Health Evidence Review Commission's Chronic Pain Task Force

December 5, 2018

9:00 AM - 12:00 PM

Crowne Plaza Portland-Lake Oswego, Plaza 2 & 3
14811 Kruse Oaks Drive
Lake Oswego, OR 97035

Section 1.0

Call to Order

AGENDA
Chronic Pain Task Force
December 5, 2018
9:00 am – 12:00 pm
Crowne Plaza Portland-Lake Oswego
Plaza 2 & 3
14811 Kruse Oaks Drive
Lake Oswego, OR 97035
(All agenda items are subject to change and times listed are approximate)

#	Time	Item	Presenter
1	9:00	Call to Order	
2	9:05	Welcome and brief reflection	Dana Hargunani Nora Stern
3	9:10	Brief overview of work to date	Ariel Smits
4	9:15	Review requested information 1) CCO survey of implementation of previous back and neck pain coverage changes and implementation of other potential coverage changes related to chronic pain 2) CEBP evidence review on opioid tapers	Ariel Smits
5	9:45	Review and discuss potential alternatives to Task Force proposal	Group
6	11:00	Public testimony	
7	11:30	Final discussion and decisions regarding proposal	Group
8	11:50	Next Steps	Ariel Smits
9	12:00	Adjournment	

MINUTES

Chronic Pain Task Force
Wilsonville Holiday Inn
Wilsonville, OR
September 20, 2018
9:30-11:30 a.m.

Members Present: Kevin Cuccaro DO; Laura Ocker; Kim Jones PhD; Nora Stern; Tracy Muday MD; Cat Buist; Holly Jo Hodges MD; David Eisen; Amanda Risser MD; Lisa Boyle; Jessica Gregg MD (via phone)

Members Absent: David Sibell MD, Andrew Gibler, Jim Shames MD, Mitch Hass, Amber Rose Dullea

Staff Present: Ariel Smits, MD, MPH; Catherine Livingston, MD MPH; Darren Coffman; Jason Gingerich; Mark Altenhofen (via phone); Daphne Peck (via phone)

Also Attending: Beth Darnall, PhD; Tom Jeanne, MD MPH; Diane Weaver (Augros); Edith Aleoff; ; Dr. Twillman PhD; Dr. Chino PhD; Stefan Strek (TLS Communities); Kera McGee; Kern Hoagland; Kelly Howard; Leonard Ramey; Dianne Gregoire; Laural Soot (Providence Health Plan); Trisha Wong, MD and Henle Runer (OHSU); BJ Cavnor (One in Four); Tim Harless; Vern Saboe (Oregon Chiropractic Association); Rick Schmitt; Patrick Starnes; Shane Sinclair, Wendy Sinclair, and Evelyn Blackburn (Oregon Pain Action Group); Patty Brennan.

1. CALL TO ORDER

The meeting was called to order at 9:30 AM. Roll was called. The minutes from the June 2018 Chronic Pain Task Force meeting were reviewed and no changes were suggested.

2. DISCUSSION

Smits reviewed the objective behind creating the Chronic Pain Task Force (CPTF), which was to consider adding OHP coverage for evidence-based treatments such as PT and cognitive behavioral therapy for fibromyalgia and chronic pain syndrome, which currently are unfunded conditions. Smits reviewed the VBBS discussion regarding the June CPTF proposal, as well as the voluminous public testimony received on the topic. She reviewed the small body of research on opioid tapers known to date, which indicate that pain does not increase and quality of life may actually increase with tapers off opioids.

Dr. Tom Jeanne from the Oregon Public Health Division gave a presentation on the current state of the opioid crisis in Oregon, as well as publically available information dashboards created by the Public Health Division.

Dr. Beth Darnall from Stanford University gave a presentation on her research into voluntary tapers from opioids and voiced her concerns about policies which require tapers down to zero for stable patients. She stressed the need for any policy regarding opioids to be patient-centered.

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3. PUBLIC TESTIMONY

Dianne Weaver testified on the behalf of Avanos, which manufactures a non-opioid medical device that applies cooled thermal radiofrequency to an area in the OR and ablates a nerve, interrupting the pain signal from the nerve to the brain. She provided a packet of materials supporting the efficiacy of this procedure. Its effects last up to 24 months.

Kate Nicholson, a civil rights attorney, had her testimony read by another attendee. She expressed concerns with the removal of choices of treatment, mainly opioids, from chronic pain patients, which goes against all professional guidelines. She personally has chronic pain, and has had various treatments including opioids. She noted that chronic pain can put patients on disability.

Richard Lawhern, a doctor at the Alliance for Treatment of Intractable Pain, had testimony read by another attendee. He stated that groups prescribed opioids do not have higher mortality than groups not prescribed opioids. He noted that only a very small minority of patients on opioids go on to abuse these medications. Addiction is not a predictable result of opioid prescribing.

Stefan Streck tesitifed. He noted that Amsterdam has a solution to the opioid issue. Heroin addicts can be given heroin by the government. He felt that the solution is to legalize heroin, and leave legitimate pain patient's prescriptions alone. He noted that the task force proposal increased cost to the public by substituting suboxone for cheaper opioids. He said the current task force proposal is also cruel.

Kera McGee testified that she has a connective tissue disorder and is a chronic pain patient. Opioid pain medications are the only thing that works for her pain. She is also a recovering addict. After overdosing on her opioid pain medications, her opioids were taken away by her provider. Her function is much worse without the opioid therapy. She is upset because doctors treat her as a criminal and at one point she felt suicidal after being taking off her medications.

Kelly Howard testified that she is a chronic pain patient, as well as a medical research specialist. She is able to work due to responsible use of pain medications. She stated that SIGN, NICE, etc say opioids are safe and effective. She noted that alternative therapies provide some benefit for her. She noted that in the SPACE trial, there was no misuse or overuse among opioid medication users.

Dr. Patricia Wong testified that she is a pediatric hematologist at OHSU who cares for sickle cell patients. She reqested other inherited chronic pain conditions be considered for removal from this proposal. Smits clarified that sickle cell and similar conditions are currently covered and not part of the current CPTF proposal.

BJ Cavnor testified that he is the Executive Director of One in Four Chronic Health. He objected to Pat Allen's op ed title. He stated that there is a difference between people misusing medications and responsible chronic pain patients. Stigma, shaming and shunning continue to affect chronic pain patients.

Tim Harless testified that he is a chronic pain patient and an advocate for the American Chronic Pain Association. This is a peer led support group. He is concerned about the suicide rate among chronic pain patients. The VA cut him off his opioids, without any support. He ties chronic pain to increased suicide risk.

Vern Saboe testified on behalf of the Oregon Chiropractic Association. He noted that the final CPTF proposal did not include chiropractic care. He wanted to clarify that chiropractors do more than spinal manipulation. Chiropractors can do physical therapy, and provide other services to chronic pain patients. He also requested that the Task Force clarify which PT modalities should be included for chronic pain patients.

Patrick Starnes testified that he is an advocate for legacy chronic pain patients. He requested that two additional members be added to the Task Force, a chronic pain patient and a pain provider. He was insulted that a pain patient was not added to the Task Force. The Task Force is missing something by not bringing all the stakeholders to the table.

Patty Brennan testified that she is a chronic pain patient with fibromyalgia. She is very stressed over the thought of an opioid taper. She has done alternate therapy for years, as well as taking opioids. She has been on the same opioid regimen for a decade. She is able to function because of the opioids and does not misuse her opioids.

Evelyn Blackburn testified that she is a chronic pain patient. She stated that she has gone down 62% in her dosage in past months. She has done lots of alternative treatments. Opioids are an important part of her protocol. She uses other medications and alternative treatments, including an anti-inflammatory diet. She requested that an evidence review of opioid tapering be done before decisions are made.

There was a general question from the audience about the referral process for alternative treamtents. There is a PA process which is a barrier, and the 30-visit limit on PT modalities is also a barrier. Another barrier is that cognitive behavioral therapy may be limited to 1 session in some CCOs.

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4. NEXT STEPS

Smits reviewed the next steps for the CPTF. First, HERC staff is working on a survey of the CCOs to see which parts of the proposed coverage policy that they would actually implement. The Center for Evidence-based Policy is going to conduct an updated review of the evidence for opioid tapering. The OHA Pharmacy and Therapeutics group is going to review treatment efficacy for fibromyalgia medications this fall. Staff will use the information from these activities as well as feedback from the meeting today to develop a revised CPTF proposal for discussion, including clarifying who qualifies as a "legacy" pain patient.

Coffman outlined the timeline for next meetings and actions.

5. ADJOURNMENT

The meeting was adjourned at 11:30 am.

Section 2.0

Revised proposal

Chronic Pain Task Force
December 2018

The Chronic Pain Taskforce approved a proposal to create a new line for a limited number of chronic pain conditions at their June 2018 meeting. This proposal was presented at the August VbBS meeting, and a large amount of written and verbal public testimony was received. The Taskforce met again in September 2018. The September meeting was mostly a listening session. The Taskforce heard a presentation from the Oregon Public Health Division on the opioid epidemic, a presentation from Beth Darnall, PhD on opioid tapering, and a large amount of public testimony. The Taskforce also discussed plans to have the Center for Evidence Based Policy (CEBP) conduct an evidence review on opioid tapering and a survey of CCOs HERC staff is preparing regarding their likely implementation actions should any of the proposed changes be adopted.

HERC staff and other OHA staff have been working on a revised proposal for consideration by the Taskforce. This revised proposal takes into account conversations with the pharmacy directors on what types of medication controls are implementable, discussions with partners in public health and experts in Oregon on best practices for opioid prescribing, as well as voluminous public input, and feedback from CCOs on possible coverage changes. This revised proposal also takes into consideration the CEBP MED report on opioid tapering. The new guideline applies to opioids prescribed for conditions which appear on the newly-funded line and not for opioids prescribed for other funded conditions (e.g. active cancer, palliative care, arthritis, etc.).

Please refer to the following documents included in your packet for fuller details:

1) The summary of findings of the CCO survey
2) The draft CEbP MED report on opioid tapering
3) June 2018 CPTF proposal to VbBS/HERC

Chronic Pain Task Force
December 2018

CCO survey take home points

1) For the back line changes:
    a. Most CCOs answering the survey are implementing all or most of the back line guideline and providing new back/neck pain services
    b. Most CCOs noted increased costs with the addition of these services
    c. Almost universally, the CCOs do not want the current back guideline or back opioid guideline merged into a broader chronic pain guideline
2) For the proposed new coverage of chronic pain conditions:
    a. Most CCOs are concerned about the increased cost of the nonpharmacological services for these conditions as well as significant concerns about the cost of Lyrica and other medications that would be covered if these conditions become funded
    b. Most CCOs do not want non-opioid medications addressed in any chronic pain guideline
    c. The CCOs were mixed on whether they thought coverage for fibromyalgia and chronic pain would improve the health of their patients or simplify administration
    d. Nearly all responding CCOs were interested in incorporating Oregon opioid prescribing guidelines (acute and chronic)

CEBP MED report on opioid tapering take home points:

1) Overall quality of the evidence is very low
2) Overall, no change in conclusions since previous review
    a. Findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction
    b. Scant evidence on harms associated with tapering strategies
3) Adverse events—mortality, suicide or overdose
    a. 5 studies in the Frank review included adverse events
        i. 1 opioid-related overdose death in a patient in a buprenorphine treatment program (after discontinuation of buprenorphine) out of a total of 5 studies (no N given)
    b. A retrospective cohort study conducted in a VA population whose opioid therapy was discontinued by their clinician (primarily for aberrant behaviors) reported that 12% of the cohort had documented suicidal ideation and nonfatal suicidal self-directed violence (SSV) in the 12 months after opioid discontinuation
        i. This study identified Hispanic ethnicity (adjusted odds ratio [OR] 7.25 (95% CI 1.96–27.18), PTSD diagnosis: 2.56 (1.23–5.32), and psychotic-spectrum disorder diagnoses (OR 3.19; 95% CI 1.14 to 8.89) were correlated with suicidal ideation and SSV in the 12 months following clinician-initiated opioid discontinuation.
    c. Other new studies did not report information on serious adverse events such as mortality, suicide, or overdose events.
4) Adverse events—opioid withdrawal symptoms
    a. In the systematic review by Frank et al., 18 studies (3 fair and 15 poor methodological quality) reported opioid withdrawal symptoms. Rates of withdrawal symptoms ranged widely across the studies (0% to 100%).
    b. The new studies we identified for this update did not provide information on withdrawal symptoms experienced by patients receiving the interventions.
5) Taper length
    a. Not able to draw any conclusions regarding rapid versus slow tapering.
6) Patient-initiated vs nonpatient-initiated tapering

a. Very little information found on this issue. In almost all of the studies included in the previous MED report and in this update, patients had some autonomy in the decision to taper their opioids.
b. VA database study found that the reason for discontinuation (patient-initiated vs. clinician-initiated) was not correlated with pain score trajectory.
c. Demidenko et al. studied clinical-initiated discontinuation of opioids
    i. Approximately 75% of the clinician-discontinued patient group had opioids stopped because of aberrant behaviors such as abnormal urine drug test results, opioid diversion, and drug misuse.
    ii. Of the total sample of 509 patients, 59 had suicidal ideation or SSV documented in their charts; 47 had suicidal ideation alone, and 12 had SSV. Half of these patients attempted suicide with overdoses of prescription medications, primarily benzodiazepine drugs. Fifteen of the 59 patients had previous suicidal ideation or SSV events before discontinuation of opioid therapy.

a. 1 new study was identified that compared mandatory opioid dose reduction in a health system in Washington to usual care
    i. The researchers found no indication that patients in the intervention clinics had clinically meaningful differences in pain intensity, interference with activities and enjoyment of life, or depressive symptoms compared with control group patients.

Additional important information/resources

A. Oregon Acute Opioid Prescribing Guidelines
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/Acute-Prescribing-Guidelines.pdf
B. Oregon Chronic Opioid Prescribing Guidelines
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/Chronic-Opioid-Prescribing-Guidelines.pdf
C. Oregon Opioid Prescribing Guidelines for Dentists
https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines-dentists.pdf
D. Institute for Chronic Pain, description of centralized pain syndromes
http://www.instituteforchronicpain.org/understanding-chronic-pain/what-is-chronic-pain/neuromatrix-of-pain

Fibromyalgia guideline issue

HERC staff have noted that action needs to be taken on current Prioritized List fibromyalgia guideline. This guideline was developed based on evidence reviews conducted in 2008 and 2013, as well as expert input. The guideline largely mirrors the current CPTF proposal, with an additional sentence: "Use of opioids should be avoided due to evidence of harm in this condition." This sentence was added to the guideline based on expert input which indicated that opioids for fibromyalgia actually exacerbated the condition and therefore were a source of harm. Subsequently, Cochrane has conducted a systematic review of oxycodone for fibromyalgia published in 2016 which showed no evidence of benefit. Kim Jones, PhD has previously testified to the CPTF regarding the possible benefits of tramadol, a type of opioid, for treatment of fibromyalgia. The OHA Pharmacy and Therapeutics Committee recently completed a review of tramadol for fibromyalgia and found no evidence of benefit for this medication.

HERC Staff Revised Recommendations for Taskforce Consideration:

1) Create a new line for five chronic pain conditions and fibromyalgia for the 2020 Biennial Review as shown below
2) Adopt a new guideline for treatments included on this line as shown below
    a. Includes wording based on GUIDELINE NOTE 135, FIBROMYALGIA stating that opioids are not covered for fibromyalgia
3) Score this new line as shown below
    a. Proposed ranking would put this line in the funded region, around line 443 (near the funding line, which is currently below line 469).
4) Modify line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME AND RELATED CONDITIONS as shown below
    a. Remove all diagnoses other than chronic fatigue syndrome and modify line title
5) Modify GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    a. Matches changes in the new chronic pain conditions guideline
6) Modify GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    a. Modifies the paragraph on tapering for chronic opioid use
    b. Removes flares of chronic pain as an indication for opioids
7) Modify GUIDELINE NOTE 92, ACUPUNCTURE as shown below
    a. Adds the new chronic pain line to the guideline
    b. **consider wording limiting all acupuncture to 30 visits a year to mirror PT guideline**
8) Delete GUIDELINE NOTE 135, FIBROMYALGIA
    a. Components are all incorporated into the new guideline

LINE: XXX
CONDITION: FIBROMYALGIA, CHRONIC PAIN SYNDROME, AND RELATED CONDITIONS
TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY

ICD-10: G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain), G89.29 (Other chronic pain), G89.4 (Chronic pain syndrome), M79.7 (fibromyalgia)

CPT: 90785, 90832-90840, 90853 (psychotherapy—for CBT and ACT), 96150-96155 (Health and behavior assessment and intervention), 97110-97124, 97140-97168, 97530, 97535 (PT/OT), 97810-97814 (acupuncture), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337,99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)

HCPCS: G0157-G0160 (PT/OT assistant), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care), G0514 (prolonged office visit)

GUIDELINE NOTE XXX TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Lines XXX

Chronic pain syndrome (ICD-10 G89.4), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), other chronic pain (ICD-10 G89.29), and fibromyalgia (ICD-10 M79.7) are included on line XXX when symptoms have been present for at least 3 months.

The following treatments are included on line XXX:

- Office evaluation, consultation and education.
    - Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers seeing chronic pain patients should be trained in pain science (e.g., a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.
- Cognitive behavioral therapy (CBT). The necessity for CBT 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.
- The following therapies, when available, may be provided: adaptive and restorative yoga, mindfulness training, massage, supervised exercise therapy (land based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following 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. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
    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) Acupuncture

Non-opioid medications are only included on line XXX if all of the following apply:

1) The medication is FDA approved or supported by compendia for treatment of chronic, non-neuropathic pain.
2) The patient is also being treated with active therapy (e.g., physical therapy, CBT) or is continuing maintenance of self-management strategies learned from such therapy.
3) The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of initial improvement of function of at least fifteen percent as compared to baseline based on a validated tool (e.g., Oswestry, SF-MPQ, MSPQ), and function is maintained thereafter. Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.

<u>Opioids for chronic pain syndrome (when not representing centralized pain syndrome), chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain</u>

Chronic opioids (>90 days) are only covered for chronic pain syndrome (ICD-10 G89.4; when not representing centralized pain syndrome), chronic pain due to trauma (ICD-10 G89.21), other chronic postprocedural pain (ICD-10 G89.28), and other chronic pain (ICD-10 G89.29) when all of the following are met:

- In alignment with the Oregon Opioid Prescribing Guideline (2017-2018 version) https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/SUBSTANCEUSE/OPIOIDS/Documents/taskforce/oregon-opioid-prescribing-guidelines.pdf
- Appropriate risk assessment has been performed (e.g., Opioid Risk Assessment Tool)
- PDMP checked at least annually and shows no aberrant behavior
- No concurrent prescribing of benzodiazepines
- Urine drug testing is performed at least once per year and is appropriate
- No illicit drug use or active substance use disorder (excluding tobacco)
- MED < 50, or between 50 and 90 with extenuating circumstances [MED=morphine equivalent daily dose]. For patients at or above 50 MED, every attempt should be made to taper according to the taper guidelines (ideally to MED <50)
- Initial functional improvement has been documented of at least 30%, and function is maintained throughout the prescribing period
- Comorbid mental health disorders are appropriately addressed
- No additional opioids are prescribed for flares of the chronic pain condition, although opioids may be prescribed separately for other acute injuries or surgeries as clinically appropriate
- Prescriber has updated opioid prescribing CME and ideally has completed the OPMC pain module
- Patient and provider have assessed the relative risks and benefits of therapy and agree benefits outweigh risks, and have completed a material risk notice https://www.oregon.gov/omb/OMBForms1/material-risk-notice.pdf
- The patient be prescribed the patient pain education module through OPMC when it becomes available

<u>Opioid tapering for fibromyalgia and other chronic pain conditions on this line</u>

Opioids are not intended for inclusion on this line for the following conditions/situations due to the evidence for harm:

- fibromyalgia
- centralized pain syndrome (sometimes coded as chronic pain syndrome, ICD-10 G89.4)
- patients who fail to meet the guideline requirements regarding opioids above who have chronic pain syndrome (when not representing centralized pain syndrome), chronic pain due to trauma, other chronic postprocedural pain, and other chronic pain conditions included on this line

If a patient is already receiving chronic opioid therapy for these conditions/situations, then tapering is indicated. Opioid tapering should be done on an individualized basis which includes a taper goal of zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly. Taper plans should include nonpharmacological treatment strategies for managing the patient's pain. 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 opioid use disorder, treatment is included on Line 4 SUBSTANCE USE DISORDER**.**

Line Scoring

Line 401 CONDITIONS OF THE BACK AND SPINE (current scoring shown)
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 2
Score: 432
Current line placement: 401

Line XXX FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 2
Need for service: 0.8
Net cost: 2
Score: 288
Approximate line placement: 443

Line 528 CHRONIC FATIGUE SYNDROME (current scoring of line FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS shown)
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1
Need for service: 0.8
Net cost: 2
Score: 112
Current line placement: 528

Line: 528

Condition: ~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65~~,135~~)

Treatment: MEDICAL THERAPY

ICD-10: ~~G89.21,G89.28-G89.29,G89.4,M79.7,~~R53.82

CPT: 90785,90832-90840,90846-90853,93792,93793,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607

HCPCS: G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513,G0514

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

Lines 361,401

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 (CBT). The necessity for CBT 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 401 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). These 30 visits count toward the visit totals in GUIDELINE NOTE XXX TREATMENT OF FIBROMYALGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS if the patient has one or more of these comorbid chronic pain conditions.
    3) 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.
    4) Chiropractic or osteopathic manipulation
    5) 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 http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

[delete the table below]

~~**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.

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

Lines 346,361,401,527

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

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:
For patients ~~on covered chronic~~ receiving long-term opioid therapy (>90 days) for conditions of the back and spine ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan which includes a taper plan ~~developed by January 1, 2017 which includes a taper with an end to opioid therapy no later than January 1, 2018~~. Opioid tapering should be done on an individualized basis and include a taper goal to zero. Tapering should be unidirectional with a shared goal set by the patient and provider, generally with a 5-10% decrease monthly. Taper plans ~~must~~ should include nonpharmacological treatment strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. 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 ~~dependence and/or addiction related to their opioids~~ opioid use disorder, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER**.**

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,202,361,401,409,461,538

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 sessions 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 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

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 XXX FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

Acupuncture is included on this line with visit limitations as in Guideline Note XXX TREATMENT OF FIBROMYAGIA, CHRONIC PAIN SYNDROME AND RELATED CONDITIONS

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 http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

*Below the current funding line

~~**GUIDELINE NOTE 135, FIBROMYALGIA**~~

~~*Line 528*~~

~~Fibromyalgia (ICD-10-CM M79.7) treatment should consist of a multi-modal approach, which should include two of more of the following:~~

~~A) medications other than opioids~~
~~B) exercise advice/programs~~
~~C) cognitive behavioral therapy.~~

~~Care should be provided in the primary care setting. Referrals to specialists are generally not required.~~
~~Use of opioids should be avoided due to evidence of harm in this condition~~

Highlights of CCO Survey

Back line implementation changes

Highlights:

1. Most CCOs are requiring a risk assessment, either to access initial nonpharmacologic therapy or therapy beyond 4 visits.
2. Most CCOs cover all the modalities listed in GL 56 "for all members with back pain." The lowest is intensive interdisciplinary rehab, covered in 45% of responses; all the others including yoga are covered for at least half, and at least 60% if you included therapies covered "for selected members for back pain."
3. Some CCOs reported provider shortages for yoga (27%), supervised exercise (10%) or intensive interdisciplinary rehab (36%).
4. Most CCOs require documentation of clinically significant progress toward therapeutic plan, either right away or after initial set of visits. 40% do not have this requirement. There were 3 comments:
    a. Not practical to implement
    b. We just approve 4 or 30
    c. We have found it difficult to consistently apply these criteria across our UR team….we plan on using InterQual
5. Most CCOs did not track outcomes from expanded coverage for therapeutic modalities from back pain other than cost. Outcomes reported:
    a. Of the 7 who tracked cost, 5 found negative outcomes for the CCO. Of these, 1 reported higher costs but reduced opioids and high MED opioids.
    b. 1 respondent reported positive outcomes for each of the following (patient satisfaction, provider satisfaction and health outcomes)
    c. 3 reported positive outcomes in terms of opioid use
    d. 1 reported that opioid use correlation was not clear
    e. 1 reported plans to evaluate cost and outcomes and impact on opioid use
6. Most (11/12) respondents are tracking therapies for back pain toward the combined limit in GL 56. One respondent commented that this is basically manual and some patients may get more.
7. Most CCOs have implemented acute prescribing limits or are planning to do so. 6 respondents said they are planning to implement 7 day maximums for acute prescribing:

	Have implemented	Planning to implement	Not planning to implement	Implemented in the past but no longer enforce	Total	Weighted Average
7 day maximum opioid prescription	33.33% 4	50.00% 6	16.67% 2	0.00% 0	12	1.83
Short acting agents only	61.54% 8	30.77% 4	7.69% 1	0.00% 0	13	1.46
Alternative medications tried	54.55% 6	18.18% 2	18.18% 2	9.09% 1	11	1.82
Plan to keep active	45.45% 5	9.09% 1	36.36% 4	9.09% 1	11	2.09
Consider alternate therapies	54.55% 6	9.09% 1	27.27% 3	9.09% 1	11	1.91
Lack of current or prior opioid misuse	45.45% 5	27.27% 3	18.18% 2	9.09% 1	11	1.91

Highlights of CCO Survey

For triggering a PA (this is the gateway; drugs that don't have a PA don't have other criteria applied), the most common methods are highlighted in green below.

Answer Choices	Responses
Nonpreferred brand drug	71.43% 10
Long-acting opioid	78.57% 11
Current prescription over a certain MED	71.43% 10
Total MMED for this patient over certain MED	50.00% 7
No prior opioid prescription for a certain time period (opioid naive)	21.43% 3
Prior authorization for all (or most) opioids	28.57% 4
Patient has high risk diagnosis (e.g. substance use disorder) on an earlier non-pharmacy claim	7.14% 1
Patients flagged as high risk (please describe below)	14.29% 2
Dose higher than previous dose	14.29% 2
Other (please describe)	14.29% 2
Total Respondents: 14	

For medications that do have a PA, the most common requirements are that the medication is for a funded condition and that there is a taper plan, but there are a variety of other criteria. 5 CCOs are implementing a hard stop at the end of the taper plan.

Answer Choices	Responses
Funded condition	92.31% 12
During first six weeks, <=7-day supply	30.77% 4
During first six weeks, prescribed with a plan to keep active and consideration of additional therapies such as spinal manipulation, physical therapy, yoga or acupuncture	23.08% 3
During days 45-90, treatment only with documented evidence of improvement of function of at least 30%	7.69% 1
If you checked the box above, and you required use of a validated tool (e.g. Oswestry, Neck Disability Index, SF-MPRQ or MSPQ), check here as well.	15.38% 2
During days 45-90, prescribed in conjunction with therapies such as spinal manipulation, physical therapy, yoga or acupuncture	30.77% 4
During days 45-90, prescribed with verification that patient is not high risk for opioid misuse or abuse.	15.38% 2
During days 45-90, each prescription is limited to 7 days	0.00% 0
During days 45-90, each prescription is limited to short acting only	30.77% 4
During first 90 days, short-acting agents only	46.15% 6

Highlights of CCO Survey

Answer Choices	Responses
During first 90 days, failure of first line pharmacologic therapy	38.46% 5
After 90 days no opioids (unless previously on long-term opioids)	23.08% 3
After 90 days require taper plan if previously on long-term opioids	76.92% 10
After taper plan ends, no opioids for back pain	38.46% 5
Responses Other (please specify)	15.38% 2

Proposed New Coverage for Chronic Pain

There was a variety of opinions about implementing an opioid guideline for a broader population. Concerns included cost, administrative burden and the need for comprehensive care and integrated behavioral health care, which is difficult to access.

Answer Choices	Responses
This would simplify administration	36.36% 4
This would complicate administration	36.36% 4
This would benefit our patients	36.36% 4
This could harm our patients	18.18% 2
The existing guideline needs to be reworked for implementability; then consider whether it should apply to other forms of chronic pain	27.27% 3
The existing guideline should be eliminated; coverage controls are not the best way to manage opioid therapy	9.09% 1
Other (see below)	9.09% 1
Responses Please add any additional thoughts below	36.36% 4
Total Respondents: 11	

There were some comments for this question:

Chronic pain is complex and requires successful integration of behavioral health, more coverage guidance without full SUD/BH integration is not likely to have a positive impact and would place additional administrative burden. Plans need maximum flexibility to meet this challenge.

Standardize MED for all.

This would require additional resources / time to review much larger population of patients for whom additional services will be requested, most of which will require authorization

GN 60 establishes best practice for managing back pain. I do not think it needs to be reworked. CCOs may implement as best meets their member needs and service area. Concern that expanding to other painful conditions may increase utilization of medications which may increase risk for side effects and drug interactions.

Q11-12 Most respondents (11/12) indicated plans for adopting opioid prescribing guidelines in their panels. Most comments referred to Oregon opioid guidelines, HERC guidelines or CDC guidelines and related to outreach/communications. Implementation was at various stages, from 2016 to "next 3-6 months."

Q15 Coverage of medications for back pain varies a fair bit. Lyrica and duloxetine have more limited coverage than other agents. Topical lidocaine, Lyrica and opioids are most likely to have PA.

	Cover without prior authorization	Cover with prior authorization	Never covered this medication	Planning to cover	Stopped covering	Total	Weighted Average
Topical lidocaine	20.00% 2	50.00% 5	30.00% 3	0.00% 0	0.00% 0	10	2.10
NSAIDS	100.00% 13	0.00% 0	0.00% 0	0.00% 0	0.00% 0	13	1.00
Acetaminophen	100.00% 13	0.00% 0	0.00% 0	0.00% 0	0.00% 0	13	1.00
Topical capsaicin	75.00% 6	12.50% 1	12.50% 1	0.00% 0	0.00% 0	8	1.38
Pregabalin (Lyrica)	0.00% 0	58.33% 7	41.67% 5	0.00% 0	0.00% 0	12	2.42
Gabapenten	91.67% 11	8.33% 1	0.00% 0	0.00% 0	0.00% 0	12	1.08
Duloxetine	72.73% 8	0.00% 0	27.27% 3	0.00% 0	0.00% 0	11	1.55
Benzodiazapines	41.67% 5	16.67% 2	33.33% 4	0.00% 0	8.33% 1	12	2.17
Muscle relaxants (e.g. cyclobenzaprine, robaxin, soma)	90.91% 10	9.09% 1	0.00% 0	0.00% 0	0.00% 0	11	1.09
Opioids	33.33% 4	66.67% 8	0.00% 0	0.00% 0	0.00% 0	12	1.67

Highlights of CCO Survey

Most CCOs would prefer HERC not address non-opioids in guideline

	Prefer HERC address this medication	Prefer HERC not address this medication	No preference	Total	Weighted Average
Gabapentin	16.67% 2	58.33% 7	25.00% 3	12	2.08
Pregabalin	33.33% 4	50.00% 6	16.67% 2	12	1.83
NSAIDS	8.33% 1	66.67% 8	25.00% 3	12	2.17
Duloxetine	8.33% 1	58.33% 7	33.33% 4	12	2.25
Other (please specify in comments)	25.00% 1	25.00% 1	50.00% 2	4	2.25

If a guideline for nonback chronic pain were to be developed, most respondents would want that guideline to address opioids, benzodiazipines, lyrica and lidocaine patches.

Answer Choices	Responses
Opioids	91.67% 11
Benzodiazipines	83.33% 10
Lyrica	91.67% 11
Gabapentin	50.00% 6
Lidocaine patches	58.33% 7
Tramadol	50.00% 6

Highlights of CCO Survey

Answer Choices	Responses
Duloxetine	33.33% 4
NSAIDs	0.00% 0
Acetominiphen	0.00% 0
None	8.33% 1

CCOs responses about cost analysis indicated cost concerns, especially related to acupuncture:

Covering acupuncture generates significant costs and requires PA implementation/enforcement.

Acupuncture was not effective in reducing opioid utilization or ED utilization for back pain

this is limited, but I can share

No info available at this time

Cost for chiropractic care has gone from $0 to ~$500K in 1 year for a plan covering 26,000 members.

yes, costs have increased related to expanding coverage

Which elements to include in ideal chronic pain guideline

Evidence-based treatment strategies that are effective, plus support to fund implementation of non-medication focused chronic pain treatment clinics.

Emphasis on supporting and encouraging those providers who deliver non-interventional, non-opioid treatments, and figuring out a way to eliminate any access to those providers who continually want to argue about what should be covered by OHP

All the evidence-based modalities and an evidence-based opioid tapers. What to do with opioids and benzos and marijuana. Encouraging pain education for providers and PATIENTS.

The more specifics the better. For example, listing what therapies for what length of time are covered. This is really helpful in keeping things standard across health plans so that patients can use what one plan does as an argument for what another plan does.

Cover only therapies (non-pharmacologic and pharmacologic) with a strong body of evidence to support positive outcomes with treatment and sustainability.

Coverage and active promotion of alternative therapies. Guideline Note 56 introduces a barrier to alternative treatments, which can further promote use of opioids or other medications for pain relief.

Highlights of CCO Survey

Regional Multi-disciplinary Centers that emphasized CBT and PT and little or no Rx/interventions. PCPs would refer all of their patients there.

Guideline to be based on the evidence; specific quantity limits or duration limits for treatments, specific guidance (and ability to exclude coverage) for medications and interventions that do not have evidence of effectiveness; measurable tools for documenting improvement or positive patient outcomes; guidance as to when medications and treatments should be discontinued

This report was commissioned by states participating in the Medicaid Evidence-based Decisions Project (MED). MED participating states have agreed to make this report publically available.

Tapering or Discontinuing Opioid Use Among Patients With Chronic Noncancer Pain: Update Report

Participant Request

November 2018

Center for Evidence-based Policy
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Overview

As state Medicaid and public health program administrators develop approaches to encourage tapering and discontinuing opioid medications, they need up-to-date information on the benefits and harms of these practices. A 2017 Medicaid Evidence-based Decisions Project (MED) report on this topic concluded that there was limited evidence on harms associated with tapering strategies, and the findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction.[1] Confidence in these findings was limited by the overall very low quality of evidence.[1]

This MED report updates the clinical evidence section of the previous report and synthesizes evidence on patient-initiated versus non-patient-initiated opioid tapering and discontinuation. Center researchers identified 9 new observational studies, all of poor methodological quality; the studies' findings were consistent with previous evidence.

Key Findings

- We identified 9 observational studies published since the last MED report:
    - 4 studies of individualized tapering developed by health care providers in partnership with patients
    - 2 studies of multidisciplinary pain programs
    - 2 studies in a cohort of patients with and without substance use disorders (SUD) whose clinicians had discontinued their opioid therapy
    - 1 study of a health plan-initiated dose reduction and risk mitigation program
- We rated all the newer studies as having poor methodological quality.
- The new evidence was consistent with previous evidence and did not raise the overall quality of the evidence ratings from very low for any of the following outcomes:
    - Reduction in morphine milligram equivalents (MME)
    - Pain and function
    - Adverse events
- A study using U.S. Department of Veterans Affairs (VA) data of patients who underwent clinician-initiated opioid discontinuation (primarily for aberrant behaviors) found that self-identified Hispanic ethnicity, posttraumatic stress disorder (PTSD) diagnosis, and psychotic-spectrum disorder diagnoses were correlated with suicidal ideation and self-harm in the 12 months after clinician-initiated opioid discontinuation.
- Other new studies did not report information on serious adverse events such as mortality, suicide, or overdose events.
- One newer study reported no differences in pain outcomes for patient-initiated or clinician-initiated opioid discontinuation 12 months after discontinuation.
- We were not able to draw any conclusions regarding rapid versus slow tapering.

Background

Opioids are frequently prescribed to treat chronic noncancer pain, but there is a lack of evidence for their effectiveness.[2] A systematic review conducted in 2015 found insufficient evidence to determine the effectiveness of long-term opioid therapy for improving pain and function.[2] Opioids have not been shown to be superior to nonopioid analgesics in head-to-head trials of up to 4 weeks' duration in terms of efficacy, safety, or tolerability.[3] A 2017 MED report found that for multiple indications including chronic noncancer pain, nonopioid analgesics were not significantly different or were significantly better than opioids for relieving pain.[4] According to the Centers for Disease Control and Prevention (CDC), there were more than 22,000 deaths from prescription opioids in 2015.[5] In light of this evidence, and in an attempt to stem the opioid epidemic, clinical practice guidelines recommend tapering and discontinuing opioid therapy for patients with chronic noncancer pain whenever possible.[6-8]

Key Questions

What is the evidence for the effectiveness and harms of various strategies for tapering or discontinuing opioids among adult patients with chronic noncancer pain? Do the effectiveness or harms of these strategies vary by the following:

a. Medication type or dosing level (e.g., particular agent, long- vs. short-acting formulation, single-drug vs. combination agent)
b. MME at the time of taper initiation or discontinuation
c. Population characteristics (e.g., diagnosis, length of time of opioid use, age, gender, comorbidities, social status, other drugs/medications (e.g., benzodiazepines, cannabinoids)
d. Patient initiated vs. non-patient initiated
e. Tapering supports (e.g., behavioral interventions, additional therapeutic modalities including pain education, other medications)
f. Rapid vs. slow tapering

PICO

Population

- Adult patients (18 years and older) using opioids for chronic (6 months or longer) noncancer pain

Interventions

- Interventions to taper opioid dose or discontinue opioid treatment

Comparators

- No tapering
- Different opioid discontinuation or tapering strategies (head-to-head comparisons)
- No comparison

Effectiveness and Harms Outcomes

- Opioid abstinence (successful discontinuation)

- Dose reduction as a percentage of MME (a measure of success with tapering)
- Self-reported pain
- Self-reported quality of life
- Self-reported function
- Mortality (including suicide, accidental overdose, other causes)
- Adverse events (e.g., overdose)

Study Designs

- Any interventional study, with or without a comparison group

Methods

We searched Ovid MEDLINE for new studies, starting from the beginning of 2017. We excluded studies involving only patients who were incarcerated or under court order related to opioid use, and studies with interventions that were not FDA-approved (e.g., cannabis). For adverse event outcomes, we reported any event that was found to be statistically significantly different between groups or had at least a 10% difference between groups. We also contacted the first author of the Frank et al.[9] systematic review to ask if there were additional studied their group had located as they looked to update their work.

Findings

Previous MED Report

The previous MED report was based on a good-quality systematic review conducted by Frank et al.[9] The systematic review included 67 studies (11 RCTs and 56 observational studies) and categorized the interventions into 8 types:

1) Interdisciplinary pain programs (31 studies), defined as "intensive multimodal treatment with an interdisciplinary team, typically organized around a biopsychosocial model of chronic pain"
2) Buprenorphine-assisted dose reduction (10 studies)
3) Behavioral interventions (6 studies), such as cognitive behavioral therapy, meditation, motivational interviewing, and self-management education
4) Detoxification with pharmacological support from drugs such as clonidine and benzodiazepines to manage withdrawal symptoms (4 studies)
5) Interventions requiring an inpatient procedure such as rapid discontinuation with lidocaine infusion or anesthesia (4 studies)
6) Ketamine-assisted dose reduction (4 studies)
7) Acupuncture (3 studies)
8) Other outpatient programs that did not fit into other categories (5 studies)[9]

Frank et al. identified 40 studies that reported the effect of dose reduction or discontinuation of long-term opioid therapy on patient outcomes, including pain, function, quality of life, opioid

withdrawal, substance use, and adverse events.[9] No study was rated as having good methodological quality, and Frank et al. downgraded the overall quality of evidence to very low for each of these outcomes using the GRADE framework.[9] Frank et al. also rated the overall quality of evidence as very low for effectiveness of strategies to reduce or discontinue opioids, based on serious risk of bias and indirectness.[9]

From the Frank et al. review and 1 additional poor-methodological-quality observational study, the previous MED report concluded that there was scant evidence on harms associated with tapering strategies, and the findings suggested that pain, function, and quality of life might improve during and after opioid discontinuation or dose reduction.[1] The confidence in these findings was limited by the very low quality of evidence overall.[1]

Overview of New Studies

We did not identify any systematic reviews or RCTs published since the end date of the searches in the last report. We included 9 observational studies published since the last MED report.[10-18] Details of the design, population characteristics, interventions, and results of the new studies are in Appendix B. Four studies (2 of interdisciplinary pain clinics, 1 of an interdisciplinary chart review, and 1 of clinician-initiated discontinuation) used a single-arm, before-after design with no control group.[10,13,15,17] Two studies compared patients who were offered, but did not participate in, a primary care-guided tapering intervention to those who did receive the intervention.[14,16] One study conducted at an outpatient interdisciplinary pain clinic compared changes over time in patients with chronic pain who were using opioids at baseline to those who did not use opioids,[12] and one compared patients enrolled in a health plan that initiated an opioid dose reduction initiative to patients from a different health plan who received usual care.[18] One case-control study used a VA database to identify patients whose clinicians had discontinued their opioid medications, and compared patients with suicidal ideation or self-harm in the 12 months after discontinuation to patients who did not have such behaviors on various clinical and patient factors.[11]

All but one study (conducted at a pain clinic in central London) took place in the United States.[13] Six interventions were conducted in primary care settings,[11,14-18] including 4 in VA clinics.[11,15-17] Two studies were conducted in outpatient pain clinics[10,12] and 1 in a residential pain treatment program.[13] Six studies were conducted at single centers.[10,12-14,16,17]

Methodological Quality of New Studies

We rated all 9 of the new studies as poor methodological quality (Appendix B, column 1). We rated 5 studies as poor quality because they had no control group.[10,11,13,15,17] We rated the others as poor quality because of a combination of serious methodological flaws including differences between groups at baseline,[12,14,16,18] lack of control for confounding,[14,16] unblinded outcome assessment,[16,18] very high loss to follow-up (e.g., 58% at 6 months in the study by Gilliam et al.[12] and 38% in the study by Darnall et al.[10]), or a very low response rate (e.g., 39.7% in the intervention group in the Thakral et al. study[18]).

Reduction in MME and Opioid Discontinuation Rates

The systematic review by Frank et al. included 67 studies that reported the effectiveness of strategies to reduce or discontinue long-term opioid treatment (3 good methodological quality, 13 fair, 51 poor).[9] The studies were heterogeneous with regard to patient populations, study completion, and rates of opioid reduction and discontinuation.[9] Although rates of successful discontinuation of opioids differed across intervention categories, the review authors could not make conclusions about the comparative effectiveness of different interventions given this heterogeneity.[1] The reviewers rated the overall quality of the evidence for these outcomes very low using the GRADE framework, downgrading the rating because of serious risk of bias and indirectness.[9]

Four of the 9 studies reported a statistically significant reduction in MME from baseline to follow-up.[10,12,13,16] Two of these studies reported results only for the subset of patients that completed the study (62% of patients in the Darnell et al. study provided 4-month follow-up data [10] and 42% of patients in the Gilliam et al. study provided 6-month follow-up data[12]). One small study of 32 patients did not find a reduction in MME after initiation of a structured monitoring plan of unspecified duration in a rural primary care office,[14] and another study reported dose reductions in some patients, but not patients on the highest doses (1,000 mg or higher).[17] Two studies reported different analyses of a VA patient population that had discontinued long-term opioid therapy, either clinician-initiated or a mix of clinician- and patient-initiated.[11,15] Reduction in mean MME was not assessed in the health system initiative study or in the VA database studies.[11,15,18] In the study by Oldfield et al., patients in the intervention group were more likely to have a trial of buprenorphine (62% vs. 2%, $P < 0.01$) and had greater reductions in MME than patients in the control group: 30 mg (interquartile range [IQR] 0–120) vs. 0 mg (IQR 0–20 decrease, $P < 0.01$).[16] Overall, the new evidence is consistent with previous evidence and does not change the rating of the quality of the evidence, which remains very low.

Pain and Function

In the systematic review conducted by Frank et al., 8 of 8 fair-quality studies that measured pain severity reported improved pain.[9] Of 28 poor-quality studies, 21 reported improved pain, 4 reported no change, and 3 reported worse pain.[9] Five of 5 fair-quality studies reported improved function.[9] Of 12 poor-quality studies, 8 reported improved function, 2 reported no change, and 2 reported decreased function.[9] Using the GRADE framework, the reviewers rated the overall quality of the evidence very low quality because of serious risk of bias in the individual studies.[9]

The new studies we identified for this update had findings that were consistent with the previous evidence. Six studies assessed self-reported pain using numeric scales or surveys or assessed function using self-reporting or provider-delivered tests such as the 6-minute walk test. [10,12-15,18] No study found an increase in pain or decreased function after the interventions; all of the studies found either decreased pain or no change compared to baseline.[10,12-15,18] For example, McPherson et al. found that for all patients, on average, pain intensity scores

decreased by one-tenth of a point per month in the 12 months after opioid discontinuation.[15] Because these studies had a high risk of bias, the overall strength of the evidence remains very low for pain and function outcomes.

Adverse Events

Mortality, Suicide, or Overdose

Only 11 studies included in the systematic review by Frank et al. (all poor methodological quality) assessed adverse events.[9] Five of the 11 assessed mortality, and 1 opioid-related overdose death was reported in 1 study of an outpatient program that offered buprenorphine-assisted dose reduction.[9] The overdose death occurred several months after the patient discontinued buprenorphine.[9]

A retrospective cohort study conducted in a VA population whose opioid therapy was discontinued by their clinician (primarily for aberrant behaviors) reported that 12% of the cohort had documented suicidal ideation and nonfatal suicidal self-directed violence (SSV) in the 12 months after opioid discontinuation.[11] This study identified Hispanic ethnicity (adjusted odds ratio [OR] 7.25 (95% CI 1.96–27.18), PTSD diagnosis: 2.56 (1.23–5.32), and psychotic-spectrum disorder diagnoses (OR 3.19; 95% CI 1.14 to 8.89) were correlated with suicidal ideation and SSV in the 12 months following clinician-initiated opioid discontinuation.[11] Other clinical and patient factors were not statistically significant in the models.[11]

None of the other new studies we identified for this update assessed or provided any information on mortality, suicide, or overdose outcomes.

Opioid Withdrawal Symptoms

In the systematic review by Frank et al., 18 studies (3 fair and 15 poor methodological quality) reported opioid withdrawal symptoms.[9] Rates of withdrawal symptoms ranged widely across the studies (0% to 100%).[9] In 4 studies, all patients reported withdrawal symptoms.[9] Frank et al. rated the overall quality of the evidence for this outcome as very low quality using the GRADE framework, downgrading the evidence for serious risk of bias and inconsistency.[9]

The new studies we identified for this update did not provide information on withdrawal symptoms experienced by patients receiving the interventions.

Subgroup Analyses

Differences in Outcomes Based on Opioid Type or MME at Baseline

The previous MED report concluded that there was inadequate reporting and analysis to evaluate differences in the effectiveness or harms of tapering or discontinuation of opioid therapy based on the type of opioid (long- vs. short-acting), number of opioids prescribed, or total MME.[1]

The newer studies contained little additional information. In the VA database study, average MME at baseline did not correlate with pain score trajectories in the 12 months after opioid

discontinuation in an adjusted analysis, although pain score prior to discontinuation did correlate with pain at a year after discontinuation.[15] McCann et al. reported that patients who elected to wean off their opioid medication had a statistically lower initial MME, but the study authors did not analyze results by initial MME in the group that attempted to taper.[14] Darnell et al. found that the likelihood of patients voluntarily decreasing their dose by more than 50% was not predicted by their starting dose.[10] Similarly, Gilliam et al. reported that additional stratification by low-dose (< 50 mg MME) versus high-dose (≥ 50 mg MME) groups did not alter the interpretation of the results, and therefore analyses were conducted comparing the broader categories of opioid and nonopioid use groups.[12]

Patient-Initiated Versus Non-patient-Initiated Tapering or Discontinuation

Policymakers and clinicians are interested in information on the effect of tapering when it is not initiated by the patient (i.e., mandatory or provider-initiated dose reductions or restrictions on opioid prescribing), but we found very little information on this issue. In almost all of the studies included in the previous MED report and in this update, patients had some autonomy in the decision to taper their opioids. We excluded studies in patients who were incarcerated or under court order, populations that might undergo involuntary dose reductions or discontinuation.

One study included in the systematic review by Frank et al. concerned tapering via a 120 mg MME opioid dose limitation policy at an academic primary care clinic.[19] However, 63% of patients on high doses (defined as >120 mg MME per day for 4 months or longer) did not actually reduce their dose below 120 mg MME after the policy's initiation.[19]

The VA database studies provide some new information related to clinician-initiated opioid discontinuation.[11,15] McPherson et al. found that, in adjusted analyses, the reason for discontinuation (patient-initiated vs. clinician-initiated) was not correlated with pain score trajectory.[15] Demidenko et al. excluded patients who initiated discontinuation of their opioid therapy (n = 91; 15.2%), and so this study did not provide comparative evidence about patient-initiated versus clinician-initiated discontinuation on suicidal ideation or SSV outcomes.[11] Approximately 75% of the clinician-discontinued patient group in the Demidenko et al.[15] study had opioids stopped because of aberrant behaviors such as abnormal urine drug test results, opioid diversion, and drug misuse. Of the total sample of 509 patients, 59 had suicidal ideation or SSV documented in their charts; 47 had suicidal ideation alone, and 12 had SSV.[15] Half of these patients attempted suicide with overdoses of prescription medications, primarily benzodiazepine drugs.[15] Fifteen of the 59 patients had previous suicidal ideation or SSV events before discontinuation of opioid therapy.[15]

We identified 1 new study that compared mandatory opioid dose reduction in a health system in Washington to usual care.[18] In 2007, the health system initiated a dosing threshold of 120 mg MME per day and providers with patients over this threshold were given supervisory guidance by medical directors.[18] In 2010, the health system added risk mitigation strategies including a risk-stratified schedule for frequency of urine drug screening and follow-up visits, treatment

contracts, care plans, modified refill processes, an online continuing education course for providers, care practice tools integrated into electronic medical records, and on-site resources for consultation.[18] Patients from clinics that were not affiliated with the health plan but that accepted the health plan's insurance served as a usual care control group (n = 653).[18] Patient-reported pain outcomes, including depression, were collected through interviews conducted in 2014 and 2015.[18] The researchers found no indication that patients in the intervention clinics had clinically meaningful differences in pain intensity, interference with activities and enjoyment of life, or depressive symptoms compared with control group patients.[18] We rated this study as poor methodological quality based on differences between the comparison groups at baseline that were not controlled for in analyses, unblinded outcome assessment, and a very low response rate to the interviews (37.5% in the intervention group and 27.8% in the control group).[18]

Differences in Outcomes Based on Population Characteristics

The previous MED report found that there was insufficient evidence to evaluate differences in outcomes based on type of chronic pain diagnosis, length of time of opioid use, age, gender, comorbidities, social status, or use of other drugs or medications.[1]

The new studies we identified for this update either did not analyze outcomes according to population characteristics, or did not find differences in outcomes based on population characteristics. Darnall et al. found that the likelihood of a greater than 50% opioid dose reduction was not predicted by baseline pain intensity, years prescribed opioids, or any psychosocial variable.[10] Guildford et al. found that demographic and pain variables did not correlate with changes in medication use.[13] Three additional studies were conducted exclusively within the VA system.[11,15,16] The other studies did not report subgroup analyses by population characteristics.

Tapering Supports

The systematic review by Frank et al. found that buprenorphine-assisted dose reduction and other detoxification programs using nonopioid drugs to support tapering showed as many as 90% of patients discontinuing opioids, whereas only 20% to 21% of patients discontinued opioids with other outpatient programs and behavioral interventions.[9] The authors of the previous MED report concluded that, because there was heterogeneity across interventions in regard to method, duration, route, dose, and frequency, and the studies lacked long-term follow-up and were of poor methodological quality, the data did not support assessment of comparative effectiveness of different models of care or opioid-tapering protocols.[1]

The new studies we identified for this update included a wide range of interventions, from an intensive, residential multidisciplinary pain program,[13] to individualized tapering developed in consultation with primary care providers,[14] to a health-systemwide multifaceted risk reduction intervention.[18] Because the studies were heterogeneous and were of poor methodological

quality, it is not possible to draw conclusions from this body of evidence about which tapering supports are more effective or safer than others.

Rapid Versus Slow Tapering

The previous report identified no evidence comparing rapid versus slower tapering or discontinuation.[1] The systematic review by Frank et al. reported that 7 of 8 fair-quality observational studies that evaluated patient outcomes were considered rapid tapering programs (conducted over 3 to 6 weeks).[9] They noted that these programs used intensive, multidisciplinary teams and were likely to have different outcomes than programs conducted in outpatient settings with less support.[9]

In a new study identified for this update, patients were given the option of a slow taper or rotation to buprenorphine.[16] The pace of tapering was flexible and developed with patient input, but generally started at a reduction of 5% of total daily dose every 2 to 4 weeks.[16] Of 66 veterans who engaged in the Opioid Reassessment Clinic, 24 (37%) opted for the slow taper.[16] Results were not presented by slow versus rapid tapering groups.[16]

The intervention in the study by Darnall et al. was a slow, individually designed taper conducted over 4 months.[10] In the interdisciplinary pain program described in Gilliam et al., tapering occurred over a mean of 10 days for patients receiving less than 100 mg MME, but could be slower for patients with a longer duration of opioid use (more than 2 years).[12] Response was monitored and adjusted as needed.[12]

Summary and Discussion

The previous MED report found very low-quality evidence that several types of interventions could be effective to reduce or discontinue long-term opioid therapy and that pain, function, and quality of life might improve with opioid dose reduction.[1] Although many studies reported positive dose-reduction outcomes, the systematic review by Frank et al. rated the overall quality of the evidence as very low for the effectiveness of all interventions to reduce or discontinue long-term opioid therapy because of methodological limitations across studies and an absence of adequately powered randomized trials.[9]

We identified 9 new studies published since the last report; these studies' findings for most outcomes were consistent with previous evidence. Because of their poor methodological quality, the new evidence does not change the rating of the overall quality of the evidence. Importantly, the preponderance of evidence from both the systematic review by Frank et al.[9] and more recent studies indicates that tapering or discontinuation of opioid therapy is not associated with increased pain, and may be associated with reduced pain and improved functional outcomes. One study conducted within the VA did identify suicide risk among a group of patients with clinician-initiated discontinuation of opioid therapy.[11] However, this study was also of poor methodological quality and the overall strength of evidence for this finding is very low.

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Appendix A. Clinical Evidence Methods

Search Strategy

We searched Ovid MEDLINE to identify systematic reviews (with and without meta-analyses), technology assessments, randomized controlled trials (RCTs), and observational studies that met the report scope using multiple terms for opioid medications, pain, and tapering or discontinuation. We limited searches to citations published after 2016. The full Ovid MEDLINE search strategy is listed below. We also contacted the lead author of the systematic review by Frank et al.[9] to ask whether they were aware of additional studies published since their review was completed.

Ovid MEDLINE Search Strategy

Database: Ovid MEDLINE(R) <1946 to September Week 1 2018>

1 (exp analgesics, opioid/ or codeine/ or hydrocodone/ or morphine/ or oxycodone/) and tu.xs. (65432)

2 (Opioid* or opiate* or codeine or clonidine or morphine or hydrocodone or oxycodone).tw,kf,rn. (134935)

3 ((pain/ or exp musculoskeletal pain/ or exp back pain/ or exp chronic pain/ or exp facial pain/ or exp headache/ or metatarsalgia/ or neck pain/ or exp neuralgia/ or exp nociceptive pain/ or pain, intractable/ or pain, referred/ or exp arthralgia/ or eye pain/ or flank pain/ or glossalgia/ or exp headache/ or exp pelvic pain/ or shoulder pain/) and dt.fs.) or "Pain Measurement"/ or Pain Threshold/ (129672)

4 pain.tw,kf,rn. (472472)

5 1 or 2 (159888)

6 3 or 4 (505637)

7 5 and 6 (45764)

8 (Taper* or wean* or (dose* adj1 reduc*) or detox* or withdraw* or discontinuat* or cessation or tolerance or conversion or substitution).tw,kf,rn. (702531)

9 7 and 8 (5906)

10 limit 9 to (english language and humans) (3262)

11 limit 10 to yr="2017 -Current" (241)

Inclusion Criteria

Any study design

Exclusion Criteria

We excluded studies if they were not published in English and studies involving only patients who were incarcerated or under court order related to opioid use and studies of interventions that were not FDA approved (e.g., cannabis).

Quality Assessment

We assessed the methodological quality of the included systematic reviews and cohort studies using standard instruments developed and adapted by MED that are modifications of instruments used by several respected organizations.[20-25] One experienced researcher independently rated the methodological quality of included studies.

Systematic Reviews

If a meta-analysis or network meta-analysis was conducted, the methodological quality of the analyses was considered in the overall rating for the systematic review. In brief, good-quality systematic reviews include a clearly focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to assess study quality and select studies for inclusion (e.g., randomized controlled trials), and assessment of similarities between studies to determine whether combining them is appropriate for evidence synthesis. Fair-quality systematic reviews have incomplete information about methods that might mask important limitations or a meaningful conflict of interest. Poor-quality systematic reviews have clear flaws that could introduce significant bias.

Quasi-experimental Studies

Good-quality quasi-experimental studies have a control group that is unexposed to the intervention being studied; methods are in place to prevent contamination bias; pre- and post-measures are done concurrently; and participant characteristics are balanced between groups or controlled for by propensity scores and/or statistical adjustment. Fair-quality quasi-experimental studies have incomplete information about methods that might mask important limitations, a meaningful conflict of interest, or are at risk for contamination bias. Poor-quality quasi-experimental studies do not have a control group (i.e., before and after studies or interrupted time series) or have other clear flaws that could introduce significant bias.

Cohort Studies

Good-quality cohort studies include a sample that is representative of the source population, have low loss to follow-up, and measure and consider relevant confounding factors. Good-quality cohort studies also list their funding source(s) and have a low potential of bias from conflicts of interest. Fair-quality cohort studies might not have measured all relevant confounding factors or adjusted for them in statistical analyses, have loss to follow-up that could bias findings, consist of a sample that is not representative of the source population, or have potential conflicts of interest that are not addressed. Poor-quality cohort studies have a clear, high risk of bias that would affect findings.

Quality of Evidence Assessment

Overall Quality of Evidence

We assigned each outcome a summary judgment for the overall quality of evidence based on the system developed by the Grading of Recommendations, Assessment, Development, and Evaluation Working Group (GRADE).[26,27] The GRADE system defines the overall quality of a body of evidence for an outcome in the following manner:

- **High:** Raters are very confident that the estimate of the effect of the intervention on the outcome lies close to the true effect. Typical sets of studies are randomized controlled trials with few or no limitations, and the estimate of effect is likely stable.
- **Moderate:** Raters are moderately confident in the estimate of the effect of the intervention on the outcome. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is different. Typical sets of studies are randomized controlled trials with some limitations or well-performed nonrandomized studies with additional strengths that guard against potential bias and have large estimates of effects.
- **Low:** Raters have little confidence in the estimate of the effect of the intervention on the outcome. The true effect may be substantially different from the estimate of the effect. Typical sets of studies are randomized controlled trials with serious limitations or nonrandomized studies without special strengths.
- **Very low:** Raters have no confidence in the estimate of the effect of the intervention on the outcome. The true effect is likely to be substantially different from the estimate of effect. Typical sets of studies are nonrandomized studies with serious limitations or inconsistent results across studies.
- **Not applicable:** Researchers did not identify any eligible articles.

Appendix B. Evidence Table: Observational Studies of Opioid Tapering or Discontinuation

Author, year Quality	Design, Setting, Years, Country, and Funding Source	Sample Size (N) and Characteristics Baseline Opioid Use and Dose (MME)	Intervention Control Condition	Main Results
Darnall et al., 2018 Poor	Before-after Community pain clinic, years NR, U.S. National Institutes of Health and National Center for Complementary and Integrative Health	N = 110 Mean age 51 (SD 12) years 60% female Race NR Median 6-year (IQR, 3-9) duration of opioid use Median 288 mg (IQR, 153-587 mg)	Physicians offered to partner with patients to slowly reduce their opioid dosages over 4 months. Patients received a self-help book on reducing opioid use, and a slow, individually designed taper. Opioid dosages were reduced up to 5% for up to 2 dose reductions in month 1. In months 2 to 4, patients were asked to further reduce use by as much as 10% per week; dose decrements were tailored to the patient. No control group	Of 110 eligible patients, 82 (75%) agreed to taper their opioid dosages 51/82 (62.2%) completed the study (provided 4-month follow-up data) No increase in pain intensity (P = 0.29) or pain interference (P = 0.44) MME for completers at 4 months: 150 mg, IQR, 54-248mg (P = 0.002 vs. baseline) The likelihood of a greater than 50% opioid dose reduction was not predicted by starting dose, baseline pain intensity, years prescribed opioids, or any psychosocial variable.
Demidenko et al., 2017 Poor	Before-after VA Health System, 2012, US U.S. Department of Veterans Affairs Substance Use Disorder Quality	N = 509 Mean age 55.0 (SD 10.4) years 5.7% female 70.7% white, 16.9% black, 2.2% Hispanic, 10.2% other/unknown	Discontinuation of opioid therapy by a clinician. Overall, 75% of patients were discontinued because of aberrant behaviors, and 7.3% because of patient safety concerns. Subjects included patients with non-fatal suicidal self-directed violence (SSV) or suicidal ideation (SI) documented in the medical record in the 12 months after discontinuation of opioids (N = 59), and patients without SSV or SI documented in	Of the sample of 600 patients, 91 were excluded because the patient initiated discontinuation of therapy (15.2%) Variables associated with an increased likelihood of SI/SSV in the year after discontinuation (adjusted OR, 95% CI): Self-identified Hispanic race: 7.25 (1.96–27.18) PTSD diagnosis: 2.56 (1.23–5.32)

	Enhancement Research Initiative and U.S. Department of Veterans Affairs Health Services Research and Development	Mean MME 75.7 (SD 89.6) mg	the medical record in the 12 months after discontinuation of opioids N = 450.	Psychotic-spectrum disorder diagnosis: 3.19 (1.14–8.89) Variables not significant in adjusted analyses: Age, male gender, white or black race, Elixhauser Medical Comorbidity Index, any Veterans Health Administration service-connected disability, bipolar disorder, other anxiety disorders, substance use disorder diagnosis, tobacco use disorder diagnosis, type of chronic pain diagnosis (musculoskeletal, neuropathic, or migraine), sleep disorder diagnosis, clinical care variables (prescribed benzodiazepine in the year prior to discontinuation, average MME in the year prior to discontinuation, reason for discontinuation of opioid therapy (aberrant behavior or patient safety concerns)
Gilliam et al., 2018 Poor	Prospective cohort Pain clinic, January 2015 to December 2015, U.S. Funding NR	N = 285 (142 patients taking opioids and 143 not taking opioids) Mean age 49.26 (SD 14.34) 62.8% female 88.7% white	Intensive, outpatient interdisciplinary rehabilitation program focusing on functional restoration. Combines functional restoration with cognitive-behavioral therapy as its chief components. The treatment model entails concurrent treatment by multiple disciplines including physicians, psychologists, vocational rehabilitative specialists, nurses and clinical nurse specialists, physical therapists, occupational therapists, pharmacists, chemical dependency counselors, and dieticians. The treatment program is 15	42% of participants who completed the program returned 6-month post-discharge questionnaire data assessing medication use and physical and emotional functioning All patients completed the taper and discontinued opioid medication For pain, function, and quality of life outcomes, opioid group and time period interactions were not statistically significant, indicating that patients improved irrespective of groups status (opioid use at baseline or not).

		Duration of pain 10.83 years (SD 10.34) Current opioid use 49.8% 12.7% were taking opioids "as needed" but not daily; 51.5% were taking 1 to 40 mg per day; 26.3% were taking 41 to 90 mg per day; 25.3% took more than 90 mg. Patients reported taking opioids for a mean (SD) of 5.8 (4.9) years Mean MME 66.2 mg Median 40.0 mg (4-330 mg)	days in duration. Patients attend programming for 8 hours daily for 15 consecutive working days. Control condition: Pre-post analysis of patients who were using vs. not using opioids at baseline	There were no between-group differences comparing the low and high opioid groups
Guildford et al., 2018 Poor	Before-after Specialty pain service in central London, UK August 2014 to April 2016	N = 452 Mean age 46.3 (SD 12.47) years 76.8% white Median pain duration 104	4-week, residential, interdisciplinary, group-based pain management program No control group	35 people (8%) did not provide posttreatment data because they dropped out of treatment. A further 61 (14%) did not provide posttreatment data but did not drop out of treatment. Statistically significant reductions were observed for all treatment outcomes and

	National Institute for Health Research Biomedical Research Centre at South London and Maudsley NHS Foundation Trust and King's College London	(range 4-703) months Mean MME 64.6 (SD 97.7) mg Median 25 mg (IQR 94.5) At the start of treatment, 71 people (16.3%) were taking doses of 120 mg/24 hours total MME or greater		process measures. Large effect sizes were observed for depression and pain interference. Medium effect sizes were observed for average pain intensity, functioning (as measured by the Work and Social Adjustment scale), walking, pain acceptance, and committed action. Small effect sizes were observed for total morphine equivalent dose, number of classes of medication, insomnia, acceptance, and decentering. The average effect size was 0.55 and ranged from 0.17 for cognitive fusion to 1.11 for pain interference. Of patients taking doses of 120 mg MME or greater at the start of treatment, 52.3% made a clinically significant reduction in MME. Demographic and pain variables did not correlate with changes in medication use.
McCann et al., 2018 Poor	Retrospective cohort One rural primary care provider practice, March 2014 to September 2015 West Virginia, U.S. Funding NR	N =32 Mean age 66.86 (range 48-81) 31% female Race NR Mean MME 24.98 mg (overall) 30.61 (SD 19.03) mg (those who	Structured monitoring plan. A list of patients with chronic noncancer pain on opioid medications was generated from a targeted search of the electronic health record of a single rural practitioner's practice to ensure that all qualifying patients in this group were notified of the specifics 3 months before the change in practice. The notification letter explained that this change was to improve care and to become compliant with both legal and professional obligations. Protocol options for the patients were to continue opioid	17 (52%) remained on opioid medications, 12 (38%) stopped opioid medications, and 3 (9%) were transferred or referred to other physicians. MME at follow-up of the 17 who remained on opioids: Mean 28.84 (SD 18.6; range 3.3–60); P = 0.457 vs. baseline Patients who elected to wean off opioid medications had a statistically lower initial MME.

		remained on opioids) 17.01 (SD 12.52) mg (those who weaned off)	medication management of their chronic pain, manage their pain without opioids, or be referred to another provider for pain management. One day each month was dedicated solely to the management of chronic pain patients on opioid medication in 1-hour blocks. Before each visit, the patients completed a packet of information pertinent to chronic pain. The data for the above history and tools were completed by the patient and available to the clinician before the visit. The packet also included information regarding the safe disposal of medication, chronic pain and the different options for treatment, opioid medication side effects, and abuse/dependency. A structured clinical note was created detailing the dates of last drug screen, the date of signing of chronic pain agreement, the date of the last review of the controlled substance database, the data from the patient-completed packet noted above as well as structured history, examination, assessment, and plan Control condition: Patients who opted to remain on opioids	Depression, pain, and quality-of-life scores demonstrated stability through the time studied

McPherson et al., 2018 Poor	Retrospective cohort VA Health System, 2012, US U.S. Department of Veterans Affairs Substance Use Disorder Quality Enhancement Research Initiative and U.S. Department of Veterans Affairs Health Services Research and Development	N = 600 (300 with a SUD and 300 without a SUD) Mean age 54.63 (SD 10.96) years 5.3% female 71.1% white, 15.6% black, 2.5% Hispanic, 10.7% other/unknown Average daily dose 75.8 mg MME	Discontinuation of opioid therapy by a clinician; 15.4% of discontinuations were patient-initiated No control	551/600 patients (91.8%) had valid pain intensity scores and were included in the analysis Pain scores decreased, on average across all patients, by approximately one-tenth of a point on the NRS per month for the year after opioid discontinuation Patients' average pre-discontinuation pain scores were significantly related to pain score slope after long term opioid therapy discontinuation -0.018 (0.008); *P* < .05 The higher an individual's average pain before discontinuation, the less reduction in pain the patient experienced over time after opioid discontinuation. No other covariates were associated with change in pain across the 12-month post-discontinuation period (diagnoses, comorbidities, other clinical variables, or reason for discontinuation of therapy [patient initiated vs. clinician initiated)
Oldfield et al., 2018 Poor	Retrospective cohort Multidisciplinary clinic in a primary care setting in a	N= 105 (66 intervention, 39 control) Mean age 62 (SD 11) 5.6% female	Opioid Reassessment Clinic (ORC): During initial assessment, patients are assessed for OUD. If they are diagnosed with OUD, they are presented with the option of transitioning to 1 of 2 opioid agonist treatments: methadone or buprenorphine. While patients may receive buprenorphine in the ORC, if the	The intervention group demonstrated a median (IQR) decrease of 30 (0–120) mg vs. the control group, for whom no decrease was detected (0 mg change, IQR, 0–20 mg increase); *P* < 0.01 Patients in the intervention group were more likely to trial buprenorphine (62% vs. 2%, *P* < 0.01) and had greater reductions in

	Veterans Health Administration hospital, U.S. March 1, 2016, to March 1, 2017	83.8% white MME median (IQR) 85 (35-180) mg (intervention) 60 (30-156) mg (control)	patient requires more structured support than the ORC can provide or if the patient opts for methadone therapy, the patient is referred via warm handoff to specialty addiction treatment settings at the same Department of Veterans Affairs facility. Patients who do not have OUD but demonstrate physiological opioid dependence where the benefits of LTOT do not outweigh the harms are offered a choice: slow opioid taper or fast taper and rotation to buprenorphine. Patient preference is the main driver determining next steps; however, patients with very high opioid doses (e.g., >400 mg morphine equivalent daily dose [MEDD]), those who are co-prescribed benzodiazepines or other sedatives, and those who are already experiencing opioid-related harms (e.g., over-sedation) are counseled that changes to their regimen need to start immediately. Control condition: Veterans referred to the ORC who did not successfully have an appointment	their MME than those in the control group (30 mg [interquartile range 0–120] vs 0 mg [IQR 0–20] decrease, $P < 0.01$) Pain outcomes not assessed
Rivich et al., 2018 Poor	Before-after Single center, January 1, 2015 to March 31, 2015, Colorado, U.S. Not funded	N = 147 Median age 61 years 10% female All were prescribed 200	Opioid Safety Initiative Initiative placed increased focus on patient education; improvement of monitoring practices, including urine drug screens, and querying of prescription drug monitoring program databases; and utilization of nonopioid and non-medication pain management modalities. Another goal was to	12 months after initial review, 34% of patients had a reduction in opioid dose with an average change of 60 mg MEDD; median MEDD decreased from 315 mg to 278 mg ($P < 0.05$) No dose change was observed in patients taking 1,000 mg MME or more at the time of initial review.

		mg MME or more Median 315 mg 44% were taking between 200 and 299 mg, 26% were prescribed 400-999 mg	encourage safe prescribing through reduction in use of high-dose long-term opioid treatment, which at time of review was defined as greater than or equal to 200 mg MEDD, and to decrease the concurrent use of benzodiazepines and opioids. Changes were implemented through policy development and performance of systematic multidisciplinary chart reviews. The chart reviews provided specific recommendations that were documented in the electronic medical record and the opioid prescriber was co-signed to the electronic chart note. Veterans Integrated Service Network (VISN) 19 policy requires the Consent for Long-Term Opioid Therapy document (which replaced the Opioid Therapy Agreement on 05/06/2014) to be reviewed and signed by both the patients and their prescriber. VISN 19 policy also mandates performance of UDS twice yearly, at a minimum, and follow-up with primary opioid prescriber at least every 6 months. If a patient did not meet these parameters at the time their chart was reviewed, the prescriber was alerted to areas where improvements in patient monitoring could be made. No control group	Pain outcomes not assessed

Thakral et al., 2018 Poor	Prospective cohort Group practice clinics September 2014 through January 2016, U.S. (Washington) Patient-Centered Outcomes Research Institute, National Institute on Aging	N= 1,588 (935 intervention, 653 control) Mean age 62 (SD 12) years 63.5% female 85.8% non-Hispanic white Mean daily MME 58 (SD 78) mg < 15 mg: 20.7% 15 to < 50 mg: 45.8% 50 to < 120 mg: 22.0% 120 mg or more: 11.5%	The group practice clinics implemented opioid risk reduction initiatives for chronic opioid therapy patients in 2 phases: dose reduction starting in 2007 and multifaceted risk mitigation strategies in 2010. During the dose reduction period, a dosing threshold of 120 mg MED per day was implemented and prescribers with high numbers of patients above this dosing threshold were given supervisory guidance by medical directors. The following strategies were implemented during the risk mitigation period: a risk- stratified schedule for the frequency of urine drug screening and follow-up visits, treatment contracts, care plans, modified refill processes, an online continuing education course for providers, care practice tools integrated into electronic medical records, and on-site resources for consultation. Control condition: Clinics that were not affiliated with Group Health but were under contract to accept Group Health insurance	Mean difference between groups (95% CI) PEG score: average of pain severity, interference with activities and interference with enjoyment of life (range = 0–10): −.03 (−.25 to .19) Pain severity (range = 0–10): .17 (−.02 to .35) Pain interference in daily activities (range = 0–10): −.12 (−.40 to .16) Pain interference in enjoyment of life (range = 0–10): −.18 (−.47 to .11) PHQ-8 score (measure of depression) (range = 0–24): −.64 (−1.19 to −.08)

Abbreviations. IQR: interquartile range; MEDD: morphine equivalent daily dose; MME: morphine milligram equivalents; NR: not reported; NRS: numeric rating scale; OUD: opioid use disorder; PTSD: posttraumatic stress disorder; SD: standard deviation; SUD: substance use disorder; UDS: urine drug screen.

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June 2018 Task Force Proposal

Taskforce recommendations:

1) Create a new line for chronic pain and fibromyalgia for the 2020 Biennial Review as shown below
2) Adopt a new guideline for this line as shown below
3) Score this new line as shown below
4) Modify line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS as shown below
    i. Remove all diagnoses other than chronic fatigue syndrome and modify line title
5) Modify GUIDELINE NOTE 56, NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    i. Matches changes in the new chronic pain conditions guideline
6) Modify GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE as shown below
    i. Adds chronic pain line to the guideline
    ii. Modifies the paragraph on tapering for chronic opioid use
    iii. Removes flares of chronic pain as an indication for opioids
7) Modify GUIDELINE NOTE 92, ACUPUNCTURE as shown below
    i. Adds the new chronic pain line to the guideline

LINE: XXX
CONDITION: CHRONIC PAIN SYNDROME AND FIBROMYALGIA
TREATMENT: LIMITED PHYSICAL MODALITIES, COGNITIVE BEHAVIORAL THERAPY, MEDICAL THERAPY
ICD-10: G89.21 (Chronic pain due to trauma), G89.28 (Other chronic postprocedural pain), G89.29 (Other chronic pain), G89.4 (Chronic pain syndrome), M79.7 (fibromyalgia)
CPT: 90785, 90832-90840, 90853 (psychotherapy—for CBT and ACT), 96150-96155 (Health and behavior assessment and intervention), 97110-97124, 97140-97168, 97530, 97535 (PT/OT), 97810-97814 (acupuncture), 98966-98969, 99051, 99060,99070,99078,99201-99215,99281-99285,99304-99337, 99340-99404,99408-99449,99487-99490,99495,99496,99605-99607 (medical office visits, including ER and SNF)
HCPCS: G0157-G0160 (PT/OT assistant), G0396-G0397 (alcohol and substance abuse screening), G0463-G0467,G0469,G0470 (FQHC care), G0490, G0511-G0513 (RFQHC care),G0514 (prolonged office visit)

GUIDELINE NOTE XXX, CHRONIC PAIN THERAPY

Lines XXX, 528

Chronic pain conditions are included on line XXX when symptoms have been present for at least 3 months and have not responded to conservative management.

The following treatments are included on line XXX:

- Office evaluation, consultation and education.
    - Pain education, if done, should include but not be limited to sleep, nutrition, stress reduction/mood, exercise, and knowledge of pain as a biopsychosocial phenomenon. All providers seeing chronic pain patients should be trained in pain science (e.g. a contemporary understanding of the central and peripheral nervous system in chronic pain), motivational interviewing, culturally sensitive care, and trauma informed care. Care should be multidisciplinary and focus on active therapies.

- Cognitive behavioral therapy (CBT)/acceptance and commitment therapy (ACT). The necessity for CBT and/or ACT 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.
- The following therapies, when available, may be provided: yoga, mindfulness training, massage, supervised exercise therapy (land based and aquatic), intensive interdisciplinary rehabilitation. HCPCS S9451 is only included on Line XXX for the provision of yoga or supervised exercise therapy.
- A total of 30 visits per year of any combination of the following 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. Once the pre-determined goals of care have been achieved, an additional two visits may be authorized for maintenance therapy to maintain these improvements. These 30 visits count toward the visit totals in GUIDELINE NOTE 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE if the patient has comorbid back or spine conditions.
    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) Acupuncture

Non-opioid medications are only included on line XXX if all of the following apply:

1) The medication is FDA approved or supported by compendia for treatment of chronic, non-neuropathic pain
2) The patient is also being treated with active therapy (e.g. physical therapy, CBT, etc.) or is continuing maintenance of self-management strategies learned from such therapy.
3) The benefit of non-opioid medication is re-evaluated at least every 90 days and medications are only continued if there is documented evidence of improvement of function of at least fifteen percent as compared to baseline based on a validated tools (e.g. Oswestry, SF-MPQ, and MSPQ). Less frequent monitoring may be appropriate for certain medications after safety and efficacy are established.

Opioids are included on this line according to GUIDELINE NOTE 60, OPIOIDS FOR CONDITIONS OF THE BACK AND SPINE AND CHRONIC PAIN.

Line Scoring

Line XXX CHRONIC PAIN SYNDROME
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 2
Need for service: 0.8
Net cost: 2
Score: 288
Approximate line placement: 443

Line 528 FIBROMYALGIA, CHRONIC FATIGUE SYNDROME, AND RELATED DISORDERS
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 0
Effectiveness: 1
Need for service: 0.8
Net cost: 2
Score: 112
Line placement: 528

Line 401 CONDITIONS OF THE BACK AND SPINE
Category: 7
HL: 4
Suffering: 3
Population effects: 0
Vulnerable population: 0
Tertiary prevention: 2
Effectiveness: 3
Need for service: 0.8
Net cost: 2
Score: 438
Approximate line placement: 401

Line: 528

Condition: ~~FIBROMYALGIA,~~ CHRONIC FATIGUE SYNDROME~~, AND RELATED DISORDERS~~ (See Guideline Notes 64,65,135)
Treatment: MEDICAL THERAPY
ICD-10: ~~G89.21,G89.28 G89.29,G89.4,M79.7,~~R53.82
CPT: 90785,90832-90840,90846-90853,93792,93793,98966-98969,99051,99060,99070,99078, 99201-99215,99281-99285,99341-99378,99381-99404,99408-99449,99487-99490,99495-99498,99605-99607
HCPCS: G0248-G0250,G0396,G0397,G0463-G0467,G0490,G0511,G0513,G0514

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

Lines 361,401

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/acceptance and commitment therapy (ACT). The necessity for cognitive behavioral therapy/ acceptance and commitment 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 401 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). These 30 visits count toward the visit totals in GUIDELINE NOTE XXX CHRONIC PAIN THERAPY if the patient has comorbid chronic pain conditions.
    3) 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.
    4) Chiropractic or osteopathic manipulation
    5) 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 http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

[delete the table below]

~~**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.

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

Lines 346,361,401,527,XXX

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

Transitional coverage for patients on long-term opioid therapy ~~as of July 1, 2016~~:

For patients ~~on covered chronic~~ receiving long-term opioid therapy ~~as of July 1, 2016, opioid medication is included on these lines only from July 1, 2016 to December 31, 2016. During the period from January 1, 2017 to December 31, 2017~~, continued coverage of opioid medications requires an individual treatment plan ~~developed by January 1, 2017~~ which includes a taper with an end to opioid therapy no later than one year from the start of the taper ~~no later than January 1, 2018~~. Taper plans must include nonpharmacological treatment strategies for managing the patient's pain ~~based on Guideline Note 56 NON-INTERVENTIONAL TREATMENTS FOR CONDITIONS OF THE BACK AND SPINE~~. If a patient has developed dependence and/or addiction related to their opioids, treatment is ~~available~~ included on Line 4 SUBSTANCE USE DISORDER**.**

GUIDELINE NOTE 92, ACUPUNCTURE

Lines 1,5,202,361,401,409,461,538

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 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

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 XXX CHRONIC PAIN SYNDROME

Acupuncture is included on this line with visit limitations as in Guideline Note XXX CHRONIC PAIN THERAPY

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 http://www.oregon.gov/oha/HPA/CSI-HERC/Pages/Evidence-based-Reports.aspx.

*Below the current funding line