride gel, sealants, resins, silver diamine fluoride, and other options. The goal of nonrestorative or microinvasive caries treatment (fluoride- and non-fluoride-based interventions) is to manage the caries disease process at a lesion level and minimize the loss of sound tooth structure. Dr. Allen requested a review of the effectiveness of non-restorative treatment of dental caries and consideration of a new guideline regarding such treatment for the Prioritized List.

From Dr. Allen

I would be interested in discussion about a guideline for nonrestorative treatment of dental caries. Many dental providers default to the most invasive treatment for early dental decay (restorative treatment) which can be traumatic for young children and irreversibly damage a permanent tooth. A few years ago, the American Dental Association published evidence-based guideline for nonrestorative treatment of carious lesions (attached) but the guidelines have been slow to be adopted in our profession. Possible reasons are lack of awareness, disbelief in nonrestorative therapy for early caries and financial incentive to use the most costly treatment option (restoration). In the spirit of HERC and the OHP Prioritized List to educate providers on the evidence and to encourage the least invasive treatment options, I would like to propose a Prioritized List guideline be developed for nonrestorative treatment of dental caries

Prioritized List history

Silver diamine fluoride (SDF) was added to line 343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: BASIC RESTORATIVE (E.G., COMPOSITE RESTORATIONS FOR ANTERIOR TEETH, AMALGAM RESTORATIONS FOR POSTERIOR TEETH) in October 2015 with a new guideline. Good evidence based on several MED reports and other systematic reviews was found for the use of silver diamine fluoride for caries arrest. There is controversy, however, about the adverse effects of SDF, including darkening of the teeth.

Non-Restorative Caries Treatment

Evidence

- 1) **Urquhart 2019**, systematic review and network meta-analysis of nonrestorative treatments for caries <https://journals.sagepub.com/doi/pdf/10.1177/0022034518800014>
 - a. N=44 trials (7,378 patients)
 - b. Active intervention compared to placebo or another active intervention
 - i. 22 interventions: sodium fluoride (NaF), stannous fluoride toothpaste or gel, acidulated phosphate fluoride (APF), difluorsilane, ammonium fluoride, polyols, chlorhexidine, calcium phosphate, amorphous calcium phosphate (ACP), casein phosphopeptide-ACP (CPP-ACP), nano hydroxyapatite, tricalcium phosphate, prebiotics and/or 1.5% arginine, probiotics, silver diamine fluoride (SDF), silver nitrate, lasers, resin infiltration, sealants, sodium bicarbonate, calcium hydroxide, and carbamide peroxide.
 - c. Four network meta-analyses suggested that sealants + 5% sodium fluoride (NaF) varnish, resin infiltration + 5% NaF varnish, and 5,000-ppm fluoride (F)(1.1% NaF) toothpaste or gel were the most effective for arresting or reversing noncavitated occlusal, approximal, and noncavitated and cavitated root carious lesions on primary and/or permanent teeth, respectively (low- to moderate-certainty evidence). Study-level data indicated that 5% NaF varnish was the most effective for arresting or reversing noncavitated facial/lingual carious lesions (low certainty) and that 38% silver diamine fluoride solution applied biannually was the most effective for arresting advanced cavitated carious lesions on any coronal surface (moderate to high certainty).
 - d. Relative risks of treatment vs no treatment for the arrest or reversal of noncavitated carious lesions on occlusal surfaces
 - i. 0.2% NaF mouthrinse + supervised toothbrushing: RR 1.95 (1.54 to 2.46), moderate certainty evidence
 - ii. 1.23% APF gel: RR 2.13 (1.79 to 2.54) moderate certainty of evidence
 - iii. 5% NaF varnish: RR 1.97 (1.63 to 2.40), moderate certainty evidence
 - iv. Resin infiltration + 5% NaF varnish: RR 3.20 (2.24 to 4.56), moderate certainty evidence
 - v. Sealant: RR 1.98 (1.61 to 2.44), moderate certainty evidence

Expert guidelines

- 1) **Slayton 2018**: Evidence-based clinical practice guideline on nonrestorative treatments for carious lesions: A report from the American Dental Association <https://jada.ada.org/action/showPdf?pii=S0002-8177%2818%2930469-0>
 - a. Expert panel recommendations
 - b. Bottom line: Although the recommended interventions are often used for caries prevention, or in conjunction with restorative treatment options, these approaches have shown to be effective in arresting or reversing carious lesions. Clinicians are encouraged to prioritize use of these interventions based on effectiveness, safety, and feasibility.
 - c. Recommendations:
 - i. To arrest advanced cavitated carious lesions on any coronal surface of primary teeth, the expert panel recommends clinicians prioritize the use of 38% SDF solution (biannual application) over 5% NaF varnish (application once per week for 3 weeks). (Moderate-certainty evidence, strong recommendation.)

Non-Restorative Caries Treatment

- ii. To arrest advanced cavitated carious lesions on any coronal surface of permanent teeth, the expert panel suggests clinicians prioritize the use of 38% SDF solution (biannual application) over 5% NaF varnish (application once per week for 3 weeks). (Low-certainty evidence, conditional recommendation.)
- iii. To arrest or reverse noncavitated carious lesions on occlusal surfaces of primary teeth, the expert panel recommends clinicians prioritize the use of sealants plus 5% NaF varnish (application every 3-6 months) or sealants alone over 5% NaF varnish alone (application every 3-6 months), 1.23% APF gel (application every 3-6 months), resin infiltration plus 5% NaF varnish (application every 3-6 months), or 0.2% NaF mouthrinse (once per week). (Moderate-certainty evidence, strong recommendation.)
- iv. To arrest or reverse noncavitated carious lesions on occlusal surfaces of permanent teeth, the expert panel recommends clinicians prioritize the use of sealants plus 5% NaF varnish (application every 3-6 months) or sealants alone over 5% NaF varnish alone (application every 3-6 months), 1.23% APF gel (application every 3-6 months), or 0.2% NaF mouthrinse (once per week). (Moderate-certainty evidence, strong recommendation.)
- v. To arrest or reverse noncavitated carious lesions on approximal surfaces of primary and permanent teeth, the expert panel suggests clinicians use 5% NaF varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% NaF varnish (application every 3-6 months), or sealants alone. (Low- to very-low-certainty evidence, conditional recommendation.)
- vi. To arrest or reverse noncavitated carious lesions on facial or lingual surfaces of primary and permanent teeth, the expert panel suggests clinicians use 1.23% APF gel (application every 3-6 months) or 5% NaF varnish (application every 3-6 months). (Moderate- to low-certainty evidence, conditional recommendation.)
- vii. To arrest or reverse noncavitated carious lesions on coronal surfaces of primary and permanent teeth, the expert panel suggests clinicians do not use 10% CPP-ACP if other fluoride interventions, sealants, or resin infiltration is accessible. (Low-certainty evidence, conditional recommendation.)
- viii. To arrest or reverse noncavitated and cavitated carious lesions on root surfaces of permanent teeth, the expert panel suggests clinicians prioritize the use of 5,000 ppm fluoride (1.1% NaF) toothpaste or gel (at least once per day) over 5% NaF varnish (application every 3-6 months), 38% SDF plus potassium iodide solution (annual application), 38% SDF solution (annual application), or 1% chlorhexidine plus 1% thymol varnish (application every 3-6 months). (Low-certainty evidence, conditional recommendation.)

Non-Restorative Caries Treatment

Current Prioritized List status

CDT code	Code description	Code placement
D1206	Topical application of fluoride varnish	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 53 PREVENTIVE DENTAL SERVICES Treatment: CLEANING, FLUORIDE AND SEALANTS
D1208	Topical application of fluoride - excluding varnish	53
D1351	Sealant-per tooth	53
D1352	Preventive resin restoration in a moderate to high caries risk patient - permanent tooth	Excluded
D1354	Interim caries arresting medicament application – per tooth [used for silver diamine fluoride]	343 DENTAL CONDITIONS (E.G., CARIES, FRACTURED TOOTH) Treatment: BASIC RESTORATIVE (E.G., COMPOSITE RESTORATIONS FOR ANTERIOR TEETH, AMALGAM RESTORATIONS FOR POSTERIOR TEETH)
D1355	Caries preventive medicament application – per tooth [used for silver diamine fluoride, silver nitrate, thymol-CHS varnish, topical providone iodine]	53
D2990	Resin infiltration of incipient smooth surface lesions	646 DENTAL CONDITIONS WHERE TREATMENT RESULTS IN MARGINAL IMPROVEMENT Treatment: elective dental services

GUIDELINE NOTE 17, PREVENTIVE DENTAL CARE

Lines 3,53

Dental cleaning is limited to once per 12 months for adults and twice per 12 months for children up to age 19 (D1110, D1120). More frequent dental cleanings may be required for certain higher risk populations.

Fluoride varnish (99188) is included on Line 3 for use with children 18 and younger during well child preventive care visits. Fluoride treatments (D1206 and D1208) are included on Line 53 PREVENTIVE DENTAL SERVICES for use with adults and children during dental visits. The total number of fluoride applications provided in all settings is not to exceed four per twelve months for a child at high risk for dental caries and two per twelve months for a child not at high risk. The number of fluoride treatments is limited to once per 12 months for average risk adults and up to four times per 12 months for high-risk adults.

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 343

D1354 is limited to silver diamine fluoride applications for the treatment (rather than prevention) of caries, with a maximum of two applications per year.

Non-Restorative Caries Treatment

OHAP discussion:

The group expressed concerns over confusion regarding when fluoride varnish would be covered. There is a guideline that allows up to four treatments a year in high risk patients for preventive care. There were questions about the use of the fluoride varnish CDT code (CDT D1206) to the caries line. The DCOs would have a hard time administering a benefit in which this code could be used for both prevention and treatment. It was pointed out that D1206 and D1208 were mouth level codes, and would not be appropriate for treatment of a specific tooth. The group generally agreed that the CDT code D1354 (Interim caries arresting medicament application – per tooth) could be used for any of the treatments in the new proposed guideline. The group requested that no codes be moved to the caries line, and that the new proposed guideline just use D1354.

There was support around the general idea of using medicaments and other non-restorative caries treatments. This type of treatment would reduce the problem of having to get into a pediatric dentist, and having kids needing to go to the OR for treatment.

HERC staff/OHAP recommendations:

- 1) Modify GN91 as shown below

GUIDELINE NOTE 91, CARIES ARRESTING MEDICAMENT APPLICATION

Line 343

D1354, when used to represent ~~is limited to~~ silver diamine fluoride applications for the treatment (rather than prevention) of caries, is limited to ~~with~~ a maximum of two applications per year.

D1354 is also included on this line to

- 1) arrest or reverse noncavitated carious lesions on occlusal surfaces using sealants plus 5% fluoride varnish (application every 3-6 months) or sealants alone (application every 3-6 months), 1.23% fluoride gel (application every 3-6 months), resin infiltration plus 5% fluoride varnish (application every 3-6 months), or 0.2% fluoride mouthrinse (once per week).
- 2) arrest or reverse noncavitated carious lesions on approximal surfaces using 5% fluoride varnish (application every 3-6 months), resin infiltration alone, resin infiltration plus 5% fluoride varnish (application every 3-6 months), or sealants alone.
- 3) arrest or reverse noncavitated carious lesions on facial or lingual surfaces using 1.23% fluoride gel (application every 3-6 months) or 5% fluoride varnish (application every 3-6 months).

Orthodontia for Handicapping Malocclusion

Question: Should the limited coverage for orthodontia be expanded to include handicapping malocclusion?

Question source: OHA Dental Rules Advisory Committee

Issue: Currently, orthodontia coverage on the Prioritized List is limited to craniofacial anomalies. The OHA dental rules RAC requested consideration of inclusion of handicapping malocclusion, similar to other state Medicaid programs. Handicapping malocclusion and/or handicapping dentofacial deformity are conditions that constitute a hazard to the maintenance of oral health and interfere with the well-being of the patient by adversely affecting dentofacial function or speech. There are scoring systems to determine when handicapping malocclusion is present, such as the Salzmann Evaluation Index or the Handicapping Labio-Lingual Deviation Index.

Orthodontia was last reviewed in 2017, and coverage was added for craniofacial anomalies with a new guideline note. Orthodontia for non-craniofacial anomalies is on an uncovered line.

Current Prioritized List status

CDT code	Code Description	Code Placement
D7298	removal of temporary anchorage device [screw retained plate], requiring flap	NEW CODE
D7299	removal of temporary anchorage device, requiring flap	NEW CODE
D7300	removal of temporary anchorage device without flap	NEW CODE
D8010	Limited orthodontic treatment of the primary dentition	42 CLEFT PALATE WITH AIRWAY OBSTRUCTION 256 DEFORMITIES OF HEAD 300 CLEFT PALATE AND/OR CLEFT LIP 618 DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA
D8020	Limited orthodontic treatment of the transitional dentition	42,256,300,618
D8030	Limited orthodontic treatment of the adolescent dentition	42,256,300,618
D8040	Limited orthodontic treatment of the adult dentition	42,256,300,618
D8050-D8060	Interceptive orthodontic treatment	42,256,300,618
D8070-D8090	Comprehensive orthodontic treatment	42,256,300,618
D8210	Removable appliance therapy	42,256,300,618
D8220	Fixed appliance therapy	42,256,300,618
D8660	Pre-orthodontic treatment examination to monitor growth and development	42,256,300,618
D8670	Periodic orthodontic treatment visit	42,256,300,618

Orthodontia for Handicapping Malocclusion

CDT code	Code Description	Code Placement
D8680	Orthodontic retention (removal of appliances, construction and placement of retainer(s))	42,256,300,618
D8681	Removable orthodontic retainer adjustment	42,256,300,618
D8690	Orthodontic treatment (alternative billing to a contract fee)	42,256,300,618
D8695	Removal of fixed orthodontic appliances for reasons other than completion of treatment	267 DENTAL CONDITIONS (TIME SENSITIVE EVENTS) Treatment: URGENT DENTAL SERVICES
D8696-D8697	Repair of orthodontic appliance	42,256,300,618
D8698-D8699	Re-cement/re-bond fixed retainer	42,256,300,618
D8701-D8702	Repair of fixed retainer	42,256,300,618
D8703-D8704	Replacement of lost or broken retainer	42,256,300,618

Orthodontia for Handicapping Malocclusion

ICD-10 Code	Code description	Current Placement
M26.211	Malocclusion, Angle's class I	618
M26.212	Malocclusion, Angle's class II	618
M26.213	Malocclusion, Angle's class II	618
M26.219	Malocclusion, Angle's class, unspecified	618
M26.220	Open anterior occlusal relationship	618
M26.221	Open posterior occlusal relationship	618
M26.23	Excessive horizontal overlap	618
M26.24	Reverse articulation	618
M26.25	Anomalies of interarch distance	618
M26.29	Other anomalies of dental arch relationship	618
M26.31	Crowding of fully erupted teeth	618
M26.33	Horizontal displacement of fully erupted tooth or teeth	618
M26.34	Vertical displacement of fully erupted tooth or teeth	618
M26.35	Rotation of fully erupted tooth or teeth	618
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)	618
M26.37	Excessive interocclusal distance of fully erupted teeth	618
M26.4	Malocclusion, unspecified	618
M26.70	Unspecified alveolar anomaly	618
Z46.4	Encounter for fitting and adjustment of orthodontic device	618
K00.1	Supernumerary teeth	645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment: COSMETIC DENTAL SERVICES
K00.2	Abnormalities of size and form of teeth	645
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified	645
K00.6	Disturbances in tooth eruption	645
K00.9	Disorder of tooth development, unspecified	645

GUIDELINE NOTE 169, ORTHODONTICS AND CRANIOFACIAL SURGERY FOR CRANIOFACIAL ANOMALIES

Line 256

Orthodontics and craniofacial surgery are included on this line only for pairing with craniofacial anomaly diagnoses when there is significant malocclusion expected to result in difficulty with mastication, speech, or other oral function. Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies.

Orthodontia for Handicapping Malocclusion

Other state policies

- 1) Washington Medicaid
 - a. Orthodontic treatment is covered for persons under the age of 21 with
 - 1) Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, or
 - 2) Other craniofacial anomalies,
 - 3) Severe malocclusions with a Washington Modified Handicapping Labiolingual Deviation Index score of 25 or higher
- 2) Connecticut Medicaid
 - a. Orthodontic treatment is covered for persons scoring 26 points or higher on the Salzmann Evaluation Index
- 3) New York State Bureau of Dental Review
 - a. Orthodontic treatment is covered for persons scoring 26 or higher on the Handicapping Labiolingual Deviation Index
- 4) California Medicaid
 - a. Orthodontic treatment is covered for
 - 1) Cleft palate
 - 2) Cranio-facial anomalies
 - 3) Deep impinging overbite when lower incisors are destroying the soft tissue of the palate, tissue laceration and/or clinical attachment must be present
 - 4) Crossbite of individual anterior teeth when clinical attachment loss and recession of the gingival margin are present
 - 5) Severe traumatic deviation
 - 6) Overjet greater than 9mm with incompetent lips or mandibular protrusion (reverse overjet) greater than 3.5mm with masticatory and speech difficulties
 - 7) Score of 26 or higher on the Handicapping Labio-Lingual Deviation Index California Modification

OHAP discussion:

The group agreed in general that handicapping malocclusion should be moved to the covered portion of the Prioritized List. There was some discussion about which score or index should be used; the general consensus was that California had a good index which other states are using and thus is a ready made index that is acceptable. Rafia noted that the Salzman Index is not used anymore.

There was vigorous discussion about the difficulty of implementation of an expansion of orthodontia. There was discussion about whether a dentist could do the evaluation, or whether it needed to be an orthodontist. There was discussion about the need for a review body to look at each request and make an individual determination on coverage. OHA would need to create such a review body, which should include orthodontists. There was concern about an inadequate orthodontist network to provide the services of such an expansion. There was considerable concern about the cost of such an expansion: the cost of additional imaging needed for evaluation, of orthodontic consultations, of the review body to look at cases at each DCO as well as HSD, extractions required for orthodontia treatment plans, the cost of any needed orthognathic surgery, and the cost of the actual orthodontic treatments.

Orthodontia for Handicapping Malocclusion

HERC staff reflected that the issues brought up were all implementation issues that would need to be worked out by OHA before such an expansion in benefits could be accomplished. This benefit expansion would not be implementable on January 1, 2022. The benefit will need to be reviewed by Office of Actuarial and Financial Analytics (OAFA), which needs to consider the additional rate increases required for both CCOs to implement the medical benefit such as orthognathic surgery and the DCOs for all the implementation steps required for evaluation and treatment of handicapping malocclusion. [OHA's goal is to implement this benefit January 1, 2023. This topic can be brought back to the Commission prior to implementation if necessary for a successful implementation.](#)

Orthodontia for Handicapping Malocclusion

HERC staff/OHAP recommendations ([effective January 1, 2023](#)):

- 1) Rename line 256 DEFORMITIES OF HEAD [AND HANDICAPPING MALOCCLUSION](#) Treatment CRANIOTOMY/CRANIECTOMY; [ORTHODONTIA](#)
- 2) Add the following ICD-10 codes from line 618 DENTAL CONDITIONS (E.G., MALOCCLUSION) Treatment: ORTHODONTIA and line 645 DENTAL CONDITIONS WHERE TREATMENT IS CHOSEN PRIMARILY FOR AESTHETIC CONSIDERATIONS Treatment: COSMETIC DENTAL SERVICES to line 256

ICD-10 Code	Code description
K00.1	Supernumerary teeth
K00.2	Abnormalities of size and form of teeth
K00.5	Hereditary disturbances in tooth structure, not elsewhere classified
K00.6	Disturbances in tooth eruption
K00.9	Disorder of tooth development, unspecified
M26.211	Malocclusion, Angle's class I
M26.212	Malocclusion, Angle's class II
M26.213	Malocclusion, Angle's class II
M26.219	Malocclusion, Angle's class, unspecified
M26.220	Open anterior occlusal relationship
M26.221	Open posterior occlusal relationship
M26.23	Excessive horizontal overlap
M26.24	Reverse articulation
M26.25	Anomalies of interarch distance
M26.29	Other anomalies of dental arch relationship
M26.31	Crowding of fully erupted teeth
M26.33	Horizontal displacement of fully erupted tooth or teeth
M26.34	Vertical displacement of fully erupted tooth or teeth
M26.35	Rotation of fully erupted tooth or teeth
M26.36	Insufficient interocclusal distance of fully erupted teeth (ridge)
M26.37	Excessive interocclusal distance of fully erupted teeth
M26.4	Malocclusion, unspecified
M26.70	Unspecified alveolar anomaly
Z46.4	Encounter for fitting and adjustment of orthodontic device

- 3) Modify GN 169 as shown below

GUIDELINE NOTE 169, ORTHODONTICS ~~AND CRANIOFACIAL SURGERY~~ FOR CRANIOFACIAL ANOMALIES AND HANDICAPPING MALOCCLUSION

Line 256

[Orthodontic treatment is included on this line for persons under the age of 21 with](#)

- 1) [Cleft lip and palate, cleft palate or cleft lip with alveolar process involvement, OR](#)
- 2) [Other craniofacial anomalies resulting in significant malocclusion expected to result in difficulty with mastication, speech, or other oral function, OR](#)
- 3) [Deep impinging overbite when lower incisors are destroying the soft tissue of the palate, tissue laceration and/or clinical attachment must be present, OR](#)
- 4) [Crossbite of individual anterior teeth when clinical attachment loss and recession of the gingival margin are present, OR](#)

Orthodontia for Handicapping Malocclusion

- 5) Severe traumatic deviation, OR
- 6) Overjet greater than 9mm with incompetent lips or mandibular protrusion (reverse overjet) greater than 3.5mm with masticatory and speech difficulties; OR
- 7) Severe malocclusions with a Handicapping Labiolingual Deviation Index California Modification score of 26 or higher.

~~Orthodontics and craniofacial surgery are included on this line only for pairing with craniofacial anomaly diagnoses when there is significant malocclusion expected to result in difficulty with mastication, speech, or other oral function.~~ Advanced dental imaging is included on this line only when required for surgical planning for repair of craniofacial anomalies.

Oral Screening

Question: Should CDT D0190 (Screening of a patient) be added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS?

Question source: HSD staff

Issue: CMS added two CDT codes in 2012 to be used to report dental screening for the purposes of EPSDT screening for Medicaid and CHIP enrollees. The two codes were D0190 (Screening of a patient) and D0191 (Assessment of a patient). These codes do not need a dentist or hygienist to be the rendering provider. These codes can be used by other medical professionals, such as physicians, nurse practitioners, registered nurses, etc. who evaluate a patient and refer them to a dental professional for further evaluation and treatment.

These codes were discussed as part of the 2012 CDT code review. D0191 was added to line 53 PREVENTIVE DENTAL SERVICES at that review, and D0190 was added to the Excluded File as this code's intended use was unclear to OHAP and HERC at the time. In 2014, D0191 was added to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS to allow preventive dental services in primary care offices and a new guideline as part of the First Tooth program and similar programs.

Of note, both D0190 and D0191 are supposed to be used and paid with another code such as a well child visit.

Current Prioritized List status

CDT Code	Code Description	Current Placement
D0190	Screening of a patient	EXCLUDED FILE
D0191	Assessment of a patient	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS 53 PREVENTIVE DENTAL SERVICES

GUIDELINE NOTE 122, ORAL HEALTH RISK ASSESSMENT IN MEDICAL SETTINGS

Line 3

D0191 is limited to children under age 6 and requires an additional specific oral health risk assessment using a standardized tool, such as AAP Bright Futures, and should be performed by a provider who has successfully completed an approved training program (such as First Tooth or Smiles for Life).

OHAP discussion:

The group noted that this code was not to be used for mass screenings. Loy noted that DCOs don't credential providers other than dentists, hygienists, etc. Therefore, it would be problematic for DCOs to cover this code that would be billed by pediatricians, family physicians, etc. If covered, would need to be covered under the medical (CCO) side. The group unanimously agreed that D0190 would be difficult for a DCO to administer and does not add value to care. The recommendation was continued non-coverage.

OHA input:

Patient centered primary care home program: reimbursing for this screening would encourage more PCPCHs to do the screenings. Oral health services is a new standard in the PCPCH model as of January 2021, so we are just now starting to see how practices implement it. So far, it seems like very few

Oral Screening

PCPCHs (other than FQHCs) have a dental provider integrated into their practice, so providing screenings – even if it’s just a quick look in the mouth with a flashlight along with a questionnaire – and a referral to a dental provider is a key step in providing comprehensive care in a primary care setting.

There is also concern that D0190 is part of the EPSDT reporting metrics for CMS, and non-coverage could be problematic.

The dental program staff believe that if D0190 is added to line 3, then they could open the code only to non-dental professionals in MMIS as well as not that the code is only payable to medical providers in the online dental guidebook and dental code database. The dental program staff believe this would address much of OHAP’s concerns with this code.

From Kaz Rafia, OHA dental director:

“Including this code on the PL has multiple benefits: it incentivizes a much-needed and critical part of the whole-body exam, it speaks to the goal of further integrating physical and oral health, and has the potential to lead to conversations between the non-dental provider and the member around oral health and its connection to physical health. Finally, it creates a lead-in to effective clinical interventions such as topical fluoride varnish.”

HERC staff recommendation:

- 1) Add CDT D0190 (Screening of a patient) to line 3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS
 - a. HSD to ensure only payable to non-dental providers

Nightmare Disorder

Question: Should nightmare disorder be moved to a higher priority line?

Question source: Dr. Ben Hoffman, OHSU pediatrics

Issue: Currently, nightmare disorder (ICD10 F51.5) is on line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA. This diagnosis has not been reviewed in the past 10 years at a minimum. Dr. Hoffman requested a review of coverage, as nightmare disorder is a distinct diagnosis which is responsive to medications and therapy.

Nightmare disorder is defined by the repeated occurrence of nightmares that cause clinically significant distress or impairment in social, occupational or other important areas of functioning, which are not attributable to the physiological effects of a substance (e.g. drug abuse or medication) and which cannot be adequately explained by coexisting mental and medical disorders.

Evidence

- 1) **Nadorff 2014**, review of pharmacologic and non-pharmacologic treatments for nightmare disorder
 - a. prazosin has consistently shown efficacy for the treatment of nightmares and distressed awakenings based on 5 RCTs.
 - b. Psychotherapeutic treatments recommended based on expert opinion (literature consists of small RCTs or case series)
 - i. Lucid dreaming
 - ii. Imagery rehearsal therapy
 - iii. Exposure, relaxation, and rescripting therapy
 - iv. Systematic desensitization
 - v. Exposure therapy

Expert guidelines

- 1) **Morgenthaler 2018:** Position Paper for the Treatment of Nightmare Disorder in Adults: An American Academy of Sleep Medicine Position Paper
 - a. Behavioral and Psychological Treatment Options
 - i. Image rehearsal therapy is recommended for the treatment of PTSD-associated nightmares and nightmare disorder.
 - ii. The following may be used for the treatment of PTSD-associated nightmares: cognitive behavioral therapy, cognitive behavioral therapy for insomnia, eye movement desensitization and reprocessing, and exposure, relaxation, and rescripting therapy.
 - iii. The following may be used for the treatment of nightmare disorder: cognitive behavioral therapy, exposure, relaxation, and rescripting therapy, hypnosis, lucid dreaming therapy, progressive deep muscle relaxation, sleep dynamic therapy, self-exposure therapy, systematic desensitization, and testimony method
 - b. Pharmacologic Treatment Options
 - i. The following may be used for the treatment of PTSD associated nightmares: the atypical antipsychotics olanzapine, risperidone and aripiprazole, clonidine, cyproheptadine, fluvoxamine, gabapentin, nabilone, phenelzine, prazosin, topiramate, trazodone, and tricyclic antidepressants.

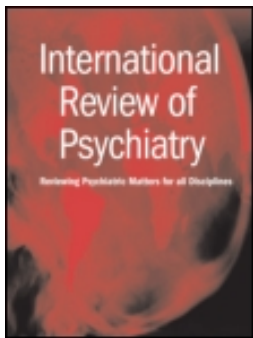
Nightmare Disorder

- ii. The following may be used for the treatment of nightmare disorder: nitrazepam, prazosin, and triazolam.
- iii. The following are not recommended for the treatment of nightmare disorder: clonazepam and venlafaxine.

BHAP input: the advisory panel unanimously agreed that nightmare disorder should be moved to a covered line.

HERC staff/BHAP recommendations:

- 1) Add ICD-10-CM F51.5 (nightmare disorder) to Line 173 POSTTRAUMATIC STRESS DISORDER
 - a. Remove ICD-10 F51.5 from line 606 DISORDERS OF SLEEP WITHOUT SLEEP APNEA



Pharmacological and non-pharmacological treatments for nightmare disorder

Michael R. Nadorff, Karen K. Lambdin & Anne Germain

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Pharmacological and non-pharmacological treatments for nightmare disorder

MICHAEL R. NADORFF^{1,2}, KAREN K. LAMBDIN¹ & ANNE GERMAIN³

¹Department of Psychology, Mississippi State University, Starkville, Mississippi, ²Menninger Department of Psychiatry, Baylor College of Medicine, Houston, Texas, and ³Department of Psychiatry, University of Pittsburgh, Pittsburgh, Pennsylvania, USA

Abstract

Interest in the treatment of nightmares has greatly increased over the last several years as research has demonstrated the clinical significance of nightmare disorder. This paper provides an overview of nightmare disorder, its clinical relevance, and the leading treatments that are available. In particular, the paper defines nightmare disorder and then summarizes the recent literature examining the clinical relevance of nightmare disorder, including its relation to post-traumatic stress disorder and other psychiatric conditions. The relation between nightmares and suicidality is also discussed. Recent findings on the treatment of nightmare with imagery rehearsal therapy and prazosin are then summarized. Lastly, the paper comments on potential future uses of nightmare treatment including using imagery rehearsal therapy or prazosin as a first-line intervention for post-traumatic stress disorder and using these treatments as an adjunctive therapy to reduce suicide risk in those at risk of suicide with nightmares.

Introduction

Nightmares have long been discussed in the context of mental health (Freud, 1955) and this interest in nightmares has re-emerged in recent years as clinically relevant sleep disorders have been identified as a common risk factor for mental disorders. Further, research has demonstrated that the relation between nightmares and negative outcomes are often independent of co-morbid disorders such as post-traumatic stress disorder (PTSD), depression, and anxiety (Nadorff et al., 2011, 2013a; Sjöström et al., 2009). Concurrently to these observations, there has been a substantial growth in the literature on effective nightmare treatments. The current review will provide a brief discussion of nightmare disorder and the relation between nightmares and psychopathology before examining the leading pharmacological and therapy-based treatment options for nightmare disorder. Lastly, we review some potential areas of growth for nightmare treatments as well as potential novel uses for these therapies.

Definition of nightmares

Nightmares, defined as vivid, disturbing, or frightening dreams that awaken the individual, are a common

form of parasomnia (Levin & Nielsen, 2007). Nightmares primarily occur during rapid eye movement (REM) sleep, and hence are more common during the second half of the night (American Academy of Sleep Medicine, 2006). The fact that nightmares occur in REM sleep differentiates them from night terrors, a parasomnia that occurs in non-REM sleep (APA, 2013).

The DSM-5 (APA, 2013) and ICSD-2 diagnostic criteria for nightmare disorder are similar in many ways. Both diagnostic systems require nightmares to be repeated negative dreams that awaken the individual from the nightmare, making the individual rapidly alert and aware of his or her surroundings. The DSM-5 requires that the nightmares not be better explained by substance use or medication, which is not required by the ICSD-2. On the other hand, the ICSD-2, but not the DSM-5, requires the individual to have difficulty falling back asleep, or for the nightmare to occur in the latter half of the night.

Bad dreams, which are negative dreams that do not lead to a startled awakening, are usually excluded from the definition of nightmares due to their lack of a startled awakening. However, bad dreams and nightmares are quite similar, as both require the recall of a negative dream, and both have been shown to be associated with sleep disruption and adverse

SPECIAL ARTICLES

Position Paper for the Treatment of Nightmare Disorder in Adults: An American Academy of Sleep Medicine Position Paper

Timothy I. Morgenthaler, MD¹; Sanford Auerbach, MD²; Kenneth R. Casey, MD, MPH³; David Kristo, MD⁴; Rama Maganti, MD⁵; Kannan Ramar, MD¹; Rochelle Zak, MD⁶; Rebecca Kartje, MD, MSHI, MBA⁷

¹Mayo Clinic, Rochester, Minnesota; ²Boston University School of Medicine, Boston, Massachusetts; ³William S. Middleton Memorial Veterans Hospital, Madison, Wisconsin;

⁴University of Pittsburgh, Pittsburgh, Pennsylvania; ⁵University of Wisconsin, Madison, Wisconsin; ⁶University of California, San Francisco, California; ⁷American Academy of Sleep Medicine, Darien, Illinois

Introduction: Nightmare disorder affects approximately 4% of adults, occurring in isolation or as part of other disorders such as posttraumatic stress disorder (PTSD), and can significantly impair quality of life. This paper provides the American Academy of Sleep Medicine (AASM) position regarding various treatments of nightmare disorder in adults.

Methods: A literature search was performed based upon the keywords and MeSH terms from the Best Practice Guide for the Treatment of Nightmare Disorder in Adults that was published in 2010 by the AASM. The search used the date range March 2009 to August of 2017, and sought to find available evidence pertaining to the use of behavioral, psychological, and pharmacologic therapies for the treatment of nightmares. A task force developed position statements based on a thorough review of these studies and their clinical expertise. The AASM Board of Directors approved the final position statements.

Determination of Position: Positions of “recommended” and “not recommended” indicate that a treatment option is determined to be clearly useful or ineffective/harmful for most patients, respectively, based on a qualitative assessment of the available evidence and clinical judgement of the task force. Positions of “may be used” indicate that the evidence or expert consensus is less clear, either in favor or against the use of a treatment option. The interventions listed below are in alphabetical order within the position statements rather than clinical preference: this is not meant to be instructive of the order in which interventions should be used.

Position Statements:

- The following therapy is recommended for the treatment of PTSD-associated nightmares and nightmare disorder: image rehearsal therapy.
- The following therapies may be used for the treatment of PTSD-associated nightmares: cognitive behavioral therapy; cognitive behavioral therapy for insomnia; eye movement desensitization and reprocessing; exposure, relaxation, and rescripting therapy; the atypical antipsychotics olanzapine, risperidone and aripiprazole; clonidine; cyproheptadine; fluvoxamine; gabapentin; nabilone; phenelzine; prazosin; topiramate; trazodone; and tricyclic antidepressants.
- The following therapies may be used for the treatment of nightmare disorder: cognitive behavioral therapy; exposure, relaxation, and rescripting therapy; hypnosis; lucid dreaming therapy; progressive deep muscle relaxation; sleep dynamic therapy; self-exposure therapy; systematic desensitization; testimony method; nitrazepam; prazosin; and triazolam.
- The following are not recommended for the treatment of nightmare disorder: clonazepam and venlafaxine.
- The ultimate judgment regarding propriety of any specific care must be made by the clinician, in light of the individual circumstances presented by the patient, accessible treatment options, and resources.

Keywords: nightmare disorder, PTSD-associated nightmares, adults

Citation: Morgenthaler TI, Auerbach S, Casey KR, Kristo D, Maganti R, Ramar K, Zak R, Kartje R. Position paper for the treatment of nightmare disorder in adults: an American Academy of Sleep Medicine position paper. *J Clin Sleep Med*. 2018;14(6):1041–1055.

INTRODUCTION

The treatment of nightmare disorder in adults was previously addressed in 2010 by the American Academy of Sleep Medicine (AASM) Best Practice Guide for the Treatment of Nightmare Disorder in Adults.¹ The AASM commissioned a task force of experts in sleep medicine to develop a position paper that updates and replaces the best practice guide. A position paper was developed, rather than a clinical practice guideline, due to limited direct evidence for many of the available

treatment options. This position paper provides guidance on the use of pharmacologic and nonpharmacologic treatment options to all practitioners who care for adult patients with nightmare disorder. The interventions listed within the position statements are in alphabetical order; this is not meant to suggest the order in which interventions should be used. The ultimate judgment regarding propriety of any specific care plan must be made by the clinician, in light of the individual circumstances presented by the patient, accessible treatment options, and resources.

HCPCS Codes in the SUD Waiver Requiring Review

Question: Should certain treatments be added to the substance use disorder line?

Question source: OHA SUD Waiver Team

Issue: OHA has applied to CMS for a waiver for an expansion of SUD services. As part of that process, CCOs will be asked to cover certain services for substance use disorder. Some of these services have not previously been paired with SUD diagnoses. HERC staff would like to review these services with BHAP for possible inclusion on line 4 SUBSTANCE USE DISORDER.

Code issues

- 1) HCPCS **H0022** Alcohol and/or drug intervention service (planned facilitation); Alcohol and drug intervention services provide treatment services and activities that assist the professionally trained interventionalist to pursue and detect alcohol and or drug addictions and to intercede to halt the progress of the addictions. These services also include early interventions.
 - a. Current placement: "Never Reviewed"
 - b. BHAP/HSC/HERC history: no prior review of this code found
 - c. Description: HCPCS code represents a planned intervention that may assist a person to abstain from SUD use.
 - d. Note: not payable by Medicare
 - e. BHAP input: This code represents facilitated intervention by treatment providers to get a patient into treatment services and as such as a pre-treatment service. Dana Peterson from the OHA SUD Waiver Team stated the team hoped to use this code to reimburse for services to get a person to reengage in SUD treatment. This code might be used by outreach co-ordinators to reach out to a person who might not have an SUD diagnosis. Savicki noted that adding coverage of this code would be a huge expansion of services. Lindsay noted that there might not be enough information to make a diagnosis of a patient at the point of using this code. All felt that this would be a valuable service. Savicki noted that this service would often be done by a peer support specialist. There were questions about how to bill for a patient who might not have medical insurance or other identification. The end decision was that this was a valuable service, and should be added to line 4; however, there are significant implementation issues that will need to be worked out by HSD prior to opening this code for use.
 - f. HERC staff/BHAP recommendation
 - i. Option 1: Add H0022 to line 4 SUBSTANCE USE DISORDER
 - ii. Option 2: Advise HSD to add H0022 to the DIAGNOSTIC PROCEDURE file
 1. may be more appropriate since a SUD diagnosis may not be present.
- 2) HCPCS **H0039** Assertive community treatment, face-to-face, per 15 minutes; Assertive community treatment uses a team based, multidisciplinary approach. The goal is to reduce the extent of hospital admissions, to improve the individual's quality of life, and to function in social situations by providing focused, proactive treatments. These services are most appropriate for individuals with severe and persistent mental illness and the greatest level of functional impairment.
 - a. Current placement: 7,22,26,96,149,173,201,203 and 16 other lines
 - b. BHAP/HSC/HERC history: no prior review of this code found
 - c. Description: Assertive community treatment (ACT) is an intensive and highly integrated approach for community mental health service delivery. ACT teams serve individuals with the most serious forms of mental illness, predominantly but not exclusively the schizophrenia spectrum disorders

HCPCS Codes in the SUD Waiver Requiring Review

- d. Evidence for use in SUD
 - i. **Penzenstadler 2019**, Systematic Review of Assertive Community Treatment (ACT) for SUD
 - 1. N=11 articles
 - a. 5 studies (N=741 patients)
 - b. Control group was standard addiction treatment
 - 2. No significant difference in substance use found between ACT and standard SUD treatment
 - 3. Data on hospitalization rates and incarceration rates varies between studies
 - 4. One study found higher quality of life with ACT
 - 5. No difference was found in cost-effectiveness between ACT and standard SUD therapy
 - 6. Conclusion: Overall, ACT is a promising approach that may be useful for promoting treatment engagement for patients with SUD
 - e. BHAP input: Members felt that this code should be reserved for patients with chronic mental illness. There might be a dual diagnosis, but SUD alone should not be the only diagnosis.
 - f. HERC staff/BHAP recommendation: do not add H0039 to line 4. Keep on chronic mental illness lines and will be available for use with patients with dual diagnoses.
- 3) HCPCS **H0043** Supported housing, per diem
 - a. Current placement: "Never Reviewed"
 - b. BHAP/HSC/HERC history: no prior review of this code found
 - c. Description: non-residential treatment housing
 - d. Note: not payable by Medicare.
 - e. BHAP input: Davis felt that this was an important service to cover. Dallia from the SUD Waiver Team stated that the team wanted to use this code to pay for follow up visit with a patient who was discharged to a subsidized housing to see how the person is doing, how community integration is progressing, etc. Members felt that the SUD Waiver Team should be using a case management code for this type of service. This code is per day, and implies a service being given. Members felt that a case management type service could be done with case management with a modifier to try to get at the Waiver Team purpose
 - f. HSD input: HSD staff plans to use a H2014 (skills training and development, per 15 minutes) with a modifier to represent this service.
 - g. HERC staff/BHAP recommendation
 - i. Advise HSD to add HCPCS H0043 to the Excluded File
- 4) HCPCS **H2023** Supported employment/education; Supported employment services are available to individuals with serious mental illness. Employment specialists assist in obtaining and maintaining employment in the community and in continuing treatment for the client to ensure rehabilitation and productive employment.
 - a. Current placement: 7,22,26,96,149,173,201,203 and 19 other lines
 - b. BHAP/HSC/HERC history: BHAP voted to removed H2023 from all lines on the Prioritized List and place on the Ancillary List in 2016. However, in 2017 based on OHA testimony: "This change is causing difficulties with the Oregon Performance Plan and their compliance with requirements of the US Department of Justice. This type of

HCPCS Codes in the SUD Waiver Requiring Review

employment has strict rules from the US DOJ and can only be used by a very limited number of serious mental health disorders. Making these codes ancillary opened them up to any diagnosis, which is in violation of US DOJ rules.”

- c. OHA received federal CMS waiver to cover this for SUD treatment. Unsure if there is a waiver of US DOJ rules
 - d. BHAP input: Members felt that addition of this code to line 4 would be appropriate if OHA has a CMS waiver allowing use for SUD. Donny Jardine from the SUD team felt that OAR could be written that would satisfy US DOJ requirements. CCO representatives noted that there are very strict criteria that behavioral health providers are required to adhere to and that SUD providers would also have to adhere to these strict criteria. HERC staff was directed to work with Waiver Team to see if this is implementable on line 4 with discussions with CMS regarding specific waiver language.
 - e. HSD input: HSD staff plans to use a H2014 (skills training and development, per 15 minutes) with a modifier to represent this service.
 - f. HERC staff/BHAP recommendation:
 - i. Make no changes to current H2023 placement
- 5) HCPCS **H2032** Activity therapy, per 15 min; Activity therapy such as music, dance, creative art, or any type of play, not for recreation, but related to the care and treatment of the patient's disabling mental health problems is reported for services per 15 minutes.
- a. Current placement: 7,22,26,96,121,149,173,193 and 30 other lines
 - b. BHAP/HSC/HERC history: no prior review of this code found
 - c. Description: activity therapy encompasses a wide range of activities with seek to engage the individual in creative endeavors that help to alter the thought processes of the patient in a positive manner. This may include art, music, movement, journaling, etc.
 - d. Evidence: difficult to search for evidence as activity therapy encompasses such a wide range of interventions. However, activity therapy appears to be commonly used in community treatment programs for SUD
 - e. BHAP input: Members agreed on addition to line 4
 - f. HERC staff/BHAP recommendation:
 - i. Add HCPCS H2032 to line 4 SUBSTANCE USE DISORDER
- 6) HCPCS **H2036** Alcohol and/or other drug treatment program, per diem; Outpatient services for alcohol and chemical dependency are structured to promote sobriety and independent living and to assist with continued treatment. Outpatient services allow patients to present for prescribed treatments and therapy and to maintain an otherwise routine home life.
- a. Current placement: “Never Reviewed”
 - b. BHAP/HSC/HERC history: no prior review of this code found
 - c. Description: SUD treatment
 - d. Note: not payable by Medicare. Appears to be a bundled code for a hospitalization for SUD treatment
 - e. BHAP input: The Waiver Team indicated that this code would be use for day treatment programs. Day treatment programs are billing as outpatient programs. The Waiver teams wants to use this code as a bundled fee for all the services (counseling, drug testing, etc.) that are provided in one day. Panel members felt that addition to line 4 was reasonable.
 - f. HERC staff/BHAP recommendation:
 - i. Add HCPCS H2036 to line 4 SUBSTANCE USE DISORDER

Effect of Assertive Community Treatment for Patients with Substance Use Disorder: A Systematic Review

Louise Penzenstadler^a Carina Soares^a Eleonora Anci^a Andrew Molodynski^c
Yasser Khazaal^{a, b, d}

^aGeneva University Hospitals, Geneva, Switzerland; ^bGeneva University, Faculty of Medicine, Geneva, Switzerland;
^cOxford Health NHS Foundation Trust, Oxford, UK; ^dResearch Center, Montreal University Institute of Mental Health,
Montreal, QC, Canada

Keywords

Addiction · Assertive community treatment · Out-patient treatment · Recovery · Substance use disorders

Abstract

Purpose: Substance use disorders (SUD) are an important health issue internationally. Traditional outpatient programmes often do not adequately address the substantial medical and social needs and in addition many patients have difficulties accessing the care needed. The assertive community treatment (ACT) model was originally developed for patients with a severe mental illness but has been adapted for patients with SUD by integrating specific SUD treatments into the traditional ACT model. This paper aims to assess the effectiveness of ACT for patients with SUD on a number of measures. **Methods:** We performed a systematic review of ACT interventions for patients with SUD by analyzing randomized controlled studies published before June 2017 found on the electronic databases PsychINFO, MEDLINE,

PsychARTICLES. Eleven publications using 5 datasets were included in the analysis. Quality of studies was analyzed using the JADAD scale or Oxford quality scoring system. Outcome measures used were substance use, treatment engagement, hospitalization rates, quality of life, housing status, medication compliance and legal problems. Patients included in the studies had a diagnosis of SUD. Two datasets included homeless patients and 2 datasets included patients with high service use. **Results and Conclusions:** The results of the very few existing randomized control studies are mixed. Treatment engagement was higher for ACT in 4 datasets. One dataset reported higher service contact rates for the ACT group than for controls. In 2 datasets a positive effect on hospitalization rates was found. Higher fidelity to the ACT model appears to improve outcomes. Substance use reduced only in half of the datasets, of which only one showed a significant reduction in the ACT group. Overall, ACT is a promising approach that may be useful for promoting treatment engagement for patients with SUD. According to earlier studies on patients with severe mental illness, patients

**CENTERS FOR MEDICARE & MEDICAID SERVICES
EXPENDITURE AUTHORITY**

NUMBER: 11-W00362/10

TITLE: Oregon Health Plan Substance Use Disorder 1115 Demonstration

AWARDEE: Oregon Health Authority

Under the authority of section 1115(a)(2) of the Social Security Act (“the Act”), expenditures made by Oregon for the items identified below, which are not otherwise included as expenditures under section 1903 of the Act shall, for the period from March 31, 2021 through March 31, 2026, unless otherwise specified, be regarded as expenditures under the state’s title XIX plan.

As discussed in the Centers for Medicare & Medicaid Services’ (CMS) approval letter, the Secretary of Health and Human Services has determined that the Oregon Health Plan Substance Use Disorder demonstration, including the granting of the expenditure authority described below, is likely to assist in promoting the objectives of title XIX of the Act.

The following expenditure authority may only be implemented consistent with the approved Special Terms and Conditions (STC) and shall enable Oregon to operate the above-identified section 1115(a) demonstration.

- 1. Residential and Inpatient Treatment for Individuals with Substance Use Disorder (SUD).** Expenditures for otherwise covered Medicaid services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).
- 2. Community Integration Services (CIS).** Expenditures for community integration services which consists of housing transition and tenancy sustaining and employment supports to assist individuals transitioning back into the community from an inpatient or other residential setting where they have received SUD treatment.

**CENTERS FOR MEDICARE & MEDICAID SERVICES
SPECIAL TERMS AND CONDITIONS**

NUMBER: 11-W-00362/10

TITLE: Oregon Health Plan Substance Use Disorder 1115 Demonstration

AWARDEE: Oregon Health Authority

I. PREFACE

The following are the Special Terms and Conditions (STC) for the “Oregon Health Plan Substance Use Disorder” section 1115(a) Medicaid demonstration (hereinafter “demonstration”), to enable the Oregon Health Authority (hereinafter “state”) to operate this demonstration. The Centers for Medicare & Medicaid Services (CMS) has granted expenditure authority authorizing federal matching of demonstration costs not otherwise matchable, which are separately enumerated. These STCs set forth conditions and limitations on the expenditure authority, and describe in detail the nature, character, and extent of federal involvement in the demonstration and the state’s obligations to CMS related to the demonstration. These STCs neither grant additional waivers or expenditure authorities, nor expand upon those separately granted. The demonstration will be statewide and is approved for a five-year period, from April 8, 2021 through March 31, 2026, unless otherwise specified.

The STCs have been arranged into the following subject areas:

- I. Preface
- II. Program Description and Objectives
- III. General Program Requirements
- IV. Eligibility and Enrollment
- V. Substance Use Disorder Program and Benefits
- VI. High Needs Supports
- VII. Cost Sharing
- VIII. Delivery System
- IX. General Reporting Requirements
- X. Monitoring
- XI. Evaluation of the Demonstration
- XII. General Financial Requirements Under Title XIX
- XIII. Monitoring Budget Neutrality for the Demonstration
- XIV. Schedule of Deliverables for the Demonstration Period

Additional attachments have been included to provide supplementary information and guidance for specific STCs.

Attachment A: Developing the Evaluation Design

Attachment B: Preparing the Interim and Summative Evaluation Reports

Attachment C: SUD Implementation Plan and SUD Health IT Plan

II. PROGRAM DESCRIPTION AND OBJECTIVES

This demonstration will provide the state with authority to provide high-quality, clinically appropriate treatment to beneficiaries with substance use disorder (SUD) while they are short-term residents in residential and inpatient treatment settings that qualify as Institutions for Mental Diseases (IMDs). It will also support state efforts to implement models of care focused on increasing support for individuals in the community and home, outside of institutions, and improve access to a continuum of SUD evidence-based services at varied levels of intensity. This continuum of care shall be based on the American Society of Addiction Medicine (ASAM) criteria and/or other nationally recognized assessment and placement tools that reflect evidence-based clinical treatment guidelines. This demonstration will also allow the state to provide community integration services which consists of housing and employment supports to individuals transitioning back into the community from an IMD or other residential setting.

During the demonstration period, the state seeks to achieve the following goals:

SUD Demonstration Goals:

1. Assist Oregon in increasing identification, initiation, and engagement of Medicaid beneficiaries diagnosed with SUD;
2. Assist the state in increasing beneficiary adherence to, and retention in, SUD treatment programs;
3. Assist Oregon in reducing inappropriate or preventable utilization of emergency departments and inpatient hospital settings through improved access to a continuum of care services; and
4. Provide a continuum of care to increase the chances of Medicaid beneficiaries of having a successful recovery process.

III. GENERAL PROGRAM REQUIREMENTS

1. **Compliance with Federal Non-Discrimination Statutes.** The state must comply with all applicable federal statutes relating to non-discrimination. These include, but are not limited to, the Americans with Disabilities Act of 1990 (ADA), Title VI of the Civil Rights Act of 1964, section 504 of the Rehabilitation Act of 1973 (Section 504), the Age Discrimination Act of 1975, and section 1557 of the Patient Protection and Affordable Care Act (Section 1557).
2. **Compliance with Medicaid and Children's Health Insurance Program (CHIP) Law, Regulation, and Policy.** All requirements of the Medicaid and CHIP programs expressed in federal law, regulation, and policy statement, not expressly waived or identified as not applicable in the waiver and expenditure authority documents (of which these terms and conditions are part), apply to the demonstration.

- 3. Changes in Medicaid and CHIP Law, Regulation, and Policy.** The state must, within the timeframes specified in federal law, regulation, or written policy, come into compliance with any changes in law, regulation, or policy affecting the Medicaid or CHIP programs that occur during this demonstration approval period, unless the provision being changed is expressly waived or identified as not applicable. In addition, CMS reserves the right to amend the STCs to reflect such changes and/or changes as needed without requiring the state to submit an amendment to the demonstration under STC 7. CMS will notify the state thirty (30) business days in advance of the expected approval date of the amended STCs to allow the state to provide comment. Changes will be considered in force upon issuance of the approval letter by CMS. The state must accept the changes in writing.
- 4. Impact on Demonstration of Changes in Federal Law, Regulation, and Policy.**
 - a. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in federal financial participation (FFP) for expenditures made under this demonstration, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change, as well as a modified allotment neutrality worksheet as necessary to comply with such change. The trend rates for the budget neutrality agreement are not subject to change under this subparagraph. Further, the state may seek an amendment to the demonstration (as per STC 7) as a result of the change in FFP.
 - b. If mandated changes in the federal law require state legislation, unless otherwise prescribed by the terms of the federal law, the changes must take effect on the earlier of the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the law, whichever is sooner.
- 5. State Plan Amendments.** The state will not be required to submit title XIX or XXI state plan amendments (SPAs) for changes affecting any populations made eligible solely through the demonstration. If a population eligible through the Medicaid or CHIP state plan is affected by a change to the demonstration, a conforming amendment to the appropriate state plan is required, except as otherwise noted in these STCs. In all such cases, the Medicaid and CHIP state plans govern.
- 6. Changes Subject to the Amendment Process.** Changes related to eligibility, enrollment, benefits, beneficiary rights, delivery systems, cost sharing, sources of non-federal share of funding, budget neutrality, and other comparable program elements must be submitted to CMS as amendments to the demonstration. All amendment requests are subject to approval at the discretion of the Secretary in accordance with section 1115 of the Act. The state must not implement changes to these elements without prior approval by CMS either through an approved amendment to the Medicaid or CHIP state plan or amendment to the demonstration. Amendments to the demonstration are not retroactive and no FFP of any kind, including for administrative or medical assistance expenditures, will be available under changes to the demonstration that have not been approved through the amendment process set forth in STC 7 below, except as provided in STC 3.
- 7. Amendment Process.** Requests to amend the demonstration must be submitted to CMS prior to the planned date of implementation of the change and may not be implemented until

approved. CMS reserves the right to deny or delay approval of a demonstration amendment based on non-compliance with these STCs, including but not limited to the failure by the state to submit required elements of a complete amendment request as described in this STC, and failure by the state to submit required reports and other deliverables according to the deadlines specified therein. Amendment requests must include, but are not limited to, the following:

- a. An explanation of the public process used by the state, consistent with the requirements of STC 12. Such explanation must include a summary of any public feedback received and identification of how this feedback was addressed by the state in the final amendment request submitted to CMS;
- b. A detailed description of the amendment, including impact on beneficiaries, with sufficient supporting documentation;
- c. A data analysis which identifies the specific “with waiver” impact of the proposed amendment on the current budget neutrality agreement. Such analysis must include current total computable “with waiver” and “without waiver” status on both a summary and detailed level through the current approval period using the most recent actual expenditures, as well as summary and detailed projections of the change in the “with waiver” expenditure total as a result of the proposed amendment, which isolates (by Eligibility Group) the impact of the amendment;
- d. An up-to-date CHIP allotment worksheet, if necessary;
- e. The state must provide updates to existing demonstration reporting and quality and evaluation plans. This includes a description of how the evaluation design and annual progress reports will be modified to incorporate the amendment provisions, as well as the oversight, monitoring and measurement of the provisions.

8. Extension of the Demonstration. States that intend to request an extension of the demonstration must submit an application to CMS from the Governor or Chief Executive Officer of the state in accordance with the requirements of 442 Code of Federal Regulations (CFR) 431.412(c). States that do not intend to request an extension of the demonstration beyond the period authorized in these STCs must submit phase-out plan consistent with the requirements of STC 9.

9. Demonstration Phase-Out. The state may only suspend or terminate this demonstration in whole, or in part, consistent with the following requirements.

- a. Notification of Suspension or Termination. The state must promptly notify CMS in writing of the reason(s) for the suspension or termination, together with the effective date and a transition and phase-out plan. The state must submit a notification letter and a draft transition and phase-out plan to CMS no less than six months before the effective date of the demonstration’s suspension or termination. Prior to submitting the draft transition and phase-out plan to CMS, the state must publish on its website the draft transition and phase-out plan for a thirty (30) day public comment period. In addition, the state must conduct tribal consultation in accordance with STC 12, if applicable. Once the thirty (30) day public comment period has ended, the state must provide a summary of the issues raised by the public during the comment period and how the state considered the comments received when developing the revised transition and phase-out plan.

- b. Transition and Phase-out Plan Requirements. The state must include, at a minimum, in its phase-out plan the process by which it will notify affected beneficiaries, the content of said notices (including information on the beneficiary's appeal rights), the process by which the state will conduct administrative reviews of Medicaid or CHIP eligibility prior to the termination of the demonstration for the affected beneficiaries, and ensure ongoing coverage for eligible beneficiaries, as well as any community outreach activities the state will undertake to notify affected beneficiaries, including community resources that are available.
- c. Transition and Phase-out Plan Approval. The state must obtain CMS approval of the transition and phase-out plan prior to the implementation of transition and phase-out activities. Implementation of transition and phase-out activities must be no sooner than fourteen (14) calendar days after CMS approval of the transition and phase-out plan.
- d. Transition and Phase-out Procedures. The state must comply with all applicable notice requirements found in 42 CFR, part 431 subpart E, including sections 431.206, 431.210 and 431.213. In addition, the state must assure all applicable appeal and hearing rights are afforded to beneficiaries in the demonstration as outlined in 42 CFR, part 431 subpart E, including sections 431.220 and 431.221. If a beneficiary in the demonstration requests a hearing before the date of action, the state must maintain benefits as required in 42 CFR §431.230. In addition, the state must conduct administrative renewals for all affected beneficiaries in order to determine if they qualify for Medicaid or CHIP eligibility under a different eligibility category prior to termination, as discussed in October 1, 2010, State Health Official Letter #10-008 and as required under 42 CFR 435.916(f)(1). For individuals determined ineligible for Medicaid, the state must determine potential eligibility for other insurance affordability programs and comply with the procedures set forth in 42 CFR 435.1200(e).
- e. Exemption from Public Notice Procedures 42 CFR Section 431.416(g). CMS may expedite the federal and state public notice requirements under circumstances described in 42 CFR 431.416(g).
- f. Enrollment Limitation during Demonstration Phase-Out. If the state elects to suspend, terminate, or not extend this demonstration, during the last six months of the demonstration, enrollment of new individuals into the demonstration must be suspended. The limitation of enrollment into the demonstration does not impact the state's obligation to determine Medicaid eligibility in accordance with the approved Medicaid state plan.
- g. Federal Financial Participation (FFP). If the project is terminated or any relevant waivers are suspended by the state, FFP must be limited to normal closeout costs associated with the termination or expiration of the demonstration including services, continued benefits as a result of beneficiaries' appeals, and administrative costs of disenrolling beneficiaries.

10. Withdrawal of Waiver or Expenditure Authority. CMS reserves the right to withdraw waivers and/or expenditure authorities at any time it determines that continuing the waiver or expenditure authorities would no longer be in the public interest or promote the objectives of title XIX and title XXI. CMS will promptly notify the state in writing of the determination

and the reasons for the withdrawal, together with the effective date, and afford the state an opportunity to request a hearing to challenge CMS' determination prior to the effective date. If a waiver or expenditure authority is withdrawn, FFP is limited to normal closeout costs associated with terminating the waiver or expenditure authority, including services, continued benefits as a result of beneficiary appeals, and administrative costs of disenrolling beneficiaries.

11. Adequacy of Infrastructure. The state will ensure the availability of adequate resources for implementation and monitoring of the demonstration, including education, outreach, and enrollment; maintaining eligibility systems; compliance with cost sharing requirements; and reporting on financial and other demonstration components.

12. Public Notice, Tribal Consultation, and Consultation with Interested Parties. The state must comply with the state notice procedures as required in 42 CFR section 431.408 prior to submitting an application to extend the demonstration. For applications to amend the demonstration, the state must comply with the state notice procedures set forth in 59 Fed. Reg. 49249 (September 27, 1994) prior to submitting such request. The state must also comply with the Public Notice Procedures set forth in 42 CFR 447.205 for changes in statewide methods and standards for setting payment rates.

The state must also comply with tribal and Indian Health Program/Urban Indian Organization consultation requirements at section 1902(a)(73) of the Act, 42 CFR 431.408(b), State Medicaid Director Letter #01-024, or as contained in the state's approved Medicaid State Plan, when any program changes to the demonstration, either through amendment as set out in STC 7 or extension, are proposed by the state.

13. Federal Financial Participation (FFP). No federal matching funds for expenditures for this demonstration, including for administrative and medical assistance expenditures, will be available until the effective date identified in the demonstration approval letter, or if later, as expressly stated within these STCs.

14. Administrative Authority. When there are multiple entities involved in the administration of the demonstration, the Single State Medicaid Agency must maintain authority, accountability, and oversight of the program. The State Medicaid Agency must exercise oversight of all delegated functions to operating agencies, MCOs, and any other contracted entities. The Single State Medicaid Agency is responsible for the content and oversight of the quality strategies for the demonstration.

15. Common Rule Exemption. The state must ensure that the only involvement of human subjects in research activities that may be authorized and/or required by this demonstration is for projects which are conducted by or subject to the approval of CMS, and that are designed to study, evaluate, or otherwise examine the Medicaid or CHIP program – including public benefit or service programs, procedures for obtaining Medicaid or CHIP benefits or services, possible changes in or alternatives to Medicaid or CHIP programs and procedures, or possible changes in methods or levels of payment for Medicaid benefits or services. CMS has determined that this demonstration as represented in these approved STCs meets the

requirements for exemption from the human subject research provisions of the Common Rule set forth in 45 CFR 46.104(d)(5).

IV. ELIGIBILITY AND ENROLLMENT

16. Eligibility Groups Affected by the Demonstration. Under the demonstration, there is no change to Medicaid eligibility. Standards and methodologies for eligibility remain set forth under the state plan. This demonstration will apply to otherwise-eligible Medicaid beneficiaries residing in an IMD for diagnoses of substance use disorder (SUD).

V. SUBSTANCE USE DISORDER PROGRAM AND BENEFITS

17. SUD Program Benefits. Effective upon CMS' approval of the SUD Implementation Plan, the demonstration benefit package for Medicaid beneficiaries will include SUD treatment services, including services provided in residential and inpatient treatment settings that qualify as an IMD, which are not otherwise matchable expenditures under section 1903 of the Act. The state will be eligible to receive FFP for Medicaid beneficiaries who are short-term residents in IMDs under the terms of this demonstration for coverage of medical assistance, including OUD/SUD services that would otherwise be matchable if the beneficiary were not residing in an IMD once CMS approves the state's Implementation Plan. The state will aim for a statewide average length of stay of 30 days or less in residential treatment settings, to be monitored pursuant to the SUD Monitoring Protocol as outlined in STC 20, to ensure short-term residential stays.

Under this demonstration beneficiaries will have access to high quality, evidence-based OUD/SUD treatment services across a comprehensive continuum of care, ranging from residential and inpatient treatment to ongoing chronic care for these conditions in cost-effective community-based settings.

18. Community Integration Services. Under this demonstration, the state also intends to provide Community Integration Services (CIS) which consists of housing and employment supports to assist individuals who meet a risk factor identified in the CIS needs-based criteria. The state will be subject to the terms and conditions for these services as outlined in section VI.

19. SUD Implementation Plan and Health IT Plan.

- a. The state must submit the SUD Implementation Plan within ninety (90) calendar days after approval of this demonstration. The state must submit the revised SUD Implementation Plan within sixty (60) days after receipt of CMS's comments. The state may not claim FFP for services provided in IMDs to beneficiaries who are primarily receiving SUD treatment and withdrawal management services until CMS has approved the SUD Implementation Plan. Once approved, the SUD Implementation Plan will be incorporated into the STCs as Attachment C and, once incorporated, may be altered only with CMS approval. After approval of the applicable implementation plans required by these STCs, FFP will be available prospectively, not retrospectively.

- b. Failure to submit a SUD Implementation Plan will be considered a material failure to comply with the terms of the demonstration project as described in 42 CFR 431.420(d) and, as such, would be grounds for termination or suspension of the SUD program under this demonstration. Failure to progress in meeting the milestone goals agreed upon by the state and CMS will result in a funding deferral as described in STC 33.
- c. At a minimum, the SUD Implementation Plan must describe the strategic approach and detailed project implementation plan, including timetables and programmatic content where applicable, for meeting the following milestones which reflect the key goals and objectives for the program:
 - i. Access to Critical Levels of Care for OUD and other SUDs. Coverage of OUD/SUD treatment services across a comprehensive continuum of care including: outpatient; intensive outpatient; medication assisted treatment (medication as well as counseling and other services with sufficient provider capacity to meet needs of Medicaid beneficiaries in the state); intensive levels of care in residential and inpatient settings; and medically supervised withdrawal management, within 12-24 months of demonstration approval;
 - ii. Use of Evidence-based SUD-specific Patient Placement Criteria. Establishment of a requirement that providers assess treatment needs based on SUD-specific, multidimensional assessment tools, such as the American Society of Addiction Medicine (ASAM) Criteria or other assessment and placement tools that reflect evidence-based clinical treatment guidelines within 12-24 months of demonstration approval;
 - iii. Patient Placement. Establishment of a utilization management approach such that beneficiaries have access to SUD services at the appropriate level of care and that the interventions are appropriate for the diagnosis and level of care, including an independent process for reviewing placement in residential treatment settings within 12-24 months of demonstration approval;
 - iv. Use of Nationally Recognized SUD-specific Program Standards to set Provider Qualifications for Residential Treatment Facilities. The state must establish residential treatment provider qualifications in licensure, policy or provider manuals, managed care contracts or credentialing, or other requirements or guidance that meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding in particular the types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
 - v. Standards of Care. Establishment of a provider review process to ensure that residential treatment providers deliver care consistent with the specifications in the ASAM Criteria or other comparable, nationally recognized SUD program standards based on evidence-based clinical treatment guidelines for types of services, hours of clinical care, and credentials of staff for residential treatment settings within 12-24 months of demonstration approval;
 - vi. Standards of Care. Establishment of a requirement that residential treatment providers offer MAT on-site or facilitate access to MAT off-site within 12-24 months of demonstration approval;

- vii. Sufficient Provider Capacity at each Level of Care including Medication Assisted Treatment for SUD/OD. An assessment of the availability of providers in the critical levels of care throughout the state, or in the regions of the state participating under this demonstration, including those that offer MAT within 12 months of demonstration approval;
- viii. Implementation of Comprehensive Treatment and Prevention Strategies to Address Opioid Abuse and SUD/OD. Implementation of opioid prescribing guidelines along with other interventions to prevent prescription drug abuse and expand coverage of and access to naloxone for overdose reversal as well as implementation of strategies to increase utilization and improve functionality of prescription drug monitoring programs;
- ix. Improved Care Coordination and Transitions between levels of care. Establishment and implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities within 24 months of demonstration approval.
- x. SUD Health IT Plan. Implementation of the milestones and metrics as detailed in STC 19(d).
- d. SUD Health Information Technology Plan (“Health IT Plan”). The SUD Health IT plan applies to all states where the Health IT functionalities are expected to impact beneficiaries within the demonstration. As outlined in SMDL #17-003, states must submit to CMS the applicable Health IT Plans, to be included as sections of the associated Implementation Plans (see STC 19 (a) and 19(c)), to develop infrastructure and capabilities consistent with the requirements outlined.

The Health IT Plan must detail the necessary health IT capabilities in place to support beneficiary health outcomes to address the SUD goals of the demonstration. The plan will also be used to identify areas of health IT ecosystem improvement. The Plan must include implementation milestones and projected dates for achieving them (see Attachment C), and must be aligned with the state’s broader State Medicaid Health IT Plan (SMHP) and, if applicable, the state’s Behavioral Health (BH) IT Health Plan.

- i. The state must include in its Monitoring Protocol (see STC 20) an approach to monitoring its SUD Health IT Plan, which will include performance metrics to be approved in advance by CMS.
- ii. The state must monitor progress, each DY, on the implementation of its SUD Health IT Plan in relationship to its milestones and timelines—and report on its progress to CMS in an addendum to its Annual Report (see STC 36).
- iii. As applicable, the state should advance the standards identified in the ‘Interoperability Standards Advisory—Best Available Standards and Implementation Specifications’ (ISA) in developing and implementing the state’s SUD Health IT policies and in all related applicable State procurements (e.g., including managed care contracts) that are associated with this demonstration.
- iv. Where there are opportunities at the state- and provider-level (up to and including usage in MCO or ACO participation agreements) to leverage federal funds associated with a standard referenced in 45 CFR 170 Subpart B, the

state should use the federally-recognized standards, barring another compelling state interest.

- v. Where there are opportunities at the state- and provider-level to leverage federal funds associated with a standard not already referenced in 45 CFR 170 but included in the ISA, the state should use the federally-recognized ISA standards, barring no other compelling state interest.
- vi. Components of the Health IT Plan include:
 - 1) The Health IT Plan must describe the state’s goals, each DY, to enhance the state’s prescription drug monitoring program (PDMP).¹
 - 2) The Health IT Plan must address how the state’s PDMP will enhance ease of use for prescribers and other state and federal stakeholders.² This must also include plans to include PDMP interoperability with a statewide, regional or local Health Information Exchange. Additionally, the SUD Health IT Plan must describe ways in which the state will support clinicians in consulting the PDMP prior to prescribing a controlled substance—and reviewing the patients’ history of controlled substance prescriptions—prior to the issuance of a Controlled Substance Schedule II (CSII) opioid prescription.
 - 3) The Health IT Plan will, as applicable, describe the state’s capabilities to leverage a master patient index (or master data management service, etc.) in support of SUD care delivery. Additionally, the Health IT Plan must describe current and future capabilities regarding PDMP queries—and the state’s ability to properly match patients receiving opioid prescriptions with patients in the PDMP. The state will also indicate current efforts or plans to develop and/or utilize current patient index capability that supports the programmatic objectives of the demonstration.
 - 4) The Health IT Plan will describe how the activities described in (i), (ii) and (iii) above will support broader state and federal efforts to diminish the likelihood of long-term opioid use directly correlated to clinician prescribing patterns.³
 - 5) The Health IT Plan will describe the state’s current and future capabilities to support providers implementing or expanding Health IT functionality in the following areas: 1) Referrals, 2) Electronic care plans and medical records, 3) Consent, 4) Interoperability, 5) Telehealth, 6) Alerting/analytics, and 7) Identity management.
 - 6) In developing the Health IT Plan, states should use the following resources:
 - 1. States may use federal resources available on Health IT.Gov (<https://www.healthit.gov/topic/behavioral-health>) including

¹ Prescription drug monitoring programs (PDMP) are electronic databases that track controlled substance prescriptions in states. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the “opioid” epidemic and facilitate a nimble and targeted response.

² *Ibid.*

³ Shah, Anuj, Corey Hayes and Bradley Martin. *Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015*. MMWR Morb Mortal Wkly Rep 2017;66.

but not limited to “Behavioral Health and Physical Health Integration” and “Section 34: Opioid Epidemic and Health IT” (<https://www.healthit.gov/playbook/health-information-exchange/>).

2. States may also use the CMS 1115 Health IT resources available on “Medicaid Program Alignment with State Systems to Advance HIT, HIE and Interoperability” at <https://www.medicaid.gov/medicaid/data-and-systems/hie/index.html>. States should review the “1115 Health IT Toolkit” for health IT considerations in conducting an assessment and developing their Health IT Plans.
- 7) States may request from CMS technical assistance to conduct an assessment and develop plans to ensure they have the specific health IT infrastructure with regards to PDMP interoperability, electronic care plan sharing, care coordination, and behavioral health-physical health integration, to meet the goals of the demonstration.

20. SUD Monitoring Protocol. The state must submit a Monitoring Protocol for the SUD programs authorized by this demonstration within one hundred fifty (150) calendar days after approval of the demonstration. The Monitoring Protocol Template must be developed in cooperation with CMS and is subject to CMS approval. The state must submit a revised Monitoring Protocol within sixty (60) calendar days after receipt of CMS’ comments. Once approved, the SUD Monitoring Protocol will be incorporated into the STCs, as Attachment D. Progress on the performance measures identified in the Monitoring Protocol must be reported via the quarterly and annual monitoring reports. Components of the Monitoring Protocol include:

- a. An assurance of the state’s commitment and ability to report information relevant to each of the program implementation areas listed in STC 19(c) and reporting relevant information to the state’s Health IT plan described in STC 19(d);
- b. A description of the methods of data collection and timeframes for reporting on the state’s progress on required measures as part of the general reporting requirements described in Section IX of the demonstration; and
- c. A description of baselines and targets to be achieved by the end of the demonstration. Where possible, baselines will be informed by state data, and targets will be benchmarked against performance in best practice settings.

21. Evaluation. The SUD Evaluation will be subject to the same requirements as the overall demonstration evaluation, as described in Sections IX (General Reporting Requirements) and XI (Evaluation of the Demonstration) of these STCs.

VI. COMMUNITY INTEGRATION SERVICES

22. Overview. The state will provide a limited set of housing and employment supports to Medicaid beneficiaries with a SUD diagnosis, who also require assistance with activities of daily living (ADLs), or a complex physical health need who are transitioning out of an

inpatient or other residential setting. Qualifying beneficiaries must be expected to benefit from supports necessary to obtain and maintain stable housing.

23. CIS Benefits. The state will provide housing and employment supports otherwise allowable under a 1915(i) SPA, including the services below, and described in greater detail in Attachment F:

- a. Individual housing and pre-tenancy services, individual housing and tenancy sustaining services, and community transition services.
- b. Pre-employment and employment support services

24. CIS Eligibility. Medicaid beneficiaries who are eligible under the Medicaid state plan and who have a SUD diagnosis will be eligible for the benefits described in this section, provided they meet the needs-based criteria and risk factors, as outlined in Attachment F.

25. CIS Eligibility and Services. Eligibility and Services describes the services and requirements that would otherwise be documented in a 1915(i) SPA, including needs-based eligibility criteria, risk factors, covered services, service definitions, payment methodology, administrative approach, and minimum provider qualifications.

26. CIS Home and Community Based Services (HCBS) Requirements. For CIS HCBS, the state assures that its MCO Quality Assessment and Performance Improvement program must encompass long-term services and supports (LTSS) specific measures set forth in the federal managed care rule at 42 CFR 438.330, and will assess and improve performance as described below in the following areas:

- a. Administrative Authority: A performance measure must be developed and tracked for authorities that the State Medicaid Agency (SMA) delegates to another agency or MCOs, unless already captured in another performance measure, including: the review and monitoring of interagency agreements (IAG)/contract evaluations and the MCO quality management review (QMR) reports submitted in accordance with requirements. The SMA is responsible for operations and oversight, and will monitor and track the MCOs' delegated activities.
- b. Eligibility Based on 1115 Requirements: A performance measure is required for the following: tracking of all new enrollees who receive an evaluation for HCBS eligibility prior to receiving services. While a performance measure to track annual eligibility determinations is not required since the state is not required to report to CMS, the state is expected to ensure annual eligibility determinations are completed.
- c. Qualified Providers: The state must have performance measures that track that providers meet licensure/certification standards, that non-certified providers are monitored to assure adherence to demonstration requirements, and that the state verifies that training is given to providers in accordance with the demonstration.
- d. Service Plan: The state must demonstrate it has designed and implemented an effective system for reviewing the adequacy of service plans for HCBS participants. Performance measures are required for individuals who have support plans that address their assessed needs, capabilities and desired outcomes; individuals whose service plan was updated/revised at least annually; and individual records that

indicate that a risk assessment was completed as required.

- e. Health and Welfare: The state must assure that it has designed and implemented an effective system for assuring HCBS participants' health and welfare. The state must have performance measures that track participants for whom critical incidents were reported in which appropriate action was taken; unexplained deaths in which appropriate action was taken; and critical incidents reported to the MCO within the required timeframes.
- f. Financial Accountability: The state must demonstrate that it has designed and implemented an adequate system for ensuring financial accountability of the HCBS program. The state must demonstrate actuarial soundness on an annual basis pursuant to 42 CFR 438.
- g. HCBS Settings Requirements: The state must assure compliance with the HCBS settings requirements for those services that could be authorized under section 1915(i) in accordance with 42 CFR 441.710.

27. CIS Reporting. The state must submit a report to CMS as an attachment to its quarterly and annual monitoring reports described in STC 36 that includes performance measure evidence of compliance at or above 86 percent with the HCBS quality assurances and measures.

28. CIS Reporting Deficiencies. The state must report, as an attachment to its quarterly and annual monitoring report described in STC 36 the deficiencies found below 86 percent compliance during the monitoring and evaluation of the HCBS demonstration assurances, an explanation of how these deficiencies have been or are being corrected, as well as the steps that have been taken to ensure that these deficiencies do not reoccur. The state must also report on the number of substantiated instances of abuse, neglect, exploitation and/or death, the actions taken regarding the incidents, and how they were resolved.

29. CIS Beneficiary Protections.

- a. The state assures there is a person-centered service plan for each individual determined to be eligible for HCBS. The person-centered service plan is developed using a person-centered service planning process in accordance with 42 CFR 441.725(a), and the written person-centered service plan meets federal requirement at 42 CFR 441.725(b). The person-centered service plan is reviewed, and revised upon reassessment of functional need as required by 42 CFR 441.725(c), at least every 12 months, when the individual's circumstances or needs change significantly, or at the request of the individual.
- b. The state agrees that the entity that authorizes the services is external to the agency or agencies that provide the HCBS services. The state also agrees that appropriate separation of assessment, treatment planning and service provision functions are incorporated into the state's conflict of interest policies.
- c. The state, either directly or through its MCO contracts, must ensure that participants' engagement and community participation is supported to the fullest extent desired by each participant.
- d. Beneficiaries may change MCOs if their residential or employment support provider is no longer available through their current plan.

VII. COST SHARING

30. Cost Sharing. Cost sharing imposed upon individuals enrolled in the demonstration is consistent with the provisions of the approved state plan.

VIII. DELIVERY SYSTEM

31. Delivery System. All demonstration beneficiaries will continue to receive services through the same delivery system arrangements as currently authorized in the state.

IX. GENERAL REPORTING REQUIREMENTS

32. Deferral for Failure to Submit Timely Demonstration Deliverables. CMS may issue deferrals in accordance with 42 CFR part 430 subpart C, in the amount of \$5,000,000 per deliverable (federal share) when items required by these STCs (e.g., required data elements, analyses, reports, design documents, presentations, and other items specified in these STCs) (hereafter singly or collectively referred to as “deliverable(s)”) are not submitted timely to CMS or are found to not be consistent with the requirements approved by CMS. A deferral shall not exceed the value of the federal amount for the current demonstration period. The state does not relinquish its rights provided under 42 CFR part 430 subpart C to challenge any CMS finding that the state materially failed to comply with the terms of this agreement. The following process will be used: 1) Thirty (30) days after the deliverable was due if the state has not submitted a written request to CMS for approval of an extension as described in subsection (b) below; or 2) Thirty (30) days after CMS has notified the state in writing that the deliverable was not accepted for being inconsistent with the requirements of this agreement and the information needed to bring the deliverable into alignment with CMS requirements:

- a. CMS will issue a written notification to the state providing advance notification of a pending deferral for late or non-compliant submissions of required deliverable(s).
- b. For each deliverable, the state may submit to CMS a written request for an extension to submit the required deliverable that includes a supporting rationale for the cause(s) of the delay and the state’s anticipated date of submission. Should CMS agree to the state’s request, a corresponding extension of the deferral process can be provided. CMS may agree to a corrective action plan submitted by the state as an interim step before applying the deferral, if the state proposes a corrective action plan in the state’s written extension request.
- c. If CMS agrees to an interim corrective plan in accordance with subsection (b), and the state fails to comply with the corrective action plan or, despite the corrective action plan, still fails to submit the overdue deliverable(s) with all required contents in satisfaction of the terms of this agreement, CMS may proceed with the issuance of a deferral against the next Quarterly Statement of Expenditures reported in Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) following a written deferral notification to the state.
- d. If the CMS deferral process has been initiated for state non-compliance with the terms of this agreement with respect to required deliverable(s), and the state submits

the overdue deliverable(s), and such deliverable(s) are accepted by CMS as meeting the requirements specified in these STCs, the deferral(s) will be released.

- e. As the purpose of a section 1115 demonstration is to test new methods of operation or service delivery, a state's failure to submit all required reports, evaluations and other deliverables will be considered by CMS in reviewing any application for an extension, amendment, or for a new demonstration.

33. Deferral of Federal Financial Participation (FFP) from IMD Claiming for Insufficient Progress Toward Milestones. Up to \$5,000,000 in FFP for services in IMDs may be deferred if the state is not making adequate progress on meeting the milestones and goals as evidenced by reporting on the milestones in the Implementation Plans and the required performance measures in the Monitoring Plan agreed upon by the state and CMS. Once CMS determines the state has not made adequate progress, up to \$5,000,000 will be deferred in the next calendar quarter and each calendar quarter thereafter until CMS has determined sufficient progress has been made.

34. Submission of Post-Approval Deliverables. The state must submit all deliverables as stipulated by CMS and within the timeframes outlined within these STCs.

35. Compliance with Federal Systems Updates. As federal systems continue to evolve and incorporate additional 1115 demonstration reporting and analytics functions, the state will work with CMS to:

- a. Revise the reporting templates and submission processes to accommodate timely compliance with the requirements of the new systems;
- b. Ensure all 1115, T-MSIS, and other data elements that have been agreed to for reporting and analytics are provided by the state; and
- c. Submit deliverables to the appropriate system as directed by CMS.

X. MONITORING

36. Monitoring Reports. The state must submit three (3) Quarterly Monitoring Reports and one (1) Annual Monitoring Report each DY. The fourth quarter information that would ordinarily be provided in a separate report should be reported as distinct information within the Annual Report. The Quarterly Monitoring Reports are due no later than sixty (60) calendar days following the end of each demonstration quarter. The Annual Monitoring Report is due no later than ninety (90) calendar days following the end of the DY. The reports will include all required elements as per 42 CFR 431.428, and should not direct readers to links outside the report. Additional links not referenced in the document may be listed in a Reference/Bibliography section. The Monitoring Reports must follow the framework provided by CMS, which is subject to change as monitoring systems are developed/evolve, and be provided in a structured manner that supports federal tracking and analysis.

- a. Operational Updates. The operational updates will focus on progress toward meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document any policy or administrative difficulties in operating the demonstration. The reports shall provide sufficient information to document key

- challenges, underlying causes of challenges, how challenges are being addressed, as well as key achievements and to what conditions and efforts successes can be attributed. The discussion should also include any issues or complaints identified by beneficiaries; lawsuits or legal actions; unusual or unanticipated trends; legislative updates; and descriptions of any public forums held. The Monitoring Report should also include a summary of all public comments received through post-award public forums regarding the progress of the demonstration.
- b. Performance Metrics. The performance metrics will provide data to demonstrate how the state is progressing towards meeting the demonstration's milestones. Additionally, per 42 CFR 431.428, the Monitoring Reports must document the impact of the demonstration in providing insurance coverage to beneficiaries and the uninsured population, as well as outcomes of care, quality and cost of care, and access to care. This may also include the results of beneficiary satisfaction surveys, if conducted, grievances and appeals. The required monitoring and performance metrics must be included in writing in the Monitoring Reports, and will follow the framework provided by CMS to support federal tracking and analysis.
 - c. Budget Neutrality and Financial Reporting Requirements. Per 42 CFR 431.428, the Monitoring Reports must document the financial performance of the demonstration. The state must provide an updated budget neutrality workbook with every Monitoring Report that meets all the reporting requirements for monitoring budget neutrality set forth in the General Financial Requirements Section XII of these STCs, including the submission of corrected budget neutrality data upon request. In addition, the state must report quarterly and annual expenditures associated with the populations affected by this demonstration on the Form CMS-64. Administrative costs should be reported separately.
 - d. Evaluation Activities and Interim Findings. Per 42 CFR 431.428, the Monitoring Reports must document any results of the demonstration to date per the evaluation hypotheses. Additionally, the state shall include a summary of the progress of evaluation activities, including key milestones accomplished, as well as challenges encountered and how they were addressed.
 - e. SUD Health IT. The state will include a summary of progress made in regards to SUD Health IT requirements outlined in STC 19(d).

37. SUD Mid-Point Assessment. The state must conduct an independent mid-point assessment by September 30, 2023. In the design, planning and conduction of the mid-point assessment, the state must require that the independent assessor consult with key stakeholders including, but not limited to: representatives of MCOs, SUD treatment providers, beneficiaries, and other key partners. The state must require that the assessor provide a report to the state that includes the methodologies used for examining progress and assessing risk, the limitations of the methodologies, its determinations and any recommendations. The state must provide a copy of the report to CMS no later than sixty (60) days after September 30, 2023. This timeline will allow for the assessment report to capture approximately the first two-and-a-half years of demonstration program data, accounting for data run-out and data completeness. The state must brief CMS on the report.

For milestones and measure targets at medium to high risk of not being achieved, the state must submit to CMS modifications to the SUD Implementation Plan, and the SUD Monitoring Protocol for ameliorating these risks. Modifications to the applicable Implementation, Financing, and Monitoring Protocol are subject to CMS approval. Elements of the mid-point assessment include:

- a. An examination of progress toward meeting each milestone and timeframe approved in the SUD Implementation Plans and toward meeting the targets for performance measures as approved in the SUD Monitoring Protocol;
- b. A determination of factors that affected achievement on the milestones and performance measure gap closure percentage points to date;
- c. A determination of selected factors likely to affect future performance in meeting milestones and targets not yet met and information about the risk of possibly missing those milestones and performance targets;
- d. For milestones or targets at medium to high risk of not being met, recommendations for adjustments in the state's SUD Implementation Plan or to pertinent factors that the state can influence that will support improvement; and
- e. An assessment of whether the state is on track to meet the budget neutrality requirements.

38. Corrective Action. If monitoring indicates that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

39. Close-Out Report. Within one hundred twenty (120) calendar days after the expiration of the demonstration, the state must submit a Draft Close-Out Report to CMS for comments.

- a. The draft close-out report must comply with the most current guidance from CMS.
- b. The state will present to and participate in a discussion with CMS on the close-out report.
- c. The state must take into consideration CMS' comments for incorporation into the final close-out report.
- d. The final close-out report is due to CMS no later than thirty (30) calendar days after receipt of CMS' comments.
- e. A delay in submitting the draft or final version of the close-out report may subject the state to penalties described in STC 32.

40. Monitoring Calls. CMS will convene periodic conference calls with the state.

- a. The purpose of these calls is to discuss ongoing demonstration operation, to include (but not limited to) any significant actual or anticipated developments affecting the demonstration. Examples include implementation activities, trends in reported data on metrics and associated mid-course adjustments, enrollment and access, budget neutrality, and progress on evaluation activities.
- b. CMS will provide updates on any pending actions, as well as federal policies and issues that may affect any aspect of the demonstration.
- c. The state and CMS will jointly develop the agenda for the calls.

41. Post Award Forum. Pursuant to 42 CFR 431.420(c), within six (6) months of the demonstration's implementation, and annually thereafter, the state must afford the public with an opportunity to provide meaningful comment on the progress of the demonstration. At least thirty (30) days prior to the date of the planned public forum, the state must publish the date, time and location of the forum in a prominent location on its website. The state must also post the most recent annual report on its website with the public forum announcement. Pursuant to 42 CFR 431.420(c), the state must include a summary of the comments in the Monitoring Report associated with the quarter in which the forum was held, as well as in its compiled Annual Report.

XI. EVALUATION OF THE DEMONSTRATION

42. Cooperation with Federal Evaluators. As required under 42 CFR 431.420(f), the state must cooperate fully and timely with CMS and its contractors in any federal evaluation of the demonstration or any component of the demonstration. This includes, but is not limited to, commenting on design and other federal evaluation documents and providing data and analytic files to CMS, including entering into a data use agreement that explains how the data and data files will be exchanged, and providing a technical point of contact to support specification of the data and files to be disclosed, as well as relevant data dictionaries and record layouts. The state must include in its contracts with entities who collect, produce or maintain data and files for the demonstration, that they must make such data available for the federal evaluation as is required under 42 CFR 431.420(f) to support federal evaluation. The state may claim administrative match for these activities. Failure to comply with this STC may result in a deferral being issued as outlined in STC 32.

43. Independent Evaluator. Upon approval of the demonstration, the state must begin to arrange with an independent party to conduct an evaluation of the demonstration to ensure that the necessary data is collected at the level of detail needed to research the approved hypotheses. The state must require the independent party to sign an agreement that the independent party will conduct the demonstration evaluation in an independent manner in accordance with the CMS-approved draft Evaluation Design. When conducting analyses and developing the evaluation reports, every effort should be made to follow the approved methodology. However, the state may request, and CMS may agree to, changes in the methodology in appropriate circumstances.

44. Draft Evaluation Design. The draft Evaluation Design must be developed in accordance with Attachment A (Developing the Evaluation Design) of these STCs. The state must submit, for CMS comment and approval, a draft Evaluation Design with implementation timeline, no later than one hundred eighty (180) days after the approval of the demonstration. Any modifications to an existing approved Evaluation Design will not affect previously established requirements and timelines for report submission for the demonstration, if applicable. The draft Evaluation Design must be developed in accordance with the following CMS guidance (including but not limited to):

- a. All applicable Evaluation Design guidance, including guidance about SUD. Hypotheses applicable to the demonstration as a whole, and to all key policies referenced above, will include (but will not be limited to): the effects of the

demonstration on health outcomes; the financial impact of the demonstration (for example, such as an assessment of medical debt and uncompensated care costs).

- b. Attachment A (Developing the Evaluation Design) of these STCs, technical assistance for developing SUD Evaluation Designs (as applicable, and as provided by CMS), and all applicable technical assistance on how to establish comparison groups to develop a Draft Evaluation Design.

45. Evaluation Budget. A budget for the evaluations must be provided with the draft Evaluation Designs. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative and other costs for all aspects of the evaluations such as any survey and measurement development, quantitative and qualitative data collection and cleaning, analyses and report generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the design or if CMS finds that the designs are not sufficiently developed, or if the estimates appear to be excessive.

46. Evaluation Design Approval and Updates. The state must submit the revised draft Evaluation Designs within sixty (60) calendar days after receipt of CMS' comments. Upon CMS approval of the draft Evaluation Designs, the documents will be included as an attachment to these STCs. Per 42 CFR 431.424(c), the state will publish the approved Evaluation Design to the state's website within thirty (30) calendar days of CMS approval. The state must implement the evaluation designs and submit a description of its evaluation implementation progress in each of the Monitoring Reports, including any required Rapid Cycle Assessments specified in these STCs. Once CMS approves the evaluation designs, if the state wishes to make changes, the state must submit a revised evaluation design to CMS for approval.

47. Evaluation Questions and Hypotheses. Consistent with Attachments A and B (Developing the Evaluation Design and Preparing the Interim and Summative Evaluation Report) of these STCs, the evaluation documents must include a discussion of the evaluation questions and hypotheses that the state intends to test. Each demonstration component should have at least one evaluation question and hypothesis. The hypothesis testing should include, where possible, assessment of both process and outcome measures. Proposed measures should be selected from nationally-recognized sources and national measures sets, where possible. Measures sets could include CMS's Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).

48. Interim Evaluation Report. The state must submit an Interim Evaluation Report for each evaluation design, as applicable, and for the completed years of the demonstration, and for each subsequent renewal or extension of the demonstration, as outlined in 42 CFR 431.412(c)(2)(vi). When submitting an application for renewal, the Evaluation Reports should be posted to the state's website with the application for public comment.

- a. The Interim Evaluation Report will discuss evaluation progress and present findings to date as per the approved evaluation design.

- b. For demonstration authority that expires prior to the overall demonstration's expiration date, the Interim Evaluation Report must include an evaluation of the authority as approved by CMS.
- c. If the state is seeking to renew or extend the demonstration, the draft Interim Evaluation Report is due when the application for renewal is submitted. If the state made changes to the demonstration in its application for renewal, the research questions and hypotheses and a description of how the design was adapted should be included. If the state is not requesting a renewal for the demonstration, the Interim Evaluation Report is due one (1) year prior to the end of the demonstration. For demonstration phase outs prior to the expiration of the approval period, the draft Interim Evaluation Report is due to CMS on the date that will be specified in the notice of termination or suspension.
- d. The state must submit the final Interim Evaluation Report sixty (60) calendar days after receiving CMS comments on the draft Interim Evaluation Report and post the document to the state's website.
- e. The Interim Evaluation Report must comply with Attachment B of these STCs.

49. Summative Evaluation Report. The draft Summative Evaluation Report must be developed in accordance with Attachment B (Preparing the Interim and Summative Evaluation Report) of these STCs. The state must submit the draft Summative Evaluation Report for the demonstration's current approval period within eighteen (18) months of the end of the approval period represented by these STCs. The Summative Evaluation Report must include the information in the approved Evaluation Design.

- a. Unless otherwise agreed upon in writing by CMS, the state must submit the final Summative Evaluation Report within sixty (60) calendar days of receiving comments from CMS on the draft.
- b. The final Summative Evaluation Report must be posted to the state's Medicaid website within thirty (30) calendar days of approval by CMS.

50. Corrective Action Plan Related to Evaluation. If evaluation findings indicate that demonstration features are not likely to assist in promoting the objectives of Medicaid, CMS reserves the right to require the state to submit a corrective action plan to CMS for approval. These discussions may also occur as part of a renewal process when associated with the state's Interim Evaluation Report. This may be an interim step to withdrawing waivers or expenditure authorities, as outlined in STC 10.

51. State Presentations for CMS. CMS reserves the right to request that the state present and participate in a discussion with CMS on the Evaluation Design, the Interim Evaluation Report, and/or the Summative Evaluation Report.

52. Public Access. The state shall post the final documents (e.g., Monitoring Reports, Close Out Report, the approved Evaluation Design, Interim Evaluation Reports, and Summative Evaluation Reports) on the state's website within thirty (30) calendar days of approval by CMS.

53. Additional Publications and Presentations. For a period of twelve (12) months following CMS approval of the final reports, CMS will be notified prior to presentation of these reports or their findings, including in related publications (including, for example, journal articles), by the state, contractor, or any other third party directly connected to the demonstration. Prior to release of these reports, articles or other publications, CMS will be provided a copy including any associated press materials. CMS will be given ten (10) business days to review and comment on publications before they are released. CMS may choose to decline to comment on or review some or all of these notifications and reviews. This requirement does not apply to the release or presentation of these materials to state or local government officials.

XIII. GENERAL FINANCIAL REQUIREMENTS UNDER TITLE XIX

54. Allowable Expenditures. This demonstration project is approved for expenditures applicable to services rendered during the demonstration approval period designated by CMS. CMS will provide FFP for allowable demonstration expenditures only so long as they do not exceed the pre-defined limits as specified in these STCs.⁴

55. Unallowable Expenditures. In addition to the other unallowable costs and caveats already outlined in these STCs, the state may not receive FFP under any expenditure authority approved under this demonstration for any of the following:

- a. Room and board costs for residential treatment service providers unless they qualify as inpatient facilities under section 1905(a) of the Act.

56. Standard Medicaid Funding Process. The standard Medicaid funding process will be used for this demonstration. The state will provide quarterly expenditure reports through the Medicaid and CHIP Budget and Expenditure System (MBES/CBES) to report total expenditures for services provided under this demonstration following routine CMS-37 and CMS-64 reporting instructions as outlined in section 2500 of the State Medicaid Manual. The state will estimate matchable demonstration expenditures (total computable and federal share) subject to the budget neutrality expenditure limit and separately report these expenditures by quarter for each federal fiscal year on the form CMS-37 for both the medical assistance payments (MAP) and state and local administration costs (ADM). CMS shall make federal funds available based upon the state's estimate, as approved by CMS. Within thirty (30) days after the end of each quarter, the state shall submit form CMS-64 (Quarterly Medicaid Expenditure Report), showing Medicaid expenditures made in the quarter that just ended. If applicable, subject to the payment deferral process, CMS shall reconcile expenditures reported on form CMS-64 with federal funding previously made available to the state, and include the reconciling adjustment in the finalization of the grant award to the state.

57. Extent of Federal Financial Participation for the Demonstration. Subject to CMS approval of the source(s) of the non-federal share of funding, CMS will provide FFP at the

⁴ For a description of CMS's current policies related to budget neutrality for Medicaid demonstration projects authorized under section 1115(a) of the Act, see State Medicaid Director Letter #18-009. Oregon Health Plan Substance Use Disorder 1115 Demonstration
Approval Period: April 8, 2021 through March 31, 2026

applicable federal matching rate for the demonstration as a whole for the following, subject to the budget neutrality expenditure limits described in Section XII:

- a. Administrative costs, including those associated with the administration of the demonstration;
- b. Net expenditures and prior period adjustments of the Medicaid program that are paid in accordance with the approved Medicaid state plan; and
- c. Medical assistance expenditures and prior period adjustments made under section 1115 demonstration authority with dates of service during the demonstration extension period; including those made in conjunction with the demonstration, net of enrollment fees, cost sharing, pharmacy rebates, and all other types of third party liability.

58. Sources of Non-Federal Share. The state certifies that its match for the non-federal share of funds for this demonstration are state/local monies. The state further certifies that such funds must not be used to match for any other federal grant or contract, except as permitted by law. All sources of non-federal funding must be compliant with section 1903(w) of the Act and applicable regulations. In addition, all sources of the non-federal share of funding are subject to CMS approval.

- a. The state acknowledges that CMS has authority to review the sources of the non-federal share of funding for the demonstration at any time. The state agrees that all funding sources deemed unacceptable by CMS shall be addressed within the time frames set by CMS.
- b. The state acknowledges that any amendments that impact the financial status of the demonstration must require the state to provide information to CMS regarding all sources of the non-federal share of funding.

59. State Certification of Funding Conditions. The state must certify that the following conditions for non-federal share of demonstration expenditures are met:

- a. Units of government, including governmentally operated health care providers, may certify that state or local monies have been expended as the non-federal share of funds under the demonstration.
- b. To the extent the state utilizes certified public expenditures (CPE) as the funding mechanism for the state share of title XIX payments, including expenditures authorized under a section 1115 demonstration, CMS must approve a cost reimbursement methodology. This methodology must include a detailed explanation of the process by which the state would identify those costs eligible under title XIX (or under section 1115 authority) for purposes of certifying public expenditures.
- c. To the extent the state utilizes CPEs as the funding mechanism to claim federal match for expenditures under the demonstration, governmental entities to which general revenue funds are appropriated must certify to the state the amount of such state or local monies that are allowable under 42 CFR 433.51 to satisfy demonstration expenditures. If the CPE is claimed under a Medicaid authority, the federal matching funds received cannot then be used as the state share needed to receive other federal matching funds under 42 CFR 433.51(c). The entities that incurred the cost must also provide cost documentation to support the state's claim for federal match.

- d. The state may use intergovernmental transfers (IGT) to the extent that such funds are derived from state or local monies and are transferred by units of government within the state. Any transfers from governmentally operated health care providers must be made in an amount not to exceed the non-federal share of title XIX payments.
- e. Under all circumstances, health care providers must retain one hundred (100) percent of the reimbursement for claimed expenditures. Moreover, consistent with 42 CFR 447.10, no pre-arranged agreements (contractual, voluntary, or otherwise) may exist between health care providers and state and/or local government to return and/or redirect to the state any portion of the Medicaid payments. This confirmation of Medicaid payment retention is made with the understanding that payments that are the normal operating expenses of conducting business, such as payments related to taxes, including health care provider-related taxes, fees, business relationships with governments that are unrelated to Medicaid and in which there is no connection to Medicaid payments, are not considered returning and/or redirecting a Medicaid payment.

60. Program Integrity. The state must have processes in place to ensure there is no duplication of federal funding for any aspect of the demonstration. The state must also ensure that the state and any of its contractors follow standard program integrity principles and practices including retention of data. All data, financial reporting, and sources of non-federal share are subject to audit.

61. Medicaid Expenditure Groups (MEG). MEGs are defined for the purpose of identifying categories of Medicaid or demonstration expenditures subject to budget neutrality, components of budget neutrality expenditure limit calculations, and other purposes related to monitoring and tracking expenditures under the demonstration. The Master MEG Chart table provides a master list of MEGs defined for this demonstration.

Table 1: Master MEG Chart					
MEG	To Which BN Test Does This Apply?	WOW Per Capita	WOW Aggregate	WW	Brief Description
SUD-IMD	Hypo 1	X		X	Expenditures for otherwise covered Medicaid services furnished to otherwise eligible individuals who are primarily receiving treatment and withdrawal management services for substance use disorder (SUD) who are short-term residents in facilities that meet the definition of an institution for mental diseases (IMD).

CIS	Hypo 2	X		X	Expenditures for community integration services which consists of housing and employment supports to assist individuals transitioning back into the community from a residential treatment setting.
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62. Reporting Expenditures and Member Months. The state must report all demonstration expenditures claimed under the authority of title XIX of the Act and subject to budget neutrality each quarter on separate forms CMS-64.9 WAIVER and/or 64.9P WAIVER, identified by the demonstration project number assigned by CMS (11-W-0036/2). Separate reports must be submitted by MEG (identified by Waiver Name) and Demonstration Year (identified by the two-digit project number extension). Unless specified otherwise, expenditures must be reported by DY according to the dates of service associated with the expenditure. All MEGs identified in the Master MEG Chart as WW must be reported for expenditures, as further detailed in the MEG Detail for Expenditure and Member Month Reporting table below. To enable calculation of the budget neutrality expenditure limits, the state also must report member months of eligibility for specified MEGs.

- a. Cost Settlements. The state will report any cost settlements attributable to the demonstration on the appropriate prior period adjustment schedules (form CMS-64.9P WAIVER) for the summary sheet line 10b, in lieu of lines 9 or 10c. For any cost settlement not attributable to this demonstration, the adjustments should be reported as otherwise instructed in the State Medicaid Manual. Cost settlements must be reported by DY consistent with how the original expenditures were reported.
- b. Premiums and Cost Sharing Collected by the State. The state will report any premium contributions collected by the state from demonstration enrollees quarterly on the form CMS-64 Summary Sheet line 9D, columns A and B. In order to assure that these collections are properly credited to the demonstration, quarterly premium collections (both total computable and federal share) should also be reported separately by DY on form CMS-64 Narrative, and on the Total Adjustments tab in the Budget Neutrality Monitoring Tool. In the annual calculation of expenditures subject to the budget neutrality expenditure limit, premiums collected in the demonstration year will be offset against expenditures incurred in the demonstration year for determination of the state's compliance with the budget neutrality limits.
- c. Pharmacy Rebates. Because pharmacy rebates are not included in the base expenditures used to determine the budget neutrality expenditure limit, pharmacy rebates are not included for calculating net expenditures subject to budget neutrality. The state will report pharmacy rebates on form CMS-64.9 BASE, and not allocate them to any form 64.9 or 64.9P WAIVER.
- d. Administrative Costs. The state will separately track and report additional administrative costs that are directly attributable to the demonstration. All administrative costs must be identified on the forms CMS-64.10 WAIVER and/or 64.10P WAIVER. Unless indicated otherwise on the Master MEG Chart table, administrative costs are not counted in the budget neutrality tests; however, these costs are subject to monitoring by CMS.

- e. Member Months. As part of the Quarterly and Annual Monitoring Reports described in Section IX, the state must report the actual number of “eligible member months” for all demonstration enrollees for all MEGs identified as WOW Per Capita in the Master MEG Chart table above, and as also indicated in the MEG Detail for Expenditure and Member Month Reporting table below. The term “eligible member months” refers to the number of months in which persons enrolled in the demonstration are eligible to receive services. For example, a person who is eligible for three months contributes three eligible member months to the total. Two individuals who are eligible for two months, each contribute two eligible member months, for a total of four eligible member months. The state must submit a statement accompanying the annual report certifying the accuracy of this information.
- f. Budget Neutrality Specifications Manual. The state will create and maintain a Budget Neutrality Specifications Manual that describes in detail how the state will compile data on actual expenditures related to budget neutrality, including methods used to extract and compile data from the state’s Medicaid Management Information System, eligibility system, and accounting systems for reporting on the CMS-64, consistent with the terms of the demonstration. The Budget Neutrality Specifications Manual will also describe how the state compiles counts of Medicaid member months. The Budget Neutrality Specifications Manual must be made available to CMS on request.

Table 2: MEG Detail for Expenditure and Member Month Reporting

MEG (Waiver Name)	Detailed Description	Exclusions	CMS-64.9 Line(s) To Use	How Expend. Are Assigned to DY	MAP or ADM	Report Member Months (Y/N)	MEG Start Date	MEG End Date
SUD-IMD	See Expenditure Authority #1	See STC 55	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	4/8/2021	3/31/2026
CIS/RSS	See Expenditure Authority #2See expenditure authority #2.	See STC 55	Follow CMS-64.9 Base Category of Service Definition	Date of service	MAP	Y	4/8/2021	3/31/2026

63. Demonstration Years. Demonstration Years (DY) for this demonstration are defined in the Demonstration Years table below.

Table 3: Demonstration Years		
Demonstration Year 1	April 8, 2021 to March 31, 2022	12 months
Demonstration Year 2	April 1 2022 to March 31, 2023	12 months
Demonstration Year 3	April 1, 2023 to March 31, 2024	12 months
Demonstration Year 4	April 1, 2024 to March 31, 2025	12 months
Demonstration Year 5	April 1, 2025 to March 31, 2026	12 months

64. Budget Neutrality Monitoring Tool. The state must provide CMS with quarterly budget neutrality status updates, including established baseline and member months data, using the Budget Neutrality Monitoring Tool provided through the Performance Metrics Database and Analytics (PMDA) system. The tool incorporates the “Schedule C Report” for comparing demonstration’s actual expenditures to the budget neutrality expenditure limits described in Section XIII. CMS will provide technical assistance, upon request.⁵

65. Claiming Period. The state will report all claims for expenditures subject to the budget neutrality agreement (including any cost settlements) within two years after the calendar quarter in which the state made the expenditures. All claims for services during the demonstration period (including any cost settlements) must be made within two years after the conclusion or termination of the demonstration. During the latter two-year period, the state will continue to identify separately net expenditures related to dates of service during the operation of the demonstration on the CMS-64 waiver forms in order to properly account for these expenditures in determining budget neutrality.

66. Future Adjustments to Budget Neutrality. CMS reserves the right to adjust the budget neutrality expenditure limit:

- a. To be consistent with enforcement of laws and policy statements, including regulations and letters, regarding impermissible provider payments, health care related taxes, or other payments, CMS reserves the right to make adjustments to the budget neutrality limit if any health care related tax that was in effect during the base year, or provider-related donation that occurred during the base year, is determined by CMS to be in violation of the provider donation and health care related tax provisions of section 1903(w) of the Act. Adjustments to annual budget targets will reflect the phase out of impermissible provider payments by law or regulation, where applicable.

⁵ 42 CFR §431.420(a)(2) provides that states must comply with the terms and conditions of the agreement between the Secretary (or designee) and the state to implement a demonstration project, and §431.420(b)(1) states that the terms and conditions will provide that the state will perform periodic reviews of the implementation of the demonstration. CMS’s current approach is to include language in STCs requiring, as a condition of demonstration approval, that states provide, as part of their periodic reviews, regular reports of the actual costs which are subject to the budget neutrality limit. CMS has obtained Office of Management and Budget (OMB) approval of the monitoring tool under the Paperwork Reduction Act (OMB Control No. 0938 – 1148) and in states agree to use the tool as a condition of demonstration approval.

- b. To the extent that a change in federal law, regulation, or policy requires either a reduction or an increase in FFP for expenditures made under this demonstration. In this circumstance, the state must adopt, subject to CMS approval, a modified budget neutrality agreement as necessary to comply with such change. The modified agreement will be effective upon the implementation of the change. The trend rates for the budget neutrality agreement are not subject to change under this STC. The state agrees that if mandated changes in the federal law require state legislation, the changes shall take effect on the day such state legislation becomes effective, or on the last day such legislation was required to be in effect under the federal law.
- c. The state certifies that the data it provided to establish the budget neutrality expenditure limit are accurate based on the state's accounting of recorded historical expenditures or the next best available data, that the data are allowable in accordance with applicable federal, state, and local statutes, regulations, and policies, and that the data are correct to the best of the state's knowledge and belief. The data supplied by the state to set the budget neutrality expenditure limit are subject to review and audit, and if found to be inaccurate, will result in a modified budget neutrality expenditure limit.

XIII. MONITORING BUDGET NEUTRALITY FOR THE DEMONSTRATION

67. Limit on Title XIX Funding. The state will be subject to limits on the amount of federal Medicaid funding the state may receive over the course of the demonstration approval. The budget neutrality expenditure limits are based on projections of the amount of FFP that the state would likely have received in the absence of the demonstration. The limit may consist of a Main Budget Neutrality Test, and one or more Hypothetical Budget Neutrality Tests, as described below. CMS's assessment of the state's compliance with these tests will be based on the Schedule C CMS-64 Waiver Expenditure Report, which summarizes the expenditures reported by the state on the CMS-64 that pertain to the demonstration.

68. Risk. The budget neutrality expenditure limits are determined on either a per capita or aggregate basis. If a per capita method is used, the state is at risk for the per capita cost of state plan and hypothetical populations, but not for the number of participants in the demonstration population. By providing FFP without regard to enrollment in the demonstration for all demonstration populations, CMS will not place the state at risk for changing economic conditions; however, by placing the state at risk for the per capita costs of the demonstration populations, CMS assures that the demonstration expenditures do not exceed the levels that would have been realized had there been no demonstration. If an aggregate method is used, the state accepts risk for both enrollment and per capita costs.

69. Calculation of the Budget Neutrality Limits and How They Are Applied. To calculate the budget neutrality limits for the demonstration, separate annual budget limits are determined for each DY on a total computable basis. Each annual budget limit is the sum of one or more components: per capita components, which are calculated as a projected without-waiver PMPM cost times the corresponding actual number of member months, and aggregate components, which project fixed total computable dollar expenditure amounts. The annual limits for all DYs are then added together to obtain a budget neutrality limit for

the entire demonstration period. The federal share of this limit will represent the maximum amount of FFP that the state may receive during the demonstration period for the types of demonstration expenditures described below. The federal share will be calculated by multiplying the total computable budget neutrality expenditure limit by the appropriate Composite Federal Share.

70. Main Budget Neutrality Test. This demonstration does not include a Main Budget Neutrality Test. Budget neutrality will consist entirely of Hypothetical Budget Neutrality Tests. Any excess spending under the Hypothetical Budget Neutrality Tests must be returned to CMS.

71. Hypothetical Budget Neutrality. When expenditure authority is provided for coverage of populations or services that the state could have otherwise provided through its Medicaid state plan or other title XIX authority (such as a waiver under section 1915 of the Act), CMS considers these expenditures to be “hypothetical;” that is, the expenditures would have been eligible to receive FFP elsewhere in the Medicaid program. For these hypothetical expenditures, CMS makes adjustments to the budget neutrality test which effectively treats these expenditures as if they were for approved Medicaid state plan services. Hypothetical expenditures, therefore, do not necessitate savings to offset the otherwise allowable services. This approach reflects CMS’s current view that states should not have to “pay for,” with demonstration savings, costs that could have been otherwise eligible for FFP under a Medicaid state plan or other title XIX authority; however, when evaluating budget neutrality, CMS does not offset non-hypothetical expenditures with projected or accrued savings from hypothetical expenditures. That is, savings are not generated from a hypothetical population or service. To allow for hypothetical expenditures, while preventing them from resulting in savings, CMS currently applies a separate, independent Hypothetical Budget Neutrality Tests, which subject hypothetical expenditures to pre-determined limits to which the state and CMS agree, and that CMS approves, as a part of this demonstration approval. If the state’s WW hypothetical spending exceeds the supplemental test’s expenditure limit, the state agrees (as a condition of CMS approval) to refund the FFP to CMS.

72. Hypothetical Budget Neutrality Test 1: The table below identifies the MEGs that are used for Hypothetical Budget Neutrality Test 1. MEGs that are designated “WOW Only” or “Both” are the components used to calculate the budget neutrality expenditure limit. The Composite Federal Share for the Hypothetical Budget Neutrality Test is calculated based on all MEGs indicated as “WW Only” or “Both.” MEGs that are indicated as “WW Only” or “Both” are counted as expenditures against this budget neutrality expenditure limit. Any expenditures in excess of the limit from Hypothetical Budget Neutrality Test are counted as WW expenditures under the Main Budget Neutrality Test.

Table 4: Hypothetical Budget Neutrality Test								
MEG	PC or Agg*	WOW Only, WW Only, or Both	TREND	DY 1	DY 2		DY 4	DY 5
SUD-IMD	PC	Both	4.5%	\$1864	\$1948	\$2036	\$2127	\$2223
CIS	PC	Both	4.5%	\$0	\$193	\$201	\$211	\$220

73. Composite Federal Share. The Composite Federal Share is the ratio that will be used to convert the total computable budget neutrality limit to federal share. The Composite Federal Share is the ratio calculated by dividing the sum total of FFP received by the state on actual demonstration expenditures during the approval period by total computable demonstration expenditures for the same period, as reported through MBES/CBES and summarized on Schedule C. Since the actual final Composite Federal Share will not be known until the end of the demonstration's approval period, for the purpose of interim monitoring of budget neutrality, a reasonable estimate of Composite Federal Share may be developed and used through the same process or through an alternative mutually agreed to method. Each Hypothetical Budget Neutrality Test has its own Composite Federal Share, as defined in the paragraph pertaining to each particular test.

74. Exceeding Budget Neutrality. CMS will enforce the budget neutrality agreement over the life of the demonstration approval period, which extends from April 8, 2021 until March 31, 2026. If at the end of the demonstration approval period the budget neutrality limit has been exceeded, the excess federal funds will be returned to CMS. If the demonstration is terminated prior to the end of the demonstration period, the budget neutrality test will be based on the time period through the termination date.

75. Course Correction. If at any time during the demonstration approval period CMS determines that the demonstration is on course to exceed its budget neutrality expenditure limit, CMS will require the state to submit a corrective action plan for CMS review and approval. CMS will use the threshold levels in the tables below as a guide for determining when corrective action is required.

Table 5: Hypothetical Budget Neutrality Test Mid-Course Correction Calculations		
Demonstration Year	Cumulative Target Definition	Percentage
DY 1	Cumulative budget neutrality limit plus:	2.0 percent
DY 1 through DY 2	Cumulative budget neutrality limit plus:	1.5 percent
DY 1 through DY 3	Cumulative budget neutrality limit plus:	1.0 percent
DY 1 through DY 4	Cumulative budget neutrality limit plus:	0.5 percent
DY 1 through DY 5	Cumulative budget neutrality limit plus:	0.0 percent

XIV. SCHEDULE OF DELIVERABLES FOR THE DEMONSTRATION PERIOD

Table 6: Schedule of Deliverables for the Demonstration Period		
Date	Deliverable	STC
30 calendar days after approval date	State acceptance of demonstration Waivers, STCs, and Expenditure Authorities	Approval letter
90 calendar days after approval date	SUD Implementation Plan	STC 19
60 calendar days after receipt of CMS comments	Revised SUD Implementation Plan and SUD Health IT Plan	STC 19
150 calendar days after Implementation Plan Completeness	SUD Monitoring Protocol	STC 20
60 calendar days after receipt of CMS comments	Revised SUD Monitoring Protocol	STC 20
180 calendar days after approval date	Draft Evaluation Design	STC 44
60 days after receipt of CMS comments	Revised Draft Evaluation Design	STC 46
No later than 60 calendar days after May 30, 2023	SUD Mid-Point Assessment	STC 37
March 31, 2024, or with renewal application	Draft Interim Evaluation Report	STC 48
60 calendar days after receipt of CMS comments	Final Interim Evaluation Report	STC 48
Within 18 months after March 31, 2025	Draft Summative Evaluation Report	STC 49
60 calendar days after receipt of CMS comments	Final Summative Evaluation Report	STC 49
Monthly Deliverables	Monitoring Calls	STC 40
Quarterly monitoring reports due 60 calendar days after end of each quarter, except 4 th quarter.	Quarterly Monitoring Reports, including implementation updates	STC 36
	Quarterly Expenditure Reports	STC 36
Annual Deliverables - Due 90 calendar days after end of each 4 th quarter	Annual Reports	STC 36

ATTACHMENT A

DEVELOPING THE EVALUATION DESIGN

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform both Congress and CMS about Medicaid policy for the future. While a narrative about what happened during a demonstration provides important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Designs

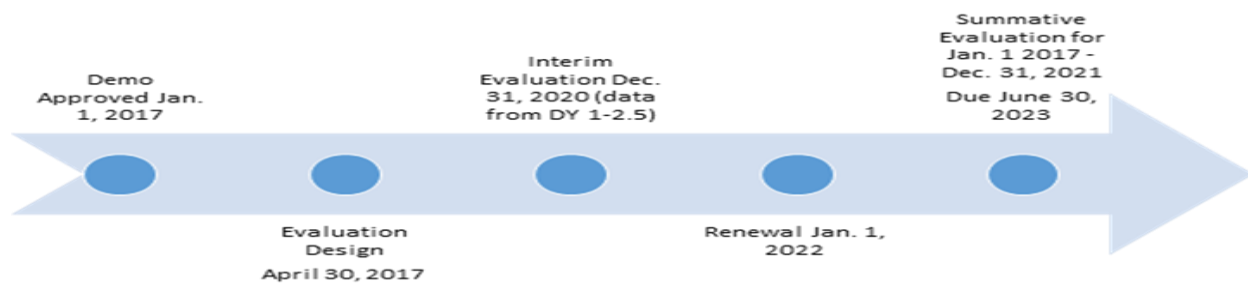
All states with Medicaid section 1115 demonstrations are required to conduct an evaluation, and the Evaluation Design is the roadmap for conducting the evaluation. The roadmap begins with the stated goals for the demonstration followed by the measurable evaluation questions and quantifiable hypotheses, all to support a determination of the extent to which the demonstration has achieved its goals.

The format for the Evaluation Design is as follows:

General Background Information;
Evaluation Questions and Hypotheses;
Methodology;
Methodological Limitations;
Attachments.

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Design and Reports. (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. The state is required to publish the Evaluation Design to the state's website within thirty (30) days of CMS approval, as per 42 CFR 431.424(e). CMS will also publish a copy to the Medicaid.gov website.



Required Core Components of All Evaluation Designs

The Evaluation Design sets the stage for the Interim and Summative Evaluation Reports. It is important that the Evaluation Design explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology (and limitations) for the evaluation. A copy of the state's Driver Diagram (described in more detail in paragraph B2 below) should be included with an explanation of the depicted information.

A. General Background Information – In this section, the state should include basic information about the demonstration, such as:

- 1) The issue/s that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, the potential magnitude of the issue/s, and why the state selected this course of action to address the issue/s (e.g., a narrative on why the state submitted an 1115 demonstration proposal).
- 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
- 3) A brief description of the demonstration and history of the implementation, and whether the draft Evaluation Design applies to an amendment, extension, renewal, or expansion of, the demonstration;
- 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; the primary reason or reasons for the change; and how the Evaluation Design was altered or augmented to address these changes.
- 5) Describe the population groups impacted by the demonstration.

B. Evaluation Questions and Hypotheses – In this section, the state should:

- 1) Describe how the state's demonstration goals are translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured.

- 2) Include a Driver Diagram to visually aid readers in understanding the rationale behind the cause and effect of the variants behind the demonstration features and intended outcomes. A driver diagram is a particularly effective modeling tool when working to improve health and health care through specific interventions. The diagram includes information about the goal of the demonstration, and the features of the demonstration. A driver diagram depicts the relationship between the aim, the primary drivers that contribute directly to achieving the aim, and the secondary drivers that are necessary to achieve the primary drivers for the demonstration. For an example and more information on driver diagrams:
<https://innovation.cms.gov/files/x/hciatwoaimsdrvrs.pdf>
- 3) Identify the state's hypotheses about the outcomes of the demonstration:
- 4) Discuss how the evaluation questions align with the hypotheses and the goals of the demonstration;
- 5) Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and/or XXI.

C. Methodology – In this section, the state is to describe in detail the proposed research methodology.

The focus is on showing that the evaluation meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable, and that where appropriate it builds upon other published research (use references).

This section provides the evidence that the demonstration evaluation will use the best available data; reports on, controls for, and makes appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what will be measured and how. Specifically, this section establishes:

- 1) *Evaluation Design* – Provide information on how the evaluation will be designed. For example, will the evaluation utilize a pre/post comparison? A post-only assessment? Will a comparison group be included?
- 2) *Target and Comparison Populations* – Describe the characteristics of the target and comparison populations, to include the inclusion and exclusion criteria. Include information about the level of analysis (beneficiary, provider, or program level), and if populations will be stratified into subgroups. Additionally discuss the sampling methodology for the populations, as well as support that a statistically reliable sample size is available.
- 3) *Evaluation Period* – Describe the time periods for which data will be included.

- 4) *Evaluation Measures* – List all measures that will be calculated to evaluate the demonstration. Include the measure stewards (i.e., the organization(s) responsible for the evaluation data elements/sets by “owning”, defining, validating; securing; and submitting for endorsement, etc.) Include numerator and denominator information. Additional items to ensure:
- a. The measures contain assessments of both process and outcomes to evaluate the effects of the demonstration during the period of approval.
 - b. Qualitative analysis methods may be used, and must be described in detail.
 - c. Benchmarking and comparisons to national and state standards, should be used, where appropriate.
 - d. Proposed health measures could include CMS’s Core Set of Health Care Quality Measures for Children in Medicaid and CHIP, Consumer Assessment of Health Care Providers and Systems (CAHPS), the Initial Core Set of Health Care Quality Measures for Medicaid-Eligible Adults and/or measures endorsed by National Quality Forum (NQF).
 - e. Proposed performance metrics can be selected from nationally recognized metrics, for example from sets developed by the Center for Medicare and Medicaid Innovation or for meaningful use under Health Information Technology (HIT).
 - f. Among considerations in selecting the metrics shall be opportunities identified by the state for improving quality of care and health outcomes, and controlling cost of care.
- 5) *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data. Discuss the quality and limitations of the data sources.

If primary data (data collected specifically for the evaluation) – The methods by which the data will be collected, the source of the proposed question/responses, the frequency and timing of data collection, and the method of data collection. (Copies of any proposed surveys must be reviewed with CMS for approval before implementation).

- 6) *Analytic Methods* – This section includes the details of the selected quantitative and/or qualitative measures to adequately assess the effectiveness of the demonstration. This section should:
- a. Identify the specific statistical testing which will be undertaken for each measure (e.g., t-tests, chi-square, odds ratio, ANOVA, regression). Table A is an example of how the state might want to articulate the analytic methods for each research question and measure.

- b. Explain how the state will isolate the effects of the demonstration (from other initiatives occurring in the state at the same time) through the use of comparison groups.
 - c. A discussion of how propensity score matching and difference in differences design may be used to adjust for differences in comparison populations over time (if applicable).
 - d. The application of sensitivity analyses, as appropriate, should be considered.
- 7) *Other Additions* – The state may provide any other information pertinent to the Evaluation Design of the demonstration.

Table A. Example Design Table for the Evaluation of the Demonstration

Research Question	Outcome measures used to address the research question	Sample or population subgroups to be compared	Data Sources	Analytic Methods
Hypothesis 1				
Research question 1a	-Measure 1 -Measure 2 -Measure 3	-Sample e.g. All attributed Medicaid beneficiaries -Beneficiaries with diabetes diagnosis	-Medicaid fee-for-service and encounter claims records	-Interrupted time series
Research question 1b	-Measure 1 -Measure 2 -Measure 3 -Measure 4	-sample, e.g., PPS patients who meet survey selection requirements (used services within the last 6 months)	-Patient survey	Descriptive statistics
Hypothesis 2				
Research question 2a	-Measure 1 -Measure 2	-Sample, e.g., PPS administrators	-Key informants	Qualitative analysis of interview material

D. Methodological Limitations – This section provides detailed information on the limitations of the evaluation. This could include the design, the data sources or collection process, or analytic methods. The state should also identify any efforts to minimize the limitations. Additionally, this section should include any information about features of the demonstration that effectively present methodological constraints that the state would like CMS to take into consideration in its review. For example:

- 1) When the state demonstration is:
 - a. Long-standing, non-complex, unchanged, or
 - b. Has previously been rigorously evaluated and found to be successful, or
 - c. Could now be considered standard Medicaid policy (CMS published regulations or guidance)
- 2) When the demonstration is also considered successful without issues or concerns that

would require more regular reporting, such as:

- a. Operating smoothly without administrative changes; and
- b. No or minimal appeals and grievances; and
- c. No state issues with CMS-64 reporting or budget neutrality; and
- d. No Corrective Action Plans (CAP) for the demonstration.

E. Attachments

- 1) **Independent Evaluator.** This includes a discussion of the state's process for obtaining an independent entity to conduct the evaluation, including a description of the qualifications that the selected entity must possess, and how the state will assure no conflict of interest. Explain how the state will assure that the Independent Evaluator will conduct a fair and impartial evaluation, prepare an objective Evaluation Report, and that there would be no conflict of interest. The evaluation design should include "No Conflict of Interest" signed by the independent evaluator.
- 2) **Evaluation Budget.** A budget for implementing the evaluation shall be provided with the draft Evaluation Design. It will include the total estimated cost, as well as a breakdown of estimated staff, administrative, and other costs for all aspects of the evaluation. Examples include, but are not limited to: the development of all survey and measurement instruments; quantitative and qualitative data collection; data cleaning and analyses; and reports generation. A justification of the costs may be required by CMS if the estimates provided do not appear to sufficiently cover the costs of the draft Evaluation Design or if CMS finds that the draft Evaluation Design is not sufficiently developed.
- 3) **Timeline and Major Milestones.** Describe the timeline for conducting the various evaluation activities, including dates for evaluation-related milestones, including those related to procurement of an outside contractor, if applicable, and deliverables. The Final Evaluation Design shall incorporate an Interim and Summative Evaluation. Pursuant to 42 CFR 431.424(c)(v), this timeline should also include the date by which the Final Summative Evaluation report is due.

ATTACHMENT B

Preparing the Interim and Summative Evaluation Reports

Introduction

For states that are testing new approaches and flexibilities in their Medicaid programs through section 1115 demonstrations, evaluations are crucial to understand and disseminate what is or is not working and why. The evaluations of new initiatives seek to produce new knowledge and direction for programs and inform Medicaid policy for the future. While a narrative about what happened during a demonstration provide important information, the principal focus of the evaluation of a section 1115 demonstration should be obtaining and analyzing data on the process (e.g., whether the demonstration is being implemented as intended), outcomes (e.g., whether the demonstration is having the intended effects on the target population), and impacts of the demonstration (e.g., whether the outcomes observed in the targeted population differ from outcomes in similar populations not affected by the demonstration). Both state and federal governments could benefit from improved quantitative and qualitative evidence to inform policy decisions.

Expectations for Evaluation Reports

Medicaid section 1115 demonstrations are required to conduct an evaluation that is valid (the extent to which the evaluation measures what it is intended to measure), and reliable (the extent to which the evaluation could produce the same results when used repeatedly). To this end, the already approved Evaluation Design is a map that begins with the demonstration goals, then transitions to the evaluation questions, and to the specific hypotheses, which will be used to investigate whether the demonstration has achieved its goals. States should have a well-structured analysis plan for their evaluation. As these valid analyses multiply (by a single state or by multiple states with similar demonstrations) and the data sources improve, the reliability of evaluation findings will be able to shape Medicaid policy in order to improve the health and welfare of Medicaid beneficiaries for decades to come. When submitting an application for renewal, the interim evaluation report should be posted on the state's website with the application for public comment. Additionally, the interim evaluation report must be included in its entirety with the application submitted to CMS.

Intent of this Guidance

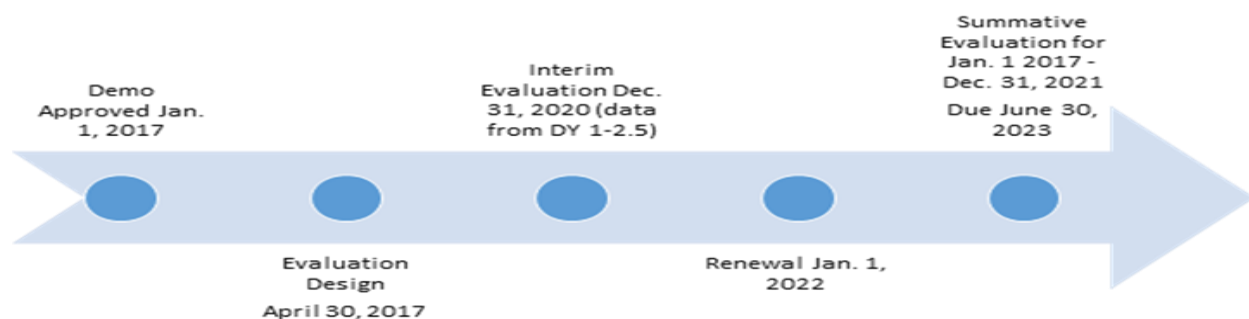
The Social Security Act (the Act) requires an evaluation of every section 1115 demonstration. In order to fulfill this requirement, the state's submission must provide a comprehensive written presentation of all key components of the demonstration, and include all required elements specified in the approved Evaluation Design. This Guidance is intended to assist states with organizing the required information in a standardized format and understanding the criteria that CMS will use in reviewing the submitted Interim and Summative Evaluation Reports.

The format for the Interim and Summative Evaluation reports is as follows:

- A. Executive Summary;
- B. General Background Information;
- C. Evaluation Questions and Hypotheses;
- D. Methodology;
- E. Methodological Limitations;
- F. Results;
- G. Conclusions;
- H. Interpretations, and Policy Implications and Interactions with Other State Initiatives;
- I. Lessons Learned and Recommendations; and
- J. Attachment(s).

Submission Timelines

There is a specified timeline for the state's submission of Evaluation Designs and Evaluation Reports. These dates are specified in the demonstration Special Terms and Conditions (STCs). (The graphic below depicts an example of this timeline). In addition, the state should be aware that section 1115 evaluation documents are public records. In order to assure the dissemination of the evaluation findings, lessons learned, and recommendations, the state is required to publish to the state's website the evaluation design within thirty (30) days of CMS approval, and publish reports within thirty (30) days of submission to CMS, pursuant to 42 CFR 431.424. CMS will also publish a copy to Medicaid.gov.



Required Core Components of Interim and Summative Evaluation Reports

The section 1115 Evaluation Report presents the research about the section 1115 Demonstration. It is important that the report incorporate a discussion about the structure of the Evaluation Design to explain the goals and objectives of the demonstration, the hypotheses related to the demonstration, and the methodology for the evaluation. A copy of the state's Driver Diagram (described in the Evaluation Design guidance) must be included with an explanation of the depicted information. The Evaluation Report should present the relevant data and an interpretation of the findings; assess the outcomes (what worked and what did not work); explain the limitations of the design, data, and analyses; offer recommendations regarding what (in hindsight) the state would further advance, or do differently, and why; and discuss the implications on future Medicaid policy. Therefore, the state's submission must include:

- A. Executive Summary** – A summary of the demonstration, the principal results, interpretations, and recommendations of the evaluation.
- B. General Background Information about the Demonstration** – In this section, the state should include basic information about the demonstration, such as:
 - 1) The issues that the state is trying to address with its section 1115 demonstration and/or expenditure authorities, how the state became aware of the issue, the potential magnitude of the issue, and why the state selected this course of action to address the issues.
 - 2) The name of the demonstration, approval date of the demonstration, and period of time covered by the evaluation;
 - 3) A brief description of the demonstration and history of the implementation, and if the evaluation is for an amendment, extension, renewal, or expansion of, the demonstration;
 - 4) For renewals, amendments, and major operational changes: A description of any changes to the demonstration during the approval period; whether the motivation for change was due to political, economic, and fiscal factors at the state and/or federal level; whether the programmatic changes were implemented to improve beneficiary health, provider/health plan performance, or administrative efficiency; and how the Evaluation Design was altered or augmented to address these changes.
 - 5) Describe the population groups impacted by the demonstration.
- C. Evaluation Questions and Hypotheses** – In this section, the state should:
 - 1) Describe how the state's demonstration goals were translated into quantifiable targets for improvement, so that the performance of the demonstration in achieving these targets could be measured. The inclusion of a Driver Diagram in the Evaluation Report is highly encouraged, as the visual can aid readers in understanding the rationale behind the demonstration features and intended outcomes.

- 2) Identify the state’s hypotheses about the outcomes of the demonstration;
 - a. Discuss how the goals of the demonstration align with the evaluation questions and hypotheses;
 - b. Explain how this Evaluation Report builds upon and expands earlier demonstration evaluation findings (if applicable); and
 - c. Address how the research questions / hypotheses of this demonstration promote the objectives of Titles XIX and XXI.

D. Methodology – In this section, the state is to provide an overview of the research that was conducted to evaluate the section 1115 demonstration consistent with the approved Evaluation Design.

The evaluation design should also be included as an attachment to the report. The focus is on showing that the evaluation builds upon other published research (use references), and meets the prevailing standards of scientific and academic rigor, and the results are statistically valid and reliable.

An interim report should provide any available data to date, including both quantitative and qualitative assessments. The Evaluation Design should assure there is appropriate data development and collection in a timely manner to support developing an interim evaluation.

This section provides the evidence that the demonstration evaluation used the best available data and describes why potential alternative data sources were not used; reported on, controlled for, and made appropriate adjustments for the limitations of the data and their effects on results; and discusses the generalizability of results. This section should provide enough transparency to explain what was measured and how. Specifically, this section establishes that the approved Evaluation Design was followed by describing:

1. *Evaluation Design* – Will the evaluation be an assessment of: pre/post, post-only, with or without comparison groups, etc.?
2. *Target and Comparison Populations* – Describe the target and comparison populations; include inclusion and exclusion criteria.
3. *Evaluation Period* – Describe the time periods for which data will be collected
4. *Evaluation Measures* – What measures are used to evaluate the demonstration, and who are the measure stewards?
5. *Data Sources* – Explain where the data will be obtained, and efforts to validate and clean the data.
6. *Analytic methods* – Identify specific statistical testing which will be undertaken for each measure (t-tests, chi-square, odds ratio, ANOVA, regression, etc.).
7. *Other Additions* – The state may provide any other information pertinent to the evaluation of the demonstration.

A. Methodological Limitations - This section provides sufficient information for discerning the strengths and weaknesses of the study design, data sources/collection, and analyses.

B. Results – In this section, the state presents and uses the quantitative and qualitative data to show to whether and to what degree the evaluation questions and hypotheses of the demonstration were achieved. The findings should visually depict the demonstration results (tables, charts, graphs). This section should include information on the statistical tests conducted.

C. Conclusions – In this section, the state will present the conclusions about the evaluation results.

- 1) In general, did the results show that the demonstration was/was not effective in achieving the goals and objectives established at the beginning of the demonstration?
- 2) Based on the findings, discuss the outcomes and impacts of the demonstration and identify the opportunities for improvements. Specifically:
 - a. If the state did not fully achieve its intended goals, why not? What could be done in the future that would better enable such an effort to more fully achieve those purposes, aims, objectives, and goals?

D. Interpretations, Policy Implications and Interactions with Other State Initiatives – In this section, the state will discuss the section 1115 demonstration within an overall Medicaid context and long range planning. This should include interrelations of the demonstration with other aspects of the state’s Medicaid program, interactions with other Medicaid demonstrations, and other federal awards affecting service delivery, health outcomes and the cost of care under Medicaid. This section provides the state with an opportunity to provide interpretation of the data using evaluative reasoning to make judgments about the demonstration. This section should also include a discussion of the implications of the findings at both the state and national levels.

E. Lessons Learned and Recommendations – This section of the Evaluation Report involves the transfer of knowledge. Specifically, the “opportunities” for future or revised demonstrations to inform Medicaid policymakers, advocates, and stakeholders is just as significant as identifying current successful strategies. Based on the evaluation results:

1. What lessons were learned as a result of the demonstration?
2. What would you recommend to other states which may be interested in implementing a similar approach?

F. Attachment - Evaluation Design: Provide the CMS-approved Evaluation Design

Section 1115 Waiver Implementation Plan

**Oregon Health Plan
Substance Use Disorder
Demonstration**

Medicaid and Children's Health Insurance Program

Submitted: May 29, 2020



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INTRODUCTION

Oregon is among many states facing a public health crisis relating to substance use disorders (SUD). Of individuals accessing SUD treatment in Oregon, 33.5% (2017) had a primary diagnosis of opioid use disorder (OUD); this rate more than doubled over a four-year period from 2013 to 2017⁶. Oregon's opioid-related overdose deaths have increased during the past decade from 73 total deaths during 2000 to its high at 336 in 2011. In 2017 there were 6.8 deaths per 100,000 Oregon residents (276 total deaths)². All deaths related to all drugs in Oregon have remained high, increasing slightly from 13.760 deaths per 100,000 population in 2009 (529) to 14.18 deaths in 2017 (578)⁷. The need is clear for continued system improvement across all substances of use.

In order to improve health outcomes and reduce deaths related to substance use disorders, Oregon must improve access to substance use disorder (SUD) treatment, increase provider capacity, and implement effective standards of care. Oregon proposes to transform the SUD delivery system through evidence-based practices, tribal-based practices, and comprehensive care. Through the SUD waiver, Oregon will bolster existing programs and initiatives and implement new strategies to build comprehensive, continuum of care services and supports.

Specifically, Oregon has requested the waiver authority to:

- a) Claim Federal reimbursement for services provided in an Institution for Mental Disease (IMD) with more than 16 beds, for the duration of time clinically deemed necessary.
- b) Expand the full SUD continuum of care to include prevention, early intervention, and crisis intervention .

¹ "SUD MMIS Treatment Data." *Oregon Health Authority*, November 28, 2018. Internal Data review

² "Prescribing and Overdose Data for Oregon." *Oregon Department of Education: 2018 Social Sciences Standards SBE First Reading Draft: Social Sciences: State of Oregon*, 2018, www.oregon.gov/oha/ph/preventionwellness/substanceuse/opioids/pages/data.aspx.

- c) Develop housing support services that will provide transition assistance and skill building for individuals with SUD.

This implementation plan provides details on OHA’s strategic approach and how this project addresses CMS’s goals and required milestones to ensure the full continuum of care succeeds in improving quality, accessibility, and outcomes for SUD/OD treatment in the most cost-effective manner over the course of the five-year waiver period from April 8, 2021 to March 31, 2026.

SECTION 1- MILESTONE CRITERIA

1. ACCESS TO CRITICAL LEVELS OF CARE FOR OUD AND OTHER SUDS

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current SUD treatment services covered by the state in each level of care. For services currently covered in the state plan, list the benefit category and page location; for services currently covered in a demonstration, include the program name and Special Term and Condition number.	Provide an overview of planned SUD treatment services to be covered by the state in each level of care: indicate whether planned services will be added to the state plan or authorized through the 1115.	Provide a list of action items needed to be completed to meet milestone requirements, if any. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item.
Coverage of outpatient services	Outpatient services are currently covered under Oregon’s Medicaid State Plan. (ASAM 1.0) State Plan:	OHA has robust monitoring and evaluation services Capacity of the Peer Delivered Services workforce has	Develop robust quarterly report for internal quality improvement strategies for SUD services (All levels) (0-6 months); Addiction Treatment, Recovery & Prevention Services; Medicaid; and

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
	<p>SUD services- Attachment 3.1-A, section 13.d- Rehabilitation, page 6-d.10 thru 6-d.19</p> <p>Adult benefit Plan- TN 17-0003 form ABP 5 coverages outpatient hospital SUD services, Physician services. TCM- Targeted group: <u>Substance Abusing Pregnant Women and Substance Abusing Parents with Children under Age 18.</u></p> <p>Supplement 1 to Attachment 3.1-A, pages 19-22.a</p> <p>Additional services covered under State Plan:</p> <p>Individual/Group counseling therapy/Individual family and/or couple counseling: Attachment 3.1-A, section 13.d-SUD rehab, page 6.d.11</p> <p>Acupuncture: Attachment 3.1-A, section 13.d-SUD rehab, page 6.d.13.</p> <p>Adult benefit Plan- TN 17-0003 form ABP 5</p> <p>Peer Delivered Services (PDS) are a covered available</p>	<p>been increased (State Plan).</p> <p>OHP SUD system benefits provide full continuum of care to include prevention, early intervention, and crisis intervention services (State Plan)</p> <p>Each year we will improve rates of identification, initiation, and engagement</p> <p>Provider capacity has expanded to adequate level for these services</p> <p>Develop provider review process around staffing levels</p> <p>Each provider will have been reviewed and confirmed has adequate staffing for this level of care</p> <p>The number and diversity of culturally specific peers within the workforce has been expanded</p>	<p>Health Policy & Analytics within OHA.</p> <p>Set scope of work for the workforce regarding prevention, early intervention, and crisis intervention services and establish reimbursement rate. (12-24months);</p> <p>Addiction Treatment Recovery & Prevention unit with Health Systems Division</p> <p>Set standards for identification, initiation, and engagement.</p> <p>Educate and engage providers around these standards and implementation. (12-24 months);</p> <p>Health Systems Division</p> <p>Develop requirement for CCOs to have a mechanism to ensure that they have adequate capacity to serve those in their region around SUD services (12-24 months);</p> <p>Health Systems Division</p> <p>Develop standard range of client to clinician ratio (12-24 months);</p> <p>Addiction Treatment Recovery & Prevention unit with Health Systems Division</p> <p>Develop provider review process around staffing levels; (12-24 months);</p> <p>Addiction Treatment Recovery & Prevention unit with Health Systems Division</p>

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
	benefit. (All levels of treatment)		Develop more culturally relevant training for PDS workers, including a tribal- specific course and Latino- specific course (12-24 months); Office of Equity & Inclusion & Behavioral Health Expand the number and diversity of culturally specific peers within the workforce (12-24 months); Health Systems division & Office of Equity and Inclusion
Coverage of intensive outpatient services	Intensive outpatient services are currently covered under Oregon's Medicaid State Plan. (ASAM 2.1; 2.5) State Plan: SUD services- Attachment 3.1-A, section 13.d- Rehabilitation, page 6-d.10 thru 6-d.19 Adult benefit Plan- TN 17-0003 form ABP 5 coverages outpatient hospital SUD services, Physician services. TCM- Targeted group: <u>Substance Abusing Pregnant Women and Substance Abusing Parents with Children under Age 18.</u>	OHA has robust monitoring and evaluation services Capacity of the Peer Delivered Services workforce has been increased (State Plan). OHP SUD system benefits provide full continuum of care to include prevention, early intervention, and crisis intervention services (State Plan) Each year we will improve rates of identification, initiation, and engagement Provider capacity has expanded to adequate level for these services	Develop robust quarterly report for internal quality improvement strategies for SUD services (All levels) (0-6 months); Addiction Treatment, Recovery & Prevention Services; Medicaid; and Health Policy & Analytics within OHA. Set scope of work for the workforce regarding prevention, early intervention, and crisis intervention services and establish reimbursement rate. (12-24 months); Health Systems Division Set standards for identification, initiation, and engagement. Educate and engage providers around these standards and implementation. (12-24 months); Health Systems Division

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
	Supplement 1 to Attachment 3.1-A, pages 19-22.a Peer Delivered Services are a covered available benefit. (All levels of treatment) Oregon and The Nine Federally Recognized Tribes of Oregon and the Urban Indian Program developed Tribal- Specific Curriculum for the Family Support Peers including some SUD work	Develop provider review process around staffing levels Each provider will have been reviewed and confirmed has adequate staffing for this level of care The number and diversity of culturally specific peers within the workforce has been expanded	Require CCOs to have a mechanism to ensure that they have adequate capacity to serve those in their region around SUD services (12-24 months); Health Systems Division Develop alternative payment methodologies for Day Treatment Services (12-24months); Health Systems Division Develop standard range of client to clinician ratio (12-24 months); Health Systems Division Develop more culturally relevant training for PDS workers, including a tribal- specific course and Latino- specific course (12-24 months); Office of Equity & Inclusion & Behavioral Health Expand the number and diversity of culturally specific peers within the workforce (12-24 months); Health Systems division & Office of Equity and Inclusion
Coverage of Medication Assisted Treatment (medications, as well as counseling and other services with sufficient provider capacity, to meet needs of Medicaid beneficiaries in the state)	Medication Assisted Treatment services are currently covered under Oregon's Medicaid State Plan. (All levels of Care) State Plan: MAT- Attachment 3.1-A, section 13.d-	OHA has robust monitoring and evaluation services Capacity of the Peer Delivered Services workforce has been increased (State Plan). OHP SUD system benefits provide	Develop robust quarterly report for internal quality improvement strategies for SUD services (All levels) (0-6 months); Addiction Treatment, Recovery & Prevention Services; Medicaid; and Health Policy & Analytics within OHA. Set standards for identification, initiation,

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
	<p>SUD rehab, page 6.d.12</p> <p>Also covered under State Plan:</p> <p>Medication management and monitoring:</p> <p>Attachment 3.1-A, section 13.d-SUD rehab, page 6.d.12</p> <p>Peer Delivered Services are a covered available benefit. (All levels of treatment)</p>	<p>full continuum of care to include prevention, early intervention, and crisis intervention services (State Plan)</p> <p>Each year we will improve rates of identification, initiation, and engagement</p> <p>Increase rates of identification, initiation, and engagement</p> <p>Provider capacity has been increased adequately at varying clinical settings (such as office-based, Emergency Department, Primary Care, Tele-health, bridge clinics, residential etc.)</p> <p>Increased qualified workforce</p> <p>Each provider will have been reviewed and confirmed has adequate staffing for this level of care</p> <p>The number and diversity of culturally specific peers within the</p>	<p>and engagement.</p> <p>Educate and engage providers around these standards and implementation (12-24 months); Health Systems Division</p> <p>Develop requirement for CCOs to have a mechanism to ensure that they have adequate capacity to serve those in their region around SUD services (12-24 months); Health Systems Division</p> <p>Develop standard range of client to clinician ratio (12-24 months); Health Systems Division</p> <p>Engage with CCOs around adequate capacity levels for MAT and their service areas. (12-24 months); Health Systems Division</p> <p>Develop provider review process around staffing levels (12-24 months); Health System Division</p> <p>Develop more culturally relevant training for peer workers, including a tribal- specific course and Latino- specific course (12-24 months); Office of Equity & Inclusion & Behavioral Health</p> <p>Expand the number and diversity of culturally specific peers within the workforce (12-24 months); Health Systems</p>

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
		workforce has been expanded	division & Office of Equity and Inclusion
Coverage of intensive levels of care in residential and inpatient settings	Residential and inpatient services are currently covered under Oregon's Medicaid State Plan. (ASAM 3.1,3.3,3.5, 3.7, 4) Currently, State funding supplements treatment that is not Medicaid-covered due to the IMD exclusion. State Plan: Attachment 3.1-A, section 13.d-SUD rehab, page 6.d.12 Peer Delivered Services are a covered available benefit. (All levels of treatment)	OHA has robust monitoring and evaluation services Increase the Peer Delivered Services workforce Each year we will improve rates of identification, initiation, and engagement Increase provider capacity Each provider will have been reviewed and confirmed has adequate staffing for this level of care The number and diversity of culturally specific peers within the workforce has been expanded	Develop robust quarterly report for internal quality improvement strategies for SUD services (All levels) (0-6 months); Addiction Treatment, Recovery & Prevention Services; Medicaid; and Health Policy & Analytics within OHA. Set scope of work for the workforce regarding SUD crisis intervention services and establish reimbursement rate. (12-24 months); Health Systems Division Set standards for identification, initiation, and engagement. Educate and engage providers around these standards and implementation (12-24 months); Health Systems Division Develop requirement for CCOs to have a mechanism to ensure that they have adequate capacity to serve those in their region around SUD services (12-24 months); Health Systems Division Develop standard range of client to clinician ratio

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
			(12-24 months); Health Systems Division Develop provider review process around staffing levels (12-24 months); Health System Division Develop more culturally relevant training for PDS workers, including a tribal- specific course and Latino- specific course (12-24 months); Office of Equity & Inclusion & Behavioral Health Expand the number and diversity of culturally specific peers within the workforce (12-24 months); Health Systems division & Office of Equity and Inclusion
Coverage of medically supervised withdrawal management	Medical Withdrawal services are currently covered under Oregon's Medicaid State Plan. (ASAM 3.7, 4) Currently, State funding supplements treatment that is not Medicaid-covered due to the IMD exclusion. State Plan: Detox- Attachment 3.1-A, section 13.d- SUD rehab, page 6.d.13. Adult benefit Plan- TN	OHA has robust monitoring and evaluation services Each year we will improve rates of identification, initiation, and engagement Each provider will have been reviewed and confirmed has adequate staffing for this level of care Each provider will have been reviewed and confirmed has adequate staffing	Develop robust quarterly report for internal quality improvement strategies for SUD services (All levels) (0-6 months); Addiction Treatment, Recovery & Prevention Services; Medicaid; and Health Policy & Analytics within OHA. Set scope of work for the workforce regarding SUD crisis intervention services and establish reimbursement rate. (12-24 months); Health Systems Division Set standards for identification, initiation, and engagement. Educate and engage providers around these

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
	17-0003 form ABP 5	for this level of care	standards and implementation (12-24 months); Health Systems Division Develop requirement for CCOs to have a mechanism to ensure that they have adequate capacity to serve those in their region around SUD services (12-24 months); Health Systems Division Develop standard range of client to clinician ratio (12-24 months); Health Systems Division Develop provider review process around staffing levels (12-24 months); Health System Division
Parity of Coverage in SUD service array.	Case Management Services for individuals with only SUD are not a covered Oregon Medicaid State Plan benefit. State Plan: Peer Delivered Services: Attachment 3.1-A, section 13.d-SUD rehab, page 6.d.14. Case Management Services (listed as care coordination) 3.1-A, section 13.d-SUD rehab, page 6.d.12	A SPA and OAR changes are completed to expand the use of case management for pre and post treatment and for community-based services and supports such as skills restoration and employment	Oregon will meet with agencies that provide these services (funded through state funds and federal grants) to develop a structure and draft regulations for this service. (12-24 months); Behavioral Health & Medicaid Develop reimbursement rates for agencies to provide this service (12-24 months); Actuarial Services & Addiction Treatment, Recovery & Prevention Services Implement service by 24 months past start (12-24 months); Health Systems Division The state will pursue a SPA and OAR changes to expand the use of case

Milestone 1 Criteria	Current State	Future State	Summary of Actions Needed
			management for pre and post treatment and for community-based services and supports such as housing and employment (12-24 months); Health Systems Division

2. USE OF EVIDENCE-BASED, SUD SPECIFIC PATIENT PLACEMENT CRITERIA

Milestone 2 Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current state use of evidence-based, SUD-specific patient placement criteria and utilization management approach to ensure placement in appropriate level of care and receipt of services recommended for that level of care	Provide an overview of planned state implementation of requirement that providers use an evidence-based, SUD-specific patient placement criterion and use of utilization management to ensure placement in appropriate level of care and receipt of services recommended for that level of care.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of requirement that providers assess treatment needs based on SUD-specific, multi-dimensional assessment tools that reflect evidence-based clinical treatment guidelines	Current State OARs 309-018 and 309-019 require SUD outpatient (O/P) and residential assessments to include all ASAM PPC dimensions.	State OARs 309-018 and 309-019 continue to require SUD O/P and residential assessments to include all ASAM PPC dimensions.	None
Implementation of a utilization management approach such that (a) beneficiaries have access to SUD services	For over 20 years Oregon has required, and continues to require, SUD Providers to assess	CCOs will be monitored to ensure prior authorization staff are adequately trained in ASAM	Refine contract language with CCOs to include ASAM (12-24 months); Health Systems Division

Milestone 2 Criteria	Current State	Future State	Summary of Actions Needed
at the appropriate level of care	<p>treatment needs based on multi-dimensional ASAM assessment tools that reflect evidence-based clinical guidelines for all levels of care, per licensing regulation and state contracts</p> <p>SUD services for individuals on Fee for Service (FFS) are retrospectively reviewed for appropriateness but do not require prior authorization. The provider is responsible to ensure the client meets the criteria for the appropriate level of care and the OARS are followed. These are reviewed during the Licensing and Certification staff and Medicaid Program Integrity staff as appropriate, or as the OARs require for licensing or certification.</p> <p>Within contracts, the CCOs are required to ensure prior authorization is no more stringent than the FFS implementation but may operationalize this differently.</p> <p>Providers and staff are to be adequately</p>	criteria and SUD treatment services	Monitor CCOs to ensure prior authorization staff are adequately trained in ASAM criteria and SUD treatment services

Milestone 2 Criteria	Current State	Future State	Summary of Actions Needed
	trained in ASAM Criteria and SUD treatment services		
Implementation of a utilization management approach such that (b) interventions are appropriate for the diagnosis and level of care	Current State OARs 309-018 and 309-019 require SUD outpatient and residential service plans to reflect information included in the assessment. Health Services Division (HSD) reviews a sample of the plans for compliance during renewal reviews.	State OARs 309-018 and 309-019 will be revised to specify services that must be provided for each ASAM level of care. State licensing/certification site reviews will include assessment of compliance with this requirement to ensure that service plans reflect appropriate interventions for the diagnosis and the ASAM level of care.	Consult with DOJ – (3-6 months); Health Systems Division Consult with providers and other stakeholders – (6-12 months); Health Systems Division Develop and implement policy and OAR amendments – (12-18 months); Health Systems Division Provide training to providers regulated by the new rules (in person, onsite technical assistance and webinar.) – (12- 24 months); Health Systems Division
Implementation of a utilization management approach such that (c) there is an independent process for reviewing placement in residential treatment settings	HSD's Licensing and Certification e Unit conducts site visits and clinical review of charts and notes every 2 years to determine compliance with OARs.	Continue to monitor placement criteria within the site and clinical reviews.	None

3. USE OF NATIONALLY RECOGNIZED SUD-SPECIFIC PROGRAM STANDARDS TO SET PROVIDER QUALIFICATIONS FOR RESIDENTIAL TREATMENT FACILITIES

Milestone 3 Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current provider qualifications for residential	An overview of planned use of nationally recognized SUD- specific program	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or

Milestone 3 Criteria	Current State	Future State	Summary of Actions Needed
	treatment facilities and how these compare to nationally recognized SUD-specific program standards, e.g., the ASAM Criteria	standards in improving provider qualifications for residential treatment facilities is provided	entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of residential treatment provider qualifications in licensure requirements, policy manuals, managed care contracts, or other guidance. Qualification should meet program standards in the ASAM Criteria or other nationally recognized, SUD-specific program standards regarding, in particular, the types of services, hours of clinical care, and credentials of staff for residential treatment settings	Current Oregon OARs 309-018 and 309-019 specify qualifications and competencies that must be met to qualify to provide SUD treatment. There is no distinction in the qualifications or competencies pertaining to levels of care. Current Oregon OAR 309-018 identifies some types of services in residential settings including smoking cessation, parenting and some life skills. There are no staffing ratios, or number of hours specified.	State OARs 309-018 and 309-019 will be revised to specify requirements for qualifications and competencies for individuals providing treatment services in each level of care, consistent with ASAM. OAR 309-018 and 309-019 will be revised to specify requirements and standards for clinical care including comprehensive services that address clinical needs and social determinants of health, staffing ratios and total hours of care provided in each level of care, consistent with ASAM.	Consult with DOJ – (3-6 months)); Health Systems Division Consult with providers and other stakeholders – (6-12 months); Health Systems Division Develop and implement policy and OAR amendments – (12-18 months); Health Systems Division Provide training to providers regulated by the new rules (in person, onsite technical assistance and webinar.) – (18-24 months); Health Systems Division
Implementation of a state process for reviewing residential treatment providers to	OARs 309-008 and 415-012 specify processes and standards for	OARs 309-008 and 415-012 will be revised to specify the process	Update and implement the process for initial and renewal certification and licensure – (6-12

Milestone 3 Criteria	Current State	Future State	Summary of Actions Needed
ensure compliance with these standards	certification and licensure of SUD O/P and residential programs. Current licensure allows programs to provide all levels of residential services. Current certification allows programs to provide all levels of outpatient services.	and standards for certification and licensure of each ASAM level of care in both O/P and residential programs. OHA/HSD-issued certificates and licenses will identify specific levels of care for each provider.	months); Licensing and Certification Unit <ul style="list-style-type: none"> Licensing and Certification Unit: Develop certificate and license types for each level of care – (6-12 months) Update licensing and certification data base – (6-12 months); Licensing and Certification Unit:
Implementation of requirement that residential treatment facilities offer MAT on-site or facilitate access to MAT off-site	In residential programs, current OAR requires that providers assist individuals to access MAT by coordinating services and making transportation available. O/P programs are not required to provide this service, although they are not permitted to deny entry to individuals who currently receive MAT.	OAR will be revised to require that residential providers make MAT available on-site or provide coordination services to off-site MAT services including assisting with access, payment issues, transportation, and daycare.	Consult with DOJ – (3-6 months); Health Systems Division Consult with providers and other stakeholders – (6-12 months); Health Systems Division Develop and implement policy and OAR amendments – (12-25 months); Health Systems Division

4. SUFFICIENT PROVIDER CAPACITY AT CRITICAL LEVELS OF CARE INCLUDING FOR MEDICATION ASSISTED TREATMENT OF OUD

Milestone 4 Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current provider capacities throughout the state to provide SUD treatment at each of the critical levels of care listed in Milestone 1.	An overview of planned improvements to provider availability and capacity intended to improve Medicaid beneficiary access to treatment throughout the State at each of the critical levels of care listed in Milestone 1 is provided.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Completion of assessment of the availability of providers enrolled in Medicaid and accepting new patients in the following critical levels of care throughout the state (or at least in participating regions of the state) including those that offer MAT; Outpatient Services; Intensive Outpatient Services; Medication Assisted Treatment (medications as well as counseling and other services);	Oregon is conducting a provider capacity study for key levels of care in the state. A capacity management and referral tracking data base is currently being implemented through a contract with a vendor: Lines for Life. In 2019 the focus will be on SUD Outpatient services including Office Based Opioid Treatment (OBOT) settings and Opioid Treatment Program (OTP) as well as MAT services Oregon has identified statewide Opioid	Provider capacity study will be completed and used to identify areas of high need. SUD services are available at appropriate client to provider ratios including reasonable access, admittance times, and reasonable geographic distances for patients to travel to clinically appropriate services. The capacity management and referral tracking data base will be implemented statewide for all critical levels of care.	Create action plan to address deficits within the delivery system identify within the capacity study. (6- 12 Months); Health Systems Division Implement the plan to address the delivery system deficits (12-24 months); Health Systems Division Assess current client to provider ratios for all levels of treatment (0-6 months); Health Systems Division Develop the appropriate client to provider ratios (6-12 months); Health Systems Division Develop a plan to address any gaps in provider ratio (12-18 months); Health System Division Begin to implement changes addressing the gaps in provider ratios that were identified in service areas (18-24 months); Health Systems Division

Milestone 4 Criteria	Current State	Future State	Summary of Actions Needed
Intensive Care in Residential and Inpatient Settings; Medically Supervised Withdrawal Management.	Use Disorder treatment capacity in both OBOT settings and OTP settings.	Regional needs have been identified and addressed for MAT in both OTP and OBOT treatments.	Implement the capacity management and referral tracking data base for all SUD residential services (ASAM levels 3-4) including MAT and withdrawal management (12-24); vendor: Lines for Life. Identify needs for MAT in OTP and OBOT settings. (6-12 months); Health Systems Division Develop plan to meet needs of MAT in OTP and OBOT settings (12-18 months); Health Systems Division Implement plan to address needs of MAT in OTP and OBOT settings (18-24 months); Health Systems Division Assess the number of covered lives, availability of prevalence, incidents and diagnosis rates by region/ CCO (12-24 months); Health Systems Division
Increase provider capacity across all levels	Oregon has contracted with the Farley Center to conduct a Healthcare Workforce Assessment was completed March 2019	The Healthcare workforce needs will be identified and addressed.	Asses the needs of the Healthcare workforce identified in the assessment. (12-24 Months); Health Systems Division Develop the plan to address workforce issues to include activities such as (focus groups, partnerships with providers and CCOs, etc....) (12-24 months); Health Systems Division

5. IMPLEMENTATION OF COMPREHENSIVE TREATMENT AND PREVENTION STRATEGIES TO ADDRESS OPIOID ABUSE AND OUD

Milestone 5 Criteria	Current State	Future State	Summary of Actions Needed
Criteria for completion of milestone	Provide an overview of current treatment and prevention strategies to reduce opioid abuse and OUD in the state.	Provide an overview of planned strategies to prevent and treat opioid abuse and OUD.	Specify a list of action items needed to be completed to meet milestone requirements as detailed above. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Implementation of opioid prescribing guidelines along with other interventions to prevent opioid abuse	In 2016, the Oregon Health Authority (OHA) convened a task force to develop opioid prescribing guidelines around chronic pain and for dentists. These guidelines include recommendations for working directly with patients on treatment planning, emphasis on non-pharmacologic and non-opioid pharmacolites. OHA adopted the opioid prescribing guidelines around chronic pain and dentistry ⁸ . These	OHA will continue to emphasize individualized patient care, non-pharmacologic treatment options, and awareness around OUD in the primary care as well as ED settings. Educated providers and implemented new guidelines and best practices around opioid use and prescribing. Evaluated Chronic and Acute pain prescribing guidelines for updates to treatment recommendations, if required.	Provide greater behavioral health supports (TA, education, etc.) for opioid prescribers and health systems. Especially in primary care and emergency settings to both assist patients in reducing total Morphine equivalent doses (MED) and identify SUD/OUD cases which may need individualized care. (12-24 months); Transformation Center & Health Systems Division Health Evidence Review Commission to align payment structure with prescribing guidelines. (0-12

⁸ “Oregon Opioid Prescribing Guidelines (Chronic).” OHA. November 2016.

<https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf>

Milestone 5 Criteria	Current State	Future State	Summary of Actions Needed
	were implemented November 17, 2016 In 2018, OHA convened a task force to develop guidelines around Acute pain and prescribing. The opioid prescribing guidelines ⁹ around Acute pain were adopted by Oregon Health Authority on October 20, 2018	Current payment structure is aligned with recommended chronic and Acute prescribing guidelines	months); Health Systems Division
Expanded coverage of, and access to, naloxone for overdose reversal	Per HB3440 (2017) passage, all training requirements, special conditions, including access by social service agencies to Naloxone, and the usage of it have been removed. All Oregonians in any settings can utilize Naloxone without prior training for other conditions. Pharmacists may dispense Naloxone at the point of sale. Oregon Health Plan fee-for-service program (directly administered by OHA) has no prior	Federal grants (STR/SOR) and other initiatives will continue to fund and increase access to naloxone statewide, especially in areas where there are gaps including rural, frontier and coastal areas. Continue cross-division partnerships and funding for the PDO position(s). Work together on opioid crisis response collectively to activities such as overdose outbreaks.	Continue to distribute Naloxone in areas of high need. (0-6 Months); Health Systems Division Continue cross-divisional collaboration at state and local level (0-24 Months); Health Systems Division Increase communication between partners around the alignment of payment structure as it relates to Naloxone to increase access to and penetration of the population at greatest risk and need. (6-12 Months); Health Systems Division Continue to encourage use and provide TA around Naloxone

⁹ “Oregon Acute Opioid Prescribing Guidelines.” OHA. October 2018.
https://www.oregon.gov/OSBN/pdfs/Resource_OregonAcuteOpioidPrescribingGuidelines.pdf

Milestone 5 Criteria	Current State	Future State	Summary of Actions Needed
	authorization for Naloxone; CCO coverage varies. Cross-division partnerships with OHA, Public Health and Health Systems Divisions as well as partnerships with local health departments to fund the Prescription Drug Overdose coordinator(s) (PDO). PDOs will continue to assist in coordinating local naloxone distribution efforts.	Continue to support CCO engagement with the Transformation Center and other resources for technical assistance (TA) around Naloxone distribution and utilization.	access, use and distribution to CCOs through the Transformation Center. (0-6 months); Transformation Center & Health Systems Division
Implementation of strategies to increase utilization and improve functionality of Prescription Drug Monitoring Programs (PDMP)	As of January 2018, medical and pharmacy directors will be allowed access to the PDMP regarding their respective entities. As of February 2018, through HB 4143, the PDMP registration is mandatory for healthcare practitioners who are authorized to prescribe schedule II through IV controlled medications. Public health and education regarding the value	Continue funding the PDMP program to data access, analysis, and improve upon the surveillance potential. Utilize this data to assess the impact of opioid use statewide and engage those communities most impacted by the effects of the opioid crisis. Continue to collaborate with healthcare licensing boards within Oregon to encourage safe and appropriate	Continue to collaborate with provider licensing boards (continuous); Health Systems Division Educate and engage with provider organizations, CCOs, and healthcare prescribers to increase the number of registered individuals who utilize the system (12-24 months); Health Systems Division

Milestone 5 Criteria	Current State	Future State	Summary of Actions Needed
	of PDMP registration and utilization are ongoing to providers and organizations.	controlled substance prescribing. The number of healthcare prescribers who use the PDMP beyond the required registration increased.	
Other	In February 2018 the passage of HB 4143 passed the (Opioid Rapid Response Project), provided resources to create more direct links between ED and appropriate treatment and resources including increased availability of MAT in the ED and using peer delivered services to facilitate the link between ED and appropriate treatment/ resources. This two-year pilot project started in January 2019 beginning in four Oregon counties. Under the Oregon State Plan currently peer delivered services are covered when delivered as part of a treatment plan	The Opioid Rapid Response Project was expanded statewide to other high risk and high burden counties. Coverage of community integration services and supports specifically for housing are implemented; ensuring safe housing in an appropriate recovery environment, special attention and effort around MAT housing	Leverage opportunities to secure more funding (federal grants, Federal opioid project funding, state funds etc.) to expand Opioid Rapid Response project statewide. (12-24 months); Health Systems Division Increase capacity of culturally-relevant PDS workforce (12-24 months); Health Systems Division Increase the number of culturally-relevant trainings (including tribal) to be developed and provided statewide (12-24 months); Office of Equity & inclusion & Health Systems Division Workforce development efforts around community integration/ housing support specialists as Medicaid participating providers (12-24 months); Health Systems Division

Milestone 5 Criteria	Current State	Future State	Summary of Actions Needed
	under the supervision of a licensed program or provider		

6. IMPROVED CARE COORDINATION AND TRANSITIONS BETWEEN LEVELS OF CARE

Milestone 6 Criteria	Current State	Future State	Summary of Actions Needed
Implementation of policies to ensure residential and inpatient facilities link beneficiaries with community-based services and supports following stays in these facilities	Provide an overview of current care coordination services and transition services across levels of care.	Provide an overview of planned improvements to care coordination services and transition services across levels of care.	Specify a list of action items needed to be completed to meet milestone requirements. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item
Creation and implementation of additional policies to ensure coordination of care for co-occurring physical and mental health conditions	Under Oregon's current structure, SUD services are covered under physical health services and behavioral health care coordination is the responsibility of the CCOs To support OHA's ED Disparity Measure for CCOs, the hospital notifications product, The Collective (formerly called Pre-Manage), has	CCOs increased their capacity to provide warmer hand offs between levels of care through enhanced coordinated care for SUD services OHA will continue to work on optimization and education on the ED disparity measure flags provided through The Collective.	Provide support to CCOs through TA and training to increase capacity and quality of SUD care transitions (12-24 months) CCO 2.0 includes language requiring CCOs use hospital event notifications and make them- and health information exchange for care coordinating-accessible to primary care, behavioral health and dental organizations. (12-24 months)

Milestone 6 Criteria	Current State	Future State	Summary of Actions Needed
	<p>added a flag for CCOs and their contracted clinics to alert when a Medicaid member with Severe and Persistent Mental Illness (SPMI) has a hospital event for a physical reason for coordination of care among CCOs and providers. Those in Medication Assisted Treatment for SUD, IV drug users, and individuals with SUD in need of withdrawal management were added as prioritized population (2020) for the CCOs in 2020.</p> <p>An educational series, specifically for CCOs was provided in early 2019 to support improving care coordination services.</p> <p>Oregon OARs clearly dictate the expectations for a patient transfer between providers in OARs 309-018-0155 and 309-018-0210. Included in these are how to</p>		

Milestone 6 Criteria	Current State	Future State	Summary of Actions Needed
	advocate for patient rights if a grievance in placement is present. Some of these guidelines are that the providers will coordinate and provide appropriate referrals, complete a transfer summary (and what is required within a summary), report all instances of transfer in the state's data system, and to provide all documentation in the service record requested by receiving provider as well as a complete transfer summary within 30 days.		

SECTION II- IMPLEMENTATION ADMINISTRATION

Oregon Demonstration Contact

Lori Coyner
 Medicaid Director
 Health Systems Division
 Oregon Health Authority
 500 Summer St.
 Salem, OR 97301-1079
 lori.a.coyner@dhsosha.state.or.us
 (503) 947-2340

Section III- Relevant Documents

Please provide any additional Documentation or information that the state deems relevant to successful execution of the implementation plan.

Attachment A- Milestone 5a- SUD Health Information Technology (IT) Plan

Section I.

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
<i>5. Implementation of comprehensive treatment and prevention strategies to address Opioid Abuse and OUD, that is: --Enhance the state's health IT functionality to support its PDMP; and --Enhance and/or support clinicians in their usage of the state's PDMP.</i>	<i>Provide an overview of current PDMP capabilities, health IT functionalities to support the PDMP, and supports to enhance clinicians' use of the state's health IT functionality to achieve the goals of the PDMP.</i>	<i>Provide an overview of plans for enhancing the state's PDMP, related enhancements to its health IT functionalities, and related enhancements to support clinicians' use of the health IT functionality to achieve the goals of the PDMP.</i>	<i>Specify a list of action items needed to be completed to meet the HIT/PDMP milestones identified in the first column. Include persons or entities responsible for completion of each action item. Include timeframe for completion of each action item</i>
Prescription Drug Monitoring Program (PDMP) Functionalities			
Enhanced interstate data sharing to provide prescribers a more comprehensive prescription history for patients with prescriptions across state lines.	Oregon PDMP can share data with states that meet privacy and security standards. Oregon has circulated Memoranda of Understanding (MOUs) to western states.	Connection of Oregon's PDMP with contiguous states to allow secure sharing of PDMP data.	(6-24 months) Oregon PDMP will continue conversations states as needed and continue to participate in data hub meetings. months); At least once a year contact will be made, more as

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>Interstate data sharing agreements are in place with Idaho, Kansas, Nevada, Texas, and North Dakota.</p> <p>Oregon PDMP joined the data sharing hub Rx Check. This will assist in resolving legal and technical barriers for interstate data sharing.</p> <p>Oregon is also a PMPI (National Association of Boards of Pharmacy) state and is an active and ongoing participant in the groups' activities. This work is ongoing, and is performed by PDMP staff, in the Public Health Division of the Oregon Health Authority, with oversight provided by the appointed Oregon PDMP Advisory Committee.</p>		<p>needed and available (12-24 months; ongoing); Injury Violence Prevention Promotion, Public Health Division.;</p> <p>-</p>
Enhanced “ease of use” for prescribers and other state and federal stakeholders	Prescribers (physicians (MD, PA, DO), Pharmacists (RPh), Nurse Practitioners (NP/CNS-PP), Dentists (DDS/DMD), and Naturopaths (ND), across Oregon, are allowed access to the	PDMP integration with most prescriber systems. Integrated PDMP supports clinician ease of use by pulling PDMP data into their electronic workflow for “one-click” access.	<p>(6-24 months), the PDMP will collaborate with HIT Commons and other stakeholders to:</p> <ul style="list-style-type: none"> – Educate on certain registration and technical thresholds

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>PDMP system after registration.</p> <p>Medical and Pharmacy Directors are allowed access for the purpose of overseeing prescribing and dispensing within their respective entities.</p> <p>Prescribers and Medical and Pharmacy Directors are allowed delegates.</p> <p>Oregon has a statewide initiative to integrate PDMP into health IT systems, including: EHRs, HIEs, pharmacy management systems, and the statewide hospital event notification system Edie.</p> <p>Oregon PDMP has partnered with the HIT Commons (public/private partnership) to help subsidize this connection.</p>		<p>required for integration of prescriber health IT systems with PDMP.</p> <p>Integrate most prescriber systems (representing 16K prescribers and 4 pharmacy chains) with PDMP. Contact will be made no less than annually but will be done as needed. (12-24 months; ongoing); Injury Violence Prevention Promotion, Public Health Division; PDMP will engage with the PDMP Advisory Council and PDMP Integration Steering Committee, no less than annually but are scheduled quarterly and as needed, to develop “ease of use” strategies (enhancements, education, etc.) for prescribers. (12-24 months; ongoing); Injury Violence Prevention Promotion, Public Health Division.</p>
Enhanced connectivity between the state’s PDMP and any statewide, regional or local health information exchange	Under the statewide initiative to integrate PDMP into health IT systems, Community Health Information	Integration of Oregon’s Community Health Information Exchanges with PDMP	PDMP and HIT Commons will continue to work with Oregon’s Community HIEs to integrate with

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>Exchanges (HIEs) can integrate with PDMP.</p> <p>Two of Oregon’s HIEs are working towards integration.</p> <p>Oregon PDMP is working with the HIT Commons (public/private partnership) to help subsidize this connection.</p>		<p>PDMP. (12-24 months; ongoing); Injury Violence Prevention Promotion, Public Health Division.</p> <p>PDMP will work with the HIT Commons, PDMP Integration Steering Committee, and HIE stakeholders to continue to assess enhancements which support clinicians use of HIE to access PDMP data (delegates, training, etc.); contact will be made no less than annually but will be done as needed. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p>
Enhanced identification of long-term opioid uses directly correlated to clinician prescribing patterns ¹⁰ (see also “Use of PDMP” #2 below)	According to statute, the Oregon PDMP may not evaluate professional practice except through licensing boards or the PDMP Advisory Commission Prescribing Practice Review Subcommittee. The subcommittee provides education	Continued leveraging of the PDMP Advisory Commission Clinics Review Subcommittee and continued collaboration with Oregon Pain Management Commission to educate prescribers	PDMP will convene the Clinical Review Subcommittee with a quorum to redefine and update thresholds for risky prescribing at minimum once per year. (12-24 months; ongoing); Injury Violence Prevention Promotion, Public Health Division.;

¹⁰ Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: <http://dx.doi.org/10.15585/mmwr.mm6610a1>.

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>and resources to the highest prescribers.</p> <p>The PDMP has collaborated with the Oregon Pain Management Commission to develop a free Continuous Medical Education (CME) module on pain management; so far more than 5,000 providers have taken the course.</p>	for informed prescribing choices.	<p>PDMP will continue to work with licensing boards to ensure that licensees are registered with the PDMP as mandated by statute; contact will be made no less than annually but will be done as needed and reviewed by the PDMP Advisory Committee quarterly. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>The PDMP will continue to promote the CME resource to stakeholders and enhance education and resources provided to the highest prescribers. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p>
Current and Future PDMP Query Capabilities			
Facilitate the state's ability to properly match patients receiving opioid prescriptions with patients in the PDMP (i.e. the state's master patient index (MPI) strategy with regard to PDMP query)	States on the AWARe platform share the same patient matching algorithm which uses the available data fields to determine which records should be consolidated to unique individuals. The proprietary vendor	The PDMP will share information with the Governor's Opioid Epidemic Taskforce to consider future changes to statute which allow data sharing in support of patient matching. Continue PDMP data quality improvement	Oregon State Statute does not currently allow for this exchange of information – OHA Government Relations and PDMP staff continue to monitor legislation as it emerges – all potential legislative

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	(Appriss) algorithm allows for certain non-exact matches such as common misspellings, nicknames, or changes in address.	efforts with propriety vendor for patient data matching processes and analytics.	<p>action monitored as a course of business through the PDMP Advisory Committee, quarterly.</p> <p>The PDMP will continue to engagement with the Governor’s Opioid Epidemic Taskforce, around the topic of allowing data sharing with the Medicaid program or collection of additional fields.</p> <p>As appropriate and in alignment with meeting agendas and topics. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>PDMP will follow any future statute changes from the legislature to enable matching of PDMP and Medicaid data or to allow submission of additional data fields. As available.</p> <p>Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>The Oregon PDMP MPI strategy is developed by the AWARe platform vendor (Appriss) and is primarily the responsibility of the</p>

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
			vendor. PDMP staff will work with the vendor to incorporate additional data fields required by any statute changes. As required and available. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)
Use of PDMP – Supporting Clinicians with Changing Office Workflows / Business Processes			
Develop enhanced provider workflow / business processes to better support clinicians in accessing the PDMP prior to prescribing an opioid or other controlled substance to address the issues which follow	Prescribers are allowed access to the PDMP system through a web portal after registration. Prescribers are allowed delegates to support clinician workflows. Oregon is in the second year of a three-year statewide initiative to integrate PDMP into health IT systems, including: EHRs, HIEs, pharmacy management systems, and the statewide hospital event notification system EDIE. Oregon PDMP has partnered with the HIT Commons (public/private partnership) to help subsidize this connection.	PDMP integration with most prescriber systems. Integrated PDMP supports clinician ease of use by pulling PDMP data into their electronic workflow for “one-click” access.	PDMP will collaborate with HIT Commons, PDMP Integration Steering Committee, and other stakeholders as needed to: <ul style="list-style-type: none"> – Educate on certain registration and technical thresholds required for integration of prescriber health IT systems with PDMP. – Integrate most prescriber systems (representing 16K prescribers and 4 pharmacy chains) with PDMP. – Share best practices and provide education on leveraging integrated workflows to support informed

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
			<p>prescribing of controlled substances.</p> <p>a.</p> <p>Contact will be made no less than annually but will be done as needed and reviewed by the PDMP Advisory Committee quarterly. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>b.</p>
<p>Develop enhanced supports for clinician review of the patients' history of controlled substance prescriptions provided through the PDMP—prior to the issuance of an opioid prescription</p>	<p>Prescribers can review individual patient records, their own prescribing history, or a threshold report listing all patients that meet certain risky prescribing thresholds (high dose, co-prescribing, etc.).</p> <p>Emergency Department (ED) physicians who have the Emergency Department Information Exchange (EDIE) integrated into their ED track boards may receive PDMP data pushed to them when a patient meets certain criteria, prompting review of patient's history before prescribing.</p> <p>Additionally, the PDMP allows</p>	<p>PDMP integration with most prescriber health IT systems. PDMP pushed to all ED physicians in Oregon with integrated EDIE in their EHR. PDMP stakeholders are educated and receive assistance.</p>	<p>PDMP staff will collaborate with HIT Commons, PDMP Integration Steering Committee, and other stakeholders as needed to:</p> <ul style="list-style-type: none"> – Enable PDMP to be pushed through EDIE for hospitals who have already integrated the EDIE solution into their EHR – Support rural hospitals who wish to integrate EDIE into their EHR through a grant provided by OHA and the Oregon Association for Hospitals and Health Systems <p>c.</p>

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	prescribers and pharmacists to enable delegates to search the PDMP on their behalf in order to support clinician review of PDMP prior to an opioid prescription issuance.		Contact will be made no less than annually but will be done as needed and reviewed by the PDMP Advisory Committee quarterly. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing) d.
Master Patient Index / Identity Management			
Enhance the master patient index (or master data management service, etc.) in support of SUD care delivery.	<p>Oregon's PDMP collection of data fields is defined by state law.</p> <p>The Oregon PDMP MPI strategy is developed by the AWARe platform vendor (Appriss). The AWARe platform uses a proprietary patient matching algorithm which uses the available data fields to determine which records should be consolidated to unique individuals. The proprietary algorithm allows for certain non-exact matches such as common misspellings, nicknames, or changes in address to achieve an acceptable sensitivity and specificity.</p> <p>The EDIE vendor, used by hospitals to</p>	<p>PDMP utilizes Appriss AWARe platform effectively to support SUD care delivery.</p> <p>PDMP data is pushed through EDIE notifications where hospitals have integrated EDIE into their HER.</p>	<p>Oregon State Statute does not currently allow for this exchange of information – OHA Government Relations and PDMP staff continue to monitor legislation as it emerges – all potential legislative action monitored as a course of business through the PDMP Advisory Committee, quarterly.</p> <p>The PDMP will continue engagement with the Governor's Opioid Epidemic Taskforce, around statute changes required to allow data sharing with the Medicaid program or collection of additional fields. As available. Injury Violence Prevention Promotion, Public</p>

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>receive pushed PDMP notifications when a patient enters the ED who meets certain criteria, also has a defined algorithm MPI that provides match and patient record merging. This supports SUD care delivery as ED physicians are notified of PDMP data, as well as historical hospital data on the patient at the point of care.</p>		<p>Health Division.; (12-24 months; ongoing)</p> <p>The PDMP will follow any future statute changes that allow data sharing between PDMP and Medicaid to enhance the state MPI in support of SUD care delivery. As available. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>PDMP staff will work with the vendor to incorporate additional data fields required by any statute changes. As available. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p>
Overall Objective for Enhancing PDMP Functionality & Interoperability			
<p>Leverage the above functionalities / capabilities / supports (in concert with any other state health IT, TA or workflow effort) to implement effective controls to minimize the risk of inappropriate opioid overprescribing—and to ensure that Medicaid does not inappropriately pay for opioids</p>	<p>Oregon PDMPs mission is primarily to support clinical decision-making. Medical Directors and Pharmacy Directors are allowed access to the PDMP to perform clinical quality assurance activities for the providers they supervise.</p>	<p>Dental Directors and CCO Medical Directors access PDMP data in support of clinical quality assurance activities.</p> <p>PDMP integration with a majority of prescriber systems supports effective controls to minimize the risk of</p>	<p>PDMP will collaborate with HIT Commons, PDMP Integration Steering Committee, and other stakeholders as needed to:</p> <ul style="list-style-type: none"> – Register CCO Medical Directors and Dental Directors if

Milestone 5a Criteria	Current State	Future State	Summary of Actions Needed
	<p>Oregon is in year two of a three-year statewide initiative to integrate PDMP into health IT systems, including: EHRs, HIEs, pharmacy management systems, and the statewide hospital event notification system EDIE.</p> <ul style="list-style-type: none"> – Legislation in 2019 added Dental Directors and CCO Medical Directors to list of authorized users of PDMP 	<p>inappropriate opioid overprescribing by leveraging system functionalities (HIE, EDIE)</p>	<p>legislation is passed.</p> <ul style="list-style-type: none"> – Educate on certain registration and technical thresholds required for integration of prescriber health IT systems with PDMP. – Integrate a majority of prescriber systems (representing 16K prescribers and 4 pharmacy chains) with PDMP. – Share best practices and provide education on leveraging integrated workflows to support informed prescribing of controlled substances. <p>e.</p> <p>Contact will be made no less than annually but will be done as needed and reviewed by the PDMP Advisory Committee quarterly. Injury Violence Prevention Promotion, Public Health Division.; (12-24 months; ongoing)</p> <p>f.</p>

Section II.

- a. Oregon has an enough health IT infrastructure and ecosystem at every appropriate level to achieve the goals of the demonstration.
- b. Oregon's SUD Health IT Plan is aligned with the state's Medicaid Health IT Plan and is a component of Oregon's Behavioral Health (BH) IT Plan. Oregon is currently initiating modernization efforts on its BH IT systems, including SUD IT systems, and will be building a cloud data warehouse, inbound and outbound data interfaces, and longitudinal assessment platforms. This work is a component of the broader Medicaid Health IT Plan which includes Medicaid Modularity and migration of HITECH Act funded systems into the Medicaid Enterprise System.

Section III.

- a. Oregon will include the applicable standards referenced in the ONC Interoperability Standards Advisory (ISA) and 45 CFR 170 Subpart B in a future amendment to the CCO contract. The opportunities to add the SUD waiver requirements to the CCO contract are through an optional amendment in mid-2021 for CCOs that choose early implementation and through the annual restatement for contract year 2022 whereby implementation will be mandatory for all CCOs. Oregon's most recent procurement for CCO contracts occurred in 2019, with contracts awarded for the period of 2020-2024; Oregon does not anticipate any need to re-procure CCO contracts during the SUD waiver implementation period.
 - i. Relevant examples of specific health IT standards referenced in the ISA that are relevant for this demonstration include:
 - 1. Electronic Prescribing – A Prescriber's Ability to Obtain a Patient's Medication History from a Prescription Drug Monitoring Program (Section II-I)
 - 2. "Direct" transport standards
 - 3. Documenting and Sharing Care Plans - Care Plan standards (CDA)
 - 4. Sending a Notification of a Patient's Admission, Discharge and/or want Transfer Status to Other Providers - ADT Alerting and Messaging
 - 5. Clinical Quality Measurement and Reporting

Demonstration Administration

Oregon Health IT Plan Contact

Steve Westburg
OHA Agency Business Systems Manager
Health Systems Division
Oregon Health Authority
500 Summer St.
Salem, OR 97301-1079
Steven.D.Westberg@dhsosha.state.or.us
(503) 931-6729

ATTACHMENT D
Reserved for SUD Monitoring Protocol

ATTACHMENT E
Reserved for SUD Evaluation Design

ATTACHMENT F: Community Integration Services and Eligibility

Target Group: Housing and employment supports eligibility is targeted to Medicaid beneficiaries with a SUD diagnosis who are enrolled under the Medicaid State Plan.

Needs-Based Criteria and Risk Factors: The Oregon Health Authority (OHA) assures there are needs-based criteria for receipt of institutional services and participation in certain waivers that are more stringent than the criteria below for receipt of Community Integration Services provided through the 1115 SUD Demonstration Waiver.

An individual must meet the following health needs-based criteria and is expected to benefit from housing or employment supports:

1. Individual has a behavioral health need, which is defined as a substance use need, where an assessment using the American Society of Addiction Medicine (ASAM) Criteria (or equivalent assessment) would indicate that the individual would meet at least ASAM level 1.0, indicating the need for outpatient Substance Use Disorder (SUD) treatment.

AND The individual meets at least one of the following sets of risk factors:

1. The individual has at least one or more of the following risk factors and is expected to benefit from housing support services:

- a. At risk of homelessness.
 - i. At risk of homelessness is defined as an individual who will lose their primary nighttime residence.
- b. Homelessness.
 - i. Homelessness is defined as lacking a fixed, regular, and adequate nighttime residence, meaning:
 - 1) Has a primary nighttime residence that is a public or private place not designed for or ordinarily used as a regular sleeping accommodation for human beings (e.g., a car, park, abandoned building, bus or train station, airport, or camping ground).
 - 2) Living in a place not meant for human habitation, in an emergency shelter, in transitional housing (including congregate shelters, transitional housing, and hotels and motels) or exiting an institution where they temporarily resided in one of the aforementioned situations.
 - 3) Fleeing domestic violence or another dangerous situation related to violence.
 - 4) An individual living with children or unaccompanied youth unstably housed. Unstably housed is defined as an individual living with children or unaccompanied youth who have not had a lease or ownership interest in a housing unit in the last 60 or more days, who have had two or more moves in the last 60 days, and who are likely to continue in such a state.

- c. History of frequent or lengthy stays in an institutional setting (as defined in 42 CFR 435.1010) or residential setting (consistent with those settings noted in OAR Chapter 309, Division 18 for residential services and residential treatment settings).
 - i. Frequent is defined as more than one time in the past 12 months.
 - ii. Lengthy is defined as at least 28 or more consecutive days within an institutional setting, assisted living facility, or residential setting.
- d. History of frequent emergency department (ED) visits and/or hospitalizations.
 - i. Frequent is defined as more than four ED visits and/or hospitalizations in the past 12 months.
- e. History of involvement with the criminal justice system.
 - i. History of involvement with the criminal justice system is defined as an individual who has been confined to a prison, jail, halfway house, boot camp, weekend program, and other justice-involved facilities in which individuals are locked up overnight, for at least 24 hours over the past 12 months.
- f. History of frequent moves or loss of housing as a result of substance use disorder (e.g., lapsed rent payments due to substance use related residential treatment or hospitalization (including withdraw management), or psychiatric hospitalization).
 - i. Frequent is defined as more than once in the past six months.

OR

2. The individual has at least one or more of the following risk factors and is expected to benefit from CIS:

- a. More than one instance of inpatient or outpatient SUD service in the past two years.
- b. At risk of deterioration of mental illness and/or SUD, including one or more of the following:
 - i. Persistent or chronic risk factors such as social isolation due to a lack of family or social supports, poverty, criminal justice involvement, or homelessness.
 - 1) OHA will apply the same definition of homelessness as required for the housing supports risk factors, as described above.
 - ii. Care for SUD requires multiple provider types, including behavioral health, primary care, long-term services and supports, or other supportive services.
 - iii. Past psychiatric history, with ongoing treatment and supports necessary to ensure functional improvement.
 - iv. Dysfunction in role performance, including one or more of the following:
 - 1) SUD disrupts employment or schooling, or put employment at risk of termination or schooling suspension.

- 2) A history of multiple terminations from work or suspensions/expulsions from school.
- 3) Cannot succeed in a structured work or school setting without additional support or accommodations.

OR

3. The individual has at least one or more of the following risk factors and is expected to benefit from employment support services:

- a. Unable to be gainfully employed for at least 90 consecutive days in the past 12 months due to a mental or physical impairment.
- b. Unable to obtain or maintain employment resulting from age, physical/sensory disability, or moderate to severe brain injury.
- c. More than one instance of inpatient or outpatient SUD service in the past two years.
- d. At risk of deterioration of mental illness and/or SUD, including one or more of the following:
 - i. Persistent or chronic risk factors such as social isolation due to a lack of family or social supports, poverty, criminal justice involvement, or homelessness.
 - 1) DMAS will apply the same definition of homelessness as required for the housing supports risk factors, as described above.
 - ii. Care for mental illness or SUD requires multiple provider types, including behavioral health, primary care, long-term services and supports, or other supportive services.
 - iii. Past psychiatric history, with ongoing treatment and supports necessary to ensure functional improvement.
 - iv. Dysfunction in role performance, including one or more of the following:
 - 1) Behaviors that disrupt employment or schooling, or put employment at risk of termination or schooling suspension.
 - 2) A history of multiple terminations from work or suspensions/expulsions from school.
 - 3) Cannot succeed in a structured work or school setting without additional support or accommodations.
 - 4) Performance significantly below expectation for cognitive/developmental level.

Housing and Employment Supports Services

Housing Supports: Housing supports services are determined to be necessary for an individual to obtain and reside in an independent community setting and are tailored to the goal of maintaining an individual's personal health and welfare in a home and community-based setting as they are transitioning from an IMD. Housing supports services may include one or more of the following components:

Individual Housing and Pre-Tenancy Services:

1. Conducting an assessment to identify the individual's needs and preferences related to housing (e.g., type, location, living alone or with someone else, identifying a roommate, accommodations needed, or other preferences).
2. Assisting individuals with budgeting for housing/living expenses, including financial literacy education on budget basics.
3. Assisting individuals with finding and applying for housing, including filling out housing, utility, and rental assistance applications and obtaining and submitting appropriate documentation.
4. Assisting individuals with completing reasonable accommodation requests as needed to obtain housing.
5. Developing an individualized housing support plan that identifies short and long-term measurable goals, how goals will be achieved and how barriers to achieving goals will be addressed.
6. Assisting with identifying and securing resources to obtain housing.
7. Ensuring the living environment is safe (including the assessment of health risks to ensure the living environment is not adversely affecting the occupants' health) and accessible for move-in.
8. Assisting in arranging for and supporting the details and activities of the move-in.

Individual Housing and Tenancy Sustaining Services:

1. Coordination with the individual to plan, participate in, review, update and modify their individualized housing support plan on a regular basis, including at redetermination and/or revision plan meetings, to reflect current needs and preferences and address existing or recurring housing retention barriers.
2. Providing assistance with securing and maintaining entitlements and benefits (including rental assistance) necessary to maintain community integration and housing stability (e.g., assisting individuals in obtaining documentation, assistance with completing documentation, navigating the process to secure and maintain benefits, and coordinating with the entitlement/benefit assistance agency).
3. Assistance with securing supports to preserve the most independent living.
4. Monitoring and follow-up to ensure that linkages are established and services are addressing community integration needs.
5. Providing supports to assist the individual in the development of independent living skills to remain in the most integrated setting (e.g., skills coaching to maintain a healthy living environment, develop and manage a household budget, interact appropriately with neighbors or roommates, reduce social isolation, utilize local transportation).
6. Providing supports to assist the individual in communicating with the landlord and/or property manager.

7. Education and training on the role, rights, and responsibilities of the tenant and landlord.
8. Providing training and resources to assist the individual with complying with his/her lease.
9. Assisting in reducing the risk of eviction by providing services to prevent eviction (e.g., to improve conflict resolution skills; coaching; role-playing and communication strategies targeted towards resolving disputes with landlords and neighbors; communicating with landlords and neighbors to reduce the risk of eviction; addressing biopsychosocial behaviors that put housing at risk; providing ongoing support with activities related to household management; and linking the tenant to community resources to prevent eviction).
10. Providing early identification and intervention for actions or behaviors that may jeopardize housing.
11. Providing a pest eradication treatment no more than one time per year that is necessary for the individual's health and safety as documented by a health care professional. This service is not intended for monthly, routine or ongoing treatments. This service is coverable when the individual is living in their own home, when not already included in a lease, and when the pest eradication is for the management of health and safety as identified in the person-centered service plan. The service is not otherwise provided under this waiver (except as part of Community Transition Services for individuals transitioning out of institutional settings and provider-owned and operated congregate living arrangements) and the Medicaid state plan, including Early and Periodic Screening, Diagnostic and Treatment (EPSDT).
12. Modifications to improve accessibility of housing (e.g., ramps, rails) and safety (e.g., grip bars in bathtubs) when necessary to ensure occupant's health, and when modification is not covered by another entity as required by law.
13. Assistance with connecting the enrollee to expert community resources to address legal issues impacting housing and thereby adversely impacting health, such as assistance with breaking a lease due to unhealthy living conditions.
14. Shared living support services that provide for the payment for the additional costs of rent and food that can be reasonably attributed to an unrelated live-in personal caregiver who resides in the same household as the individual. Payment will not be made when the individual lives in the caregiver's home or in a residence that is owned or leased by the provider of Medicaid services.

Community Transition Services:

1. Supports designed to assist individuals transitioning out of institutional settings and provider-owned and operated congregate living arrangements, not to exceed \$5,000 per member per lifetime, regardless of the number of services. Supports cover expenses

necessary to enable individuals to obtain an independent, community-based living setting. Specifically, allowable expenses may include: security deposits required to obtain a lease on an apartment or home; essential household furnishings required to occupy and use a community domicile, including furniture, window coverings, food preparation items, and bed/bath linens; set-up fees or deposits for utility or service access, including telephone, electricity, heating and water; services necessary for the individual's health and safety such as pest eradication and one-time cleaning prior to occupancy; moving expenses; necessary home accessibility adaptations; and activities to assess need, arrange for, and procure needed resources.

Services Not Included in the CIS Housing Benefit:

1. Payment of rent or other room and board costs.
2. Capital costs related to the development or modification of housing.
3. Expenses for utilities or other regular occurring bills.
4. Goods or services intended for leisure or recreation.
5. Duplicative services from other state or federal programs.
6. Services to individuals in a correctional institution or an Institution of Mental Disease (IMD) (other than services that meet the exception to the IMD exclusion).
7. Community Transition Services are furnished only to the extent that they are reasonable and necessary as determined through the service plan development process, clearly identified in the service plan and only when the person is unable to meet such expense or when the services cannot be obtained from other sources. Community Transition Services do not include monthly rental or mortgage expense, food, regular utility charges, and/or household appliances or items that are intended for purely diversional/recreational purposes.

Employment Supports: Employment supports services are determined to be necessary for an individual to obtain and maintain employment in the community. Employment supports services will be individualized and may include one or more of the following components:

Pre-Employment Services (individual and small group):

1. Pre-vocational/job-related discovery or assessment.
2. Assessment of workplace readiness (e.g., people skills, technology knowledge).
3. Person-centered employment planning.
4. Individualized job development and placement (e.g., job fairs, interviews).
5. Mentoring (e.g., on how to change cultural behavior, re-entry from incarceration).
6. Career coaching (e.g., resume coaching, interview coaching).
7. Job carving.
8. Benefits education, planning, and training.
9. Transportation (provided either as a separate transportation service to employment services or to the individual's job, or services included in the rate paid to the provider of employment services).
10. Soft skill training (e.g., interpersonal skills, customer service, answering the phone, workplace culture).

11. Volunteer work and paid internships.
12. Job preparation training (e.g., coaching on appropriate personal hygiene and attire, timeliness, workplace behavior and communication, reliability).
13. Training to improve executive functioning skills (e.g., sustaining attention, organizing, and task prioritization).
14. Behavioral modification (e.g., to increase emotional maturity, to develop alternative coping mechanisms for adverse behaviors such as alcohol/drug use).
15. Coordination with other care providers to address behavioral health needs that impact an individual's ability to secure and maintain employment.

Employment Sustaining Services (individual and small group):

1. Job coaching (including situational assessments).
2. Career advancement services.
3. Negotiation with employers.
4. Job analysis.
5. Training and systemic instruction
6. Benefits education and planning.
7. Financial and health literacy.
8. Transportation (provided either as a separate transportation service to employment services or to the individual's job, or included in the rate paid to the provider of employment services).
9. Payment for public transportation (e.g., bus passes, mass transit vouchers) to support the enrollee's ability to participate in work/community engagement and to gain access to community services, activities, and resources.
10. Account credits for cost-effective private forms of transportation (e.g., taxi, ridesharing) in areas without access to public transit in order to enable individuals to participate in work/community engagement and to gain access to community services, activities, and resources.
11. Transportation education assistance in gaining access to public or mass transit, including access locations, pilot services available via public transportation, and how to purchase transportation passes.
12. Assistance with linking to high quality child care and after-school programs and programs that increase adults' capacity to participate in work/community engagement activities.
13. Asset development.
14. Follow-along supports.
15. Peer supports for employment provided by a co-worker or other job site personnel, provided that the services furnished (e.g., emotional support, connections to resources) are not part of the normal duties of the co-worker, supervisor or other personnel and these individuals meet the pertinent qualifications for the provider of service.

Services Not Included in the Employment Supports Benefit:

1. Generalized employer contacts that are not connected to a specific enrolled individual or an authorized service.
2. Employment support for individuals in sub-minimum wage, or sheltered workshop settings.
3. Facility-based habilitation or personal care services.

4. Wage or wage enhancements for individuals.
5. Duplicative services from other state or federal programs.
6. Medicaid funds to defray the expenses associated with starting up or operating a business.

Provider Qualifications: Contracted CIS providers must assure staff providing housing and employment supports services maintain appropriate qualifications in order to effectively serve enrollees. Staff providing Community Integration Services must receive OHA approved housing supports trainings in accordance with evidence-based principles and practices, as well as other applicable trainings in accordance with the Oregon Health Authority contract. Below are the minimum provider staff qualifications. OHA and its CCOs (contingent upon OHA review and approval) may also impose licensure/certification/accreditation requirements beyond the minimum provider qualifications outlined below.

Provider type	Education and Experience	Skills	Services
Housing Supports	<ul style="list-style-type: none"> • Education (e.g., Bachelor's degree, Associates degree, certificate) in a human/social services field or a relevant field; and/or • An individual certified as a recovery mentor or a peer support specialist or with commensurate experience; and/or • At least one year of relevant professional experience and/or training in the field of service. 	Knowledge of principles, methods, and procedures of services included under housing supports services, or comparable services meant to support an individual's ability to obtain and maintain stable housing.	Individual Housing and Pre-Tenancy Services. <ul style="list-style-type: none"> • Individual Housing and Tenancy Sustaining Services. • Community Transition Services.
Employment Supports	Education (e.g., Bachelor's degree, Associates degree, certificate) in a human/social services field or a relevant field; and/or <ul style="list-style-type: none"> • An individual certified as a recovery mentor or a peer support 	Knowledge of principles, methods, and procedures of services included under employment supports services, or comparable services meant to support an individual's	<ul style="list-style-type: none"> • Pre-Employment Services (individual and small group). • Employment Sustaining Services (individual and small group).

	specialist or with commensurate experience; and/or <ul style="list-style-type: none"> • At least one year of relevant professional experience and/or training in the field of service. 	ability to obtain and maintain stable employment.	
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Administrative Approach: The state will provide a set of housing supports to certain high need Medicaid beneficiaries enrolled in the managed care delivery system by contracting with Oregon’s CCOs to provide the approved Community Integration Services and related activities. The state will maintain authority, accountability, oversight, and evaluation of the CIS program, including oversight of delegated activities to its CCOs and any other contracted entities, as well as oversight of the CIS quality strategy described in STCs 26 – 29.

The state will leverage multiple pathways to ensure a “no wrong door” approach to identifying enrollees who may be eligible for these services. Multiple entities, including CCOs, state agencies, community organizations, and providers, will play a critical role in identifying individuals for the CIS benefit. The state will send information it receives regarding potentially eligible enrollees to the MCOs to determine eligibility for the benefit. The state will develop standardized CIS screening questions that CCOs will use to determine CIS eligibility. The state will validate the eligibility determination provided by the CCOs.

The state will develop standardized elements for a CIS assessment to be performed by CCOs, and review/approve any changes to the assessment proposed by the CCOs. The state will require the MCOs to ensure their care coordinators develop the CIS person-centered care plan that reflects enrollees’ housing and employment-related needs, goals, and preferences, and to connect enrollees to providers and services authorized by the CCO. The state will require that CCOs, in collaboration with providers, track and report the services provided to High Needs Supports enrollees, ensuring accountability for service delivery and payment. The state will conduct periodic audits of payments to verify accurate reporting and spending.

The following activities will be delegated to CCOs; the state will monitor and ensure CCO compliance and performance with respect to these functions:

- Develop, manage, and contract with a network of CIS providers to deliver and pay claims for Community Integration Services.
- Screen members to identify those potentially eligible for Community Integration Services.
- Conduct the CIS eligibility screening to determine CIS eligibility based on the eligibility criteria set forth above.
- Perform ongoing data surveillance/identification of members to monitor any changes to the member’s CIS status.
- Oversee the provision of the standardized CIS assessment and the development/maintenance of the CIS person-centered care plan by the CCO care coordinators.

- Authorize Community Integration Services and care plan modifications.
- Work with CCOs to ensure care management and monitor/track enrollees' access to services and progress against their goals.

Payment Methodology: As applicable for any community integration services provided through managed care, the state will demonstrate that it has designed and implemented an adequate system for ensuring financial accountability of the CIS program. Working closely with the CCOs, the state will establish a payment floor for the federally-approved CIS. The services will be priced based on factors such as the intensity of services, duration of services, geography, contracted provider per unit cost, and comparable fee-for-service (FFS) service costs. The state will allow CCOs to negotiate CIS payment rates above the payment floor. Once the CIS program is fully implemented in a manner envisioned by the state, OHA may consider revising the payment methodology approach to remove the payment floor and allow CCOs to negotiate provider payment rates. The state will require CCOs to reimburse network providers authorized to deliver these services based on the standards and requirements set forth by the state. The state will conduct periodic audits of payments to verify accurate reporting and spending. The state will work with CMS to determine if a State Directed Preprint pursuant to 42 CFR 438.6(c) is required for these payments, and if so, will submit a preprint(s) for approval prior to implementation of the payments as required under 42 CFR 438.6(c)(2). Further, the state will demonstrate actuarial soundness pursuant to 42 CFR Part 438.

2024 Biennial Review

Selective Mutism

Question: Should the selective mutism line be merged into either the social phobia or the anxiety line?

Question source: HERC staff; Dr. Ben Hoffman, pediatrician; other pediatric advocates

Issue: Selective mutism is a severe anxiety disorder in which a patient is unable to speak in certain social situations despite fluent speech in other situations. It usually starts in childhood but can persist into adulthood if untreated. Treatment is generally psychotherapy and/or speech therapy, but some anxiety medications have been shown to be helpful in some cases. Selective mutism is co-occurring with severe anxiety in most cases, particularly with social anxiety disorder. Selective mutism can have a profound effect on a patient's life. Selective mutism is a relatively rare disorder. Estimates on its point prevalence have been obtained in clinic or school samples in various countries and typically range between 0.03% and 1.9% depending on the setting.

Selective mutism (ICD-10-CM F94.0) is currently the only diagnosis on line 473 SELECTIVE MUTISM. Review of HSC and HERC minutes could not find information on why this diagnosis was prioritized to this position. At one point, this diagnosis was on line 426 Avoidant Disorder of Childhood or Adolescence; Elective Mutism, and it is unclear when this line was changed.

Similar diagnoses are on line 458 SIMPLE PHOBIAS AND SOCIAL ANXIETY DISORDER (social phobia, ICD-10-CM F40.1) and Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED (generalized anxiety disorder, ICD-10-CM F41.1).

Evidence

- 1) **Steains 2021**, meta-analysis of RCTS of psychological interventions for selective mutism
 - a. N=5 RCTs (233 patients)
 - b. The results of the analyses showed psychological interventions to be more effective than no treatment, with the overall weighted effect size of $g = 0.87$, indicating a large mean treatment effect
 - c. Conclusion: this meta-analysis provides support for the efficacy of treatment for selective mutism
- 2) **Muris 2021**, review of diagnosis and management of selective mutism in children
 - a. There is a clear link between selective mutism and fear and anxiety, particularly social anxiety.
 - b. cognitive-behavioral therapy (CBT) is generally recognized as the most feasible intervention for children with this disorder
 - c. There may be a role in SSRI's for treatment option
 - d. Conclusion: SM is a rare but debilitating disorder that has puzzled researchers and clinicians for a long time. Empirical insights indicate that SM is mainly fear- and anxiety-driven and as such clinicians need to approach the condition as an anxiety disorder.

Claims review

In 2019, 40 unique recipients had claims for ICD-10-CM F94.0 (Selective mutism). These recipients had a variety of other ICD-10-CM codes in their claims, including social phobia, other disorders of psychological development, conduct disorders, acute stress reaction). The most common procedures billed with F94.0 were psychotherapy and speech/hearing therapy.

2024 Biennial Review Selective Mutism

BHAP input

The panel members strongly felt that selective mutism was a form of severe anxiety and should be covered like any other anxiety disorder. Marshall noted that this is quite a disabling disorder which is a long term condition unless treated. Keith Cheng, a child psychiatrist, gave verbal testimony that this condition prevents children from attending school.

The group felt that waiting for the 2024 biennial review to move the line to a covered position was too long. HERC staff proposed moving the only ICD-10 code on that line ((ICD-10-CM F94.0) to the generalized anxiety line and having line 473 SELECTIVE MUTISM simply show as a struck out line on the Prioritized List until the 2024 biennial review list.

BHAP rescored line 473, recommended that suffering be changed from a 1 to a 3, due to high level of suffering of the patient and the family, and that need for treatment be changed from 0.8 to 1.

BHAP members did not feel that speech therapy needed to be paired with this diagnosis.

**2024 Biennial Review
Selective Mutism**

HERC staff summary:

Selective mutism is similar to anxiety disorder or social anxiety disorder. Cognitive behavioral therapy appears to be effective for treatment, and the disorder is debilitating when untreated. BHAP strongly feels that this diagnosis should be covered similarly to other anxiety disorders.

HERC staff/BHAP recommendations:

- 1) For implementation on January 1, 2022 Prioritized List:
 - a. Add ICD-10-CM F94.0 (Selective mutism) to Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED
 - i. Remove F94.0 from line 473
 - b. Strike through line 473 SELECTIVE MUTISM
- 2) For implementation on January 1, 2024 Prioritized List:
 - a. Merge line 473 into line 414
 - b. See scoring of those lines below for comparison

~~Line: 473~~

~~Condition: SELECTIVE MUTISM~~

~~Treatment: MEDICAL/PSYCHOTHERAPY~~

~~ICD-10:~~

~~CPT: 90785,90832,90840,90846,90853,90882,90887,98966,98972,99051,99060,99202,99215,99224,99324,99355,99366,99368,99415,99423,99439,99449,99451,99452,99487,99491,99495,99498,99605,99607~~

~~HCPCS: G0068,G0071,G0088,G0090,G0176,G0177,G0248,G0250,G0425,G0427,G0459,G0463,G0467,G0469,G0470,G0511,G2012,G2064,G2065,G2211,G2212,G2214,G2251,G2252,H0004,H0023,H0032,H0038,H2010,H2012,H2014,H2021,H2022,H2027,H2032,H2033,S9484~~

Line 473 SELECTIVE MUTISM (staff/BHAP proposed scores shown first, then current scoring in parentheses)

Category: 7 (7)

Healthy life years: 1 (1)

Suffering: 3 (1)

Population effects: 0

Vulnerable population: 0

Tertiary prevention: 1

Effectiveness: 4

Need for treatment: 1 (0.8)

Net cost: 4

Score: 400 (192)

Line placement: 409 (473)

Line 414 OVERANXIOUS DISORDER; GENERALIZED ANXIETY DISORDER; ANXIETY DISORDER, UNSPECIFIED

Category: 7

Healthy life years: 2

Suffering: 2

Population effects: 0

Vulnerable population: 1

2024 Biennial Review
Selective Mutism

Tertiary prevention: 1
Effectiveness: 3
Need for treatment: 1
Net cost: 4
Score: 360
Line placement: 414

REVIEW ARTICLE

WILEY

Efficacy of psychological interventions for selective mutism in children: A meta-analysis of randomized controlled trials

Sophie Y. Steains  | John M. Malouff  | Nicola S. Schutte 

University of New England, Armidale, New South Wales, Australia

Correspondence

John M. Malouff, University of New England
School of Psychology, Armidale, NSW 2351,
Australia.
Email: jmalouff@une.edu.au

Abstract

Background: Selective mutism is a rare childhood anxiety disorder characterized by a consistent failure to speak in certain social situations where speech is expected, despite fluent speech in other situations. The purpose of this meta-analysis was to investigate the efficacy of psychological interventions for selective mutism in randomized controlled trials (RCTs).

Methods: Five RCTs with a total of 233 participants were analysed using a random-effects model. A quality assessment of the included studies revealed that psychometrically sound measures and treatment manuals were used across all studies.

Results: The results of the analyses showed psychological interventions to be more effective than no treatment, with the overall weighted effect size of $g = 0.87$, indicating a large mean treatment effect. This effect did not significantly differ with whether only selective mutism specific or nonselective mutism specific measures were included in the analysis.

Conclusions: These findings provide support for the efficacy of psychological treatment for selective mutism. Future research could examine the effects of the successful treatments identified in this meta-analysis when compared with a psychological placebo or another bona fide treatment.

KEYWORDS

child anxiety, efficacy, meta-analysis, selective mutism, treatment

1 | INTRODUCTION

Selective mutism is a childhood anxiety disorder that affects 0.2 to 1.9% of the school-aged population (Viana et al., 2009). The disorder is characterized by consistent failure to speak in social situations where speech is expected (e.g., at school) despite fluent speech in other situations (e.g., at home; American Psychiatric Association, 2013). According to the Diagnostic and Statistical Manual of Mental Disorders-5 (American Psychiatric Association, 2013), this failure to speak must be evident for at least 1 month and lead to impairment in educational or occupational achievement, or social communication. Furthermore, it cannot be better attributed to unfamiliarity with the spoken language, a communication disorder, or other developmental, learning, or psychotic disorders.

The etiology of selective mutism is currently unknown; however, the disorder is likely the result of the interplay of various genetic, temperamental, environmental, and neurodevelopmental factors (Muris & Ollendick, 2015). These factors can include shy and inhibited temperament (Muris et al., 2016), family history of anxiety (Chavira et al., 2007; Kristensen & Torgersen, 2002), bilingualism (Elizur & Perednik, 2003; Steinhausen & Juzi, 1996), speech and language impairments (Kristensen, 2000; Manassis et al., 2007), and a low level of social skills (Carbone et al., 2010). There is considerable overlap in the symptomatology of selective mutism and social anxiety disorder, with a recent meta-analysis finding an average comorbidity rate of 69% (Driessen et al., 2019).

The mean age of onset of selective mutism is between 2 and 5 years old, although the disorder usually remains undetected until

Current Challenges in the Diagnosis and Management of Selective Mutism in Children

This article was published in the following Dove Press journal:
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Peter Muris ^{1,2}

Thomas H Ollendick^{3,4}

¹Department of Clinical Psychological Sciences, Faculty of Psychology and Neuroscience, Maastricht University, Maastricht, the Netherlands;

²Departement Sielkunde, Stellenbosch University, Stellenbosch, South Africa;

³Department of Psychology, Virginia Polytechnic Institute and State University, Blacksburg, VA, USA; ⁴Department of Psychology, University of Roehampton London, London, UK

Abstract: Selective mutism (SM) is a childhood disorder characterized by a consistent failure to speak in specific social situations (eg, school) despite speaking normally in other settings (eg, at home). This article summarizes evidence supporting the recent classification of SM as an anxiety disorder and discusses the implications of this re-classification for the assessment and treatment of SM in clinical practice. Meanwhile, clinicians should also realize that SM sometimes is a heterogeneous disorder in which other problems are also present that complicate the management of children with SM. As examples, we discuss speech and language problems, developmental delay, and autism spectrum disorders.

Keywords: selective mutism, anxiety disorder, assessment, treatment

Introduction

Selective mutism (SM) is a psychological condition usually occurring during childhood that is characterized by a total absence of speech in specific social situations while speech production appears to be normal in other situations. For example, children with SM may not respond to a question posed by the teacher in class and/or do not speak to peers at school, but do verbally communicate with parents, siblings, or other familiar people encountered in the home environment. To formally establish the diagnosis, current classification systems presume that the selective non-speaking behavior is required to be present for at least 1 month, should not be attributable to a lack of knowledge of, or discomfort with, the spoken language required in the social situation, and has to interfere significantly with daily functioning in school, work, or social life. Furthermore, the disturbance is not better explained by a communication disorder (eg, childhood-onset fluency disorder) and does not occur exclusively during the course of autism spectrum disorder, schizophrenia, or another psychotic disorder.^{1,2}

SM is a relatively rare disorder. Estimates on its point prevalence have been obtained in clinic or school samples in various countries and typically range between 0.03% and 1.9% depending on the setting (eg, clinic vs school/general population) and ages of the children in the sample.³ SM is typically an early-onset condition, starting usually before the age of 5 years and often becoming a focus of clinical attention when children enter school.¹ The course of SM is variable: some children continue to demonstrate the prototypical muteness associated with the disorder, but in many young people the selective non-speaking behavior gradually diminishes while symptoms of social reticence and social anxiety often remain.^{4,5}

Correspondence: Peter Muris
Department of Clinical Psychological Sciences, Faculty of Psychology and Neuroscience, Maastricht University, P.O. Box 616, Maastricht, 6200 MD, The Netherlands
Email peter.muris@maastrichtuniversity.nl