Health Evidence Review Commission

May 21, 2020
1:30 PM - 3:30 PM

Virtual meeting

Webinar Registration URL: https://attendee.gotowebinar.com/rt/4485730763563131149

Public listen-in only line: 1-888-204-5984, participant code 801373

Section 1.0

Call to Order

AGENDA

HEALTH EVIDENCE REVIEW COMMISSION-VALUE-BASED BENEFITS SUBMCOMMITTEE

JOINT MEETING

ONLINE MEETING

May 21, 2020

1:30-3:30 pm

(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter	Action Item
1	1:30 PM	Call to order	Kevin Olson	
2	1:35 PM	Approval of minutes (March 12, 2020)	Kevin Olson	X
3	1:40 PM	Director's report	Jason Gingerich	
4	1:45 PM	• Update on COVID specific code changes due to the COVID-19 emergency • Update on telehealth codes	Jason Gingerich Ariel Smits Liz Walker	
5	2:00 PM	Review of the 2020 AHRQ reports on • Non-pharmacologic treatments for pain • Non-opioid pharmacologic treatments for pain • Opioid treatments for pain Review of Washington HTA report on lumbar surgery	Ariel Smits	
6	2:45 PM	Questions or input for HERC staff from Commissioners	Ariel Smits	
7	3:00 PM	Public comment		
8	3:25 PM	Next steps • Schedule next meeting – August 13, 2020, TBD	Kevin Olson	
9	3:30 PM	Adjournment	Kevin Olson	

MINUTES

HEALTH EVIDENCE REVIEW COMMISSION
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 12, 2020

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-Chair; Leda Garside, RN, MBA (by phone at 1:45 pm); Gary Allen, DMD; Devan Kansagara, MD (by phone, at 1:40 pm); Leslie Sutton (by phone); Adriane Irwin, PharmD, Kathryn Schabel, MD; Max Kaiser, DO (by phone at 1:42 pm); Mike Collins (by phone).

Members Absent: Lynnea Lindsey, PhD; Michael Adler, MD.

Staff Present: Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Jason Gingerich; Daphne Peck, Jaime Taylor.

Also Attending: Dana Hargunani, MD (Oregon Health Authority); Amy Alpaugh, JD (Department of Justice).

Call to Order

Kevin Olson, Chair of the Health Evidence Review Commission (HERC), called the meeting to order; roll was called.

Minutes Approval
Meeting materials, pages 4-12

MOTION: To approve the minutes of the 1/16/2020 meeting as presented. CARRIES 8-0. *(Absent: Kaiser, Garside, Kansagara)*

Director's Report
Meeting materials, pages 69-73

Staffing
Gingerich said the COVID-19 pandemic might impact the staff's work by reassignments and that he would keep the members posted. He said a policy analyst will soon be hired.

Topics
Gingerich said the Agency for Healthcare Research and Quality's (AHRQ) research report on back pain has been delayed, so the Commission's review of the topic will also be delayed pending release of the report.

Ariel Smits asked the Commission for permission to make needed changes to the Prioritized List for urgent issues which arise due to COVID-19.

MOTION: To allow staff latitude to make changes to the List related to COVID-19. CARRIES 8-0.
(Absent: Kaiser, Garside, Kansagara)

Membership
Jason Gingerich welcomed acupuncturist Deb Espesete to the Commission.

Gingerich asked the Commission to appoint Regina Dehen, ND, LAc, to the Value-based Benefits Subcommittee (VbBS).

MOTION: To appoint Dr. Dehen to VbBS. CARRIES 10-0. *(Absent: Garside)*

Members and staff then introduced themselves in roundtable fashion.

Presentation
Gingerich gave a brief presentation (pages 69-72) on the HERC Onboarding Process Improvement Project. He said staff are working on an agency-wide work improvement project.

He said staff will send out a survey to the members and public to get feedback.

Hodges asked about having a retreat. Gingerich said that is one of the options in the survey.

Orientation to 2020 Biennial Review
Meeting materials, pages 75-88

Smits gave a brief overview of the presentation. There was no substantive discussion.

Value-based Benefits Subcommittee (VbBS) Report on Prioritized List Changes
Meeting materials, pages 90-154

Ariel Smits reported the VbBS met earlier in the day, 3/12/2020. She summarized the subcommittee's recommendations.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2020 Prioritized List)
- Add bone marrow transplant as a treatment for sickle cell disease with a new guideline
- Add procedure codes for peripheral nerve ablations to an unfunded line
- Recommend to HSD that procedure codes for bone grafts are placed on the Ancillary File
- Add acupuncture procedure codes to all cancer lines with a guideline note entry to the acupuncture guideline
- Move the female genital mutilation status codes from an uncovered line to a covered line
- Remove an unused store-and-forward code from many lines and place on uncovered line
- Make various straightforward code and guideline note changes

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2020 Prioritized List unless otherwise stated)

- Update the psoriasis guideline to include validated quality of life assessment tools
- Adopt a new guideline on female genital mutilation
- Update the telehealth guideline (effective as soon as feasible)
- Adopt a new statement of intent about telephone services in an outbreak (effective as soon as feasible)

Kansagara wondered how the statement of intent applied to the yearly flu season. Livingston suggested to add "as defined by the Oregon Health Authority." Gingerich said it is hard to pin down who the correct authority should be and suggested bringing this point back in October. Olson wondered what kind of financial incentive might be created by this policy, if clinics might use the generousness of the policy for financial gain. He said that there is no evidence that this policy will improve access. Gingerich said it is hoped that each CCO will enact good policies guided by this statement of intent. It is meant to remove barriers for this kind of service, an extension of the "right care, right time" concept. Schabel said not all surgical follow up appointments are appropriate for telehealth visits, such as when x-rays are needed or when patients have concerning symptoms. Still, many times it is appropriate. Visits may include viewing a normally-healing wound on camera; 90 percent of the time, there is nothing wrong.

Irwin said this policy may inadvertently cause inequity as not everyone, especially those in rural Oregon, has stable phone lines and internet. Schabel said at OHSU, if a rural patient does not have the ability to do a telehealth visit, they contact their primary care office or a local skilled nursing facility that has the capabilities.

Staff asked permission to publish a new interim modification Prioritized List with just the telehealth and telemedicine guideline changes, by Monday, March 16. All the changes approved in January as well as the other items discussed today would be incorporated into the October 1, 2020 list.

2022 BIENNIAL REVIEW (changes to the 1/1/2022 Prioritized List)

- Combine the medical and surgical chronic pancreatitis lines and prioritize the combined line above the funding line
- Rescore the line for treatment of foreign bodies in the ear and nose to a higher-priority line
- Rescore the line for treatment of Meniere's disease to a lower-priority line

MOTION: To accept the VbBS recommendations on Prioritized List changes, as stated above. See the VbBS minutes of 3/12/2020 for a full description. CARRIES: 11-0.

Government Ethics

Meeting materials, pages 155-174

Dana Hargunani introduced the topic and welcomed Amy Alpaugh from the Oregon Department of Justice. Alpaugh has been working with the HERC team over the last six months to think through the processes and procedures around conflicts of interest (COI) for both the HERC and the Pharmacy and

Therapeutics Committee (P&T). The goal is to better align our processes with Oregon ethics law. The COI forms are nearing completion and will be brought to the Commission at a later date.

Alpaugh, an assistant attorney general, gave an overview of the presentation (pages 155-174).

Gingerich said staff will bring proposals for modifying HERC policies and procedures related to conflicts of interests and related issues to a future meeting.

The Commission discussed several examples of other possible conflicts of interest or ethics violations. Hargunani said she is taking a list of questions with these types of examples to the Ethics Commission on behalf of the agency. Individuals would have to approach the Ethics Commission directly. Members voiced concern that doing so would take even more time away from their practices and participation on this Commission is as a volunteer. Some expressed dismay about the work this may require.

Hargunani said there have been questions come up about what information we might request from public members who testify when we know or suspect that they may have their own financial relationship to the discussion topic. She asked Alpaugh to clarify. Alpaugh said that members of the public who come to testify are not public officials and are not subject to these laws. You may ask for their conflicts of interest and take into account what they chose to share.

Gingerich said this has happened at a recent meeting where we asked for testifiers to declare their potential conflicts of interest and they did not, so it was recorded in the minutes that they did not address it. Alpaugh said you can ask members of the public to declare conflicts of interest but not require them to do so.

Hodges said there has been a lot of interest from outside of Oregon and wondered about asking if they were a citizen of Oregon and are on the Oregon Health Plan.

Hargunani said the P&T Committee has a written statement related to this, which we may adopt or adapt for this Commission. She said public members must be allowed to testify whether or not they have or declare conflicts of interest.

Alpaugh said the anyone may contact the Ethics Commission by phone or email to get answers to specific questions.

Hargunani said staff will report back with the information from the Ethics Commission and an update on procedures at a future meeting.

Public Comment

There was no public comment.

Adjournment

Meeting adjourned at 4:30 pm. Next meeting is tentatively scheduled from 1:30-4:30 pm on Thursday, May 21, 2020 at Clackamas Community College Wilsonville Training Center, Rooms 111-112, Wilsonville, Oregon.

Value-based Benefits Subcommittee Recommendations Summary
For Presentation to:
Health Evidence Review Commission on March 12, 2020

For specific coding recommendations and guideline wording, please see the text of the 3/12/2020 VbBS minutes.

RECOMMENDED CODE MOVEMENT (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Add bone marrow transplant as a treatment for sickle cell disease with a new guideline
- Add procedure codes for peripheral nerve ablations to an unfunded line
- Recommend to HSD that procedure codes for bone grafts are placed on the Ancillary File
- Add acupuncture procedure codes to all cancer lines with a guideline note entry to the acupuncture guideline
- Move the female genital mutilation status codes from an unfunded line to a funded line
- Remove a telehealth store-and-forward code from many lines and place on unfunded line
- Make various straightforward code and guideline note changes

ITEMS CONSIDERED BUT NO RECOMMENDATIONS FOR CHANGES MADE

- None

RECOMMENDED GUIDELINE CHANGES (changes to the 10/1/2020 Prioritized List unless otherwise noted)

- Update the psoriasis guideline to include validated quality of life assessment tools
- Adopt a new guideline on female genital mutilation
- Update the telehealth guideline (effective as soon as feasible due to the COVID-19 emergency)
- Adopt a new statement of intent about telephone services in an outbreak

2022 BIENNIAL REVIEW (changes to the 1/1/2022 Prioritized List)

- Combine the medical and surgical chronic pancreatitis lines and prioritize to a line above the funding line
- Rescore the line for treatment of foreign bodies in the ear and nose to a higher priority line
- Rescore the line for treatment of Meniere's disease to a lower priority line

VALUE-BASED BENEFITS SUBCOMMITTEE
Clackamas Community College
Wilsonville Training Center, Rooms 111-112
Wilsonville, Oregon
March 12, 2020
9:00 AM – 1:00 PM

Members Present: Kevin Olson, MD, Chair; Holly Jo Hodges, MD, MBA, Vice-chair; Gary Allen, DMD; Kathryn Schabel, MD; Brian Duty, MD (arrived 9:15); Mike Collins (arrived 10:25 via phone); Adriane Irwin, PharmD.

Members Absent: None.

Staff Present: Jason Gingerich; Ariel Smits, MD, MPH; Cat Livingston, MD, MPH; Daphne Peck, Jaime Taylor.

Also Attending: Regina Dehen, ND, LAc (via phone); Maria Rodriguez, MD (OHSU, via phone).

- **Roll Call/Minutes Approval/Staff Report**

  The meeting was called to order at 9:00 am and roll was called. A quorum of members was present at the meeting. Minutes from the January 16, 2020 VbBS meeting were reviewed and approved with no suggested changes.

  Gingerich introduced the nominated VbBS member Regina Dehen, ND, LAc and welcomed her to the subcommittee. Her position was officially voted on at the HERC meeting later on March 12th.

  Smits reviewed the errata document. She also discussed HERC staff efforts to ensure COVID-19 testing and treatment are covered. Gingerich requested that members who become aware of any coverage related issues having to do with COVID-19 should bring these issues to HERC staff's attention immediately. Gingerich announced that an updated version of the Prioritized List will be published very soon with the telehealth guideline update to highlight coverage of visits with synchronous audio and video, as part of a broader public health measure.

- **Topic: Straightforward/Consent Agenda**

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

  Recommended Actions:
  1) Remove 31090 (Sinusotomy, unilateral, 3 or more paranasal sinuses (frontal, maxillary, ethmoid, sphenoid)) from line 364 ACUTE SINUSITIS
  2) Add 27709 (Osteotomy; tibia and fibula) to line 359 DEFORMITY/CLOSED DISLOCATION OF JOINT AND RECURRENT JOINT DISLOCATIONS
  3) Remove CPT 58565 (Hysteroscopy, surgical; with bilateral fallopian tube cannulation to induce occlusion by placement of permanent implants) from lines 1 PREGNANCY and 6 REPRODUCTIVE SERVICES
  4) Remove CPT 58340 (Catheterization and introduction of saline or contrast material for saline infusion sonohysterography (SIS)) and 74740 (hysterosalpingography) from line 6 REPRODUCTIVE SERVICES
     a. Advise HSD to add to the Excluded File as an infertility procedure
  5) Delete GN68 as shown in Appendix A

  MOTION: To approve the recommendations stated in the consent agenda. CARRIES 5-0. *(Absent: Collins)*

- **Topic: Female genital mutilation treatment**

  Discussion: Livingston reviewed the summary document. Dr. Maria Rodriguez from OHSU Gynecology was available by phone as an expert. A member expressed surprise that this topic had not come up before and others said it would likely have been covered via exception.

  Recommended Actions:
  1) Add the female genital mutilation status codes N90.810-N90.818 Line 120 ABUSE AND NEGLECT
  2) Delete N90.81X from Line 658 GENITOURINARY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY
  3) Add these CPT codes to Line 120

13131	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 1.1 cm to 2.5 cm
56441	Lysis of labial adhesions

  4) Add a new guideline SURGERIES RELATED TO FEMALE GENITAL MUTILATION as shown in Appendix B
  5) Rename line 629 BENIGN ~~CERVICAL~~ GYNECOLOGICAL CONDITIONS

  MOTION: To approve the coding and guideline recommendations as presented. CARRIES 5-0. *(Absent: Collins)*

- **Topic: Biennial review: overall discussion of topics**

  Discussion: Smits gave a presentation on prioritization and the Biennial Review. Smits reviewed suggested topics to date. Members questions were all answered. There were no action items.

- **Topic: Biennial review: Surgical treatment of chronic pancreatitis**

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

  Recommended Actions:
  1) Combine the medical and surgical lines for chronic pancreatitis and maintain prioritization at line 250
  2) Change the treatment description of line 250 to "MEDICAL AND SURGICAL THERAPY"
  3) Add all CPT codes from line 599 to line 250 that do not currently appear there

  MOTION: To recommend the line changes as presented. CARRIES 6-0.

- **Topic: Biennial review: foreign body in the ear and nose**

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

  Recommended Actions:
  1) Rescore the line for foreign bodies in the ear and nose as shown below

     Line XXX FOREIGN BODY IN EAR AND NOSE
     Line prioritization (no current scores—line hand placed previously. Scores proposed below are based on the scoring for line 499 CERUMEN IMPACTION with suffering changed from 0 to 1; tertiary prevention changed from 0 to 1 and need for treatment changed from 0.9 to 1)
     Category: 7
     Healthy life years: 1
     Suffering: 1
     Population effects: 0
     Vulnerable population: 1
     Tertiary prevention: 1
     Effectiveness: 4
     Need for treatment: 1
     Net cost: 4
     Score: 320
     Line placement: 428 (current funding line 471)

  MOTION: To recommend the line scoring changes as presented. CARRIES 6-0.

- **Topic: Biennial review: Meniere's disease**

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

Recommended Actions:

1) Rescore the Meniere's line as shown below

Reprioritization of MENIERE'S DISEASE Treatment: MEDICAL AND SURGICAL TREATMENT

(Current scores for line 417 shown in parentheses)

Category: 7 (7)
Healthy life years: 4 (4)
Suffering: 2 (2)
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1 (3)
Need for treatment: 1 (1)
Net cost: 3 (3)
Score: 120 (360)
Line placement: 520 (417)

MOTION: To recommend the line changes as presented. CARRIES 6-0.

- **Topic: Bone marrow transplant for sickle cell disease**

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

Recommended Actions:

1) Add the ICD-10 D57.0 series (sickle cell disease with crisis) and D57.1 (Sickle-cell disease without crisis) to line 113 APLASTIC ANEMIAS; AGRANULOCYTOSIS Treatment: BONE MARROW TRANSPLANT
2) Modify the line title of line 113 to APLASTIC ANEMIAS; AGRANULOCYTOSIS; SICKLE CELL DISEASE
3) Add a guideline to line 113 as shown in Appendix B

MOTION: To recommend the code, line title, guideline note changes as presented. CARRIES 6-0.

- **Topic: Peripheral nerve ablation**

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

Recommended Actions:

1) Add CPT 64640 (Destruction by neurolytic agent; other peripheral nerve or branch) to line 662/GN173 with a guideline entry as shown in Appendix A
    a. Advise HSD to remove CPT 64640 from the Ancillary File
2) Add CPT 64632 (Destruction by neurolytic agent; plantar common digital nerve) to line 662/GN173 with a guideline entry as shown in Appendix A
    a. Remove CPT 64632 from line 539 LESION OF PLANTAR NERVE; PLANTAR FASCIAL FIBROMATOSIS.

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Bone grafts**

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

Recommended Actions:
1) Remove CPT 20955-20973 (bone grafts/osteocutaneous grafts) from all current lines on the Prioritized List
2) Advise HSD to place CPT 20955-20973 on the Ancillary Procedures File

MOTION: To recommend the code changes as presented. CARRIES 6-0.

- **Topic: Cranial electrical stimulation guideline entry update**

Discussion: Smits reviewed the summary document. A member noticed that the date of last review for cranial electrical stimulation was incorrect; the date was changed to the correct date.

Recommended Actions:
1) Modify GN173 as shown in Appendix A

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0.

- **Topic: Acupuncture for cancer related pain**

Discussion: Smits reviewed the summary document. There was discussion about whether coverage of acupuncture should be limited to "active" cancer patients, or whether patients "in remission" with continued pain should be included. There was discussion about a desire to cover neuropathic pain resulting from cancer treatment. The decision of the group was to approve the guideline note entry as proposed by staff, limiting to "active" cancer; this decision can be readdressed in the future if needed.

Recommended Actions:
1) Add acupuncture (CPT 97810-97814) to any line with ICD-10 G89.3 (Neoplasm related pain (acute) (chronic))
2) Modify GN92 as shown in Appendix A

MOTION: To recommend the code and guideline note changes as presented. CARRIES 6-0.

- **Topic: Psoriasis guideline update**

Discussion: Smits reviewed the summary document. There was discussion that a statement of "other validated tools" be added. It was pointed out that the tool scores in the staff proposal needed to be slightly modified to meet the "severe" definition in those scoring tools.

Recommended Actions:
1) Modify GN21 as shown in Appendix A

MOTION: To recommend the guideline note changes as modified. CARRIES 6-0.

- **Topic: Telehealth guideline**

Discussion: Livingston and Gingerich reviewed a presentation that described different areas of telehealth and Livingston introduced the summary document. Hodges queried why telehealth codes would not just be allowed to be wide open and members addressed the potential role of telehealth in the current COVID-19 pandemic. Schabel stated there is a role for tiers of telehealth, based on complexity or time. Members discussed whether or not there would be potential for overuse. One example was that specialty care is usually rationed to ensure appropriate use and that self-referral could be problematic.

Livingston discussed specific language to consider and Hodges raised the concern about language limiting the role of telehealth. For example, that not all primary care clinics can be PCPCHs and that would be a barrier, particularly in rural areas. The goal of expansion of telehealth would need to be much more open to enable rural areas and small doc shops to also be able to offer access. If limitations are placed on telehealth then it defeats purpose of increasing access. Schabel raised a devil's advocate perspective of potential abuse of this through working at home and seeing patients all day but avoiding providing in person clinical care. Hodges stated that through the credentialing process plans could make sure that in-person primary care was also being delivered, that telehealth only providers would not be credentialed by CCOs. Adler raised concern about the meaning of urgent care, particularly in rural areas. Olson spoke about the differences between urgent, emergent, and on-demand care. Hodges pointed out that plans can contractually manage this, for example, if excess on-demand care was seen. Olson and Schabel discussed other factors that might affect overutilization.

Irwin raised a concern about whether the guideline would be able to address pharmacist expanding role and provision of health services and their consultation with clinicians. She gave examples such as naloxone, PrEP, rapid flu testing and the difficulty of the pharmacy business model so closely tied to drug distribution. Members discussed that this topic is important, and complex, and needs to be addressed separately from the scope of the telehealth guideline currently under discussion. Staff agreed to meet with Irwin to discuss this issue further.

The conversation shifted back to whether concerns about overutilization justified a need for language limiting use of telehealth. Members discussed that there is a workforce shortage and an underserved population. While the evidence Livingston presented demonstrated some overuse in direct-to-consumer telehealth, it was felt to not be relevant to the OHP population. Olson gave an example that one expensive cancer drug would cover 2000 RVU codes that will be overbilled and fundamentally access is important. Members agreed that they wanted the new guideline to not be restrictive of telehealth and to go into effect as quickly as possible. This is an emergently developing issue in their clinical settings.

The conversation shifted to reimbursement rates and members discussed how that felt different than HERC's typical process and seemed more appropriate for a policy statement. Members and HERC staff felt it was appropriate to address the direction of the HERC in a statement of intent while others are navigating the policy pieces in other parts of the agency.

Duty gave an example from his clinical setting that patients are offered audio/visual appointments or telephone appointments and that the vast majority of them choose telephone. There was discussion about this unusual time (COVID-19 pandemic) and the need to not limit, as well as concerns about low reimbursement and administrative burden. Members raised concerns that OHP patients frequently experience various difficulties accessing care and this will help to reduce them. If overutilization is seen, there is the ability to implement changes to the guidelines down the road and it is better to err on the side of overpaying for access.

Recommended Actions:

1) Modify Ancillary Guideline A5 as shown in Appendix A.
2) Remove G2010 from 600+ lines and place it on Line 662 CONDITIONS FOR WHICH CERTAIN INTERVENTIONS ARE UNPROVEN, HAVE NO CLINICALLY IMPORTANT BENEFIT OR HAVE HARMS THAT OUTWEIGH BENEFITS
3) Adopt a new Statement of Intent as shown in Appendix C.

MOTION: To recommend the code and guideline note changes as modified and adopt a new Statement of Intent. CARRIES 5-0. (Absent: Duty)

- **Public Comment:**

  No additional public comment was received.

- **Issues for next meeting:**
  There were no outstanding topics

- **Next meeting:**

  May 21, 2020 at Clackamas Community College, Wilsonville Training Center, Wilsonville Oregon, Rooms 111-112.

- **Adjournment:**

  The meeting adjourned at 12:55 PM.

Appendix A
Revised Guideline Notes

GUIDELINE NOTE 21, SEVERE INFLAMMATORY SKIN DISEASE

Lines 424,480,502,530,539,654

Inflammatory skin conditions included in this guideline are:

A) Psoriasis
B) Atopic dermatitis
C) Darier disease
D) Pityriasis rubra pilaris
E) Discoid lupus

The conditions above are included on Line 424 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) ~~e.g. inability to use hands or feet for activities of daily living, or significant facial involvement preventing normal social interaction~~) AND one or more of the following:

A) At least 10% of body surface area involved
B) Hand, foot or mucous membrane involvement.

Otherwise, these conditions above are included on Lines 480, 502, 530, 539 and 654.

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 68, HYSTEROSCOPIC BILATERAL FALLOPIAN TUBE OCCLUSION**~~

~~*Line 6*~~

~~Placement of permanent implants in the fallopian tubes to induce bilateral occlusion (CPT code 58565) is covered only if the procedure is done in the office setting, not in the ambulatory surgical center or hospital setting.~~

Appendix A
Revised Guideline Notes

~~Hysterosalpingography (58340, 74740) is covered only for the follow-up testing after placement of permanent implants in the fallopian tubes to induce bilateral occlusion.~~

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5, 92,111,112,114,125,129,133,135,157,158,191,199,200,202,361, 208,210,214,215,229,234,237,238,258,259,261,262,271,276,286,287,294,314,315,316,329,342, 372,396,397,401,409, 420,434,461,538, 558

Inclusion of acupuncture (CPT 97810-97814) on the Prioritized List has the following limitations:

Line 1 PREGNANCY

Acupuncture pairs on Line 1 for the following conditions and codes.

Hyperemesis gravidarum

ICD-10-CM: O21.0, O21.1

Acupuncture pairs with hyperemesis gravidarum when a diagnosis is made by the maternity care provider and referred for acupuncture treatment for up to 12 sessions of acupressure/acupuncture per pregnancy.

Breech presentation

ICD-10-CM: O32.1

Acupuncture (and moxibustion) is paired with breech presentation when a referral with a diagnosis of breech presentation is made by the maternity care provider, the patient is between 33 and 38 weeks gestation, for up to 6 session per pregnancy.

Back and pelvic pain of pregnancy

ICD-10-CM: O99.89

Acupuncture is paired with back and pelvic pain of pregnancy when referred by maternity care provider/primary care provider for up to 12 sessions per pregnancy.

Line 5 TOBACCO DEPENDENCE

Acupuncture is included on this line for a maximum of 12 sessions per quit attempt up to two quit attempts per year; additional sessions may be authorized if medically appropriate.

Line 92 and all other cancer-related lines

Acupuncture is paired only with the ICD-10 code G89.3 (Neoplasm related pain (acute) (chronic)) when there is active cancer and limited to 12 total sessions per year; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 202 CHRONIC ORGANIC MENTAL DISORDERS INCLUDING DEMENTIAS

Acupuncture is paired with the treatment of post-stroke depression only. Treatments may be billed to a maximum of 30 minutes face-to-face time and limited to 12 total sessions per year, with documentation of meaningful improvement; patients may have additional visits authorized beyond these limits if medically appropriate.

Line 361 SCOLIOSIS

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 401 CONDITIONS OF THE BACK AND SPINE

Acupuncture is included on this line with visit limitations as in Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE.

Line 409 MIGRAINE HEADACHES

Appendix A
Revised Guideline Notes

Acupuncture pairs on Line 409 for migraine (ICD-10-CM G43.0, G43.1, G43.5, G43.7, G43.8, G43.9), for up to 12 sessions per year.

Line 461 OSTEOARTHRITIS AND ALLIED DISORDERS

Acupuncture pairs on Line 461 for osteoarthritis of the knee only (ICD-10-CM M17), for up to 12 sessions per year.

*Line 538 TENSION HEADACHES

Acupuncture is included on Line 538 for treatment of tension headaches (ICD-10-CM G44.2), for up to 12 sessions per year.

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.

*Below the current funding line.

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
K1002	Cranial electrotherapy stimulation system (CES)	No clinically important benefit (of CES) for chronic pain; insufficient evidence of effectiveness for all other indications	March 2020
64632	Destruction by neurolytic agent; plantar common digital nerve	Insufficient evidence of effectiveness	March 2020
64640	Destruction by neurolytic agent; other peripheral nerve or branch	Insufficient evidence of effectiveness	March 2020
97014, 97032, 0278T, E0720, E0730, G0283	Transcutaneous electrical nerve stimulation (TENS), frequency specific microcurrent therapy, microcurrent electrical stimulation, and all similar therapies; Scrambler therapy; ~~Cranial electrical stimulation;~~ all similar transcutaneous electrical neurostimulation therapies	~~No clinically important benefit (CES) or insufficient evidence of effectiveness (all other) for chronic pain; insufficient evidence of effectiveness for all other indications~~ Insufficient evidence of effectiveness for chronic pain and all other	January 2020

Appendix A
Revised Guideline Notes

		indications	

GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ELECTRONIC/TELEPHONIC SERVICES[1]

Telehealth (Synchronous audio/video visits)

Telehealth visits are defined as synchronous visits with both audio and video capability. The patient may be at home or in a health care setting. The originating site code Q3014 may only be used by appropriate health care sites. Codes eligible for telehealth services include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, ~~96150-96154~~, 96156-96171, 97802-4, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0436-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088.

Telehealth visits are covered for inpatient and outpatient services for new or established patients.

Telehealth consultations are covered for emergency and inpatient services.

Billing for telehealth visits requires the same level of documentation, medical necessity and coverage determinations as in-person visits.

Patient to Clinician Services (via telephone or electronic)
Telephonic and electronic services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063) between a patient and clinician must meet the following criteria:

A) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past 36 months.
B) Documentation must:
   1) model SOAP charting, or be as described in program's OAR;
   2) include patient history, provider assessment, treatment plan and follow-up instructions;
   3) support the assessment and plan;
   4) be retained in the patient's medical record and be retrievable.
C) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.
D) Ensure permanent storage (electronic or hard copy) of the encounter.
E) Meet HIPAA standards for privacy.
F) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
G) Not be billed when the same services are billed as care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).

[1] This guideline was later revised based on authority given to staff at the HERC meeting; for the latest version see the March 13, 2020 Prioritized List.

Appendix A
Revised Guideline Notes

H) When a telephone or electronic service refers to an E/M service performed and billed by the physician within the previous seven days, it is not separately billable, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
I) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
J) If the service relates to and takes place within the postoperative period of a procedure provided by the physician, the service is considered part of the procedure and is not be billed separately.

Examples of reimbursable telephone or electronic services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/electronic consultations include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Consultations (telephonic and electronic)

Requirements for coverage of electronic or telephonic interprofessional consultation are as follows:

Consulting Providers (99451, 99446-9)

- Consult must be requested by another provider
- Can be for a new or exacerbated condition
- Cannot be reported more than 1 time per 7 days for the same patient
- Cumulative time spent reported, even if time occurs over multiple days
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the next 14 days
- Cannot be reported if the patient was seen by the consultant within the past 14 days
- Request and reason for consultation request must be documented in the patient's medical record
- Requires a minimum of 5 minutes

Requesting Providers (99452)

- eConsult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services, non-direct

Appendix A
Revised Guideline Notes

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

Appendix B
New Guideline Notes

GUIDELINE XXX BONE MARROW TRANSPLANT FOR SICKLE CELL DISEASE

Line 114

Allogeneic hematopoietic cell transplantation for sickle cell disease is included on this line only when:

1) Patient has a related human leukocyte antigen (HLA) matched donor; *or*
2) Patient has an unrelated or HLA mismatched related donor AND severe sickle cell disease (e.g. recurrent chest syndrome, recurrent vaso-occlusive crises, red blood cell alloimmunization on chronic transfusion therapy).

GUIDELINE NOTE XXX SURGERIES RELATED TO FEMALE GENITAL MUTILATION

Line 120

Female genital mutilation of children or adults is not included on any line on the Prioritized List, including returning a woman to her former status after delivery.

Repair of female genital mutilation (e.g. Type II or III) with defibulation or lysis of adhesions is included on this line when causing interference in function (i.e. urinary, menstrual, or potential future vaginal childbirth) or causing recurrent complications including chronic pain related to the mutilation. Clitoral reconstruction is not included on this line due to an unclear risk/benefit ratio.

Appendix C

New Statement of Intent

STATEMENT OF INTENT 6: TELEPHONIC SERVICES DURING AN OUTBREAK OR EPIDEMIC

During an outbreak or epidemic of an infectious disease, reducing administrative barriers (e.g. increasing reimbursement rates) for telephonic evaluation and management services (CPT 99441-99443) and assessment and management services (CPT 98966-98968) is appropriate to ensure access to care while avoiding and preventing unnecessary potential infectious exposure.

Section 2.0

Staff Report

Errata
May 2020

1) The lines referenced in GN65 were incorrect. The line numbers were corrected.
GUIDELINE NOTE 65, SEVERE CYSTIC ACNE

Lines 452,522

Acne is only included on Line ~~419~~ 452 if it is severe, defined as the presence of the following characteristics: persistent or recurrent inflammatory nodules and cysts AND ongoing scarring. Otherwise, acne diagnoses are included on Line ~~514~~ 522.

Note that acne with recurrent abscesses or communicating sinuses is covered according to Guideline Note 132 ACNE CONGLOBATA AND ACNE FULMINANS.

This erratum affects Prioritized List(s): 1/2020

2) Add CPT 54160 (Circumcision, surgical excision other than clamp, device, or dorsal slit; neonate (28 days of age or less)) to lines 21 VESICOURETERAL REFLUX and 413 BALANOPOSTHITIS AND OTHER DISORDERS OF PENIS.

This erratum affects Prioritized List(s): 1/2019, 10/2019, 1/2020. 3/13/2020

3) CPT code 46948 (Hemorrhoidectomy, internal, by transanal hemorrhoidal dearterialization, 2 or more hemorrhoid columns/groups, including ultrasound guidance, with mucopexy, when performed) was removed from line 472 KERATOCONJUNCTIVITIS.

This erratum affects Prioritized List(s): 1/2019, 10/2019, 1/2020. 3/13/2020

4) Delete Guideline Note 178, "VITAL SITE DEFINITION FOR BURN LINES."

This erratum affects Prioritized List(s): 1/2020, 3/13/2020

5) Guideline Note 130 was revised as shown below:
GUIDELINE NOTE 130, BLEPHAROPLASTY

Line 471

Blepharoplasty is covered when 1) a minimum of 30 degrees of visual field loss exists with upper lid skin/margin in repose, 2) upper eyelid position contributes to difficulty tolerating a prosthesis in an anophthalmic socket, OR 3) essential blepharospasm or hemifacial spasm is present.

This erratum affects Prioritized List(s): 1/2019, 10/2019, 1/2020, 3/13/2020

Novel Coronavirus ICD10 Coding

The following are the ICD10 codes and procedure codes which may be commonly used for patients with suspected or confirmed COVID-19, along with their placements on the Prioritized List/other HSD lists.

These recommendations are from staff of the Health Evidence Review Commission (HERC), and have been updated April 16, 2020. Placements are from the March 13, 2020 Prioritized List, including errata and change to incorporate new codes since the original posting.

This document and the Prioritized List will continue to be updated based on new evidence and information.

ICD-10-CM code	**Code descriptions**	**Current Placement** ***(Italicized lines are unfunded)***	**Notes**
J12.81	Pneumonia due to SARS-associated coronavirus	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES	Placement updated 4/8/2020
J12.89	Other viral pneumonia	304 VIRAL PNEUMONIA	
B97.29	Other coronavirus as the cause of diseases classified elsewhere	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES	To be used as a secondary code Placement updated 4/8/20
J20.8	Acute bronchitis due to other specified organisms	459 ACUTE BRONCHITIS AND BRONCHIOLITIS	
J40	Bronchitis, not specified as acute or chronic	*635 CHRONIC BRONCHITIS*	
J22	Unspecified acute lower respiratory infection	*657 RESPIRATORY CONDITIONS WITH NO OR MINIMALLY EFFECTIVE TREATMENTS OR NO TREATMENT NECESSARY*	
J98.8	Other specified respiratory disorders	*657*	
J80	Acute respiratory distress syndrome	233 ADULT RESPIRATORY DISTRESS SYNDROME; ACUTE RESPIRATORY FAILURE; RESPIRATORY CONDITIONS DUE TO PHYSICAL AND CHEMICAL AGENTS	
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases	3 PREVENTION SERVICES WITH EVIDENCE OF EFFECTIVENESS	
R05	Cough	DIAGNOSTIC WORKUP FILE (DWF)	
R06.02	Shortness of breath	DWF	
R50.9	Fever, unspecified	DWF	
U07.1	COVID-19	399 INFLUENZA, NOVEL RESPIRATORY VIRUSES	New code; Placement updated 4/8/2020

Procedures

CPT code	Code descriptions	Current Placement *(Italicized lines are unfunded)*	Notes
86328	Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (eg, reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	New code—May have limited clinical utility	Advise HSD to place on Diagnostic Procedure File
86769	Antibody; severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19])	New code—May have limited clinical utility	Advise HSD to place on Diagnostic Procedure File
87635	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique	New code	Advise HSD to place on Diagnostic Procedure File
87798	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; amplified probe technique, each organism	DIAGNOSTIC PROCEDURES	
99201-99215 90832-90853 90791-90792 Many other codes	Office visits	Covered on most lines Covered for diagnostic purposes regardless of diagnosis Should be covered by telemedicine/phone when billed per payer guidelines. Other visit/valuation/assessment/therapy codes are covered as well when clinical value approximates in person service. See Guideline Note A5.	
99281-99285	ER visits	Same as 99201-99215	

Novel Coronavirus ICD10 Coding

CPT code	Code descriptions	Current Placement *(Italicized lines are unfunded)*	Notes
98966-98968 99441-99443 99421-99423 98970-98972 G2061-G2063	Telephone or online assessments/telephone or online evaluation and management services	Covered on most lines Covered for diagnostic purposes regardless of diagnosis Correct code depends on communication medium and provider type	
G2010	Remote evaluation of recorded video and/or images submitted by an established patient (e.g., store and forward), including interpretation with follow-up with the patient within 24 business hours, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment	600+ lines	
G2012	Brief communication technology-based service, e.g. virtual check-in, by a physician or other qualified health care professional who can report evaluation and management services, provided to an established patient, not originating from a related e/m service provided within the previous 7 days nor leading to an e/m service or procedure within the next 24 hours or soonest available appointment; 5-10 minutes of medical discussion	Similar to telephone codes above. This code can be used for services provided by telephone or synchronous audio/video	See above
U0001	2019 Novel Coronavirus Real Time RT-PCR Diagnostic Test Panel (CDC test)	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES
U0002	2019-nCoV Coronavirus, SARS-CoV-2/2019-nCoV (COVID-19) using any technique, multiple types or subtypes (includes all targets).	New code	Advise HSD to place on DIAGNOSTIC PROCEDURES

Section 3.0

New Discussion Items

Telehealth Changes to the Prioritized List

May 21, 2020

Oregon Health Authority

Expanding OHP Telemedicine

- **Goal:** Ensure continued access for physical, oral and behavioral health services for Oregonians
- March 2020 HERC meeting:
  - Staff had conducted an evidence and policy review and recommended significant expansion of the telehealth benefit (Ancillary Guideline A5, Telehealth, Teleconsultations, and Online/Telephonic Services)
- During COVID-19 public health emergency (PHE), this benefit has been further expanded based on HERC's authorization to make emergency changes to coverage during the PHE
- OHP is now paying telehealth modalities billed using 'in-person' codes on-par with in person visits for OHP FFS providers (whether delivered via audio/video (A/V), or telephonically)

Key Changes to Ancillary Guideline A5 since March

- Added an introductory paragraph describing COVID-19 PHE and Governor's Executive order, stating that *italicized* portions of A5 apply only during COVID-19 PHE
- Provided a comprehensive definition of telehealth and telehealth services, including:
  - The 3 channels of telehealth delivery: A/V, telephonic, and online
  - Broad flexibility in the settings in which the patient and provider may use telehealth (home, community or otherwise private settings)
  - When billing for A/V or telephone using "in person" codes, only telehealth services that "**reasonably approximate the clinical value**" of an in-person service are covered
  - OHA increased rates for telephone codes, aligning with the new Statement of Intent

Key Changes to Ancillary Guideline A5 since March

- When using ordinary “in-person” codes, telehealth delivery via A/V is preferred, but telephonic audio-only communication is an acceptable replacement during the COVID-19 PHE
- Certain encryption requirements are not enforced by state and federal authorities during the COVID-19 PHE
  - Applications like FaceTime, Zoom, Skype, Google Hangouts, and Facebook Messenger are acceptable for use (but compliant platforms are preferred)
  - Verbal consent is OK during COVID-19 PHE
- Expanded the broad array of telehealth services to include other services (e.g. neurological assessments, ER, physical therapy, occupational therapy, dental assessment, etc.) when value approximates in-person care

Key Changes to Ancillary Guideline A5 since March

- For Fee-for-Service: Use of in-person codes can be billed with the appropriate modifiers and place of service 02 to indicate telehealth delivery (CCOs may have different guidance about POS)

- Broad coverage of behavioral health services
  - psychological assessment services, neurological assessments, group psychotherapy, some preventive services, therapies, skills training

- Allowance of new patients via telehealth
  - including telephone and asynchronous online delivery during COVID-19 PHE

After COVID-19?

- Many changes specified only in effect during COVID-19 PHE
- HERC will need to consider which changes to continue after the emergency…
- OHA will be evaluating experience and evidence on utilization and clinical value going forward

Questions?

Staff made several changes to Guideline Note A5 since it was approved at the March 12, 2020 meeting, based on the Commission's direction to make changes to the guideline note as necessary to facilitate the COVID response.

Approved version (as published March 13, 2020):

GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ELECTRONIC/TELEPHONIC SERVICES

Telehealth (Synchronous audio/video visits)

Telehealth visits are defined as synchronous visits with both audio and video capability. The patient may be at home or in a health care setting. The originating site code Q3014 may only be used by appropriate health care sites. Codes eligible for telehealth services include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-4, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0436-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088.

Telehealth visits are covered for inpatient and outpatient services for new or established patients.

Telehealth consultations are covered for emergency and inpatient services.

Billing for telehealth visits requires the same level of documentation, medical necessity and coverage determinations as in-person visits.

Patient to Clinician Services (via telephone or electronic)
ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ELECTRONIC/TELEPHONIC SERVICES (CONT'D)

Telephonic and electronic services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2012, G2061-G2063) between a patient and clinician must meet the following criteria:

A) Ensure pre-existing relationship as demonstrated by at least one prior office visit within the past 36 months.
B) Documentation must:
    1) model SOAP charting, or be as described in program's OAR;
    2) include patient history, provider assessment, treatment plan and follow-up instructions;
    3) support the assessment and plan;
    4) be retained in the patient's medical record and be retrievable.

C) Medical decision making (or behavioral health intervention/ psychotherapy) is necessary.
D) Ensure permanent storage (electronic or hard copy) of the encounter.
E) Meet HIPAA standards for privacy.
F) Include a patient-clinician agreement of informed consent, which is discussed with and signed by the patient and documented in the medical record.
G) Not be billed when the same services are billed as care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
H) When a telephone or electronic service refers to an E/M service performed and billed by the physician within the previous seven days, it is not separately billable, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
I) This service is not billed if the service results in the patient being seen within 24 hours or the next available appointment.
J) If the service relates to and takes place within the postoperative period of a procedure provided by the physician, the service is considered part of the procedure and is not be billed separately.

Examples of reimbursable telephone or electronic services include but are not limited to:

A) Extended counseling when person-to-person contact would involve an unwise delay.
B) Treatment of relapses that require significant investment of provider time and judgment.
C) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/electronic consultations include but are not limited to:

A) Prescription renewal.
B) Scheduling a test.
C) Reporting normal test results.
D) Requesting a referral.
E) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
F) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Consultations (telephonic and electronic)

Requirements for coverage of electronic or telephonic interprofessional consultation are as follows:

Consulting Providers (99451, 99446-9)

- Consult must be requested by another provider
- Can be for a new or exacerbated condition
- Cannot be reported more than 1 time per 7 days for the same patient
- Cumulative time spent reported, even if time occurs over multiple days
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the next 14 days
- Cannot be reported if the patient was seen by the consultant within the past 14 days
- Request and reason for consultation request must be documented in the patient's medical record
- Requires a minimum of 5 minutes

Requesting Providers (99452)

- eConsult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site and with the provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services, non-direct

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

As revised April 13, 2020. New text shown in blue (deleted text not shown)

ANCILLARY GUIDELINE A5, TELEHEALTH, TELECONSULTATIONS AND ONLINE/TELEPHONIC SERVICES

As referred to in this guideline note, the COVID-19 emergency is defined as per Oregon Governor Kate Brown's executive order 20-03 and any subsequent executive order extending or reinstating a state of emergency related to COVID-19. Italicized portions of this guideline note apply only during the COVID-19 emergency.

Telehealth (Synchronous visits including audio and video. Audio-only telephone services can be provided using these codes only during the COVID-19 emergency and if providing the service via synchronous audio and video is not available or feasible)

Telehealth services described in this section are defined as synchronous services with both audio and video capability, when billed with the same codes that would be billed for in-person services, and when mode of delivery is indicated by the use of specific modifiers and/or place of service codes specified by the plan. The patient may be in the community or in a health care setting. The provider may be in any location in which appropriate privacy can be ensured. The clinical value of the telehealth service delivered must reasonably approximate the clinical value of services delivered in-person.

During the COVID-19 emergency, telephone (audio-only) visits are an acceptable replacement for the equivalent service provided by synchronous audio and video, if synchronous audio and video capabilities are not available or feasible.

Certain requirements for encryption will not be enforced by federal authorities (or required by OHP) during the COVID-19 emergency. This means services such as Facetime, Skype or Google Hangouts can be used for service delivery. HIPAA-compliant platforms are preferred when available. See https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html for details.

When a COVID-19 emergency declaration is not in effect, codes eligible for telehealth delivery include 90785, 90791, 90792, 90832-90834, 90836, 90837-90840, 90846, 90847, 90951, 90952, 90954, 90955, 90957, 90958, 90960, 90961, 90963, 90964-90970, 96116, 96156-96171, 96160, 96161, 97802-97804, 99201-99205, 99211-99215, 99231-99233, 99307-99310, 99354-99357, 99406-99407, 99495-99498, G0108-G0109, G0270, G0296, G0396, G0397, G0406-G0408, G0420, G0421, G0425-G0427, G0438-G0439, G0442-G0447, G0459, G0506, G0508, G0509, G0513, G0514, G2086-G2088. During a COVID-19 emergency, additional codes are covered when otherwise appropriate according to this guideline note and other applicable coverage criteria.

The originating site code Q3014 can be billed only when the patient is present in an appropriate health care setting and receiving services from a provider in another location.

Telehealth visits are covered for inpatient and outpatient services for new or established patients.

Telehealth consultations are covered for emergency and inpatient services.

Billing for telehealth services requires the same level of documentation, medical necessity, and coverage determinations as in-person visits.

Patient to Clinician Services billed using specified codes indicating telephone or online service delivery

Telephonic and online services, including services related to diagnostic workup (CPT 98966-98968, 99441-99443, 99421-99423, 98970-98972, G2010, G2012, G2061-G2063) between a patient and clinician must:

K) Be provided only for established patients *(This requirement does not apply during a COVID-19 emergency)*

L) Be documented as follows:
   1) using model SOAP charting, or as described in program's OAR;
   2) include patient history, provider assessment, treatment plan and follow-up instructions;
   3) support the assessment and plan;
   4) be retained in the patient's medical record and be retrievable.

M) Include medical decision making or service delivery (e.g. behavioral health intervention/psychotherapy, other forms of therapy).

N) Include permanent storage (online or hard copy) of the encounter.

O) Meet applicable HIPAA standards for privacy.

P) Include patient-clinician agreement of informed consent, discussed with and agreed to by the patient and documented in the medical record. (During the COVID-19 emergency, verbal consent is sufficient.)

Q) Not include any of the following:
   1) Services which are part of care plan oversight or anticoagulation management (CPT codes 99339-99340, 99374-99380 or 99363-99364).
   2) Services related to a service performed and billed by the physician or qualified health professional within the previous seven days, regardless of whether it is the result of patient-initiated or physician-requested follow-up.
   3) Services which result in the patient being seen within 24 hours or the next available appointment.
   4) Services which relate to or take place within the postoperative period of a procedure provided by the physician. (Such a service is considered part of the procedure and is not be billed separately.)

Examples of reimbursable telephone or online services include but are not limited to:

D) Extended counseling when person-to-person contact would involve an unwise delay or exposure to COVID-19.

E) Treatment of relapses that require significant investment of provider time and judgment.

F) Counseling and education for patients with complex chronic conditions.

Examples of non-reimbursable telephone/online consultations include but are not limited to:

G) Prescription renewal.

H) Scheduling a test.

I) Reporting normal test results.

J) Requesting a referral.
K) Follow up of medical procedure to confirm stable condition, without indication of complication or new condition.
L) Brief discussion to confirm stability of chronic problem and continuity of present management.

Clinician-to-Clinician Consultations (telephonic and online or using electronic health record)

Coverage of interprofessional consultations delivered online, through electronic health records or by telephone is included as follows:

Consulting Providers (CPT 99451, 99446-99449)

- For new or established patients
- Consult must be requested by another provider.
- Can be for a new or an exacerbated condition.
- Cannot be reported more than 1 time per 7 days for the same patient.
- Must report cumulative time spent, even if time occurs over multiple days.
- Cannot be reported if a transfer of care or request for face-to-face visit occurs as a result of the consultation within the following 14 days.
- Cannot be reported if the patient was seen by the consultant within the past 14 days.
- The request and reason for consultation is documented in the patient's medical record.
- Requires a minimum of 5 minutes of medical consultation, discussion and/or review

Requesting Providers (CPT 99452)

- Consult must be reported by requesting provider (not for the transfer of a patient or request for face-to-face consult)
- Reported only when the patient is not on-site with the requesting provider at the time of consultation
- Cannot be reported more than 1 time per 14 days per patient.
- Requires a minimum of 16 minutes. Includes time for referral prep and/or communicating with the consultant.
- Can be reported with prolonged services, non-direct

Limited information provided by one clinician to another that does not contribute to collaboration (e.g., interpretation of an electroencephalogram, report on an x-ray or scan, or reporting the results of a diagnostic test) is not considered a consultation.

STATEMENT OF INTENT 6: TELEPHONIC SERVICES DURING AN OUTBREAK OR EPIDEMIC

During an outbreak or epidemic of an infectious disease, reducing administrative barriers (e.g. increasing reimbursement rates) for telephonic evaluation and management services (CPT 99441-99443) and assessment and management services (CPT 98966-98968) is appropriate to ensure access to care while avoiding and preventing unnecessary potential infectious exposure.

Section 4.0

Previously Discussed Items

Updated Evidence Review for Neck and Back Conditions

May 21, 2020

Ariel Smits, Medical Director
Health Evidence Review Commission

Oregon Health Authority

AHRQ 2020 NON-PHARMACOLOGIC NON-INVASIVE THERAPIES

Summary of Changes In 2020 AHRQ Report

- 2018 report: 218 publications (202 trials)
- 2020 report: added 34 publications (31 trials)
- For low back pain
  - SOE was upgraded from low to moderate for short-term functional improvement with exercise but downgraded to low for pain improvement (due to increased inconsistency across trials), and effect size for pain improvement increased to moderate.
  - Effect size for yoga was upgraded to moderate for short-term function but downgraded to small for short-term pain.
- For neck pain
  - new evidence for massage led to an effect size upgrade for function from none to small short term, and added evidence for intermediate-term pain.

Table i. Changes in effect size or SOE between the 2018 report and the 2019 update report

Condition	Intervention (Comparator)	Outcome, Timing	Prior (2018) Report	2019 Update	Change
LBP	**Exercise** (vs. UC, AC, or placebo)	Function, short term	Small effect Low SOE 6 RCTs (N=553)	Small effect Moderate SOE 9 RCTs (N=1,056)	SOE upgraded one level
		Pain, short term	Small effect Moderate SOE 6 RCTs (N=553)	Moderate effect Low SOE 10 RCTs (N=1,098)	Effect size upgraded one level; SOE downgraded one level[a]
	Physical modalities: Interferential therapy (vs. placebo)	Function and pain, short term	No evidence	No effect Low SOE 1 new RCT (N=150)	New evidence
	Mind-body practices: Yoga (vs. AC or WL)	Function, short term	Small effect Moderate SOE 6 RCTs (N=922)	Moderate effect Moderate SOE 8 RCTs (N=1,149)	Effect size upgraded one level
		Pain, short term	Moderate effect Low SOE 5 RCTs (N=770)	Small effect Low SOE 7 RCTs (N=997)	Effect size downgraded one level
Neck pain	**Exercise** (Pilates) (vs. acetaminophen)	Function, short term	Insufficient evidence 1 RCT (N=40)	Small effect Low SOE 1 new trial (N=64)	SOE upgraded one level, new evidence[b]
		Pain, short term	Insufficient evidence 1 RCT (N=40)	Large effect Low SOE 1 new trial (N=64)	SOE upgraded one level, new evidence[b]
	Manual Therapies: Massage (vs. AC or WL)	Function, short term	No effect Low SOE 1 RCT (N=58)	Small effect Low SOE 2 RCTs (N=150)	Effect size upgraded one level
		Pain, short term	No evidence	Moderate effect Low SOE 1 new RCT (N=92)	New evidence

AHRQ 2020
Non-Pharmacologic Treatments for Chronic Pain

- **Key Messages**
- Interventions that improved function and/or pain for ≥1 month:
  - **Low back pain:** Exercise, psychological therapy, spinal manipulation, low-level laser therapy, massage, mindfulness-based stress reduction, yoga, acupuncture, multidisciplinary rehabilitation (MDR)
    - No change from 2018 report
  - **Neck pain:** Exercise, low-level laser, mind-body practices, massage, acupuncture
    - 2018 report: Exercise, low-level laser, Alexander Technique, acupuncture
- Some interventions did not improve function or pain.
- Serious harms were not observed with the interventions.

AHRQ 2018 Non-pharmacologic Therapies Low Back Pain

	Function *Short-Term* *Effect Size SOE*	Function *Intermediate - Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Exercise	slight +	slight ++	none +	slight ++	none ++	none ++
Psychological Therapies: CBT	slight +	slight +	insufficient evidence	slight +	none +	insufficient evidence
Psychological Therapies: Biofeedback, Imagery	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence	insufficient evidence
Physical Modalities: Magnetic Pads	insufficient evidence	none +	no evidence	insufficient evidence	none +	no evidence
Manual Therapies: Massage (Myofascial Release)	no evidence	slight +	none +	insufficient evidence	insufficient evidence	slight +
Mindfulness Practices: MBSR	none ++	no evidence	no evidence	none ++	no evidence	no evidence
Mind-Body Practices: Qigong, Tai Chi	slight +	no evidence	no evidence	moderate +	no evidence	no evidence
Acupuncture	slight ++	slight ++	no evidence	none +	none +	no evidence
Multidisciplinary Rehabilitation	slight +	slight +	slight +	none +	slight +	none +

Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months
Effect Size: none, slight/small, moderate, or large improvement
Strength of Evidence: + = low, ++ = moderate, +++ = high
CBT = cognitive-behavioral therapy; MBSR = mindfulness-based stress reduction; none = no effect/no statistically significant effect; SOE = strength of evidence

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AHRQ 2020 Non-pharmacologic Therapies Low Back Pain

Table 64. Chronic low back pain: effects of nonpharmacological interventions compared with usual care, placebo, sham, attention control, or waitlist[a]

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Exercise	small[b] ++	none +	none +	moderate[c] +	small +	moderate +
Psychological Therapies: CBT Primarily	small ++	small ++	small ++	small ++	small ++	small ++
Physical Modalities: Short-Wave Diathermy	insufficient evidence	no evidence	no evidence	insufficient evidence	no evidence	no evidence
Physical Modalities: Ultrasound	insufficient evidence	no evidence	no evidence	none +	no evidence	no evidence
Physical Modalities: Interferential Therapy[d]	none +	no evidence	no evidence	none +	no evidence	no evidence
Physical Modalities: Low-Level Laser Therapy	small +	none +	no evidence	moderate +	none +	no evidence
Manual Therapies: Spinal Manipulation	small +	small +	no evidence	none +	small ++	no evidence
Manual Therapies: Massage	small ++	none +	no evidence	small ++	none +	no evidence
Manual Therapies: Traction	none +	no evidence	no evidence	none +	no evidence	no evidence

Continued on next slide

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AHRQ 2020 Non-pharmacologic Therapies Low Back Pain (cont'd)

Table 64. Chronic low back pain: effects of nonpharmacological interventions compared with usual care, placebo, sham, attention control, or waitlist[a] (Cont'd)

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Mindfulness Practices: MBSR	none +	none +	none +	small ++	small +	none +
Mind-Body Practices: Yoga	moderate[e] ++	small +	no evidence	small[f] +	moderate ++	no evidence
Acupuncture	small +	none +	none +	small ++	none +	small +
Multidisciplinary Rehabilitation	small +	small +	none +	small ++	small ++	none +

Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months
Effect Size: none, small, moderate, or large improvement
Strength of Evidence: + = low, ++ = moderate, +++ = high
CBT = cognitive-behavioral therapy; MBSR = mindfulness-based stress reduction; none = no effect/no statistically significant effect; SOE = strength of evidence.
[a] SOE and effect size based on totality of evidence from prior report and new trials.
[b] SOE upgraded one level from prior report.
[c] Effect size upgraded one level from prior report and SOE downgraded one level.
[d] No interferential therapy trials were in the prior review.
[e] Effect size upgraded one level from prior report.
[f] Effect size downgraded one level from prior report.

AHRQ 2018 Non-pharmacologic Therapies Neck Pain

Table 49. Chronic neck pain: effects of nonpharmacological interventions compared with usual care, placebo, sham, attention control, or waitlist

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Exercise	none +	no evidence	no evidence	none +	no evidence	no evidence
Psychological Therapies: PT-lead relaxation training	none +	none +	no evidence	none +	none +	no evidence
Physical Modalities: Low-Level Laser Therapy	moderate ++	no evidence	no evidence	moderate ++	no evidence	no evidence
Physical Modalities: Traction, Electromagnetic field	insufficient evidence	no evidence	no evidence	insufficient evidence	no evidence	no evidence
Manual Therapies: Massage	none +	none +	no evidence	no evidence	no evidence	no evidence

AHRQ 2018 Non-pharmacologic Therapies Neck Pain

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Mind-Body Practices: Alexander Technique	slight +	slight +	no evidence	no evidence	no evidence	no evidence
Acupuncture	slight +	slight +	none +	none +	none +	none +

Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months
Effect Size: none, slight/small, moderate, or large improvement
Strength of Evidence: + = low, ++ = moderate, +++ = high
none = no effect/no statistically significant effect; PT = physical therapist; SOE = strength of evidence.

AHRQ 2020 Non-pharmacologic Therapies Neck Pain

Table 66. Chronic neck pain: effects of nonpharmacological interventions compared with usual care, placebo, sham, attention control, or waitlist[a]

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Exercise	none +	none +	small +	none +	none +	none +
Psychological Therapies: PT-Led Relaxation Training	none +	none +	no evidence	none +	none +	no evidence
Physical Modalities: Low-Level Laser Therapy	moderate ++	no evidence	no evidence	moderate ++	no evidence	no evidence
Physical Modalities: Traction, Electromagnetic field	insufficient evidence	no evidence	no evidence	insufficient evidence	no evidence	no evidence
Manual Therapies: Massage	small[b] +	none +	no evidence	moderate[c] +	no evidence	no evidence

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AHRQ 2020 Non-pharmacologic Therapies Neck Pain

Intervention	Function *Short-Term* Effect Size SOE	Function *Intermediate-Term* Effect Size SOE	Function *Long-Term* Effect Size SOE	Pain *Short-Term* Effect Size SOE	Pain *Intermediate-Term* Effect Size SOE	Pain *Long-Term* Effect Size SOE
Mind-Body Practices: Alexander Technique	small +	small +	no evidence	no evidence	no evidence	no evidence
Acupuncture	small +	small +	none +	none +	none +	none +

Short-Term: 1 to <6 months; Intermediate-Term: ≥6 to <12 months; Long-Term: ≥12 months
Effect Size: none, small, moderate, or large improvement
Strength of Evidence: + = low, ++ = moderate, +++ = high
none = no effect/no statistically significant effect; PT = physical therapist; SOE = strength of evidence.
[a] SOE and effect size based on totality of evidence from prior report and new trials.
[b] Effect size upgraded one level from prior report.
[c] There was no evidence for short-term pain in the prior report.

Current Back/Neck Line Coverage

- Current coverage (LBP):
  - Cover all areas with at least some evidence of effectiveness other than low level laser therapy
  - Do not cover areas without evidence (e.g. traction)
- Current coverage (neck pain)
  - Cover all areas with at least some evidence of effectiveness other than low level laser therapy
  - Cover with little or no evidence of effectiveness

AHRQ 2020 NON OPIOID PHARMACOLOGIC THERAPIES

2020 AHRQ Non-Opioid Pharmacologic Therapy

- 185 RCTs
- 5 systematic reviews
- Included only studies of 12 weeks duration or longer

2020 AHRQ Non-Opioid Pharmacologic Therapy

- **Key Messages**
  - In the short term, small improvements (e.g., 5 to 20 points on a 0 to 100 scale) in pain and/or function were seen with SNRI antidepressants for low back pain
  - In the intermediate term, evidence was limited, with evidence of benefit for serotonin norepinephrine reuptake inhibitor (SNRI) antidepressants in low back pain.
  - In the long term, evidence was too limited to draw conclusions. In general, evidence on quality of life was limited and no treatment achieved a large improvement in pain or function.
  - Small to moderate, dose-dependent increases in withdrawal due to adverse events were found with SNRIs duloxetine and milnacipran, anticonvulsants pregabalin and gabapentin, and NSAIDs. Large increases were seen with oxcarbazepine. NSAIDs have increased risk of serious gastrointestinal, liver dysfunction, and cardiovascular adverse events.

AHRQ 2020 OPIOID THERAPY

Opioid Therapy

- 115 randomized controlled trials (RCTs), 40 observational studies, and 7 studies of predictive accuracy
  - 134 were new to this update
- Opioids were associated with small benefits versus placebo in short-term pain, function, and sleep quality. There was a small dose-dependent effect on pain, and effects were attenuated at longer (3 to 6 month) versus shorter (1 to 3 month) follow-up.
- Opioids were associated with increased risk of discontinuation due to adverse events, gastrointestinal adverse events, somnolence, dizziness, and pruritus versus placebo.
- In observational studies, opioids were associated with increased risk of an opioid abuse or dependence diagnosis, overdose, all-cause mortality, fractures, falls, and myocardial infarction versus no opioid use; there was evidence of a dose-dependent risk for all outcomes except fracture and falls.

Opioid Therapy

- In observational studies, opioids were associated with increased risk of an opioid abuse or dependence diagnosis, overdose, all-cause mortality, fractures, falls, and myocardial infarction versus no opioid use; there was evidence of a dose-dependent risk for all outcomes except fracture and falls
- There were no differences between opioids and nonopioid medications in pain, function, or other short-term outcomes.
- Opioid plus nonopioid combination therapy was associated with little improvement in pain at short-term follow-up versus an opioid alone.
- Co-prescription of benzodiazepines or gabapentinoids was associated with increased risk of overdose versus an opioid alone.
- No RCT evaluated intermediate- or long-term benefits of opioids versus placebo

Opioid Therapy

- **Conclusions.** At short-term follow-up, for patients with chronic pain, opioids are associated with small beneficial effects versus placebo but are associated with increased risk of short-term harms and do not appear to be superior to nonopioid therapy. Evidence on intermediate-term and long-term benefits remains very limited, and additional evidence confirms an association between opioids and increased risk of serious harms that appears to be dose-dependent.
- Research is needed to develop accurate risk prediction instruments, determine effective risk mitigation strategies, clarify risks associated with co-prescribed medications, and identify optimal opioid tapering strategies.

WASHINGTON HTA 2018
SURGERY FOR LUMBAR RADICULOPATHY

WA HTA 2018 Surgery vs Non-surgical Treatment for Lumbar Radiculopathy

- 7 RCTs (N = 1,158) compared microdiscectomy or discectomy to nonsurgical interventions.
- Surgery reduced leg pain by 6 to 26 points more than nonsurgical interventions as measured on a 0 to 100-point visual analog scale of patient-reported pain at up to 26 weeks follow-up
  - Differences between groups did not persist at 1 year or later.
- The evidence was mixed for functioning and disability as measured by the Oswestry Disability Index, Roland-Morris Disability Questionnaire, and Short Form 36 (SF-36) Physical Functioning subscale in follow-up through 26 weeks
  - No between-group differences were observed at 1 year or later.
- Surgery and nonsurgical interventions produced similar improvements in quality of life, neurologic symptoms, and return to work

WA HTA 2018 Surgery vs Non-surgical Treatment for Lumbar Radiculopathy

- No surgical deaths occurred in any study and surgical morbidity was infrequent. The incidence of reoperations among participants who underwent surgery ranged from 0% to 10%.
- Studies reported higher quality-adjusted life years for participants who underwent surgery compared to nonsurgical interventions, but similar or higher costs.
- The average cost per quality-adjusted life year gained from a health care payor perspective ranged from $51,156 to $83,322 in 2010 United States (U.S.) dollars.

WA HTA 2018 Surgery vs Non-surgical Treatment for Lumbar Radiculopathy

- **Conclusions:** Most findings are based on a body of RCT evidence graded as low to very low certainty. Compared with nonsurgical interventions, surgery reduces pain and improves function more up to 26 weeks follow-up, but this difference does not persist at 1 year or longer. Minimally-invasive surgery, microdiscectomy, and discectomy are generally comparable with respect to efficacy and surgical morbidity; findings are mixed for reoperations. Surgery may be cost-effective when compared with nonsurgical interventions, depending on a decision maker's willingness to pay threshold, but the evidence is inconclusive about the cost-effectiveness of minimally-invasive surgery.

Washington Coverage Decision

- **HTCC coverage determination:**
- Surgery for lumbar radiculopathy or sciatica is a **covered benefit with conditions**.
- **Limitations of coverage:**
  - Open discectomy or microdiscectomy with or without endoscopy (lumbar laminectomy, laminotomy, discectomy, foraminotomy) are covered with the following conditions:
    - For adult patients with lumbar radiculopathy with subjective and objective neurologic findings that are corroborated with an advanced imaging test (i.e., Computed Tomography (CT) scan, Magnetic Resonance Imaging (MRI) or myelogram), AND
    - There is a failure to improve with a minimum of six weeks of non-surgical care, unless progressive motor weakness is present

WASHINGTON HTA 2015
SURGERY FOR LUMBAR DISC DISEASE

WA HTA 2015 Surgery vs Non-surgical Treatment for Lumbar Disc Disease

- Fusion vs interdisciplinary rehab
  - 3 RCTs (N=473)
  - Moderate evidence of no difference in pain or function
- Fusion vs PT or exercise
  - 2 RCTs (N=335)
  - Moderate evidence of small benefits of surgery seen over 1-2 years of f/u (e.g., faster return to work); differences diminish over time
- Fusion vs other therapies
  - No studies found
- Overall complications to fusion
  - 9-20% overall, 1-3% serious
  - Mean 12.5% reoperation over 5 yrs
- Comparative cost
  - >$100,000 per QALY over 2 years for surgery vs non-operative management

Washington Coverage Decision

- **HTCC Coverage Determination:**
  - Lumbar fusion for degenerative disc disease uncomplicated by comorbidities is **not a covered benefit.**
  - The population addressed in this decision includes individuals > 17 years of age with chronic (3 or more months) lumbar pain and uncomplicated degenerative disc disease; excluded conditions include radiculopathy, spondylolisthesis (> Grade 1) or severe spinal stenosis, as well as acute trauma or systemic disease affecting the lumbar spine (e.g., malignancy).

Comparison of Prioritized List Coverage to Washington Coverage

- Very similar coverage
  - Only cover lumbar surgery with radiculopathy and MRI findings
  - Require 6 weeks of conservative therapy prior to surgery without red flags
  - No coverage of disc disease alone
- Difference: PL requires evidence of central or foraminal spinal stenosis

DISCUSSION

Issues for Discussion

- Non-surgical non-pharmacologic coverage:
  - Consider adding low level laser therapy coverage
  - Discuss limitations on coverage of massage
    - include in 30 visit limit for other “hands on” therapies?
- Non-opioid pharmacologic coverage
  - Coverage determined by Pharmacy and Therapeutics Committee
    - Not in any PL guideline
- Opioid coverage
  - Any changes required?
- Surgical coverage
  - Consider removing requirement for evidence of central or foraminal stenosis
    - Simplify to “MRI findings consistent with symptoms” or similar wording

Additional Issues

- "Collected" back issues to consider
  - One level vs two level cervical artificial disks
    - Currently restrict to one level
    - WA HTA supports two level
  - Should the artificial disk guideline be folded into the general back surgery guideline?
  - Diagnostic spinal injections
    - Minor Prioritized List changes to clarify non-coverage recommended

Other Issues for Discussion?

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
      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

Corticosteroid injections for low back pain with or without radiculopathy are only included on Line 529.

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-Cordicosteroid Percutaneous Interventions. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE

Lines 361,402

Patients seeking care for back pain should be assessed for potentially serious conditions ("red flag" symptoms requiring immediate diagnostic testing), as defined in Diagnostic Guideline D4. Patients lacking red flag symptoms should be assessed using a validated assessment tool (e.g. STarT Back Assessment Tool) in order to determine their risk level for poor functional prognosis based on psychosocial indicators.

For patients who are determined to be low risk on the assessment tool, the following services are included on these lines:

- Office evaluation and education,
- Up to four total visits, consisting of the following treatments: OMT/CMT, acupuncture, and PT/OT. Massage, if available, may be provided as part of these four total visits.
- First line medications: NSAIDs, acetaminophen, and/or muscle relaxers. Opioids may be considered as a second line treatment, subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.

For patients who are determined to be medium- or high risk on the validated assessment tool, as well as patients undergoing opioid tapers as in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE, the following treatments are included on these lines:

- Office evaluation, consultation and education
- Cognitive behavioral therapy. The necessity for cognitive behavioral therapy should be re-evaluated every 90 days and coverage will only be continued if there is documented evidence of decreasing depression or anxiety symptomatology, improved ability to work/function, increased self-efficacy, or other clinically significant, objective improvement.
- Prescription and over-the-counter medications; opioid medications subject to the limitations on coverage of opioids in Guideline Note 60 OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE. See evidence table.
- The following evidence-based therapies, when available, may be provided: yoga, massage, supervised exercise therapy, intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line 402 for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following evidence-based therapies when available and medically appropriate. These therapies are only included on these lines if provided by a provider licensed to provide the therapy and when there is documentation of measurable clinically significant progress toward the therapy plan of care goals and objectives using evidence based objective tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
    1) Rehabilitative therapy (physical and/or occupational therapy), if provided according to Guideline Note 6 REHABILITATIVE AND HABILITATIVE THERAPIES. Rehabilitation services provided under this guideline also count towards visit totals in Guideline Note 6. CPT 97124 is included in this category.
    2) Chiropractic or osteopathic manipulation
    3) Acupuncture

Mechanical traction (CPT 97012) is not included on these lines, due to evidence of lack of effectiveness for treatment of back and neck conditions.

The development of this guideline note was informed by HERC coverage guidances on Low Back Pain Non-Pharmacologic, Non-Invasive Intervention, Low Back Pain, Pharmacological and Herbal Therapies. See https://www.oregon.gov/oha/HPA/DSI-HERC/Pages/Evidence-based-Reports.aspx.

GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE

Lines 346,361,402,529

Opioid medications are only included on these lines under the following criteria:

For acute injury, acute flare of chronic pain, or after surgery:

1) During the first 6 weeks opioid treatment is included on these lines ONLY:
   a) When each prescription is limited to 7 days of treatment, AND
   b) For short acting opioids only, AND
   c) When one or more alternative first line pharmacologic therapies such as NSAIDs, acetaminophen, and muscle relaxers have been tried and found not effective or are contraindicated, AND
   d) When prescribed with a plan to keep active (home or prescribed exercise regime) and with consideration of additional therapies such as spinal manipulation, physical therapy, yoga, or acupuncture, AND
   e) There is documented verification that the patient is not high risk for opioid misuse or abuse.
2) Treatment with opioids after 6 weeks, up to 90 days after the initial injury/flare/surgery is included on these lines ONLY:
   a) With documented evidence of improvement of function of at least thirty percent as compared to baseline based on a validated tools (e.g. Oswestry, Neck Disability Index, SF-MPQ, and MSPQ).
   b) When prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga, or acupuncture.
   c) With verification that the patient is not high risk for opioid misuse or abuse. Such verification may involve
      i) Documented verification from the state's prescription monitoring program database that the controlled substance history is consistent with the prescribing record
      ii) Use of a validated screening instrument to verify the absence of a current substance use disorder (excluding nicotine) or a history of prior opioid misuse or abuse
      iii) Administration of a baseline urine drug test to verify the absence of illicit drugs and non-prescribed opioids.
   d) Each prescription must be limited to 7 days of treatment and for short acting opioids only

3) Long-term opioid treatment (>90 days) after the initial injury/flare/surgery is not included on these lines except for the taper process described below.

<u>Transitional coverage for patients on long-term opioid therapy:</u>

Current Prioritized List for Back and Spine Conditions

For patients receiving long-term opioid therapy (>90 days) for conditions of the back and spine, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan when clinically indicated. Opioid tapering should be done on an individualized basis with a shared goal set by the patient and provider based on the patient's overall status. Taper plans should include nonpharmacological treatment strategies for managing the patient's pain. During the taper, behavioral health conditions need to be regularly assessed and appropriately managed. In some situations (e.g., in the setting of active substance use disorder, history of opioid overdose, aberrant behavior), more rapid tapering or transition to medication assisted treatment may be appropriate and should be directed by the prescribing provider. If a patient has developed an opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER.

Evidence Table of Effective Treatments for the Management of Low Back Pain

Intervention Category*	Intervention	Acute < 4 Weeks	Subacute & Chronic > 4 Weeks
Self-care	Advice to remain active	•	•
	Books, handout	•	•
	Application of superficial heat	•	
Nonpharmacologic therapy	Spinal manipulation	•	•
	Exercise therapy		•
	Massage		•
	Acupuncture		•
	Yoga		•
	Cognitive-behavioral therapy		•
	Progressive relaxation		•
Pharmacologic therapy (Carefully consider risks/harms)	Acetaminophen	•	•
	NSAIDs	•(▲)	•(▲)
	Skeletal muscle relaxants	•	
	Antidepressants (TCA)		•
	*Benzodiazepines***	•(▲)	•(▲)
	*Tramadol, opioids***	•(▲)	•(▲)
Interdisciplinary therapy	Intensive interdisciplinary rehabilitation		•

- Interventions supported by grade B evidence (at least fair-quality evidence of moderate benefit, or small benefit but no significant harms, costs, or burdens). No intervention was supported by grade "A" evidence (good-quality evidence of substantial benefit).

▲ *Carries greater risk of harms than other agents in table.*

NSAIDs = nonsteroidal anti-inflammatory drugs; TCA = tricyclic antidepressants.

*These are general categories only. Individual care plans need to be developed on a case by case basis. For more detailed information please see: http://www.annals.org/content/147/7/478.full.pdf

**Associated with significant risks related to potential for abuse, addiction and tolerance. This evidence evaluates effectiveness of these agents with relatively short term use studies. Chronic use of these agents may result in significant harms.

Comparative Effectiveness Review
Number 227

Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update

AHRQ
Agency for Healthcare
Research and Quality

Comparative Effectiveness Review

Number 227

Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
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Noninvasive Nonpharmacological Treatment for Chronic Pain: A Systematic Review Update

Structured Abstract

Objectives. We updated the evidence from our 2018 report assessing persistent improvement in outcomes following completion of therapy for noninvasive nonpharmacological treatment for selected chronic pain conditions.

Data sources. Electronic databases (Ovid MEDLINE®, Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews) through November 2017 (for prior report) and from September 2017 through September 2019 (for this update report), reference lists, ClinicalTrials.gov, and our previous report.

Review methods. Using predefined criteria, we selected randomized controlled trials (RCTs) of noninvasive nonpharmacological treatments for five common chronic pain conditions (chronic low back pain; chronic neck pain; osteoarthritis of the knee, hip, or hand; fibromyalgia; and tension headache) that reported results for a at least 1 month postintervention. We analyzed effects and assessed strength of evidence (SOE) at short term (1 to <6 months following treatment completion), intermediate term (≥6 to <12 months), and long term (≥12 months).

Results. We included 233 RCTs (31 new to this update). Many were small (N<70), and evidence beyond 12 months after treatment completion was sparse. The most common comparison was with usual care. Evidence on harms was limited, with no evidence suggesting increased risk for serious treatment-related harms for any intervention. Effect sizes were generally small for function and pain.

Chronic low back pain: Psychological therapies were associated with small improvements compared with usual care or an attention control for both function and pain at short-term, intermediate-term, and long-term followup (SOE: moderate). Function improved over short and/or intermediate term for exercise, low-level laser therapy, spinal manipulation, massage, yoga, acupuncture, and multidisciplinary rehabilitation (SOE moderate at short term for exercise, massage, and yoga; low for all others). Improvements in pain at short term were seen for massage, mindfulness-based stress reduction, acupuncture, and multidisciplinary rehabilitation (SOE: moderate), and exercise, low-level laser therapy, and yoga (SOE: low). At intermediate term, spinal manipulation, yoga, multidisciplinary rehabilitation (SOE: moderate) and exercise and mindfulness-based stress reduction (SOE: low) were associated with improved pain. Compared with exercise, multidisciplinary rehabilitation improved both function and pain at short and intermediate terms (small effects, SOE: moderate.)

Chronic neck pain: In the short term, low-level laser therapy (SOE: moderate) and massage (SOE: low) improved function and pain. Exercise in general improved function long term, and combination exercise improved function and pain both short and long term compared with usual care (SOE: low). Acupuncture improved function short and intermediate term, but there was no pain improvement compared with sham acupuncture (SOE: low). Compared with acetaminophen, Pilates improved both function and pain (SOE: low).

Osteoarthritis pain: Exercise resulted in small improvements in function and pain at short-term (SOE: moderate) and long-term (SOE: low), and moderate improvement at intermediate-term (SOE: low) followup for knee osteoarthritis versus nonactive comparators. Small improvements in function and pain with exercise were seen for hip osteoarthritis short term (SOE: low). Functional improvement persisted into intermediate term, but pain improvement did not (SOE: low).

Fibromyalgia: Functional improvements were seen with exercise, mind-body practices, multidisciplinary rehabilitation (SOE: low) and acupuncture (SOE: moderate) short term compared with usual care, attention control, or sham treatment. At intermediate term, there was functional improvement with exercise and acupuncture (SOE: moderate), cognitive-behavioral therapy (CBT), mindfulness-based stress reduction, myofascial release, and multidisciplinary rehabilitation (SOE: low). Long term, functional improvements persisted for multidisciplinary rehabilitation without improvement in pain (SOE: low). Compared with exercise, tai chi conferred improvement in function short and intermediate term (SOE: low). Pain was improved with exercise (short and intermediate term, SOE moderate), and for CBT (short term), mindfulness practices, and multidisciplinary rehabilitation (intermediate term) (SOE low).

Chronic tension headache: Evidence was sparse and the majority of trials were of poor quality. Spinal manipulation resulted in moderate improvement in pain short term.

Conclusions. Trials identified subsequent to the earlier report largely support previous findings—namely that exercise, multidisciplinary rehabilitation, acupuncture, CBT, mindfulness practices, massage, and mind-body practices most consistently improve function and/or pain beyond the course of therapy for specific chronic pain conditions. Additional research, including comparisons with pharmacological and other active controls, on effects beyond the immediate post-treatment period is needed, particularly for conditions other than low back pain.

Comparative Effectiveness Review
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Nonopioid Pharmacologic Treatments for Chronic Pain

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April 2020

Nonopioid Pharmacologic Treatments for Chronic Pain

Structured Abstract

Objectives. To evaluate the effectiveness and comparative effectiveness of nonopioid pharmacologic agents in patients with specific types of chronic pain, considering effects on pain, function, quality of life, and adverse events.

Data sources. Electronic databases (Ovid® MEDLINE®, Embase®, PsycINFO®, CINAHL®, Cochrane Central Register of Controlled Trials, and Cochrane Database of Systematic Reviews) through September 10, 2019, reference lists, data requests, and previous reviews.

Review methods. Randomized controlled trials (RCTs) of nonopioid pharmacologic agents in patients with chronic pain were selected using predefined criteria and dual review. This review focused on seven common chronic pain conditions (neuropathic pain, fibromyalgia, osteoarthritis, inflammatory arthritis, low back pain, chronic headache, sickle cell disease), with effects analyzed at short term (1 to <6 months following treatment completion), intermediate term (≥6 to <12 months), and long term (≥12 months). Magnitude of effects were described as small, moderate, or large using previously defined criteria, and strength of evidence was assessed. Meta-analyses were conducted where data allowed, stratified by duration within each intervention type, using random effects models. We evaluated effect modification through subgroup and sensitivity analyses, including specific drug, dose, study quality, and pain type.

Results. We included 185 RCTs in 221 publications and 5 systematic reviews.
In the short term, anticonvulsants (pregabalin, gabapentin, and oxcarbazepine for neuropathic pain, pregabalin/gabapentin for fibromyalgia), serotonin-norepinephrine reuptake inhibitor (SNRI) antidepressants (duloxetine for neuropathic pain, fibromyalgia, osteoarthritis, and low back pain, milnacipran for fibromyalgia), and nonsteroidal anti-inflammatory drugs (NSAIDs) (for osteoarthritis and inflammatory arthritis) were associated with mostly small improvements (e.g., 5 to 20 points on a 0 to 100 scale) in pain and function. Function was not found to be improved with duloxetine for low back pain or pregabalin/gabapentin for neuropathic pain. Moderate improvement in quality of life was seen with duloxetine in patients with neuropathic pain, and small improvements in patients with osteoarthritis, but evidence was insufficient to draw conclusions for other drugs and conditions. While most comparisons of drugs and doses did not identify differences, diclofenac improved pain and function moderately more than celecoxib. In the intermediate term, limited evidence (1 RCT) showed memantine moderately improved pain, function, and quality of life in patients with fibromyalgia; improvements in pain, but not function, were maintained in the intermediate term with duloxetine and milnacipran for fibromyalgia. Other drugs studied, including acetaminophen (osteoarthritis), capsaicin (neuropathic pain), cannabis (neuropathic pain), amitriptyline (fibromyalgia, neuropathic pain), and cyclobenzaprine (fibromyalgia) had no clear effects. Withdrawal from study due to adverse events was significantly increased with nonopioid drugs, with the greatest increase over placebo seen with cannabis. Large increases in risk of adverse events were seen with pregabalin (blurred vision, cognitive effects, dizziness, peripheral edema, sedation, and weight gain), gabapentin (blurred vision, cognitive effects, sedation, weight gain), and cannabis (nausea, dizziness). Dose

reductions reduced the risk of some adverse events with SNRI antidepressants. In the short term small increases in risk of major coronary events and moderate increases in serious gastrointestinal events (both short and long term) were found with NSAIDs.

Conclusions. In the short term, small improvements in pain and/or function were seen with SNRI antidepressants for neuropathic pain, fibromyalgia, osteoarthritis, and low back pain; pregabalin/gabapentin for neuropathic pain and fibromyalgia; oxcarbazepine for neuropathic pain; and NSAIDs for osteoarthritis and inflammatory arthritis. Improvement in function was not found with duloxetine for low back pain and pregabalin/gabapentin for neuropathic pain. Intermediate- and long-term outcomes were mostly not assessed. Increased incidence of drug class–specific adverse events led to withdrawal from treatment in some patients, suggesting that careful consideration of patient characteristics is needed in selecting nonopioid drug treatments.

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Opioid Treatments for Chronic Pain

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Opioid Treatments for Chronic Pain

Structured Abstract

Objectives. Chronic pain is common, and opioid therapy is frequently prescribed for this condition. This report updates and expands on a prior Comparative Effectiveness Review on long-term (≥1 year) effectiveness and harms of opioid therapy for chronic pain, including evidence on shorter term (1 to 12 months) outcomes.

Data sources. A prior systematic review (searches through January 2014), electronic databases (Ovid MEDLINE®, Embase®, PsycINFO®, Cochrane CENTRAL, and Cochrane Database of Systematic Reviews through August 2019), reference lists, and clinical trials registries.

Review methods. Predefined criteria were used to select studies of patients with chronic pain prescribed opioids that addressed effectiveness or harms versus placebo, no opioid use, or nonopioid pharmacological therapies; different opioid dosing methods; or risk mitigation strategies. Effects were analyzed at short-term (1 to <6 months), intermediate-term (≥6 to <12 months), and long-term (≥12 months) followup. Studies on the accuracy of risk prediction instruments for predicting opioid use disorder or misuse were also included. Random effects meta-analysis was conducted on short-term trials of opioids versus placebo, opioids versus nonopioids, and opioids plus nonopioids versus an opioid or nonopioid alone. Magnitude of effects was classified as small, moderate, or large using predefined criteria, and strength of evidence was assessed.

Results. We included 115 randomized controlled trials (RCTs), 40 observational studies, and 7 studies of predictive accuracy; 134 were new to this update. Opioids were associated with small benefits versus placebo in short-term pain, function, and sleep quality. There was a small dose-dependent effect on pain, and effects were attenuated at longer (3 to 6 month) versus shorter (1 to 3 month) followup. Opioids were associated with increased risk of discontinuation due to adverse events, gastrointestinal adverse events, somnolence, dizziness, and pruritus versus placebo. In observational studies, opioids were associated with increased risk of an opioid abuse or dependence diagnosis, overdose, all-cause mortality, fractures, falls, and myocardial infarction versus no opioid use; there was evidence of a dose-dependent risk for all outcomes except fracture and falls.

There were no differences between opioids and nonopioid medications in pain, function, or other short-term outcomes. Opioid plus nonopioid combination therapy was associated with little improvement in pain at short-term followup versus an opioid alone. Co-prescription of benzodiazepines or gabapentinoids was associated with increased risk of overdose versus an opioid alone. No RCT evaluated intermediate- or long-term benefits of opioids versus placebo. One trial found stepped therapy starting with opioids to be associated with higher pain intensity and no difference in function or other outcomes versus stepped therapy starting with nonopioid therapy.

Limited evidence indicated no differences between long- and short-acting opioids in effectiveness, but long-acting opioids were associated with increased risk of overdose. One RCT

found a taper support intervention associated with greater improvement in function but no difference in pain versus usual care.

Estimates of diagnostic accuracy for various risk prediction instruments were highly inconsistent, and there was no evidence on the effectiveness of risk mitigation strategies for improving clinical outcomes, with the exception of one study that found provision of naloxone associated with decreased emergency department visits.

Trials of patients with prescription opioid dependence found buprenorphine maintenance associated with better outcomes than buprenorphine taper and similar effects of methadone versus buprenorphine. Evidence was insufficient to evaluate benefits and harms of opioid therapy in patients at higher risk for opioid use disorder.

Conclusions. At short-term followup, for patients with chronic pain, opioids are associated with small beneficial effects versus placebo but are associated with increased risk of short-term harms and do not appear to be superior to nonopioid therapy. Evidence on intermediate-term and long-term benefits remains very limited, and additional evidence confirms an association between opioids and increased risk of serious harms that appears to be dose-dependent. Research is needed to develop accurate risk prediction instruments, determine effective risk mitigation strategies, clarify risks associated with co-prescribed medications, and identify optimal opioid tapering strategies.

Back Lines and Guidelines Review 2020
Issue 1670 Document links

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