U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services

Dr. Todd Graham Pain Management Study
Final Report

September 2024

Contents

This Report is dedicated to the memory of the late Dr. Todd Graham, who served the South Bend, Indiana community for more than thirty years as a physical medicine and rehabilitation specialist. Dr. Graham was loved by his family, respected by his co-workers, and appreciated by his patients living with pain. The late Representative Jackie Walorski, who introduced legislation to improve pain management in Medicare, is also acknowledged for her key role.

EXECUTIVE SUMMARY

Background

Section 6086 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Public Law 115-271) requires the Secretary of Health and Human Services (HHS) to conduct a study analyzing best practices as well as payment and coverage for pain management services under Medicare and submit a Report to Congress. The Report is required to contain "options for revising payment to providers and suppliers of services and coverage related to the use of multi-disciplinary, evidence-based, non-opioid treatments for acute and chronic pain management for individuals" under Parts A and B of Medicare.

The statute requires that the study include:

(1) An analysis of Medicare payment and coverage with respect to five specific issues including treatments and technologies for pain and substance use disorders such as those that help prevent overdose, multi-disciplinary treatment models, and specialty pain care.

(2) An evaluation of three specific items including barriers to accessing care, costs and benefits associated with potential coverage expansion, and relevant federal guidance on pain management.

(3) An assessment of HHS guidance since January 1, 2016 relating to the prescribing of opioids.

(4) A description of legislative and administrative options for accomplishing eight specific policies, which include improving coverage and payment for pain management therapies, among others.

(5) An analysis of the impact of potential effects of implementing the specific legislative and administrative options with respect to Medicare expenditures and preventing or reducing opioid addiction for Medicare beneficiaries.

The Secretary is required to transmit the Report to the Committees of jurisdiction and post the Report on the public CMS website.

This Report identifies suggested options as described for Congress and the Centers for Medicare & Medicaid Services (CMS) to consider in the development of future coverage and payment for

treatment and services to address pain care in the Medicare program, acknowledging statutory, regulatory, and policy boundaries and constraints, and feasibility of implementation. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) and its contractor conducted this Study, in consultation with CMS.

Chronic pain affects as many as one in five American adults, and one in 13 American adults have chronic pain that significantly disrupts function.[1] Pain is the most common reason people seek medical care, and more than 20 percent of office visits are associated with pain.[2] In the United States, more than forty percent of all adults report having pain on some days in the past 6 months, and chronic pain and high impact chronic pain (pain that results in substantial restrictions to daily activities) are experienced by more than 20 percent and 8 percent of adults, respectively.[3] The latter group, people living with high impact pain, report more severe pain, more mental health issues and cognitive impairments, more difficulty with self-care, and higher health care use than others living with chronic pain.[4]

A recent Centers for Disease Control and Prevention (CDC) study using National Health Interview Survey pain data reports similar results although the question on duration of pain shifted from "pain on some days in the last 6 months" to the "last 3 months (to align with the International Association of the Study of Pain (IASP) definition of chronic pain).[5;6]

Pain exacts a substantial economic toll: medical expenditures and lost productivity related to pain result in a cost to the United States estimated at $635 billion.[7] In people with Medicare coverage, pain has an even more striking impact - nearly 80 percent report experiencing chronic pain, with the same number having chronic pain in more than one location.[8] Over half of these beneficiaries say that chronic pain limits their life or work, and one third say that their pain affects their family members or significant others.[9]

HHS has led several initiatives to address the impact of pain. The Department issued the National Pain Strategy (NPS) in 2016.[10] It addressed six key areas of care: population research, prevention and care, disparities, service delivery and payment, professional education and

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[1] https://www.sciencedirect.com/science/article/pii/S0278584617304670?via%3Dihub

[2] Tang, N. and C. Crane. 2006. Suicidality in chronic pain: A review of the prevalence, risk factors, and psychological links. Psychological Medicine 36: 575-586

[3] https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain

[4] Pitcher MH, Von Korff M, Bushnell MC, Porter L. Prevalence and profile of high impact chronic pain in the United StatesHYPERLINK "https://www.nccih.nih.gov/tools/privacy#nccih-linking-policy"/tools/privacy#nccih-linking-policy. *Journal of Pain*. 2019;20(2):146-160.

[5] https://www.cdc.gov/mmwr/volumes/72/wr/mm7215a1.htm

[6] https://www.iasp-pain.org/publications/iasp-news/iasp-announces-revised-definition-of-pain/

[7] https://doi.org/10.1016/j.jpain.2012.03.009

[8] https://www.cms.gov/files/document/mcbs-2018-survey-file-chronic-pain-infographic.pdf

[9] https://doi.org/10.15585/mmwr.mm6736a2

[10] https://www.iprcc.nih.gov/sites/default/files/documents/NationalPainStrategy_508C.pdf

training, and public education/communication. The NPS' vision is to ''decrease the prevalence of pain across its continuum from acute to high-impact chronic pain and its associated morbidity and disability across the lifespan,'' and ''to reduce the burden of pain for individuals, their families, and society as a whole.'' In 2019, HHS released the Pain Management Best Practices Inter-Agency Task Force Report: Updates, Gaps, Inconsistencies, and Recommendations, which focuses on the development of person-centered pain treatment plans to establish a diagnosis and set measurable outcomes such as improvements in quality of life, function, and activities of daily living.[11] That report emphasized multi-modal, multidisciplinary approaches that include various modalities for the treatment of acute and chronic pain and identified five broad treatment categories: medications (including opioids and nonopioids), restorative therapies, interventional approaches, behavioral approaches, and complementary and integrative health. It stressed the importance of special populations including older adults and persons with relapsing conditions, Veterans, and people who receive palliative care. Relapsing conditions that involve chronic pain include, for example, multiple sclerosis, trigeminal neuralgia, Parkinson's disease, chronic regional pain syndrome, porphyria, systemic lupus erythematosus, lumbar radicular pain, and migraines.

Medicare is the largest payer for health care in the United States, serving more than 66 million people in 2023.[12] Pain is an increasingly urgent concern as growing numbers of older adults enroll in Medicare. [13] Primary care clinicians and specialists are already facing an array of challenges in treating pain and associated chronic disease in the Medicare population,[14] comprised mostly of older adults, where conditions such as arthritis, bone and joint disorders, back and neck pain, cancer and other conditions that may involve pain are common.[15] Inappropriately treated or untreated pain may translate to increased costs to Medicare as more beneficiaries experience physical decline, incapacitation, and frailty.[16] Additional risks in untreated pain include use of illegal drugs, injurious falls, mental disorders such as depression and anxiety, substance use, early mortality, cognitive impairment, and increased suicide risk and

[11] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

[12] https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment

[13] https://www.cms.gov/files/document/mcbs-2018-survey-file-chronic-pain-infographic.pdf

[14] https://www2.ccwdata.org/web/guest/medicare-charts/medicare-chronic-condition-charts

[15] https://www2.ccwdata.org/documents/10280/19099065/b2-prevalence-current-year.jpg

[16] https://data.cms.gov/sites/default/files/2023-09/Medicare%20Beneficiaries%20at%20a%20Glance%20DY2021.pdf

suicide.[17;18;19;20;21;22;23;24] Chronic pain is estimated to double the risk of death by suicide.[25] Suicidal ideation in people with chronic pain over the lifetime is about twenty percent, and about nine percent of Americans who died by suicide were living with pain.[26] [2728] In comparison in 2021, according to the Substance Abuse and Mental Health Administration's National Survey on Drug Use and Health, almost five percent of adults ages 18 or older (about 12.3 million people) had serious thoughts of suicide, and among adolescents ages 12 to 17, nearly thirteen percent (about 3.3 million people) had serious thoughts of suicide.[29;30;31;32] To address the urgent and growing public health of suicide, the federal government released the 2024 National Strategy for Suicide Prevention, which seeks to prevent suicide, identify and support people at increased risk through treatment and crisis intervention, prevent re-attempts, promote long-term recovery, and support survivors of suicide loss.[33]

Data and Methods

This Report used a multi-component approach to:

1. Analyze feedback from interested party discussions, listening sessions, and requests for information pertaining to barriers to care, Medicare coverage of pain treatments, and Medicare beneficiaries with SUDs.
2. Conducting a literature review of barriers to pain management treatment for Medicare beneficiaries.

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[17] https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes

[18] https://pubmed.ncbi.nlm.nih.gov/33000168/

[19] https://doi.org/10.1017/S0033291705006859

[20] https://pubmed.ncbi.nlm.nih.gov/21752179/

[21] https://acrjournals.onlinelibrary.wiley.com/doi/epdf/10.1002/acr.23268

[22] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2629448

[23] https://www.ncbi.nlm.nih.gov/books/NBK574562/?report=printable

[24] https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2629448

[25] https://www.mentalhealth.va.gov/suicide_prevention/docs/FSTP-Chronic-Pain.pdf

[26] https://www.sciencedirect.com/science/article/pii/S0278584617304670?via%3Dihub

[27] https://academic.oup.com/painmedicine/article/15/11/1835/1834890

[28] https://www.researchgate.net/profile/Catherine-Crane/publication/7351344_Suicidality_in_chronic_pain_A_review_of_the_prevalence_risk_factors_and_psychological_links/links/0c960516421f7cc6c5000000/Suicidality-in-chronic-pain-A-review-of-the-prevalence-risk-factors-and-psychological-links.pdf

[29] https://www.samhsa.gov/data/data-we-collect/nsduh-national-survey-drug-use-and-health

[30] https://pubmed.ncbi.nlm.nih.gov/30208405/

[31] Petrosky, E., R. Harpaz, K. Fowler, et al. 2018. Chronic pain among suicide decedents, 2003 to 2014: Findings from the national violent death reporting system. Annals of Internal Medicine 169, no. 7: 448–55.

[32] https://pubmed.ncbi.nlm.nih.gov/30208405/

[33] https://www.hhs.gov/programs/prevention-and-wellness/mental-health-substance-abuse/national-strategy-suicide-prevention/index.html

3. Conducting an environmental scan and document analysis of Federal guidelines for pain management and opioid prescribing published after January 1, 2016.
4. Recording Medicare Part A and B coverage in a list of acute and chronic pain treatments to inform the Report (Appendix D).
5. Conducting a cost-benefit analysis describing the potential effects of implementing these options, including the impact on Medicare expenditures.

Findings

Barriers to Care

Section 6086(c)(2)(A) of the SUPPORT Act requires the Report include an evaluation of barriers inhibiting Medicare beneficiaries from accessing treatments and technologies described in provisions described in section 6086(c)(1) of the Act such as those that address acute or chronic pain, overdose, and withdrawal.

Multiple barriers that may impede the ability of Medicare beneficiaries to access non-opioid treatment for acute and chronic pain were identified by interested parties. These included a lack of Medicare coverage for some modes of pain treatment, insufficient payment for provider time, and limited access to pain specialists, or integrated care models. Some treatments, such as physical and occupational therapy are covered by Medicare, and beneficiaries with traditional Medicare can see a physical therapist without a referral or physician visit, although a physician must certify the plan of care.[34] Coverage may vary for other treatments by specific pain diagnosis, such as coverage for acupuncture, which is only for treating chronic low back pain.[35] Limited access to pain specialists or integrated care models in some areas of the country often results in primary care physicians as the main source of treatment for people living with chronic pain, although their training in this area may be limited.[36] There are also reports that some primary care practitioners routinely refuse to assume the care of new patients already using opioid medication.[37] Additional barriers to pain treatment access include inadequate provider and patient education on pain care, limited access to transportation and telehealth technology, and poor care coordination across providers. Using human-centered design CMS created the Chronic Pain Experience Visual to illustrate the many barriers and challenges people with pain face in accessing effective pain care.[38]

[34] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c01.pdf

[35] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373

[36] https://journalofethics.ama-assn.org/article/undergraduate-medical-education-pain-management-across-globe/2013-05

[37] https://doi.org/10.1001/jamanetworkopen.2019.6928

[38] https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf

Guidelines for Pain Management and Opioid Prescribing

Section 6086(c)(3) of the SUPPORT Act requires the Report include "an assessment of all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids." This section further requires that such "assessment shall consider incorporating into such guidance relevant elements of the Department of Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain'' published February 2017, including adoption of elements of the Department of Defense and Department of Veterans Affairs pain rating scale.[39;40]

In the CDC's Guideline for Prescribing Opioids for Chronic Pain—United States, 2016, the CDC communicated its intent to evaluate and reassess evidence and recommendations as new research became available and to determine when new evidence would prompt an update.[41] To serve as a foundation for scientific evidence for the updated Guideline, the CDC funded the Evidence-based Practice Centers at the Agency for Health Care Research and Quality (AHRQ) to conduct systematic reviews of the scientific evidence in five areas: (1) noninvasive nonpharmacological treatments for chronic pain; (2) nonopioid pharmacologic treatments for chronic pain; (3) opioid treatments for chronic pain; (4) treatments for acute pain; and (5) acute treatments for episodic migraine.[42;43;44;45;46;47] The CDC has indicated that "a key aim of pain management is the provision of individualized, patient-centered care that focuses on optimizing function and supporting activities of daily living" and "in this context, our ultimate goal is to help people set and achieve personal goals to reduce pain and improve function."[48]

In 2022 the CDC Clinical Practice Guideline for Prescribing Opioids for Pain was published in the *Morbidity and Mortality Weekly Report* (MMWR)**.**[49] The publication updated and replaced the CDC 2016 Guideline for Prescribing Opioids for Chronic Pain. The CDC also released a suite of tools and resources to help people living with pain and clinicians understand and use the recommendations in the new Guideline in their pain care decision-making, and improve communication between clinicians and patients, empowering them to make collaborative and informed person-centered decisions related to pain care. The Guideline provides recommendations for adult outpatients with acute pain, sub-acute pain, and chronic pain. The

[39] https://www.healthquality.va.gov/Guidelines/Pain/Cot/Vadodotcpg022717.Pdf
[40] https://www.va.gov/PAINMANAGEMENT/docs/DVPRS_2slides_and_references.pdf
[41] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm
[42] https://effectivehealthcare.ahrq.gov/about/epc
[43] https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research
[44] https://effectivehealthcare.ahrq.gov/products/nonopioid-chronic-pain/research
[45] https://effectivehealthcare.ahrq.gov/products/opioids-chronic-pain/research
[46] https://effectivehealthcare.ahrq.gov/products/treatments-acute-pain/research
[47] https://effectivehealthcare.ahrq.gov/products/migraine-treatments/research
[48] https://www.cdc.gov/media/releases/2022/s0210-prescribing-opioids.html
[49] https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w

CDC noted that the "2022 Clinical Practice Guideline is voluntary; it provides recommendations and does not require mandatory compliance. It is intended to be flexible to support, not supplant, clinical judgment and individualized, patient-centered decision-making…and is not intended to be applied as inflexible standards of care across patient populations by health care professionals, health systems, third party payers, organizations, or governmental jurisdictions." The 2022 Guideline's overall goals are: improved communication between clinicians and patients about the risks and benefits of pain treatment, including opioid therapy for pain; improved safety and effectiveness for pain treatment, resulting in improved function and quality of life for patients experiencing pain; and a reduction in the risks associated with long-term opioid therapy, which could include opioid use disorder, overdose, or death.

Coverage Under Medicare Parts A and B for Acute and Chronic Pain Interventions

Section 6086(c)(1) of the SUPPORT Act requires the Report include an analysis of Medicare payment and coverage with respect to five specific categories of services.

A list of treatments for pain care was developed for the Report that included the coverage status of those treatments under Medicare, such as whether there is a Medicare National Coverage Determination (NCD) or Local Coverage Determination (LCD), and whether the treatment was evaluated in AHRQ's systematic reviews of pain treatments (including those developed to support this Report), to fill evidence gaps.[50] The process of constructing the list revealed the heterogenous nature of coverage for certain treatments across the regional jurisdictions of each Medicare Administrative Contractor (MAC).[51] To inform how these regional or LCDs occur, this Report describes the process for covering new treatments. The Medicare Coverage Database contains all NCDs and LCDs, local articles, and proposed NCDs.[52]

Several options including three treatments with coverage limitations and some level of evidence of effectiveness were identified for coverage consideration: 1) Part B Medicare coverage of acupuncture for fibromyalgia, 2) Part B Medicare coverage of massage therapy for chronic low back pain, and 3) Part B Medicare coverage of Cognitive Behavioral Therapy (CBT) for chronic low back pain.[53] Medicare does not presently cover massage therapy.[54] Additionally, Medicare Advantage Organizations (MAOs) may not offer a massage benefit or reimburse licensed massage therapists via supplemental benefits, per section 30.3 of the Medicare Managed Care Manual. By law, only certain provider types may enroll in Medicare; these include physicians,

[50] https://effectivehealthcare.ahrq.gov/products/collections/improving-pain-management

[51] https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/who-are-macs

[52] https://www.cms.gov/medicare-coverage-database/search.aspx

[53] Evidence of effectiveness was determined using topic briefs and systematic reviews developed by the Agency for Health Research and Quality (AHRQ) for the Dr. Todd Graham Pain Management Study. More information about this work is included in Chapter 4.

[54] https://www.medicare.gov/coverage/massage-therapy

physician's assistants, nurse practitioners, and clinical nurse specialists.[55] Most recently Medicare recognized Marriage and Family Therapists and Mental Health Counselors under a new services benefit category under Medicare Part B that was included in the Consolidated Appropriations Act of 2023, but currently there is no benefit category for massage therapist services.[56;57] The Congress could Regarding CBT, in the 2023 Medicare Physician Fee Schedule final rule (87 FR 69541) the Secretary clarified that coverage of CBT is available beyond Medicare's psychotherapy service through the Health and Behavior Assessment and Intervention (HBAI) Services series of Healthcare Common Procedure Coding System (HCPCS) codes.[58;59]This clarification is also described in this Report.

Legislative and Administrative Options for Improving Coverage and Payment of Nonopioid Pain Treatments

Section 6086(a) requires that the Secretary's Report to Congress contain "options for revising payment to providers and suppliers of services and coverage related to the use of multi-disciplinary, evidence-based, non-opioid treatments for acute and chronic pain management for Medicare beneficiaries." Section 6086(c) requires that the Secretary's Report to Congress include eight specific options described in section 6086(d). Section 6086(d) specifies that the options are "legislative and administrative options for accomplishing" eight specific types of policies. Legislative proposals included in Reports to Congress are limited to items included in the President's budget.[60]

In accordance with Section 6086(a) as described above, we identified the following options, which include improving coverage for pain management therapies:

1. Providing Medicare coverage for acupuncture for the treatment of fibromyalgia.
2. Providing Medicare coverage for Cognitive Behavioral Therapy (CBT) for the treatment of chronic low back pain.
3. Providing Medicare coverage for massage therapy for the treatment of Chronic Low Back Pain.
4. Making telehealth flexibilities permanent that could impact care for Medicare beneficiaries with chronic pain.
5. Exploration of adding quality measures specific to chronic pain, including through the Merit-based Incentive Payment System (MIPS).

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[55] https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855i.pdf
[56] https://www.cms.gov/files/document/marriage-and-family-therapists-and-mental-health-counselors-faq.pdf
[57] https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf
[58] https://www.govinfo.gov/content/pkg/FR-2022-11-18/pdf/2022-23873.pdf
[59] https://www.cms.gov/files/document/mln1986542-medicare-mental-health-coverage.pdf
[60] https://www.whitehouse.gov/omb/budget/

Medicare Coverage Determination Process

To be eligible for coverage under Medicare, health care services must fit into one of more than fifty categories of benefits described in statute.[61] CMS has been delegated legal authority by the Secretary of HHS to specify which procedures, devices, and services are covered in the benefit categories, and under what conditions. Section 1862(a)(1)(A) of the Social Security Act states that Medicare cannot pay for any items or services that are not "reasonable and necessary" for the diagnosis and treatment of an illness or injury or to improve functioning of a malformed body part.[62] It generally excludes certain services and items from coverage, such as, most cosmetic surgeries, hearing aids, eyeglasses, and routine foot and dental care. NCDs are made through an evidence-based process, with opportunities for public participation.[63] In some instances, CMS' research is supplemented by assessment or consultation with the Medicare Evidence Development & Coverage Advisory Committee.[64] In the absence of a national coverage policy, an item or service may be covered at the discretion of the (Medicare Administrative Contractor) MAC based on a LCD.[65]

Medicare Expenditure Impacts of Selected Options

Section 6086 —The impact analysis described in this subsection consists of an analysis of any potential effects implementing the options described in subsection (d) would have (1) on preventing or reducing opioid addiction for individuals receiving benefits under the Medicare program; and (2) expenditures under the Medicare program. The estimates are derived from a 2022 CMS Office of the Actuary Pain Management Cost/Benefit Analysis technical memorandum.

Acupuncture for fibromyalgia costs were estimated to range from roughly $887 million (for Medicare beneficiaries receiving 12 sessions) to $1.5 billion (for beneficiaries receiving 20 sessions), annually. Information is limited regarding the impact on overall health care costs of providing this service to people with Medicare, and there is uncertainty surrounding the impact on Medicare spending. Some savings could result, for example, from reductions in hospital and clinician visits, and costs for prescription drugs, which could potentially be decreased through pain relief derived from acupuncture treatment. The estimate was modeled based on 2020 costs for Medicare coverage of acupuncture for low back pain, using the same coverage guidelines for care.[66] Beneficiaries with fibromyalgia tend to have higher average prescription drug spending compared to the overall Medicare population; in 2019, fibromyalgia patients spent 81.5 percent

[61] https://www.cms.gov/medicare/coverage/determination-process

[62] https://www.ssa.gov/OP_Home/ssact/title18/1862.htm

[63] https://www.cms.gov/medicare/coverage/determination-process

[64] https://www.cms.gov/medicare/regulations-guidance/advisory-committees/evidence-development-coverage

[65] https://www.cms.gov/medicare/coverage/determination-process/local

[66] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=295

more on prescription drugs compared to the average Medicare beneficiary ($7,240 versus $3,990). Currently there is an NCD that bars coverage for acupuncture for fibromyalgia which would need to be reconsidered and revised if a change in policy is warranted[67].

Massage therapy for chronic lower back pain costs were estimated to be roughly $5.1 billion if all people who were eligible were to receive this treatment (based on a maximum of six visits per year). As is the case with acupuncture for fibromyalgia, there is a limited amount of research on the cost savings and the efficacy of massage therapy for chronic low back pain. The estimate was based on 2020 costs for massage, assuming physical therapists would deliver the massage therapy. Because chronic low back pain is common in people with Medicare, hospital and clinician visits and costs for prescription drugs could potentially be decreased through pain relief from massage therapy for low back pain.[68]

Cognitive Behavioral Therapy for Chronic Low Back Pain costs were estimated to be roughly $8.6 billion based on eight appointments per year of sixty minutes each, using an estimate of 16.5 percent of the Medicare population diagnosed with chronic low back pain, based on payment codes for psychotherapy using 2020 costs. As discussed in the 2023 PFS (87 FR 69404) final rule section on Chronic Pain Management and Treatment Services (CPM), Cognitive Behavior Therapy can also be furnished to Medicare beneficiaries without a diagnosed mental disorder under the Health and Behavior Assessment and Intervention (HBAI) codes. For people with Medicare who have a diagnosed mental disorder, the psychotherapy benefit can be used to furnish Cognitive Behavior Therapy. As chronic low back pain is common in people with Medicare, hospital and clinician visits, and costs for prescription drugs, could potentially be decreased through pain relief from Cognitive Behavior Therapy.

Discussion

This Report has been informed by reviews from the Agency for Healthcare Research and Quality, which have shown there are effective nonopioid treatments for pain management, and[69] also that there is a need for more research in this area.[70] The National Institute of Health's (NIH) Helping to End Addiction Long-term (HEAL) Initiative is a prominent example of a multi-agency effort to speed scientific solutions to address the national overdose crisis, including the challenges of treating pain.[71] The HEAL Initiative encompasses research to understand, manage, and treat pain, substance use disorders, and overdose. The HEAL pain research portfolio is supporting the development of pain medications and medical devices to treat persons with chronic pain, as well as testing integrative pain management strategies in a variety of common

[67] https://www.sciencedirect.com/science/article/pii/S0049017222001111

[68] https://www.cms.gov/files/document/mcbs-2018-survey-file-chronic-pain-infographic.pdf

[69] https://effectivehealthcare.ahrq.gov/products/nonopioid-chronic-pain/research

[70] https://effectivehealthcare.ahrq.gov/products/collections/improving-pain-management

[71] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=295

pain conditions. HEAL is also funding research to reduce disparities in pain care. NIH's Pain Consortium includes an array of other activities that enhance pain research and promote collaboration across researchers with programs and activities addressing pain.[72] As one example, the NIH/Department of Veterans Affairs/DoD Pain Management Collaboratory is testing a number of nonpharmacological approaches for the management of pain in Military and Veterans health care systems.[73]

[72] https://www.painconsortium.nih.gov/

[73] https://painmanagementcollaboratory.org/

SECTION 1.
INTRODUCTION

According to a 2023 report from the CDC, in 2016 about 50 million U.S. adults experienced chronic pain, resulting in substantial health care costs and lost productivity.[74] The report showed that in 2021, an estimated 20.9 percent of U.S. adults (51.6 million persons) experienced chronic pain, and 6.9 percent (17.1 million persons) experienced high-impact chronic pain (e.g. chronic pain that results in substantial restriction to daily activities) with a higher prevalence among non-Hispanic American Indian or Alaska Native adults, adults identifying as bisexual, and adults who were divorced or separated.[75] Another 2023 study from the National Institutes of Health (NIH) showed that new cases involving chronic pain occur more often among U.S. adults than new cases of several other common health conditions, including diabetes, depression, and high blood pressure. Among people living with chronic pain, almost two-thirds are still living with pain a year later. Only about ten percent of people with chronic pain in the NIH study were living pain free one year later after reporting chronic pain.[76]

Acute pain often occurs after surgeries, injuries, or accidents and may persist and transition to become chronic pain.[77] Definitions of chronic pain vary, but pain is typically considered chronic when it persists for at least three months.[78] CMS finalized two new Medicare billing codes for 2023 for Chronic Pain Management and Treatment (G3002 and G3003), using a definition of chronic pain as "persistent or recurring pain lasting longer than 3 months." People living with chronic pain may experience reduced physical functioning, reduced quality of life, and conditions such as depression and substance use disorders (SUDs).[79;80] Some form of chronic pain affects as many as one in five American adults, and one in 13 American adults have chronic pain that significantly disrupts their "work, social, recreational, and self-care activities."[81;82]

Chronic pain is disproportionately prevalent among older adults, adults living in poverty, and people enrolled in Medicaid and other public health insurance.[64] More than 85 percent of the Medicare population is over age 65.[83] In addition to negative impacts on quality of life, people with acute and chronic pain often incur substantial financial costs, including high medical

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[74] https://www.cdc.gov/mmwr/volumes/72/wr/mm7215a1.htm

[75] https://www.nccih.nih.gov/research/research-results/prevalence-and-profile-of-high-impact-chronic-pain

[76] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2804995

[77] https://doi.org/10.1111/pme.12751

[78] https://doi.org/10.17226/13172

[79] https://doi.org/10.1001/jama.280.2.147

[80] https://doi.org/10.1093/fampra/18.3.292

[81] https://www.iprcc.nih.gov/sites/default/files/HHSNational_Pain_Strategy_508C.pdf

[82] https://www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm?s_cid=mm6736a2_w

[83] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/BeneficiarySnapshot/Downloads/Bene_Snaphot.pdf

expenditures.[84] One study estimated national annual medical costs for chronic pain ranging from $261 to $300 billion, and Medicare is estimated to bear one-quarter of these costs.[85] In 2012, the total costs of chronic pain in the United States—calculated as the sum of direct health care costs and costs of lost productivity—were estimated to be at least $560 to $635 billion per year—more than the cost for cancer or diabetes or heart disease—and this figure has likely increased in the past decade.[86]

Pain management can be complicated by SUDs, prescription opioid misuse, and even the perception of the risk of opioid misuse. Over the past decade annual overdose deaths due to prescription opioids, either alone or combined with synthetic opioids, has plateaued at 16,700.[87]The 2022 National Survey on Drug Use and Health [88]assessed misuse of prescription pain relievers in people age 12 and older and found about three percent misused prescribed pain relievers in the past year. Nearly 45 percent used someone else's medication and about 67 percent reported the misuse was to help relieve their physical pain. The increase in overdose rates is now largely driven by illicitly manufactured synthetic opioids such as fentanyl and increasingly, stimulants (e.g. cocaine, methamphetamine) and most recently, fentanyl adulterated with the veterinary tranquilizer xylazine and novel potent opioids, such as nitazines – with significant impacts across America.[89;90]

Given the Medicare population and its high need for effective, accessible, and safe pain management, it is critical that CMS examine payment and coverage of non-opioid pain treatments to align with the latest treatment evidence and pain management guidelines and offer effective services and supports to people living with pain, people living with SUD, and people with co-occurring pain and SUD.

Section 6086(a) of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), enacted October 24, 2018 (Public Law 115-271) requires the Secretary of the Health and Human Services to conduct the Dr. Todd Graham Pain Management Study. The SUPPORT Act addresses the nation's overdose crisis through treatment, prevention, recovery, education, and enforcement. As outlined in the SUPPORT Act, the purpose of the Dr. Todd Graham Pain Management Study is to analyze best practices and payment and coverage for pain management services under Title XVIII of the

[84] https://doi.org/10.1016/j.mayocp.2014.09.010

[85] https://doi.org/10.1037/a0035514

[86] https://doi.org/10.1016/j.jpain.2012.03.009

[87] https://nida.nih.gov/research-topics/trends-statistics/overdose-death-rates

[88] https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-nnr.pdf

[89] https://www.cdc.gov/overdose-prevention/about/what-you-should-know-about-xylazine.html?

[90]https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2808868?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=082923

Social Security Act, and to submit to the Congress a report containing options for revising payment for non-opioid treatments for acute and chronic pain. In developing the report, the Secretary is required to consult with relevant Federal and non-Federal interested parties. The report is required to include:

- An analysis of payment and coverage under Title XVIII of the Social Security Act
- **An evaluation of the following:**
    - (1) Barriers inhibiting individuals entitled to benefits under Part A or enrolled under Part B of such title from accessing treatments and technologies.
    - (2) Costs and benefits associated with potential expansion of coverage under such title to include items and services not covered under such title that may be used for the treatment of pain, such as acupuncture, therapeutic massage, and services furnished by integrated pain management programs.
    - (3) Pain management guidance published by the Federal Government that may be relevant to coverage determinations or other coverage requirements under Title XVIII of the Social Security Act.
- An assessment of all guidance published by the Department of Health and Human Services on or after January 1, 2016, relating to the prescribing of opioids.
- Options for improving coverage of and payment for pain management therapies without the use of opioids.
- An impact analysis of the potential effects of implementing the options identified above including costs to the Medicare program.

This Report presents findings from a multi-component study as part of the legislative requirement in Section 6086 of the SUPPORT Act. ASPE and its contractor conducted this study and drafted this Report in consultation with CMS. The research and the Report are organized around the following questions:

- What barriers to accessing pain treatment interventions exist for Medicare beneficiaries entitled to benefits under Part A or enrolled under Part B?
- What guidance is published by the Federal government on pain management and the prescribing of opioids?
- What is the coverage of, and payment for, evidence-based interventions for acute and chronic pain, under Medicare Parts A and B?
- What legislative and administrative options exist to improve coverage of, and payment for, pain interventions in Medicare?

- What are the costs and benefits of legislative and administrative options from the Medicare payer perspective?

SECTION 2.
BARRIERS TO ACCESSING TREATMENT

Interested party feedback from various public engagements, including listening sessions held for the Dr. Todd Graham Pain Management Study were held to gather more information on acute and chronic pain management treatments. A literature review of peer-reviewed articles and government reports was also conducted. Below is a brief outline of the methods for each approach, followed by a summary that integrates the findings.

2.1 Approach

2.1.1 Interested Party Consultation Analysis

A document analysis was conducted to summarize interested party perspectives on pain management issues from multiple engagement efforts. ***Exhibit 1*** provides the list of interested party engagement documents that was reviewed and summarized for the analysis (see Appendix A). A code book with 31 key concepts ("codes") supported a deductive-inductive qualitative analysis. The codebook contained 14 deductive codes according to questions above and a framework for financial, cognitive, and structural barriers to care.[91]Many of the barriers to treatment communicated by interested parties are indicated in CMS's Chronic Pain Experience graphic, which used a human-centered design process through robust engagement with clinicians, patients, caregivers, third-party vendors, federal partners, and CMS employees.[92]

- *Financial:* When high needs populations are uninsured or under-insured and cannot access critical health care, including instances where treatments are not covered by insurance.
- *Structural:* The availability of health care services within or outside of health care facilities, including location of and transportation to facilities, waiting times, and continuity of care.
- *Cognitive:* The patients' belief and knowledge of prevention and treatment, such as awareness of health resources and facts, health literacy, and understanding of diagnosis and treatment, as well as the provider-patient communication during the health care visit; providers may also have cognitive barriers such as distrust, misunderstanding of laws or policies, lack of understanding of treatment array, etc.

[91] https://doi.org/10.1353/hpu.2011.0037

[92] https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf

Exhibit 1. Interested Party Engagement Documents

Transcripts from CMS listening sessions held for the Dr. Todd Graham Pain Management Study on August 27, 2020, and September 16, 2020. Participants included pain specialists, health care providers, patients, caregivers, and patient advocate representatives from health care organizations and associations. The questions included four topic areas: barriers to care, Medicare coverage, Medicare beneficiaries with SUD, and pain coverage during the COVID-19 pandemic, as well as general feedback and additional information.[93]	Summaries of CMS Advisory Panels on Outreach and Education Support in 2020.[94]
Feedback letters from health care organizations and associations to the Department of Health and Human Services (HHS) in follow-up to the CMS listening sessions.	Presentation slides from published reports of the Centers for Disease Control and Prevention's (CDC's) Engagement Event Summary Report and the Pain Management Best Practices Inter-Agency Task Force Summary Report of Public Comments. In the two public comment periods, nearly 3,000 comments were received and analyzed. The public comments predominantly came from people living with pain and professional associations.
	Public comment summaries led by CDC in 2019. Similar to the transcripts and feedback letters, public comments were submitted by providers, patients, caregivers, and patient advocate representatives from health care organizations and associations.

2.1.2 Literature Review

A multi-step approach was used to analyze barriers to treatment for Medicare beneficiaries with acute and chronic pain. Transcripts from the interested party engagement and listening sessions listed above were reviewed to identify commonly cited barriers to treatment. Based on this review, key words and search strategies were developed for a literature review of peer-reviewed articles and government reports published from 2010 to 2021. With assistance from an advisory committee that consisted of experts in Medicare payment policies, pain management, and opioid prescribing, and the help of an experienced librarian, a preliminary list of search terms, exclusion and inclusion criteria, and a list of databases was developed and used to search to identify relevant studies. Data was extracted from included articles into themes and categorized within the broader framework developed by Carrillo *et al.* (2011) to synthesize and highlight key findings.[73]

[93] For more information about the listening session, including the specific questions asked, presentation, audio recording, and transcripts, visit the CMS webpage located here: Pain Management Partners | CMS and 2020-08-27-Pain-Management | CMS

[94] The Advisory Panel on Outreach and Education was first chartered in 1999 to advise and make recommendations to the Secretary of the U.S. Department of Health and Human Services (HHS) and the Administrator of CMS on the effective implementation of national Medicare, Medicaid, Children's Health Insurance Program (CHIP) and Health Insurance Marketplace outreach and education programs. For more information, please visit the CMS webpage at: Advisory Panel on Outreach and Education | CMS

2.2 Findings

2.2.1 Limitations to Current Medicare Coverage for Pain Treatment

Participants identified issues with Medicare pain management coverage because of limited numbers of covered visits for certain services (***see Exhibit 2***).

Exhibit 2. Frequency Limits/Caps for Certain Services

- Physical therapy
- Acupuncture (chronic low back pain)

Interested parties reported limiting the number of visits for certain services left Medicare beneficiaries and providers with fewer options for pain treatment and resulted in lapsed care, and other negative consequences. Patients, family members, caregivers, and advocates described having had difficulties, for example, in the past with insufficient physical therapy coverage. During the first listening session, one patient advocate noted that "the number of sessions per year […] that can be funded under Medicare[…]had left patients with periods of weeks between treatments." These limits on physical therapy services were eliminated in the Bipartisan Budget Act of 2018; beneficiaries with Original Medicare without supplemental insurance now pay twenty percent of the Medicare-allowed amount for medically necessary outpatient physical therapy.[95;96]

2.2.2 Lack of Medicare Coverage for Some Modes of Pain Treatment

In both the interested party feedback and literature review, a lack of Medicare coverage for some pain treatment modalities was identified as a significant barrier to pain treatment. One example was the lack of availability of Cognitive Behavioral Therapy, or CBT. It may have been unclear to some interested parties that CBT can be furnished in Medicare on an outpatient basis as psychotherapy to beneficiaries with a diagnosed mental disorder. Revisions in 2020 to the Health and Behavior Intervention and Assessment codes facilitated CBT payment to people with Medicare with physical health issues including those that could cause pain. The Medicare statute does not provide coverage of interventions such as yoga and Tai Chi, which some clinicians may recommend for pain, and which were mentioned in feedback discussions.

[95] https://www.congress.gov/bill/115th-congress/house-bill/1892/text

[96] https://www.medicare.gov/coverage/physical-therapy-services

Exhibit 3. Examples of Services and Treatments Currently Not Covered by Medicare

- Massage therapy
- Platelet-rich plasma injections
- Yoga
- Pilates
- Tai Chi

Patients, caregivers, and advocates highlighted the challenges that result from lack of Medicare coverage of these and other treatments. They emphasized the need to expand coverage for behavioral health services for pain, and for exercise program treatments aimed at addressing the psychological and physical aspects of pain. They cited yoga and psychotherapy as interventions that could be included in comprehensive pain management programs.

Providers and patients reported that providers are limited in their abilities to deliver or access these nonopioid pain management treatments due to a lack of coverage (***see Exhibit 3***). One key reason for this lack of access to treatments such as exercise programs, aquatic therapy, and Tai Chi as reported by interested parties was the risk of the person incurring potentially expensive out-of-pocket costs due to non-covered insurance status. Some of the nation's Area Agencies on Aging, which serve certain geographic areas in each state, coordinate services that can help older adults remain in their homes and communities. One provider noted that "many a time these patients …would rather take … oxycodone, or other opioid medication(s) because insurance pays for it."[97] Interested parties provided numerous examples of non-covered treatments where people living with pain could incur costs such as the ones above, as well as non-opioid medications or other substances, and therapeutic exercise programs.[98] For some treatments such as certain antidepressants and psychotherapy, interested parties reported that Medicare, or Medicare Part D may cover the treatment - but not for a pain diagnosis or a diagnosis that may involve pain.

Interested parties noted that the lack of coverage for certain specialized services/providers results in people with pain having limited access to the nonopioid-based services that those providers offer. They commented that people with musculoskeletal conditions lack adequate access to different types of providers for specific services—for example, these individuals may lack access to chiropractic services for certain conditions. Medicare covers chiropractic services when furnished by a doctor of chiropractic for manual manipulation of the spine to correct a vertebral

[97] https://acl.gov/programs/aging-and-disability-networks/area-agencies-aging

[98] https://www.nccih.nih.gov/health/cannabis-marijuana-and-cannabinoids-what-you-need-to-know

subluxation, under Part B.[99] Two large provider advocacy groups wrote in a feedback letter to CMS that "traditional (fee-for service) Medicare plans limit access to [integrative health care] providers…only providing coverage for chiropractic physicians." Although the letter from advocates did not define integrative health providers, common integrative health care practices include therapeutic massage, mindfulness-based stress reduction, yoga, and Tai Chi.[100;101] Interested parties reported that although current Medicare coverage reimburses for the use of what they termed "massage techniques" when delivered by physical therapists, it does not cover traditional massage therapy, or therapeutic massage. The CPT code 97140, for "manual therapy" paid under Medicare is described by the American Medical Association as manual therapy techniques, 1 or more regions, each 15 minutes (mobilization/manipulation, manual lymphatic drainage, manual traction). The CPT code paid under Medicare for "massage therapy," 97124, is described as therapeutic procedure, 1 or more areas, each 15 minutes; massage, including effleurage, petrissage, and/or tapotement (stroking, compression, percussion). According to the National Institutes of Health's National Center for Integrative and Complementary Health, massage therapy involves various types and techniques.[102]

Even when some pain treatments are covered, Medicare coverage can depend on other factors such as geographic location or the person's diagnosis. Medicare coverage for certain pain treatments may vary based on location because coverage issued under LCDs can vary across the MACs. For example, the Wisconsin Physicians Service Insurance Corporation has a LCD in place stating when vertebroplasty will be considered reasonable and necessary for osteoporotic conditions when specific criteria are met, where other MACs do not have a stated policy on this service and would consider coverage on a case-by-case basis.[103] Medicare coverage for pain treatments may also vary by diagnosis, such as for acupuncture, which is currently only covered for beneficiaries with chronic low back pain. Medicare coverage of acupuncture for chronic low back pain was established after a national coverage analysis was performed and the published medical literature was evaluated by CMS. Auxiliary personnel furnishing acupuncture must be under the appropriate level of supervision of a physician, physician assistant, or nurse practitioner/clinical nurse specialist, as required by CMS Medicare regulations.[104] Other contributing factors for lack of coverage for pain care include the slow pace at which clinical research is completed and results are disseminated into practice. There may be logistical challenges of changing coverage policies that require accompanying changes to credentialing,

[99] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57889&ver=3&bc=CAAAAAAAAAAA

[100] https://www.nccih.nih.gov/health/yoga-what-you-need-to-know

[101] https://www.nccih.nih.gov/health/tai-chi-what-you-need-to-know

[102] https://www.nccih.nih.gov/health/massage-therapy-what-you-need-to-know

[103] https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=38213

[104] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373

billing, referral, authorization, and other procedures.[105;106;107] Although non-opioid treatments are frequently recommended as first options for many people living with chronic pain, interested parties report that Medicare coverage policies are impeding factors to access the range of interventions depicted in the report as the "Toolbox." The broader challenges in pain care access are shown illustrated in CMS's Chronic Pain Experience Visual.[108]

2.2.3 Insufficient Payment for Provider Time

Medicare payment methodologies for physician services are specified by statute, however interested parties claimed in listening sessions that Medicare payment for certain services for individuals with pain is inadequate.[109] Across both listening sessions and in the Medicare's Advisory Panel on Outreach and Education summary, interested parties including providers and people with pain emphasized the importance of having sufficient time to discuss current and prospective pain management treatment options and "to collect patient data and… engage patients with such data to help them make treatment decisions." Patients and pain advocates also claimed that current Medicare payment is not adequate for time to develop individualized, person-centered approaches to pain management.[110]

According to the published literature, patients and primary care providers (PCPs) report there is inadequate time to appropriately assess pain in primary care settings**.** Given that PCPs often treat multiple chronic conditions that may involve pain, "half of physicians felt that appointment times were too short to address all of the patient's [pain] issues and provide lifestyle counseling".[111] Another study found that patients unanimously felt they had "too little time allotted with their PCP" for treatment of pain.[112] The same study also reported that physicians "ranked lack of time to evaluate patient-reported [pain assessment] tools as the primary barrier to their use".[101]

CMS regularly revises coding and billing rules for Evaluation and Management (E/M) visits paid under the PFS), including changes so that time spent with the patient can be used to select appropriate visit levels. Starting in 2023 CMS finalized two new payment codes to describe monthly chronic pain management and treatment (CPM) services. The code descriptors include the following elements: *diagnosis; assessment and monitoring; administration of a validated pain rating scale or tool; the development, implementation, revision, and/or maintenance of a person-centered care plan that includes strengths, goals, clinical needs and desired outcomes; overall treatment management; facilitation and coordination of any necessary behavioral health*

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[105] https://doi.org/10.1037/a0035514
[106] https://doi.org/10.1089/acm.2018.0431
[107] https://doi.org/10.1179/2042618613Y.0000000036
[108] https://www.cms.gov/files/document/cms-chronic-pain-journey-map.pdf
[109] https://www.cms.gov/medicare/regulations-guidance/advisory-committees/panel-outreach-education
[110] https://www.cms.gov/medicare/regulations-guidance/advisory-committees/panel-outreach-education
[111] https://doi.org/10.1111/ijcp.13627
[112] https://doi.org/10.1016/j.pec.2020.08.038

treatment; medication management; pain and health literacy counseling; any necessary chronic pain related crisis care; and ongoing communication and coordination between relevant practitioners furnishing care, such as physical and occupational therapy, complementary and integrative care approaches, and community-based care, as appropriate. The CY 2023 PFS Fact Sheet stated that CMS believes "the chronic pain management and treatment HCPCS codes will improve payment accuracy for these (CPM) services, prompt more practitioners to welcome Medicare beneficiaries with chronic pain into their practices, and encourage practitioners already treating Medicare beneficiaries who have chronic pain to spend the time to help them manage their condition within a trusting, supportive, and ongoing care partnership."[113]

2.2.4 Limited Access to Pain Specialists or Integrated Care Models

Underlying the barriers described above is the lack of integrated specialty care providers to whom clinicians can offer patient referrals. The Agency for Healthcare Research and Quality has defined these pain care models as "centered in and integrated with primary care, which have embedded or easy access to multidisciplinary providers and services."[114] As one study stated, "integrated comprehensive pain care models (i.e., multimodal, multidisciplinary, and interdisciplinary rehabilitation programs) are neither widely available nor sufficiently reimbursed despite demonstrated long-term cost and health care utilization advantages.[115] In the absence of integrated care programs, people with pain are often required to coordinate their own care with different specialists for multiple chronic conditions, which can be expensive and time-consuming.[116] The HHS Pain Management Task Force (PMTF) Report[117] includes additional information on these models which the Report indicates could include psychological and behavioral health interventions through various delivery methods such as in-person, telehealth, internet self-management, mobile applications, group sessions, and telephone counseling.

Clinicians and patients/clients alike frequently report that they are often unable to receive timely patient/specialist referrals.[118] Some providers are unaware that there are pain specialists, which may include various provider types (e.g. neurologists, anesthesiologists, physical therapists, mental health professionals) with special training in pain management, and who may work in pain clinics.[106] One study reported physician concerns about patient costs of care due to a lack of insurance coverage, time off work needed for appointments, and travel expenses; 70 percent of physicians in this study reported challenges with coordinating multimodal care pertaining to the referral system and specialist inflexibility.[119] Even if a patient receives a referral to a specialty

[113] https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule

[114] https://effectivehealthcare.ahrq.gov/products/integrated-pain-management/protocol

[115] https://doi.org/10.1093/pm/pny307

[116] https://doi.org/10.1186/1472-6882-13-225

[117] https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf

[118] https://doi.org/10.1179/2042618613Y.0000000036

[119] https://doi.org/10.1111/ijcp.13627

program (e.g., interdisciplinary chronic pain management programs or outpatient physical therapy programs) these reportedly receive poor uptake, are low in quantity or poorly staffed, and are frequently too short in duration to confer long-lasting improvements to patients' longer-term pain.[120] Medicare Part A generally covers inpatient pain rehabilitation programs for four weeks if "the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain".[121] In 1988, CMS issued a transmittal clarifying the scope of this benefit.[109] Medicare Part B covers outpatient rehabilitation program services if the facility is Medicare certified, the patient has a physician referral, and the services delivered follow an approved treatment plan.[122] CMS issued another transmittal in 1988 clarifying that these programs are covered if patient's pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability by patient to function independently has resulted from the pain.[123]

Inadequate collaboration and communication among providers is another common issue in part due to the lack of relevant specialty care providers, inadequate training, and time constraints.[124] Several studies reported patient frustrations relating to poor care coordination, conflicting pain management approaches, and difficulty obtaining coverage for or access to specialty care.[125;126] Lyons (2013) found that older patients believed "some providers would be unwilling to engage in collaborative practice," based on dismissive or invalidating statements from professionals in response to patient requests for specialty back pain treatments, in addition to generally insufficient time in appointments for clinical evaluation.[127] These concerns highlight how poor communication in practice can hamper not only individual patient-clinician interactions, but also provider collaboration to coordinate care. In 2019 the PMTF expressed similar findings based on its review of existing gaps The Task Force noted that coordinated, multidisciplinary care is challenging to provide with existing payment mechanisms and recommended that CMS develop a code "for pain care coordination as well as team and group conferences to enable multidisciplinary care".[128] The new Chronic Pain Management and Treatment codes, G3002 and

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[120] https://www.apa.org/pubs/journals/releases/amp-a0035514.pdf

[121] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=23&ncdver=1&NCAId=238&ver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Entire+State&KeyWord=wounds&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=270.3&ncd_version=4&basket=ncd%25253A270%25252E3%25253A4%25253ABlood%25252DDerived+Products+for+Chronic+Non%25252DHealing+Wounds&bc=gAAAABIAAAAA&

[122] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

[123] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=240

[124] https://doi.org/10.1007/s11606-018-4323-z

[125] https://doi.org/10.1111/pme.12626

[126] https://doi.org/10.1007/s11136-019-02412-5

[127] https://doi.org/10.1186/1472-6882-13-225

[128] https://www.hhs.gov/opioids/prevention/pain-management-options/index.html

G3003, are expected to help CMS in gain more knowledge about pain in the Medicare population through data, and clinician and beneficiary experience, and help address the gap identified in the PMTF report. Medicare also covers chronic care management services for beneficiaries with multiple (two or more) chronic conditions expected to last at least 12 months or until the patient's death, or that place the person at significant risk of death, acute exacerbation and or decompensation, or functional decline.[129]

There are limited resources to train providers, resulting in provider shortages of both PCPs and specialists to treat pain. The lack of clinical training for psychologists is reportedly a contributing factor. Pain psychologists have expertise in treating people with chronic pain and use techniques such as CBT to help manage the thoughts, emotions, and behaviors that can accompany chronic pain. In a survey of 62 directors of graduate and postgraduate psychology programs, more than a quarter of programs with health psychology coursework excluded pain treatment, and only 28 percent of these programs dedicated more than 10 hours to pain instruction; 100 percent of respondents indicated interest in learning about pain psychology instruction, indicating an interest in clinical education in pain psychology.[130] As the same study notes, "pain psychology is not a recognized specialty by the American Psychological Association, and therefore has no formal standing within the organization;" the lack of formal certification for pain psychologists, in addition to the lack of formal education, is believed to contribute to the low availability of these specialists.[118]

Even with the recognized effectiveness of many therapies, full implementation is hampered by limited resources. For example, some treatments such as mindfulness techniques require high training costs, limiting provider supply.[131] In other cases, researchers identified the absence of standardized licensure requirements for some treatments (such as acupuncture) as a barrier to service provision and coverage for care.[132] In poorer resourced settings, clinics are "only able to provide suboptimal pain management due to limited resources for medical, psychological, and adjunctive care".[133] As a result of these limitations, many studies reported that wait times for appointments and referrals are exceedingly long. For example, one study noted that "PCPs often expressed frustrations with lack of timely pain patient access to the necessary system resources," across all areas of specialty care.[134]

Due to limited access to specialty care, PCPs are often left as the only resource to treat many pain patients, despite potentially having had insufficient clinical training in pain management

[129] https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf

[130] https://doi.org/10.1093/pm/pnv095

[131] https://doi.org/10.1097/MLR.0000000000001377

[132] https://doi.org/10.2147/JPR.S185652

[133] https://doi.org/10.1097/NJH.0000000000000312

[134] https://doi.org/10.1186/s12875-016-0566-0

during their medical education.[135] Most PCPs do not receive training in behavioral interventions, such as CBT, so in the absence of available specialist referrals or integrated care settings where these could be provided, PCPs largely provide usual care, like various pharmacological treatments and/or referrals to physical and/or occupational therapy. Even in the use of pharmacological treatments, PCPs - and patients and caregivers - have expressed significant concerns about PCPs' abilities and capacity to appropriately and effectively manage patients' pain.[136]

2.2.5 Racial and Ethnic Disparities

Racial and ethnic biases and disparities serve as barriers to effective pain treatment. As people in minority groups are disproportionately socioeconomically disadvantaged, they are also at increased risk of experiencing cost, disparities in insurance coverage, and other barriers to pain management. Racial and ethnic minorities more frequently report that their provider did not ask them about their pain, and also say that they were frequently judged by providers to be in less pain than nonminority patients.[137] Non-concordance between patients and providers in racial and ethnic background has been associated with lower levels of patient trust and satisfaction; one study of over 5,000 patients attributed this to "issues related to trust and poor rapport in an environment in which most doctors do not share the same physical and cultural characteristics" as their patients.[138] These barriers can also hinder awareness and acceptability of pain treatment options among minority patients. One study found that non-White patients, specifically Black or African Americans, had less exposure to information about palliative care than White patients.[139]

Racial and ethnic minority patients may also be faced with additional barriers and disparities throughout the treatment process. They are less likely to receive comprehensive pain assessment, less likely to have timely diagnosis of pain, experience poorer follow-up after pain has been identified and longer delays in implementation of treatment, and report more severe pain and less pain relief from analgesics compared to nonminority patients.[140;141;142] Minority patients also experience a higher likelihood of missed appointments and abrupt discontinuation of their treatment, and a higher perceived unmet need for pain management.[126;143;144] There is also evidence for undertreatment of pain among Black and African American patients, who are less frequently prescribed opioids and analgesics, less likely to receive surgical pain treatments when

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[135] https://doi.org/10.1016/j.suponc.2010.10.006
[136] https://doi.org/10.1016/j.pec.2020.08.038
[137] https://doi.org/10.1073/pnas.1516047113
[138] https://doi.org/10.1213/ANE.0000000000001794
[139] https://doi.org/10.1089/jpm.2011.0217
[140] https://doi.org/10.17226/13172
[141] https://doi.org/10.1016/j.explore.2018.02.001
[142] https://doi.org/10.1002/pon.4218
[143] https://doi.org/10.3390/ijerph17207535
[144] https://doi.org/10.1002/cncr.28801

appropriate, and less likely to receive pain medications when they visit the emergency department.[127;128] Sickle cell disease (SCD), the most commonly inherited blood disorder in the U.S. is an extremely painful, life-long condition that occurs mostly in Blacks or African-Americans. Pain is most often the symptom that causes people with SCD to visit the hospital or emergency department and some have poor experiences like long wait times, overcrowding, and other challenges.[145;146;147] In September 2023 CMS issued its Sickle Cell Disease Action Plan, which highlighted the need for acute and chronic pain management in this population[148] and HHS hosted a Sickle Cell Disease Summit in 2024.[149]

2.2.6 Limited Access to Transportation and Technology

People with pain have reported disruptions in their care due to a lack of transportation and/or impaired mobility. One representative from a major pain advocacy group explained in a listening session that "pain patients have tremendous mobility, transportation, and stamina issues in getting to doctors' offices. Driving or finding transportation, waiting in line, [and] using public transit are all very difficult to manage with severe pain and mobility issues."

Although the COVID-19 pandemic increased the use of telehealth, which can reduce transportation burden, some people with pain, especially people living in rural areas, may have insufficient internet bandwidth to support telehealth visits. Some low-income individuals lack the necessary electronic devices (e.g., smartphones, computers or tablets) to use telehealth services.[150] Medicare beneficiaries are less likely to have the necessary equipment for telehealth services.[151] One study of telehealth access of Medicare beneficiaries during the pandemic found that about 41.4 percent of Medicare beneficiaries surveyed "lacked access to a desktop or laptop computer with a high-speed internet connection at home, and 40.9 percent lacked a smartphone with a wireless data plan".[152] A representative from a major pain advocacy group noted during a listening session that "a lot of people because of COVID had been using Zoom…but there's a lot of people who don't have access to those kinds of electronics." Whether online or in person, patients who cannot meet with their providers often experience delays in receiving care, which can greatly impact their health and quality of life. Telehealth policies in Medicare fluctuate and change. Telehealth substitutes for an in-person visit, and generally involves two-way, interactive

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[145] https://www.cdc.gov/sickle-cell/complications/pain.html?CDC_AAref_Val=https://www.cdc.gov/ncbddd/sicklecell/complications.html

[146] https://www.cdc.gov/sickle-cell/media/fact-sheets/living-well/do-you-use-the-ed-for-scd.pdf

[147] https://www.changeforscd.com/beyond-vaso-occlusive-episodes-complications/challenges

[148] https://www.cms.gov/blog/cms-launches-action-plan-sickle-cell-disease-month

[149] https://www.hhs.gov/about/news/2024/09/25/readout-hhs-hosts-inaugural-sickle-cell-disease-scd-summit.html

[150] https://www.cms.gov/medicare/coverage/telehealth/list-services

[151] https://telehealth.hhs.gov/providers/preparing-patients-for-telehealth/telehealth-and-remote-patient-monitoring

[152] https://doi.org/10.1001/jamainternmed.2020.2666

technology that permits communication between the provider and the person receiving care. During the COVID-19 public health emergency, CMS used emergency waiver and other regulatory authorities to allow access more services.[153] Section 4113 of the Consolidated Appropriations Act, 2023[154] extended many of these flexibilities through December 31, 2024, and made some of them permanent. Patients, consumers, and caregivers are impacted by shifting flexibilities based on telehealth statutory and regulatory authorities.[155;156]

2.2.7 Additional Barriers to Pain Treatment Access

Interested parties identified additional barriers to accessing pain management services and treatments. Specifically, they noted that inadequate provider and patient education for appropriate pain care, poor care coordination across providers, and limited access to patient physical and mental health histories are routinely hindering access to appropriate pain management services and treatments.

Interested parties expressed concern that pain treatment options are not being incorporated in pain management planning because patients and providers are unaware of the array of treatment options. They emphasized the need to educate both groups about treatments that may be suitable for individual patients' needs, thereby reducing provider/patient reliance on or any overuse of prescription medications. For example, in public comments, a group representing providers explained its position that "an over-reliance on addictive pain medications…has come about for several reasons… lack of awareness of the benefits of massage therapy by physicians or other health care professionals as part of an integrative medical approach to treat pain; and a lack of patient awareness about how massage therapy might manage their pain."

Interested parties including people with pain also noted that limited access to patient information and a lack of care coordination across providers serve as barriers to pain management.[157] They said that when care information is siloed by providers, it weakens the capacity for coordination and successful pain management. One provider attributed inadequate payment for time spent with patients as a barrier to appropriate care coordination and stated that care coordination requires "multidisciplinary consultative care which often involves record review and counseling as key components of dealing with high-dose seriously ill patients." Patients described having multiple providers and treatment plans and noted that poor communication and coordination among providers often requires people with pain to take the burden of coordinating care upon themselves. For example, one patient commented "we [patients] currently have nine physicians

[153] https://www.cms.gov/files/document/mln901705-telehealth-services.pdf

[154] https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

[155] https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf

[156] https://www.cms.gov/files/document/mln901705-telehealth-services.pdf

[157] In 2015, Medicare began paying for Chronic Care Management (CCM) under procedure codes 99490, 99491, 99487, and 99489.The CCM codes cover care management services, including care coordination, for patients with two or more chronic conditions expected to last at least 12 months or until death.

in the mix, and we are the individuals who are coordinating our care, because we are not lucky enough to be in a program where our providers are speaking to each other." Providers discussed how patient histories can be used to determine what drug or dosage should be prescribed.

Interested parties also identified issues with state-based Prescription Drug Monitoring Program (PDMP) data such as how data does not always reflect all relevant elements of the person's drug use, or their history. PDMPs are state-based electronic databases that track certain prescriptions within a state[158] and can contribute to clinical decision-making. PDMPs have functional and operational commonalities, but there are differences between states based on state policies, statutes, and regulations[159].

2.2.8 Concerns with Unintended Consequences of Efforts to Reduce Opioid Prescribing

Interested parties discussed serious concerns that continuing efforts to reduce opioid prescribing are having further unintended negative impacts on people who appropriately use opioid medication to manage pain. Interested parties also discussed provider reluctance to prescribe opioid medication due to fear of possible penalties (e.g., suspension, loss of medical licenses, reporting) resulting from monitoring of prescribing patterns by CMS, the Drug Enforcement Administration, the Department of Justice, and the states.

In one listening session and in public comments to the PMTF, people with pain and pain advocates discussed the difficulty of finding pain management providers who accept Medicare, especially in rural areas, who could prescribe necessary and appropriate opioids for pain. One patient described the need to travel a long distance to consult a new pain specialist after the patient's local provider stopped providing pain management services. Interested parties reported that some patients say they have difficulty finding pain management specialists because clinicians are fearful of prescribing pattern monitoring efforts. In a public comment, one patient reported losing two pain management physicians, each of whom purportedly abruptly dropped their patients due to concerns around how the CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain was implemented, and unease surrounding increased monitoring of provider prescribing patterns.

Although these concerns of the impact of monitoring were repeated throughout all listening sessions, the CDC 2016 Guideline - written for PCPs furnishing care to adults in outpatient settings - may have been misunderstood and misapplied as setting hard limits for opioid morphine milligram equivalents (MME) that became the basis for regulatory, administrative and enforcement actions. In response to these and other concerns, the CDC finalized an updated Clinical Practice Guideline in 2022. In a 2019 commentary in the *New England Journal of*

[158] https://www.cdc.gov/overdose-prevention/php/interventions/prescription-drug-monitoring-programs.html#:~:text=A%20prescription%20drug%20monitoring%20program,a%20nimble%20and%20targeted%20response.

[159] https://www.pdmpassist.org/

Medicine, the authors had advised against misapplication of the first Guideline that risked patient health and safety, citing applications to populations outside its scope, dosages that resulted in "hard limits," cutting off opioid medications and abrupt tapering, and misapplication to people using medication for opioid use disorder (MOUD).[160] Like the CDC 2016 Guideline, the new guidance is meant to be voluntary, and is intended to guide shared decision-making between clinicians and patients, rather than to be implemented as absolute limits of policy or practice by clinicians, health systems, insurance companies, or governmental entities.[161] In February 2024, the Medicaid Child and Adult Core Sets Annual Review Workgroup, in performing its 2026 Annual Review, voted to remove a measure from the set based on CDC recommendation: Use of Opioids at High Dosage in Persons Without Cancer (OHD-AD) in part based on its potential to cause patient harm, misalignment with the CDC's updated prescribing guideline, and lack of person-centered/individualized approach to prescribing.[162] The measure describes the percentage of (Medicaid) beneficiaries aged 18 and older who received prescriptions for opioids with an average daily dosage greater than or equal to 90 morphine milligram equivalents (MME) over a period of 90 days or more. Medicaid's Child and Adult Core Sets are a foundational tool for understanding the quality of health care provided, and help CMS and states assess access to and quality of health care being provided to Medicaid and CHIP beneficiaries; expert members from the government and the private sector discuss and carefully consider measures for removal or addition to strengthen and improve the sets.

Interested parties noted that barriers to appropriate opioid prescribing may be impacting access to care for both acute and chronic pain. They said that the CDC's 2016 Guideline' recommendation that providers avoid increasing opioid dosages above 90 MME or more per day is an issue for people who depend on, and are already stable at, higher dosage levels, and is not consistent with a person-centered, individualized approach to care.[163] The 2022 Guideline emphasizes general principles rather than specific MME thresholds.

Interested parties expressed concerns that some quality measures CMS uses (e.g., Use of Opioids at High Dosage in Persons Without Cancer [OHD])[53]are driving providers to reduce, or continue to reduce, opioid dosages for people who are stable on doses that are calibrated at the individual level to effectively treat pain. While acknowledging the concern of SUD, one representative from a group in a listening session maintained that "opioids do help a large number of patients living with pain." And in public comments, a provider group noted that opioids remain critical to relieve pain for patients following surgeries, injuries, or other painful procedures. The 2022

[160] https://archive.cdc.gov/#/details?url=https://www.cdc.gov/media/releases/2019/s0424-advises-misapplication-guideline-prescribing-opioids.html

[161] https://www.govinfo.gov/content/pkg/FR-2022-02-10/pdf/2022-02802.pdf

[162] https://www.mathematica.org/features/maccoresetreview

[163] The CDC's 2016 Guideline for Prescribing Opioids for Chronic Pain had recommended using the lowest effective dose when initiating opioid treatment and reassessing evidence of individual benefits and risks when considering increasing dosage.

Guideline emphasizes that it is a voluntary clinical tool to improve communication between clinicians and patients, can empower them to make informed decisions about safe and effective pain care, provides flexibility to clinicians and patients in support of individualized, patient-centered care, and is not intended to be used as an inflexible, one-size-fits-all policy, or applied as a rigid standard of care that replaces clinical judgement about personalized treatment.

SECTION 3.
PAIN MANAGEMENT GUIDANCE PUBLISHED BY THE FEDERAL GOVERNMENT

An environmental scan was conducted in 2022 to help describe the current state of Federal pain management and opioid prescribing guidelines, promote appropriate coverage, improve access to care and services, and understand pain care costs.

3.1 Methods

The environmental scan included peer-reviewed and gray literature to identify Federal pain management and opioid prescribing guidelines. *Opioid prescribing* refers to opioid prescribing for pain, and not for medication for opioid use disorder (MOUD) treatment using methadone, naltrexone, and buprenorphine.[164] A broad search was conducted that included guidelines for treating pain in people with OUD, and included the use of opioids in people using high-dose opioid therapy. The guidelines search was limited to those published by the U.S. Federal government on or after January 1, 2016. The final set of guidelines were analyzed to summarize their characteristics and describe differences. The Department of Veterans Affairs has also issued separate information on opioid deprescribing,[165] headache,[166] and various other educational materials.[167]

3.2 Findings

There are several relevant guidelines for pain management and opioid prescribing from different Federal departments and agencies.

1. CDC 2016 Guideline for Prescribing Opioids for Chronic Pain[168]
2. CDC 2022 Clinical Practice Guideline for Prescribing Opioids for Pain[169]
3. Department of Veterans Affairs (VA)/Department of Defense (DoD) Clinical Practice Guideline for Opioid Therapy for Chronic Pain, Version 3.0[170]

[164] https://nida.nih.gov/about-nida/organization/cctn/ctn/research-studies/towards-personalized-medicine-in-medication-opioid-use-disorder-moud-analyses-veterans-health

[165] https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/508/10-1548_PAIN_OpioidDeprescribingDiscussionTool_P97068.pdf

[166] https://www.healthquality.va.gov/guidelines/Pain/headache/index.asp

[167] https://www.pbm.va.gov/PBM/academicdetailingservicehome.asp#OSI

[168] https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm

[169] https://www.cdc.gov/mmwr/volumes/71/rr/pdfs/rr7103a1-H.pdf

[170] https://www.healthquality.va.gov/Guidelines/Pain/Cot/Vadodotcpg022717.pdf

4. Department of Health and Human Services (HHS) Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics[171]
5. Indian Health Services (IHS) Indian Health Services Health Manual Chapter 30 - Chronic Non-Cancer Pain Management | Part 3 – Professional Services[172]
6. IHS Recommendations for Management of Acute Dental Pain[173]
7. Department of Veterans Affairs Clinical Practice Guideline for Diagnosis and Treatment of Low Back Pain, Version 2.0[174]
8. Department of Veterans Affairs 2022 Clinical Practice Guideline for the Use of Opioids in the Management of Chronic Pain[175]

Reflecting the diversity of the guidelines, most focus on chronic pain; two focus on acute pain, and one is relevant to both. Some focus on treatment with prescription opioid medication, where others focus on general pain management. Some focus on sources of pain, e.g. lower back and dental pain, headache. One guideline focuses on reducing or discontinuing opioids for people with extended use of high-dose opioid therapy and one on the treatment of OUD, because this guideline includes recommendations for managing pain in people who also have an OUD. No Federal pain guidelines are specific to older adults or people with disabilities, who comprise most of the Medicare population. More than seven percent of Medicare beneficiaries, for example, have end stage renal disease (ESRD)[176], and moderate to severe pain affects more than half of the people living with ESRD.[177]

Guidelines developed by VA/DoD focus on Veterans and military personnel. Two guidelines were developed by the Indian Health Service. These guidelines likely reach a narrow segment of providers. For example, providers outside the VA/DoD may be unaware of VA guidelines. The IHS guideline on managing acute dental pain likely reaches an even narrower segment of providers, as this guideline targets dentists but no other health care providers. In contrast, the CDC 2016 Guideline and the updated 2022 Guideline received considerable attention in academic and gray literature. Many of the guidelines exclude people with cancer and surgical pain, and people receiving palliative and end-of-life care, as opioid medications tend to be used more frequently, and at higher doses, in these groups. Appendix B provides the full list of guidelines reviewed.

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[171] https://www.hhs.gov/system/files/Dosage_Reduction_Discontinuation.pdf

[172] https://www.ihs.gov/ihm/pc/part-3/p3c30/

[173] https://www.ihs.gov/doh/documents/Recommendations%20for%20Acute%20Dental%20Pain%20Management.pdf

[174] https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf

[175] https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOpioidsCPG.pdf

[176] https://www.cms.gov/files/document/data-snapshot-ckd-march-2022.pdf

[177] https://www.researchgate.net/publication/273995412_Pain_in_end-stage_renal_disease_A_frequent_and_neglected_clinical_problem

3.2.1 Pain Treatment Guidance Published by the Federal Government

Because of the diversity of the guidelines in terms of content, purpose, and intended audience, this summary presents common findings. The guidelines generally recommend against using opioids as a first-line therapy for most people, and instead recommend the use of nonopioid-based pharmacological and nonpharmacological therapies for chronic and acute pain. The exception was the IHS's dental guideline, which recommends opioid medication as a first-line therapy for certain acute dental pain.

Numerous guidelines suggest specific nonopioid-based oral and topical medications, such as Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), Acetaminophen (APAP), skeletal muscle relaxants, lidocaine, and methyl salicylate, for certain types or individuals with acute or chronic pain, based on a person-centered approach to care. Several suggest specific nonpharmacologic therapies such as psychotherapy (e.g., CBT), physical therapy, acupuncture, exercise therapy (e.g. swimming, stretching), and movement-based therapy (e.g., yoga, Pilates, Tai Chi). The VA/DoD guidelines for lower back pain are most specific on first-line treatment: NSAIDs (recommendation strength "strong") and CBT (recommendation strength "strong"). **Exhibit 4** summarizes some nonopioid therapies suggested for by the different Federal guidelines and is organized by pharmacotherapy and interventional procedures, complementary and integrative health interventions, and behavioral health and psychotherapy interventions.

Exhibit 4. Nonopioid Pain Management Therapies Suggested by Federal Guidelines

Nonopioid Pain Management Therapy	Number of Guidelines Suggesting Therapy
Anti-inflammatory medications (e.g., NSAID)*	8
Acetaminophen*	6
Antidepressants*	5
Anticonvulsants*	5
Physical therapy*	5
Topicals (e.g., Lidocaine, capsaicin)*	4
Skeletal muscle relaxants*	3
Occupational therapy*	2
Spinal injection, nerve block, joint injection*	2
Nerve stimulator*	1
Ultrasound stimulation*	1
Acupuncture**	5
General exercise therapy (e.g., clinician-directed, swimming, stretching, aquatherapy)**	4

Movement-based therapy (e.g., yoga, Pilates, Tai Chi)**	4
Chiropractic/osteopathic/spinal mobilization/manipulation therapy**	3
Massage**	3
Weight management**	2
Ice, heat, rest**	2
Meditation**	1
Elevation of affected limb**	1
Culturally specific spiritual practices**	1
Cognitive behavioral therapy***	5
General behavioral/psychological therapy***	2
Pain school or behavioral groups, ***	2
Support groups/community support	2
Mindfulness-based stress reduction***	2
Acceptance and commitment therapy***	2
Dialectical behavior therapy***	1
Progressive relaxation therapy***	1

***** Pharmacotherapy and Interventional Procedures
** Complementary and Integrative Health Interventions
*** Behavioral Health/Psychotherapy Interventions

Note: This exhibit should be interpreted with the understanding that, although some interventions were suggested with more frequency, this could also be because of the diversity of the Federal guidelines reviewed in terms of content, purpose, and intended audience.

3.2.2 Opioid Prescribing Guidelines

When opioids are appropriate to treat chronic and acute pain, guidelines may recommend a combination of opioid therapy with non-pharmacological and non-opioid pharmacologic therapies, such as those described above, to better manage pain and reduce opioid dependence. Additionally, guidelines recommended prescribing the lowest effective dose of opioids. Numerous guidelines still refer directly to the CDC 2016 Guideline for Prescribing Opioids for Chronic Pain to "avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day;"; the updated Guideline does not make dosage recommendations based on MME. Two guidelines expand on the CDC's 2016 recommendation by noting that the risks for overdose and death significantly increase starting as low as 20–50 MME/day. Guidelines also recommend limits on the days supplied for opioids, and several specifically note that 3–7 days should generally be sufficient to treat acute pain. Guidelines

recommend the use of immediate release opioids over extended-release opioids for chronic and acute pain.

Guidelines recommend including individual risk assessments associated with opioid prescribing when developing treatment plans. Tailored treatment plans should optimally provide information about benefits of naloxone for certain patients who have histories of overdose or substance use or misuse and recommend against concurrent prescription of opioids and benzodiazepines whenever possible. Additionally, guidelines recommend providers review PDMP data before initiating drug regimens and periodically throughout treatment, which is now required by law in many states. Guidelines also recommend assessing illicit drug use and possible diversion with urine drug testing, especially for high-risk people. There are various types of urine drug test "panels," which refers to the number of drugs tested. The most common is a five-panel test that includes cannabinoids, which may be used by some people for painful conditions; increasingly, states have permitted its use for medical purposes, although cannabis is a Schedule 1 controlled substance under federal law.[178] In 2024 the U.S. Department of Justice issued a proposed rule[179] to consider moving marijuana from a schedule I to a schedule III drug under the Controlled Substances Act.[180] The 2022 CDC Guideline has said that the effectiveness of cannabis for painful conditions is limited and inconsistent across studies and in 2023 SAMHSA issued an advisory on cannabidiol potential harms, side effects, and unknowns.[181]

For people with OUD, most guidelines recommend offering evidence-based medication for OUD with buprenorphine or methadone, or injectable, extended-release naltrexone,[182] combined with behavioral therapies, although the type of behavioral therapies recommended are not well described. The 2022 Clinical Practice Guideline states "that if clinicians are unable to provide treatment themselves they should arrange for patients with OUD to receive care from a SUD treatment specialist or from an Opioid Treatment Program certified by the Substance Abuse and Mental Health Services Administration."[183] Medicare covers both office-based OUD Treatment, and OTP care.[184;185]

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[178] https://www.dea.gov/sites/default/files/2020-06/Marijuana-Cannabis-2020_0.pdf

[179] https://www.dea.gov/sites/default/files/2024-05/Scheduling%20NPRM%20508.pdf

[180] https://www.govinfo.gov/content/pkg/USCODE-2014-title21/html/USCODE-2014-title21-chap13-subchapI.htm

[181] https://store.samhsa.gov/sites/default/files/pep22-06-04-003.pdf

[182] https://www.fda.gov/drugs/information-drug-class/information-about-medications-opioid-use-disorder-moud

[183] Dowell D, Ragan KR, Jones CM, Baldwin GT, Chou R. CDC Clinical Practice Guideline for Prescribing Opioids for Pain — United States, 2022. MMWR Recomm Rep 2022;71(No. RR-3):1–95. DOI: http://dx.doi.org/10.15585/mmwr.rr7103a1.

[184] https://www.cms.gov/medicare/payment/opioid-treatment-programs-otp/billing-payment/office-based-substance-use-disorder-sud-treatment-billing

[185] https://www.medicare.gov/publications/12085-Opioid-Treatment-Programs.pdf

3.2.3 Identified Gaps in Guidelines

The review of pain treatment and opioid prescribing guidelines identified several gaps that are consistent with the gaps identified in the PMTF report.[186] Most guidelines do not explicitly recommend a person-centered approach during treatment planning, which could include identifying comorbidities (e.g., SUD, depression), and social determinants of health that can impact access to pain management services. Although Federal guidelines generally discuss integrating psychological approaches to pain treatment (e.g., CBT), more specific and detailed guidelines for how to best treat individuals with concurrent mental disorders are likely warranted. Relatedly, patient and provider education approaches are needed to address barriers to acceptance of and participation in psychological treatments. Section 2002 of the SUPPORT Act required CMS to add regulatory language to the existing requirements for Medicare's Initial Preventive Physical Examination and Annual Wellness Visit to explicitly include elements regarding screening for potential substance use disorders, and a review of current opioid prescriptions.[187] The latter includes an assessment of OUD risk factors, evaluation of pain severity and current treatment plan, information on non-opioid treatment options, and specialist referral, as appropriate. It does not apply to the group of beneficiaries living with chronic pain not using opioid medication.

Guidelines also typically reference "opioid therapy" broadly, often referring to long-term opioid therapy without clear differentiation from intermittent as needed/PRN use for chronic pain. While the guidelines typically state to use lowest dosage at shortest duration possible, there is little guidance related to intermittent, occasional use of opioid medication that may still labeled "long term opioid therapy", but due to the lesser frequency (not around the clock, but rare PRN use, often situation dependent), which does most often not result to the same degree of tolerance and physical dependence.

Guidelines do not provide recommendations for specific populations (e.g., populations with different medical conditions that could involve pain, or people with concurrent mental disorders). For example, current Federal guidelines do not provide specific opioid prescribing guidance, or other pain medication guidance, for older adults, who may be at increased risk for respiratory depression, falls, cognitive impairment, and decreased renal and hepatic function, and often take multiple medications for multiple chronic conditions. Additionally, although the guidelines recommend using PDMP data prior to initiating treatment with controlled substances, more specific guidance regarding how to access and interpret PDMP data may be warranted. Although some guidelines recommend the use of urine drug screening before initiating opioid therapy, guidelines do not commonly recommend scheduling routine urine drug screening to assess, for

[186] https://www.hhs.gov/opioids/prevention/pain-management-options/index.html

[187] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

example, illicit drug use or diversion; this is left to the clinician's judgement based on individual factors. Additionally, use of drug screening such as UDT may not be covered by insurance, and frequent use of screening such as UDT may be considered a potential marker of fraud, waste, or abuse by payers.

3.2.4 Pain and Substance Use Disorder (SUD) Screening Tools

Brief and publicly available pain screening tools published after January 1, 2005, and brief and publicly available SUD and substance misuse screening tools published after January 1, 2010 were reviewed. There are multiple validated screening tools for both pain and SUD, including substance misuse. NIH published a related list of pain assessment resources for professionals including pain and pain-related questionnaires in 2022.[188]

There are a number of brief and publicly available pain screening tools (see Appendix C) to support pain management. These screening tools have been validated in adult populations aged 18 and older in primary care and community settings. Along with screening for pain, these tools are used for pain management and tracking pain levels and function over time. All seven screening tools are applicable to chronic pain; the screening tools assess nonspecific chronic pain (5), chronic headache/migraine (1), and chronic low back pain (1). The time-to-complete pain screening tools was not routinely reported, but the tools ranged in length from 3 to 41 items.

Fifteen brief and publicly available screening tools for SUD (Appendix C) were identified, including substance misuse, that have been validated on adults 18 and older in primary care and community settings. Of the 15, six applied to a single substance and nine applied to two or more. The SUD screening tools applied to illicit drugs or prescription medications (9), alcohol (9), opioids (3), and tobacco (3). The time-to-complete SUD and substance misuse screening tools was not routinely reported, and the tools ranged in length from 1 to 17 items.

[188] https://www.painconsortium.nih.gov/resource-library/pain-assessment-resources-professionals

SECTION 4.
COVERAGE AND PAYMENT FOR EVIDENCE-BASED TREATMENTS

This section details existing Medicare coverage for inpatient and outpatient pain treatments. It includes the methods used to compile a comprehensive list of pain treatments and the coverage status under Medicare Parts A and B. It also includes an overview of the processes CMS and the MACs use to consider and issue coverage determinations of specific treatments followed by a discussion of service coverage and billing under both Medicare Parts A and B.

4.1 Methods and Findings

Interventions for acute and chronic pain interventions were compiled from a pain treatment list sourced from:

- Department of Health and Human Services Pain Management Best Practices Inter-Agency Task Force Report
- Agency for Healthcare Research and Quality (AHRQ)'s reviews of pain treatments and treatment modalities
- Information from the U.S. Pain Foundation[189]

AHRQ systematic reviews, including those that filled evidence gaps on pain, were important for identifying acute and chronic pain treatments and in subsequent sections, helping to assess which treatments were evidence-based.[190] In addition to two systematic reviews, AHRQ produced three topic briefs that provided additional context around subject areas with a less established evidence base, such as treatment of acute and chronic pain for people with a history of SUD.[191;192;193;194;195] AHRQ systematic reviews of acute and chronic pain treatments provided additional information for assessing the evidence base of treatments, in particular where Medicare coverage was not already established, and AHRQ's work informed what coverage options to consider as Report options.

The acute and chronic pain interventions were reviewed for completeness and organized into the following pain treatment categories:

- Complementary and Integrative Care
- Pharmacotherapy

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[189] https://uspainfoundation.org/
[190] https://effectivehealth care.ahrq.gov/products/improving-pain-management/rapid-evidence
[191] https://effectivehealth care.ahrq.gov/products/interventional-treatments-pain/research
[192] https://effectivehealth care.ahrq.gov/products/integrated-pain-management/research
[193] https://effectivehealth care.ahrq.gov/sites/default/files/pdf/topic-brief1-care-coordination.pdf
[194] https://effectivehealth care.ahrq.gov/sites/default/files/pdf/topic-brief2-opioid-withdrawal.pdf
[195] https://effectivehealth care.ahrq.gov/sites/default/files/pdf/topic-brief3-SUD.pdf

- Procedures
- Psychotherapy

4.1.1 Overview of Coverage Determinations

Medicare coverage is limited to items and services that are reasonable and necessary for the diagnosis or treatment of an illness or injury, within the scope of a Medicare defined benefit category, and not statutorily excluded from coverage. NCDs are made through an evidence-based process that includes opportunities for public participation. LCDs are also evidence-based and include public participation. Some coverage decisions are in regulation or are available in the Medicare Coverage Database (MCD), the National Coverage Determination Manual or in the Medicare Benefit Policy Manual.[196;197] The NCDs and LCDs specify the parameters of Medicare coverage such as certain interventions for particular indications and the number of covered services. Using the MCD, coverage determinations were matched to the treatments identified in the list.

As evidence for a treatment develops for services that are not statutorily excluded from coverage and fall within a Medicare benefit category, CMS can issue an NCD. NCDs are made through an evidence-based process, with opportunities for public participation, and state whether or not a particular item or service is covered nationally by Medicare.[198;199] NCDs are developed using a process required by statute in section 1862(l) of the Social Security Act and other provisions of the Act. There are also procedural rules for making NCDs(78 Fed. Reg. 48,164 Aug. 7, 2013). In the absence of an NCD, coverage of an item or service may be addressed through an LCD created by a regional MAC under section 1862(a)(1)(A). Each MAC is responsible for processing all Medicare claims filed in the state or states under its purview. MACs have the authority to make reasonable and necessary coverage decisions and can make LCDs that establish a consistent policy within a particular geographic area.[200] MACs develop LCDs through a similar process as CMS for items or services that do not have a national coverage policy.[171;172;173] If no NCD or LCD exists for a given treatment, then coverage is determined by the MAC on a case-by-case basis. There is potential local variation in LCDs, and Medicare beneficiaries may face barriers to accessing care due to location, including for pain care.[201]

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196 https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

197 https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS012673

198 https://www.cms.gov/Medicare/Coverage/DeterminationProcess

199 https://www.ssa.gov/OP_Home/ssact/title18/1869.htm

200 https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19008.pdf

201 https://oig.hhs.gov/oei/reports/oei-01-11-00500.asp

Taking this variation into account, the pain treatment list categorized interventions as completely covered, partially covered, or not covered by Medicare. Complete coverage was defined as national coverage without limitations, and partial coverage was defined as coverage with limitations. These limitations include coverage for some indications but not others, coverage for a specific course of treatment (e.g., a limited number of applications of a treatment in a given time period, continued coverage dependent on signs of recovery), or local coverage. Some of the treatments identified that showed positive clinical findings, but also had coverage or statutory-based barriers to access include: acupuncture for fibromyalgia, and CBT and massage therapy for chronic lower back pain. Options for access to these treatments are given further consideration in ***Section 5*** and in the cost-benefit analysis in ***Section 6***.

4.1.2 Medicare Part A: Pain Treatment Payment and Coverage

As required by statute, Medicare payment for short-term, acute care hospitalizations is made under the Inpatient Prospective Payment System (IPPS). There is a second prospective payment system for long-term care hospitals and a third system under Part A that covers inpatient rehabilitation facilities.[202] There is also a separate payment system for services furnished in a skilled nursing facility under Part A that are paid under the Skilled Nursing Facility Prospective Payment System. This section will focus on how pain treatments are handled for inpatient hospital stays under the IPPS.

The IPPS is prospective in that payment rates for services are set prior to the beginning of the upcoming fiscal year through Federal rulemaking. Medicare assigns each inpatient stay to a Medicare severity diagnosis related group (MS–DRG), which is primarily based on the patient's clinical conditions and treatment strategies. Clinical conditions are defined by the principal diagnosis—the main issue requiring inpatient care—and up to 24 secondary diagnoses indicating other conditions that were present at admission (comorbidities) or developed during the hospital stay (complications). The treatment strategy—surgical or medical—is defined by the presence or absence of up to 25 procedures performed during the stay. Generally, payment for all the services provided during an inpatient stay is bundled into a single prospectively determined payment for a given MS-DRG.

There are no MS-DRGs specific to pain treatment or pain management; however, pain may be treated as a symptom under any MS-DRG as needed (e.g., after most major surgeries).[203] Further, some MS-DRGs specify a diagnosis that would primarily require pain treatment or involve pain as a contributing factor to the diagnosis. For example, MS-DRGs 91-93 contain the

[202] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS

[203] https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0001.html

ICD-10-PCS codes for chronic pain syndrome. [204;205] Payment for pain treatment or pain management is included in the payment for the MS-DRG for that stay.

Though pain treatments are generally considered one part of a suite a bundle of services offered in a patient's stay, there is some coverage under Part A for pain rehabilitation, specifically in an inpatient setting. Inpatient admissions to pain rehabilitation programs are covered if "the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain".[206] Inpatient pain rehabilitation programs are generally covered for four weeks. After four weeks, additional rehabilitation services that may be needed are expected to be provided through an outpatient pain rehabilitation program.

4.1.3 Medicare Part B: Pain Treatment Payment and Coverage

Coverage and payment for Medicare Part B services is generally determined based on the statutory benefit category, the supplier type, the care delivery setting, and whether there is an applicable NCD or LCD. The mechanisms used for determining coverage and payment vary based on the care delivery setting. This section focuses on coverage in office settings (physicians and other health professionals), in outpatient hospital departments and ambulatory surgery centers (ASCs), and in freestanding physical therapy, outpatient rehabilitation, and comprehensive outpatient rehabilitation facilities. The Medicare Coverage Database lists references to various types of pain coverage, for example, Acupuncture for Low Back Pain, and Chiropractic Services. [207]

Services provided in office settings (by physicians and other health professionals). Pain management services provided in an office setting by physicians and other health professionals are paid under the PFS, as required by statute. Generally, drugs administered intravenously or infused in a physician's office are paid under Part B using the average sales price methodology specified in statute. Many non-opioid drugs in the pain treatment list are covered under Part B. Medicare coverage for continued oral prescriptions of these drugs would be covered under the Part D Prescription Drug Program.[208]

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[204] DRG 91 "Other disorders of the nervous system with MCC (Major complication or comorbidity)"; DRG 92 "Other disorders of nervous system with cc (complication or comorbidity)"; DRG 93 "Other disorders of nervous system without CC/MCC"

[205] https://www.cms.gov/icd10m/version37-fullcode-cms/fullcode_cms/P0072.html

[206] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=23&ncdver=1&keyword=%22Some%20pain%20rehabilitation%20programs%20may%20utilize%20services%20and%20devices%20which%22&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact

[207] https://www.cms.gov/medicare-coverage-database/search.aspx

[208] https://www.cms.gov/medicare/coverage/prescription-drug-coverage

Non-drug treatments may also be furnished in the physician office setting and could be limited by the capabilities of the clinician. In addition to pain interventions that might be offered in the office setting, there are also multidisciplinary, multimodal treatment models and models of care that could be offered in the office setting. Examples of these models and their current coverage status under Medicare are discussed below.

Integrated pain management programs are multidisciplinary programs that follow a biopsychosocial model of pain care and are integrated with primary care. These programs provide services such as care coordination, medication management, psychosocial care, physical therapy, and occupational therapy. An AHRQ systematic review found that integrated pain management programs "may provide small to moderate improvements in function and small improvements in pain in patients with chronic pain compared with usual care."[209] The PMTF described these programs as "innovative payment models that recognize and reimburse holistic, integrated, multimodal pain management, including behavioral health." Currently, there are no LCDs or NCDs to specifically provide coverage for integrated pain management programs, although certain components of the programs (e.g. psychotherapy, chronic pain management and treatment) can be covered by Medicare.

Pain medical homes apply the concept of the patient-centered medical home specifically to pain management.[210;211] Medical homes coordinate between various provider types and settings of care, while offering comprehensive treatments and maintaining a person-centered model—giving more choice and autonomy to people when making decisions about their care.[212] Individuals with chronic pain may experience improved pain management through integrated physical and behavioral health care, or referral to or provision of community-based services such as environmental modifications, personal care, and caregiver supports. Medicare Parts A and B do not provide any enhanced payments when beneficiaries receive covered services through a pain medical home. Some states (including Missouri and Rhode Island) have used Medicaid section 1115 demonstration waivers to furnish primary care integration of complementary and integrative care and other non-opioid pain treatments into their Medicaid programs.[213;214]

Chronic care management (CCM) services in Medicare are covered for individuals with multiple (two or more) chronic conditions expected to last at least 12 months or for the life of the person with Medicare. CCM can benefit a beneficiary with pain and multiple chronic conditions

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[209] https://effectivehealth care.ahrq.gov/products/integrated-pain-management/research

[210] https://www.ahrq.gov/ncepcr/research/care-coordination/pcmh/index.html

[211] https://doi.org/10.1016/j.anclin.2015.07.009

[212] https://pcmh.ahrq.gov/page/defining-pcmh

[213] Medicaid Acting Deputy Administrator and Director Anne Marie Costello (2020). [Letter to Todd Richardson, Director MO HealthNet Division, Missouri Department of Social Services].

[214] https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Waivers/1115/downloads/ri/Comprehensive-Demonstration/ri-global-consumer-choice-compact-stc-12232013-12312018.pdf

and/or mental disorders by promoting preventive care and care coordination, increasing access to care, and reducing unnecessary services, so long as the person meets the eligibility criteria for CCM. Medicare covers CCM furnished to people with Medicare with multiple chronic conditions under Part B.[215]

Collaborative care models coordinate services for people with multiple chronic conditions to improve the experience of care and health outcomes. Collaborative care can be particularly beneficial for people with pain and multiple chronic conditions and/or mental disorders by integrating physical and behavioral health services. Medicare reimburses for Behavioral Health Integration services using the Psychiatric Collaborative Care Model (CoCM), billable through the PFS.[216]

Behavioral health integration (BHI) is integration of physical and behavioral health services to meet both medical and behavioral health needs.[189] BHI provides comprehensive care and reduces fragmented, unnecessary, or duplicative care. Medicare makes payment for BHI services delivered using the Psychiatric CoCM, a model of behavioral health integration that enhances usual primary care by adding care management and psychiatric consultation.[189] Medicare also covers "General BHI" which describes services using models of care other than CoCM. As of January 1, 2023, General BHI can also be billed by clinical psychologists and clinical social workers when they are serving as the focal point of monthly care integration.[189]

Chronic Pain Management and Treatment Services (CPM) as described above, are now separately payable under Medicare beginning January 1, 2023.

National Coverage Determinations and Annual Wellness Visit

There are some NCDs related to the coverage of various modalities for the treatment of pain that offer opportunities for the patient and clinician to discuss a pain treatment plan or options for treatment. The Medicare Annual Wellness Visit addresses a range of health concerns including an evaluation of pain for certain individuals (only patients using opioid medications).[217] Acupuncture for chronic low back pain is covered up to a maximum of 20 sessions per year, for some beneficiaries, and implantable electrical nerve stimulators are covered for certain patients with chronic intractable pain.[218;219] Medicare NCDs can be found at https://www.cms.gov/medicare-coverage-database/search.aspx.

Services Provided in Outpatient Hospital Departments and Ambulatory Surgical Centers (ASC). Pain medication in the outpatient hospital setting paid under Part B is generally treated as

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[215] https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/chroniccaremanagement.pdf

[216] https://www.cms.gov/files/document/mln909432-behavioral-health-integration-services.pdf

[217] https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html

[218] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=373

[219] https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=240

packaged supplies under the Outpatient Prospective Payment System (OPPS) and the payment is bundled with the primary procedure or treatment. Services in ASCs are generally paid similarly to services provided in outpatient hospital departments.[220;221]Payment for services through the OPPS is based on ambulatory payment classifications (APCs), which are classifications of clinically similar groups of services that are identified by HCPCS codes.

Some exceptions exist for specific, costly drugs which are separately paid at 106 percent of the ASP under the OPPS. When Part B does not cover a drug administered in the outpatient setting, the hospital usually charges the patient for the drug.[193]

The bipartisan The Non-Opioids Prevent Addiction in the Nation (NO PAIN) Act was signed into law in December 2023 as section 4135 of the Consolidated Appropriations Act, 2023 (P.L. 117-328)[222]. The Act directs CMS to provide separate payment for certain drugs, biologicals, and medical devices furnished in Hospital Outpatient Departments and Ambulatory Surgical Centers that meet the statutory criteria starting in 2025. It also requires a RTC on limitations, gaps, and barriers to access, or deficits in Medicare coverage or reimbursement.

Services Provided in Freestanding Facilities, Outpatient Rehabilitation Facilities, and Comprehensive Outpatient Rehabilitation Facilities. Certain types of providers are recognized as certified providers of outpatient therapy by Medicare and can be paid for physician services. "Freestanding" facilities refer to entities that provide services to people with Medicare but are unconnected to another provider such as a hospital.[223] In general, at outpatient rehabilitation facilities (ORFs), whether freestanding or not, outpatient therapy is covered if several conditions are met. This includes an individual need for therapy services, the establishment of a plan for furnishing these services from a physician or non-physician practitioner, and services must be furnished while the patient is under the care of a physician who certifies the plan.[224]

Within the general category of ORFs, there are comprehensive outpatient rehabilitation facilities (CORFs). CORFs have the same coverage requirements but are designed specifically around a multidisciplinary approach to rehabilitation and must include consultative and supervisory services in support of physical therapy, occupational therapy, speech-language therapy, or respiratory therapy. Because of the individualized nature of treatment plans and focus on multidisciplinary approaches, freestanding therapy providers, ORFs, and CORFs are positioned to offer multimodal pain treatment approaches such as multidisciplinary rehabilitation (MDR) and multidisciplinary pain programs (MPPs).

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[220] http://www.medpac.gov/docs/default- source/reports/mar19_medpac_ch16_sec.pdf?sfvrsn=0

[221] While CMS bundles most ancillary items and services with the primary service, it pays separately for certain ancillary items and services considered integral to surgical procedures, including many drugs. For separately payable drugs, CMS pays the ASC the same amount it pays under the OPPS.

[222] https://www.congress.gov/117/bills/hr2617/BILLS-117hr2617enr.pdf

[223] https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-413/subpart-E/section-413.65

[224] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf

Multidisciplinary Rehabilitation (MDR) is a coordinated program that seeks to combine biopsychosocial treatment components to improve recovery from, and management of, pain that involves at least two different specialties.[225] In its systematic review of "Noninvasive Nonpharmacological Treatment for Chronic Pain," the AHRQ found mixed but encouraging evidence for MDR in addressing several types of pain including fibromyalgia, but limited improvements for osteoarthritis and chronic lower back pain.[197] Medicare covers MDR for the treatment of pain in the CORF context.[226]

Multidisciplinary Pain Programs (MPPs) are also coordinated programs that seek to combine biopsychosocial treatment components to improve recovery from, and management of, pain. In its technical brief on MPPs, AHRQ defines MPPs as involving four key components: medical therapy including medication management, behavioral therapy (e.g., CBT), physical reconditioning (e.g., physical therapy), and education for self-management.[227] MPPs showed success restoring physical and emotional functioning and controlling pain. However, access to these treatment programs is limited due to an overall lack of coverage and a tendency for managed care organizations to "carve out" certain portions of the integrated program, which can reduce the program's efficacy.[199] As with MDR, currently Medicare does not extend coverage to MPPs, but some settings with Medicare coverage (e.g., CORFs) are structured to encourage a multidisciplinary approach to pain management.[228]

[225] https://effectivehealth care.ahrq.gov/sites/default/files/pdf/noninvasive-nonpharm-pain-update.pdf
[226] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c12.pdf
[227] https://effectivehealth care.ahrq.gov/sites/default/files/pdf/pain-chronic_technical-brief.pdf
[228] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_k_corf.pdf

SECTION 5.
LEGISLATIVE AND ADMINISTRATIVE OPTIONS

Medicare coverage information along with efficacy information from AHRQ evidence reviews was used for this section, as was feedback from interested parties and literature reviewed on barriers to accessing treatment, in addition to treatments identified from published federal guidelines.

5.1 Methods

Treatments for legislative and administrative options were considered if they had either partial or no Medicare Part A or B coverage and were included in an AHRQ pain-related evidence review during the past decade. For efficacy evidence summaries and strength of evidence scores from the relevant AHRQ evidence reviews were extracted. Treatments identified from the pain treatment list had at least one "moderate" strength of evidence score and showed some improvement in treating the relevant pain condition.

From the interested party feedback, literature review, and federally published guidelines, a list was compiled of other possible legislative and administrative options.

5.2 Findings

5.2.1 Legislative and Administrative Options for Expanding or Revising Medicare Part A and B Coverage and Payment for Acute and Chronic Pain Management

Three treatments (***see Exhibit 5***) were identified for potential coverage consideration: 1) acupuncture for fibromyalgia, 2) massage therapy for chronic low back pain, and 3) CBT for chronic low back pain.

Exhibit 5. Treatment Description and Coverage Detail for Identified Treatments

Treatment	Description	Coverage detail
Acupuncture for Fibromyalgia	Acupuncture is a traditional Chinese medicine technique that uses thin needles on strategic points. Strength of evidence is moderate at short and intermediate term for functional improvement.[229]	There is explicit non-coverage under National Coverage Determinations for Acupuncture for fibromyalgia (30.3.1). Acupuncture is covered for chronic low back pain. Acupuncturists are not Medicare recognized providers and cannot bill Medicare directly. Certain providers who fulfill state requirements can furnish acupuncture under Medicaid, and others must provide the services under appropriate supervision. [230]

[229] https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research#field_report_title_4

[230] https://www.cms.gov/files/document/r10337ncd.pdf#page=7

Massage Therapy for Chronic Low Back Pain	Massage therapy involves applying gentle and strong pressure to the muscles and joints to ease pain and tension. Strength of evidence is moderate at short term for pain improvement and moderate at short and intermediate term for function.[231]	Massage therapy is not covered by Medicare. Massage therapists are not Medicare recognized providers and cannot bill Medicare.
Cognitive Behavioral Therapy (CBT) for Chronic Low Back Pain	CBT is a psychological therapy used to change thought patterns. Strength of evidence is moderate for short, intermediate and long term pain and functional improvement.	Medicare Part B does not explicitly cover psychological therapies for the treatment of pain and coverage is only offered to people with Medicare diagnosed with a mental disorder.

5.2.1.1 Acupuncture for Fibromyalgia

Acupuncture is a traditional Chinese medicine technique that involves inserting thin needles on strategic points of the body.[232;233] In an AHRQ evidence review, acupuncture for fibromyalgia was associated with small improvement in short-term and intermediate function, with no effect on pain compared to a sham treatment or waitlist.[234] Strength of evidence was rated as moderate for functioning outcomes and low for pain outcomes.

There is a non-coverage NCD for acupuncture for fibromyalgia. At the time that policy was issued, CMS determined that there was no convincing evidence to support coverage. Upon review through the coverage determination process, acupuncture became covered under an NCD for certain beneficiaries with chronic lower back pain for up to 12 visits in 90 days as that review concluded that the evidence was sufficient to support coverage. An additional eight sessions are covered if the beneficiary shows improvement, though no more than 20 sessions are covered in a year and treatment must stop if there are no signs of improvement.

Assumptions for Part B Medicare coverage of acupuncture for fibromyalgia[235] were made with the same coverage limitations applied to chronic lower back pain. That is, coverage could be considered for up to 12 visits in 90 days, with eight additional sessions covered if the beneficiary shows improvement, and with no more than 20 sessions covered in a year. Acupuncturists are not recognized providers under the Medicare program and cannot directly bill for services.[236]

[231] https://effectivehealthcare.ahrq.gov/products/noninvasive-nonpharm-pain-update/research#field_report_title_4

[232] https://www.mayoclinic.org/tests-procedures/acupuncture/about/pac-20392763

[233] https://www.nccih.nih.gov/health/acupuncture-in-depth

[234] https://effectivehealth care.ahrq.gov/products/noninvasive-nonpharm-pain-update/research

[235] ICD-10-CM M79.7 "fibromyalgia"

[236] https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf

5.2.1.2 Massage Therapy for Chronic Low Back Pain

Massage therapy involves manipulation of the soft tissue of the body, using varying degrees of pressure and movement.[237;238] An AHRQ evidence review found that massage therapy for chronic low back pain was associated with small improvements in short-term functioning and short-term pain, compared with sham treatment or usual care. Strength of evidence was rated as moderate for short-term outcomes.

Massage therapy as furnished by massage therapists is categorically denied coverage by traditional Medicare.[239] Massage therapists are not Medicare recognized providers and cannot bill Medicare. However, physical therapists may incorporate certain elements or techniques of massage therapy into physical therapy services if deemed medically necessary as part of a physical therapy service as described above.

As a coverage option, Part B Medicare coverage of massage therapy for chronic low back pain could be considered for up to six one-hour sessions in one year. Coverage of massage therapy could be considered only for delivery by physical therapists, and not by massage therapists.

5.2.1.3 Cognitive Behavioral Therapy (CBT) for Chronic Low Back Pain

CBT is a type of psychological treatment that involves efforts to change thought patterns, and behaviors.[240] The basic premise of CBT is that cognitions, emotions, and behaviors are linked, and that there are multi-directional causal relationships among them. By working with cognition or thoughts the person can change the experience of emotions like depression or anxiety, and behaviors. CBT can help the person to identify negative "scripts" that may activate when certain stimuli are present, helps raise awareness of these, can stop them, and substitute other thought patterns. This is generally accomplished in a time-limited fashion, typically weekly sessions for 8-12 weeks. A 2020 AHRQ review found that CBT was associated with some improvements in pain for people living with chronic low back pain[241], and it may also help individuals living with fibromyalgia.[242]

An AHRQ evidence review found that CBT for chronic lower back pain is associated with small improvements in function and pain in short, medium, and long-term follow-up compared to usual care or attention control. Strength of evidence was rated as moderate for all outcomes.

Although there is not a procedure code specific to CBT, Medicare Part B includes coverage of CBT through psychotherapy codes. Coverage of psychotherapy has thus been primarily for

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[237] https://www.mayoclinic.org/tests-procedures/massage-therapy/about/pac-20384595

[238] https://www.nccih.nih.gov/health/massage-therapy-what-you-need-to-know

[239] https://www.medicare.gov/coverage/massage-therapy

[240] https://www.nccih.nih.gov/health/relaxation-techniques-what-you-need-to-know

[241] https://effectivehealthcare.ahrq.gov/sites/default/files/related_files/surveillance-report-3-noninvasive-nonpharma.pdf

[242] https://acrjournals.onlinelibrary.wiley.com/doi/10.1002/art.42672

persons with a mental disorder diagnosis, although there are two pain related diagnoses for which coverage is mentioned: F45.41, Pain disorder exclusively related to psychological factors, and F45.42, Pain disorder with related psychological factors.[243] However, CBT to treat chronic low back pain is not specifically mentioned, and one consideration for this Report was to weigh adding chronic low back pain to the diagnoses for which psychotherapy (including CBT) is covered.

Psychotherapy is billed with HCPCS codes that reflect the amount of time spent with the patient, and family may or may not be present during these therapy sessions. To bill these codes, the psychotherapist must provide a mental health diagnosis using an ICD-10 code and/or Diagnostic and Statistical Manual (DSM) code.[244;245] Further guidance on psychotherapy billing and coverage of mental health services in Medicare can be found in the Medicare Learning Network Mental Health MLN booklet issued in March 2022.[246] People living with chronic pain experience more behavioral health issues including depression, anxiety, and SUD. Although estimates vary, nearly half may have depression.[247]

A second set of procedure codes, the Health and Behavior Assessment and Intervention (HBAI) services codes, is intended to be used for psychological assessment and treatment when the primary diagnosis is a medical condition, such as a condition that could involve acute or chronic pain. This family of codes was revised in 2020. Health behavior assessment is conducted through health-focused clinical interviews, behavioral observation and clinical decision-making, and includes evaluation of the person's responses to disease, illness or injury, outlook, coping strategies, motivation and adherence to medical treatment. Health behavior interventions are provided individually, to a group (two or more patients), and/or to the family, with or without the patient present, and include promotion of functional improvement, minimization of psychological and/or psychosocial barriers to recovery, and management of and improved coping with medical conditions.[248] The HBAI codes are not used for mental health services, but rather apply to services that address the psychological, behavioral, emotional, cognitive, and interpersonal factors in the treatment/management of people diagnosed with physical health issues. Use of HBAI codes requires a physical health diagnosis (ICD-10) to be the primary diagnosis. The HBAI codes capture services related to physical health, such as adherence to medical treatment, symptom management, health-promoting behaviors, health-related risky

[243] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57520&ver=23&keyword=psychotherapy&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

[244] https://www.cms.gov/Medicare/Coding/ICD10

[245] https://www.psychiatry.org/psychiatrists/practice/dsm

[246] https://www.cms.gov/files/document/mln1986542-medicare-mental-health.pdf

[247] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9509520/

[248] https://www.apaservices.org/practice/reimbursement/health-codes/health-behavior

behaviors, and adjustment to physical illness. The HBAI codes and the psychotherapy codes cannot be billed contemporaneously.

The revised HBAI revised codes are well-suited to offer CBT to people with chronic pain when the person does not have a concurrent mental disorder, and are described in the MCD.[249] Based on recent coding changes, people with Medicare experiencing acute or chronic pain, with or without a mental disorder, are currently able to receive CBT through one of these two pathways.

5.2.2 Other Legislative and Administrative Options

5.2.2.1 Consider Making Telehealth Flexibilities Permanent for Chronic Pain

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) broadened the waiver authority under section 1135 of the Social Security Act.[250] Under this authority, the Secretary waived some restrictions on the types of physicians and practitioners who may bill for telehealth services, effectively opening telehealth to all health care physicians and practitioners who can bill Medicare for professional services. During the PHE for COVID-19, the Secretary made temporary changes to pay for certain services delivered via telehealth at the facility or non-facility rate based on the site of service that the visit would be furnished in if in-person.[251] The Secretary also waived restrictions on the type of telecommunications systems that can be used to furnish telehealth services, allowing certain telehealth services to be audio-only telephone; this includes certain E/M services, and behavioral health counseling and educational services.[218] As part of the Consolidated Appropriations Act of 2021, after the PHE, the originating site (location of the patient) was expanded to include services furnished in any geographic area and in the patient's home for telehealth services for purposes of the diagnosis, evaluation, or treatment of a mental health disorder.[252] Many of the telehealth flexibilities available during the COVID-19 public health emergency have been extended following its end in May 2023, to allow more time for data collection and consideration for permanent changes.[253] Because physical access to pain management services is an identified treatment barrier, consideration might be given to an approach that makes telehealth flexibilities permanent for pain management treatments where there is strong evidence that services can effectively be furnished via telehealth to provide care for people with Medicare with pain. Medicare's new Chronic Pain Management and Treatment codes were added to the Category 1 telehealth list with the exception of the first visit, which must be performed in person, without the use of telecommunications technology.

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[249] https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=52434&ver=39&

[250] https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf

[251] https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet

[252] https://www.cms.gov/files/document/mm12549-cy2022-telehealth-update-medicare-physician-fee-schedule.pdf

[253] https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-proposed-rule

5.2.2.2 Explore Adding Quality Measures Specific to Chronic Pain

Under the Merit-Based Incentive Payment System (MIPS) quality payment program, clinicians can participate in incentive payment systems or alternative payment models that use quality measures to assess performance.[254] There are over 200 quality measures that can be used to assess performance in the quality payment program; however, there are no quality measures that focus on chronic pain.[255;256] Given estimates that one in 10 American adults have chronic pain that significantly disrupts their work, social, and/or self-care activities,[257] including many older adults and people with disabilities, consideration might be given to exploring developing quality measures specific to chronic pain in MIPS. Once developed and endorsed, consideration might be given to using the measures in MIPS.

[254] https://qpp.cms.gov/about/qpp-overview
[255] https://qpp.cms.gov/mips/explore-measures
[256] https://cmit.cms.gov/cmit/#/
[257] https://doi.org/10.15585/mmwr.mm6736a2

SECTION 6.
IMPACT OF POTENTIAL LEGISLATIVE AND ADMINISTRATIVE OPTIONS ON MEDICARE EXPENDITURES[258]

This section estimates the potential costs of three options for expanding coverage to include acupuncture for fibromyalgia as well as CBT and massage therapy for chronic low back pain. Part of the analysis is an assessment of potential offsets from substituting these treatments for more expensive care. Below is an explanation of how the analysis of increased expenditures and potential offsets was conducted for the three treatments/options. This section is derived from a 2022 CMS Office of the Actuary Pain Management Cost/Benefit Analysis technical memorandum.

6.1 Methods

The first step in the analysis was to identify how diagnoses for fibromyalgia and chronic lower back pain are coded, and how providers bill for acupuncture, CBT, and massage therapy. The International Classification of Diseases 10th Revision, Clinical Modification (ICD-10-CM) diagnosis codes associated with fibromyalgia and chronic lower back pain were identified. To identify frequency of billing and costs associated with each treatment Current Procedural Terminology/Health care Common Procedure Coding System (CPT/HCPCS) codes used to bill for these services were identified.

6.1.1 Financial Estimates

Using Medicare claims data and the relevant ICD-10-CM codes, annual costs for Medicare beneficiaries with fibromyalgia and chronic lower back pain in excess of the costs of an average beneficiary were estimated. Using the CPT and HCPCS codes for each treatment, an average annual expenditures for each of the treatments under consideration was identified. Because the existing research is limited regarding the impact on overall health care expenditures of providing these additional benefits to Medicare beneficiaries, there is uncertainty surrounding the impact on Medicare spending. To assess the impact of uncertainty, illustrations of the potential expenditure impacts were done based on assumptions regarding the specific conditions, treatments, and Medicare coverage discussed in this Report.

[258] The material for this section comes from a Pain Management Cost/Benefit Analysis technical memorandum from the CMS Office of the Actuary which was finalized on January 3rd, 2022. The authors include Alyssa C. Gross, Shelby L. Meadowcroft, and John D. Shatto.

6.2 Findings

6.2.1 Acupuncture for Fibromyalgia

Acupuncture is a form of treatment that involves inserting needles in certain points of the body, with electrical stimulation sometimes included.[259] Medicare currently covers this treatment for chronic lower back pain. Previous studies have found that acupuncture may reduce fibromyalgia's symptoms of pain and fatigue.[260;261]

The increased expenditures for covering acupuncture services were estimated based on the assumption that the maximum number of allowable appointments would follow current Medicare coverage requirements for acupuncture to treat chronic lower back pain. Under these assumptions, Medicare would cover up to 12 sessions within 90 days, and if there are signs of improvement, Medicare would cover an additional eight sessions, bringing the maximum number of possible sessions to 20 each year.[262] The estimate assumes that each session would last for one hour.

The average Medicare payment for a 15-minute acupuncture session in 2020 was about $29. Medicare payment amounts from the following codes in the HCPCS: 20560, 20561, 97810, 97811, 97813, and 97814. (Medicare payment for these codes is currently allowed for chronic lower back pain.) **Exhibit 6** provides a description for each of these codes.

Exhibit 6. HCPCS Codes for Acupuncture

HCPCS Code	HCPCS Definition
20560	Insertion of needle in 1 or 2 muscles
20561	Insertion of needle in 3 or more muscles
97810	Acupuncture—1 or more needles, first 15 minutes
97811	Acupuncture—1 or more needles, each additional 15 minutes
97813	Acupuncture—1 or more needles with electrical stimulation, first 15 minutes
97814	Acupuncture—1 or more needles with electrical stimulation and re-insertion of needles

Based on recent data, for an individual receiving the full course of acupuncture (12 visits), with each visit lasting one hour, Medicare expenditures would be roughly $1,415 per year. If the individual received the maximum number of visits (20), the Medicare expenditures would be about $2,359 per year.

[259] https://www.mayoclinic.org/tests-procedures/acupuncture/about/pac-20392763
[260] https://doi.org/10.2147/JPR.S186227
[261] https://doi.org/10.4065/81.6.749
[262] https://www.medicare.gov/coverage/acupuncture

Medicare data indicate that 1.0 percent of beneficiaries—roughly 627,000 people according to the 2021 Medicare Trustees Report—have been diagnosed with fibromyalgia. Therefore, the estimate has this assumption. Using this prevalence rate and the per beneficiary expenditure estimates, annual expenditures of acupuncture for fibromyalgia range from roughly $0.9 billion (based on receipt of 12 sessions using 2021 data) to $1.5 billion (if everyone received 20 sessions). There is no mechanism to reliably predict how many of the people with Medicare living with fibromyalgia pain might use acupuncture.

There is a lack of existing research to guide estimation of expenditures. Available literature tends to focus on patient improvement rather than intervention costs, baseline costs of care for fibromyalgia, and/or offsets attributable to the use of acupuncture as a treatment option.[263];[264];[265];[266];[267];[268];[269];[270];[271] Studies that either note or specifically address expenditures do not separately analyze the Medicare-aged population; rather, they generally include adults of all ages,[109; 114-117] and/or they are conducted outside of the U.S., making cost comparisons difficult.[232;233;272] Additionally, the number of treatment sessions used in interventions varies widely, leading to imperfect comparisons regarding costs. For example, intervention treatment ranges from six treatments over 2–3 weeks to 20 treatments over 10 weeks, and session length ranged from 20 minutes to 40 minutes. Finally, the symptoms of fibromyalgia can differ significantly in their expression and severity—recommended treatment (and associated costs) would vary from person to person—but it is difficult to estimate these effects given the lack of existing research. There may be offsets in the reduction of prescribed medications or doctor visits, but there are no published studies on this.

Because of the lack of available research, Medicare claims data were analyzed to assess the additional expenditures associated with acupuncture relative to the total medical expenditures for beneficiaries with fibromyalgia. In 2019, Medicare expenditures for beneficiaries diagnosed with fibromyalgia ($14,551) exceeded the average Medicare beneficiary expenditures for those enrolled in Parts A and B ($11,529), or 26.2 percent higher. After adjustment for risk, the 2019

[263] https://doi.org/10.4065/81.6.749
[264] https://www.medicare.gov/coverage/acupuncture
[265] https://doi.org/10.1186/s12891-016-1027-6
[266] https://doi.org/10.2165/11535250-000000000-00000
[267] https://doi.org/10.1111/j.1742-1241.2007.01480.x
[268] https://doi.org/10.7326/0003-4819-143-1-200507050-00005
[269] https://doi.org/10.1093/pm/pnx263
[270] https://doi.org/10.1093/pm/pnx322
[271] https://doi.org/10.1136/acupmed-2015-010950
[272] https://doi.org/10.1007/s40273-014-0137-y

expenditures were $11,767, which was only 0.2 percent higher than the cost for the average beneficiary.[273]

Further analysis is needed regarding expenditures for prescription drugs for fibromyalgia patients and the ways in which the use of these drugs may be decreased by means of acupuncture. In 2019, for beneficiaries diagnosed with fibromyalgia, Medicare spent approximately $7,240 annually on Part D prescription drugs, or 81.5 percent more per year than the average beneficiary (for whom spending was an average of $3,990). While there may be a potential for offsets if acupuncture is offered as a treatment, there is uncertainty about whether expenditures for a beneficiary with fibromyalgia would be reduced. It is unknown, for example, if acupuncture is not a good substitute for drugs at the population or person level. Therefore it is possible that a beneficiary with fibromyalgia could receive both acupuncture and drugs at a higher expenditure level, but this is unknown.

6.2.2 Massage Therapy for Chronic Low Back Pain

Massage therapy involves the manipulation of soft tissue in the body in order to treat certain conditions, including pain.[274] Although massage therapy can be administered by different practitioners and professionals, the estimate assumes that only physical therapists, and not massage therapists, will furnish this treatment. Costs are calculated under the assumption that beneficiaries with a chronic low back pain diagnosis will be permitted to receive up to six one hour sessions per year.[275]

The average cost of a 60-minute massage therapy session in 2020 was about $82. This cost was based on the Medicare payment amount for HCPCS 97124—defined as "therapeutic massage to 1 or more areas, each 15 minutes." (Medicare payment under this code is currently allowed if the service meets the requirements for covered therapy services.) Based on a maximum number of six visits per year, the Medicare cost would have been approximately $494 per beneficiary per year in 2020. CMS maintains a website that displays payments under the Medicare Physician Fee Schedule by HCPCS code, including by area to area. This display tool is an aid for physicians and nonpractitioners looking for PFS payment rates.[276]

As is the case with other treatments included in this analysis, there is limited research on the cost savings and efficacy of massage therapy for chronic lower back pain. Herman *et al*., 2019, which is the most recent study reviewed, found that massage therapy cost payers $54 per patient

[273] This result suggests that beneficiaries diagnosed with fibromyalgia generally have more comorbidities than just that one condition. The adjusted amount is an estimate of the average cost for fibromyalgia alone compared to the average cost for a Medicare beneficiary.

[274] https://www.mayoclinic.org/tests-procedures/massage-therapy/about/pac-20384595

[275] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=N&NCAId=295

[276] https://www.cms.gov/medicare/physician-fee-schedule/search/overview

compared to usual care after factoring in changes in health care utilization.[277] Cherkin *et al*., 2001, found that after massage therapy, which cost an average of $377 per patient (and $48 per treatment), participants' treatment for chronic lower back pain decreased, but the results were not statistically significant, and overall chronic lower back pain costs were not calculated.[278] Hollinghurst *et al*., 2008[279], found that the massage therapy intervention cost £160, but because this study was conducted in the U.K., costs may not be comparable to those in the U.S. health care system. Notably, the two studies conducted in the U.S. used massage therapists to carry out their intervention, while this analysis assumes that only physical therapists will administer massage therapy—a distinction that could lead to a difference in costs.[243; 244]

Based on Medicare claims data, the portion of the Medicare population that was diagnosed with chronic lower back pain in 2019 is approximately 16.5 percent. Accordingly, more than 10.3 million beneficiaries would have the option to receive massage therapy in 2020. If all those who were eligible were to receive this new treatment, the total Medicare cost, at $494 per beneficiary for each year, would be roughly $5.1 billion. There is no mechanism to reliably predict how many of the people with Medicare living with chronic lower back pain might use massage therapy.

In 2019, patients with chronic low back pain spent approximately 51.5 percent more than the average Medicare fee-for-service (FFS) population, totaling $17,464. After the 2019 costs are risk adjusted, a patient diagnosed with chronic low back pain still spent about 18.1 percent more than an average beneficiary. The rest of this difference was due mostly to musculoskeletal surgery; the average cost for inpatient care of a chronic low back pain-diagnosed beneficiary over 2014–2019 was approximately $5,747 annually with a large portion of spending attributable to inpatient hospital services (32.9 percent).

Making these services available may also encourage more beneficiaries to use them. In particular, massage therapy is a potentially popular treatment that may see increased utilization. Although previous research has shown that 20–30 percent of older adults have chronic low back pain, this estimate assumes that only 16.5 percent of the Medicare population has been diagnosed with the condition, which leaves a substantial number of individuals who may ultimately be diagnosed should massage therapy become a covered treatment.[280;281;282] The estimate assumes a "clean period" (defined as no treatment related to back pain for 6 months prior) and then at least 3 months of chronic lower back pain.

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[277] https://doi.org/10.1097/BRS.0000000000003097
[278] https://doi.org/10.1001/archinte.161.8.1081
[279] https://www.bmj.com/content/337/bmj.a884
[280] https://doi.org/10.1097/BRS.0b013e3181557955
[281] https://doi.org/10.1111/j.1526-4637.2003.03042.x
[282] https://doi.org/10.1097/00007632-199909010-00011

6.2.3 Cognitive Behavioral Therapy (CBT) for Chronic Low Back Pain

CBT is a type of psychological treatment that helps a person become aware of ways of thinking that may be automatic but are inaccurate and harmful and involves efforts to change thinking patterns, and usually behavioral patterns as well.[283]

Based on an intervention treatment used in the literature, the estimate assumes that although there are no limits to the number of appointments Medicare beneficiaries may receive, patients will average eight appointments per year.[284] Research has shown that while CBT adds additional costs compared to the usual care for chronic lower back pain, this treatment is associated with statistically significant gains in participants' quality of life.[249;285]

The average cost of a 60-minute psychotherapy session in 2023 was about $147. This cost was based on the Medicare payment amount for HCPCS 90837—defined as "psychotherapy, 60 minutes." The average 2023 cost of HBAI codes 96158 and 96159 (individual intervention), for 30 minutes and each additional fifteen minutes, respectively are about $67 and $23.[286]

The portion of the Medicare population that is currently diagnosed with chronic lower back pain is approximately 16.5 percent. This could lead to upwards of 10.3 million beneficiaries with the potential to receive CBT. Using a cost of $835 per beneficiary for each year, this could total roughly $8.6 billion, based on 2019 costs. There is no mechanism to reliably predict how many of the people with Medicare living with chronic lower back pain might use massage therapy.

The literature review provides costs information to assist this CBT analysis, with certain limitations. Herman *et al.*, 2019, found that the costs of CBT amounted to $77 on average.[287] However, the CBT treatment in this study consisted of a group-based education program, where this analysis assumes that treatments are provided in one-on-one sessions, which are more expensive per patient. Additionally, CBT was found to be less effective (compared to other treatments that were studied. Herman *et al.*, 2017 and Lamb *et al.*, 2010 calculated intervention ($150 and £187 respectively) and average treatment costs ($2,760 and £422, respectively).[288] Notably, participants in the Lamb *et al.*, 2010 study included adults of all ages (as opposed to adults of Medicare age only), and because the study was conducted in the United Kingdom, cost-estimate comparisons are not ideal. Study designs in the literature are not exact matches with the Medicare population in the U.S. [289] and are included here as a general reference.

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[283] https://www.nccih.nih.gov/health/relaxation-techniques-what-you-need-to-know

[284] https://doi.org/10.1097/BRS.0000000000002344

[285] Herman *et al.*, 2019.

[286] https://www.apaservices.org/practice/reimbursement/health-codes/2022-health-behavior-assessment-codes-factsheet.pdf

[287] https://doi.org/10.1097/BRS.0000000000003097

[288] https://doi.org/10.1097/BRS.0000000000002344

[289] https://doi.org/10.1016/S0140-6736(09)62164-4

Medicare can pay for CBT under the HBAI codes for people with Medicare without mental disorders who have various types of chronic pain, and through the psychotherapy codes for people with pain who have a diagnosed mental disorder. If practitioners are hesitating to furnish CBT to this group because of any uncertainty around use of the HBAI codes, this Report will help assure access to CBT is not impeded for either group.

SECTION 7.
SUMMARY OF FINDINGS AND CONCLUSION

7.1 Summary of Findings

What barriers to accessing pain treatment interventions exist for Medicare beneficiaries entitled to benefits under Part A or enrolled under Part B?

Barriers to accessing pain treatment interventions for Medicare Parts A and B beneficiaries include a lack of Medicare coverage for some modes of pain treatment, statutorily defined Medicare benefit categories, insufficient payment for provider time, and limited access to pain specialists or integrated care models.

Some treatments, for example psychotherapy, are clearly covered by Medicare, but providers and beneficiaries are not always aware of the availability of payment for health and behavior assessment and intervention for pain, including cognitive behavior therapy, without accompanying psychological symptoms. Other treatments may vary in coverage by specific pain diagnosis, such as acupuncture, which is only covered for chronic low back pain. Additionally, there is a mental health provider shortage and thus many psychologists and therapists trained in CBT may not accept Medicare.

Insufficient payment for provider time to specifically manage chronic pain has been partially addressed in the final 2023 PFS rule (Document Citation 87 FR 69404) with new payment codes.

Limited access to pain specialists or integrated care models often leaves primary care physicians to treat patients living with chronic pain, despite insufficient clinical training; and there is a concurrent issue with shortages of PCPs willing to provide pain care. Multiple studies also reported inadequate primary care pain management services, underuse of drug screening when appropriate, and omission of key safety information when counseling patients on the range of medications and other substances that may be used to address pain.

Additional barriers to pain treatment access include inadequate provider and patient education on pain care options, limited access to transportation and telehealth technology, poor care coordination across providers, and limited provider access to patient physical and mental health histories.

What guidance is published by the Federal government on pain management and the prescribing of opioids?

Guidelines typically recommend against using opioid medication as a first-line therapy for acute and chronic pain for most patients and instead suggest specific nonopioid-based oral and topical medications and nonpharmacologic therapies such as psychotherapy, physical therapy, acupuncture, and exercise therapy.

When opioids are appropriate to treat chronic and acute pain, guidelines generally recommend a combination of opioid therapy with nonpharmacological and nonopioid pharmacological therapies. Many guidelines still refer to the CDC 2016 Guideline for Prescribing Opioids for Chronic Pain. As noted above, the 2016 Guideline was updated in 2022 to provide for more flexible, patient-centered, and individualized pain care. Guidelines suggest including individual risk assessments associated with opioid prescribing when developing treatment plans, and the AHRQ has begun research on clinical decision support tools.[290] Guidelines also recommend providers review PDMP data before initiating opioid regimens, and periodically throughout treatment. For people with pain who also have an OUD, most guidelines recommended offering MOUD such as buprenorphine and methadone, and options for pain such as acetaminophen (APAP), NSAID, and topicals, behavioral therapies, and complementary and integrative care such as acupuncture and therapeutic massage.

What is the coverage of, and payment for, evidence-based interventions for acute and chronic pain, under Medicare Parts A and B?

For short-term, acute care hospitalizations (covered by Medicare Part A), payments are made using the IPPS. IPPS pays a single bundled payment and is based on broad diagnosis groupings designed for payment of treatment of similar conditions with varying degrees of severity. For pain rehabilitation, inpatient admissions are covered only if "the pain is attributable to a physical cause, the usual methods of treatment have not been successful in alleviating it, and a significant loss of ability to function independently has resulted from the pain".[291]

Treatment coverage and payment for Medicare Part B services is determined based on the provider type, care delivery setting, and whether there is an applicable NCD or LCD. Thus, pain treatment coverage may vary depending on which MAC serves the beneficiary's geographic location/jurisdiction.[292].

Some treatments identified with coverage or statutory-based limitations include acupuncture for fibromyalgia, as well as CBT and massage therapy for chronic low back pain. Beyond individual treatment coverage, there are multidisciplinary, multimodal treatment models, such as integrated pain management programs and pain medical homes, for which Medicare does not currently provide coverage. However, Medicare does provide coverage for freestanding therapy providers,

[290] https://digital.ahrq.gov/ahrq-funded-projects/scaling-interoperable-clinical-decision-support-patient-centered-chronic-pain-care

[291] https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=23&ncdver=1&keyword=%22Some%20pain%20rehabilitation%20programs%20may%20utilize%20services%20and%20devices%20which%22&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=AAAAAAQAAAAA&KeyWordLookUp=Doc&KeyWordSearchType=Exact

[292] https://www.cms.gov/medicare/coding-billing/medicare-administrative-contractors-macs/whats-mac

outpatient rehabilitation providers, and CORFs, and these are able to furnish multimodal treatment approaches due to the individualized nature of treatment plans and multidisciplinary approaches.

What legislative and administrative options exist to improve coverage of, and payment for, pain interventions in Medicare?

Three treatments from the pain treatment list for coverage consideration were identified.

- Part B Medicare coverage of acupuncture for Fibromyalgia could be considered for up to 12 visits in 90 days, with eight additional sessions covered if the beneficiary shows improvement, and with no more than 20 sessions covered in a year. Note that separate from the level of evidence available for this service, acupuncturists are not recognized providers of the Medicare program and cannot bill directly for their services.
- Part B Medicare coverage of massage therapy for chronic low back pain could be considered for six 60-minute sessions in a year, with documentation necessary to support continued treatment through this modality. Only physical therapists would be approved to deliver the massage therapy.
- Part B Medicare coverage of psychotherapy would explicitly cover CBT could add the diagnosis of chronic low back pain to the psychotherapy coverage list. Several other considerations were identified. However, based on recent changes to the HBAI codes and the discussion in this Report, such action is likely not needed.
- Making certain telehealth flexibilities, such as changes to the definition of originating site, and payment for audio-only telehealth, permanent to furnish care for patients with chronic pain could be considered.
- Developing and obtaining endorsement of quality measures specific to chronic pain and then adding to the MIPS could be considered.

What are the increased Medicare expenditures for these legislative and administrative options?

- Increased Medicare expenditures for coverage of acupuncture for fibromyalgia were estimated to range from $0.9 billion (for those receiving only 12 sessions) to $1.5 billion (for those receiving 20 sessions, based on 2021 data).
- Massage therapy for chronic lower back pain costs were estimated to be roughly $5.1 billion if all those who were eligible were to receive this new treatment (based on the maximum of six visits per year), based on 2020 data.

- CBT for chronic lower back pain costs were estimated to be roughly $8.6 billion using the 2020 data for psychotherapy.

7.2 Strengths and Weaknesses of Approach and Analysis

This Report draws on a wide variety of data sources, including consultations with interested parties, peer-reviewed literature, Federal pain management and opioid prescribing guidelines, Medicare coverage documentation, AHRQ evidence reviews, and Medicare claims data. The methodological approaches were tailored to the different analytic questions. The Report also benefited from input from persons with expertise in pain management and Medicare coverage. The approach to identifying potential legislative and administrative options for consideration was evidence-based using coverage information from a pain treatment list coupled with AHRQ evidence reviews for treatments with coverage limitations. The analysis used Part A and B Medicare claims data to estimate increased expenditures.

This Report's weaknesses stem from a lack of information in several key areas. First, the literature on barriers to accessing pain management treatment is not focused on access issues for Medicare beneficiaries, who have certain characteristics (e.g. age, disability, multiple chronic conditions) that other populations do not.[293] The literature does not address specific access issues related to Medicare coverage, or Medicare beneficiaries. Second, evidence reviews can only be based on the available evidence which, in the case of pain management is limited both in the number and strength of studies for pain management outside opioid medications. Therefore, strength of evidence scores were often rated as low either due to an insufficient volume of supporting literature or to poor quality studies. This limited the number of evidence-based legislative and administrative options that could be considered. Third, there is limited literature on potential offsets to the increased expenditures for the five potential legislative and administrative options. Specifically, without information about the expected service take-up, the estimates assume that all eligible beneficiaries with the associated condition would use the new benefit.

7.3 Conclusion

Pain management, especially the management of chronic pain, is a pressing health care issue and has a significant impact on people with Medicare, where more than 80 percent of all beneficiaries report they regularly experience chronic pain. This Report is the legislated study as required in Section 6086 of the SUPPORT Act. It summarizes a multi-component study that examined barriers to treatment access, guidelines for pain management and opioid prescribing, coverage of pain treatments under Medicare Parts A and B, and potential legislative and administrative options.

[293] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Medicare_Beneficiary_Characteristics

There are effective options for pain management as well as barriers to accessing certain pain management treatments for Medicare beneficiaries, including the lack of coverage for some treatments. This Report contains legislative or administrative options that could be considered: Part B coverage of acupuncture for fibromyalgia, Part B coverage of massage therapy for chronic low back pain, Part B coverage of CBT for chronic low back pain, making telehealth flexibilities permanent to furnish care for patients with chronic pain, and adding quality measures specific to chronic pain after the development and endorsement process.

Finally, as noted in research limitations, more research on the treatment of chronic pain could be conducted. Some research is now taking place under the NIH's HEAL Initiative[294], which is advancing device-based treatments for people who currently have no effective ways to manage their pain, and supporting target identification, late-stage translational therapeutic and diagnostic device development, verification and validation activities, and early clinical studies in pain.

Chronic pain is especially common[295],[296] [297]in older adults, but the effective treatment of acute and chronic pain is important for each American, across the lifespan. Everyone is subject to experiencing acute or chronic pain as the result of an accident, illness, genetic condition, surgery, aging, disability, and many other common causes. Better understanding of the Medicare toolbox of effective pain treatments that can potentially preserve and improve quality of life can enhance the health and wellbeing of people living with pain and their families, caregivers, friends, communities, and the nation. This Report is a step to achieving those goals.[298]

[294] https://heal.nih.gov/

[295] https://www.sciencedirect.com/science/article/pii/S0278584619300831

[296] https://www.apa.org/pubs/journals/releases/amp-a0035794.pdf

[297] https://medscimonit.com/abstract/index/idArt/911260

[298] https://www.hhs.gov/sites/default/files/pmtf-fact-sheet-access-to-care-508-08-30-2019.pdf

APPENDIX A
SUMMARY OF CONSULTATION WITH INTERESTED PARTIES

Type	Document	Publication Date
Include		
Public Comments	CMS Deidentified Comments from Individuals to Dr. Todd Graham Pain Management Study Mailbox	9/16/2020
Public Comments	Pain Management Best Practices Inter-Agency Task Force Public Comments from Organizations	8/6/2018
Public Comments	Pain Management Best Practices Inter-Agency Task Force Public Comments from Multiple Interested Parties	8/27/2020
Feedback Letter	The American Society of Anesthesiologists (ASA) Feedback Letter	10/14/2020
Feedback Letter	American Massage Therapy Association (AMTA) Feedback Letter	8/27/2020
Feedback Letter	American Physical Therapy Association Feedback Letter	9/22/2020
Feedback Letter	The American Association of Nurse Practitioners (AANP) Feedback Letter	9/2/2020
Feedback Letter	The Restless Legs Syndrome Foundation (RLS) Feedback Letter	9/16/2020
Report	CDC Final Report on Interested Parties Engagement Event Presentation Slides	11/18/2020
Report	Pain Management Best Practices Inter-Agency Task Force Summary of Public Comments Report Presentation Slides	9/25/2018
Summary	CMS Advisory Panel on Outreach and Education Executive Summary for January 15, 2020	1/15/2020
Summary	CMS Advisory Panel on Outreach and Education Meeting Summary for September 23, 2020	9/23/2020
Transcript	CMS Listening Session on Pain Management Transcript for August 27, 2020	8/27/2020
Transcript	CMS Listening Session on Pain Management Transcript for September 16, 2020	9/16/2020

APPENDIX B
FEDERAL GUIDELINES

1. Dowell, D., Haegerich, T. M., & Chou, R. (2016). CDC guideline for prescribing opioids for chronic pain--United States, 2016. *MMWR Recommendations and Reports*, *65*(No. RR-1), 1-49. https://dx.doi.org/10.15585/mmwr.rr6501e1

2. U.S. Department of Health and Human Services. (2019, Oct). *HHS guide for clinicians on the appropriate dosage reduction or discontinuation of long-term opioid analgesics*. https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf

3. U.S. Department of Veterans Affairs, Department of Defense. (2017, Feb). *Clinical practice guideline for opioid therapy for chronic pain, Version 3.0*. https://www.healthquality.va.gov/guidelines/Pain/cot/VADoDOTCPG022717.pdf

4. U.S. Department of Veterans Affairs, Department of Defense. (2017, Sep). *Clinical practice guideline for diagnosis and treatment of low back pain*. https://www.healthquality.va.gov/guidelines/Pain/lbp/VADoDLBPCPG092917.pdf

5. U.S. Department of Veterans Affairs. (2016, Sep). *A VA clinician's guide to identification and management of opioid use disorder*. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/45_OUD_Provider_AD_Educational_Guide_IB_933_P96813.pdf#

6. U.S. Department of Veterans Affairs. (2017, Jul). *Acute pain management: Meeting the challenges*. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/Pain_Provider_AcutePainProviderEducationalGuide_IB10998.pdf#

7. U.S. Department of Veterans Affairs. (2017, Aug). *Transforming the treatment of chronic pain: Moving beyond opioids*. https://www.pbm.va.gov/PBM/AcademicDetailingService/Documents/Academic_Detailing_Educational_Material_Catalog/Pain_ChronicPainProviderEducationalGuide_IB101000.pdf#

8. Indian Health Service. (2018, Feb 13). *Chapter 30 - Chronic non-cancer pain management | Part 3 – Professional services*. https://www.ihs.gov/ihm/pc/part-3/p3c30/

9. Indian Health Service. (2020, November). *Recommendations for management of acute dental pain*. https://www.ihs.gov/doh/documents/Recommendations%20for%20Acute%20Dental%20Pain%20Management.pdf

10. Dowell, D., Ragan, K, Jones, C., Baldwin, G & Chou, R. (2022). CDC practice guideline for prescribing opioids for --United States, 2022. *MMWR Recommendations and Reports, 71(3);* 1-95 No. RR-1), 1-49. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm?s_cid=rr7103a1_w

11. VA/DoD Clinical Practice Guideline. (2022). Use of Opioids in the Management of Chronic Pain Work Group. Washington, DC: U.S. Government Printing Office. https://healthquality.va.gov/guidelines/Pain/cot/VADoDOpioidsCPG.pdf

APPENDIX C
PAIN AND SUD SCREENING TOOLS

Pain Screening Tools

Tool	Year Validated	Population	Health Setting	Pain Type	Tool Length	Tool Creator	Available in Spanish?	Can be self-administered?	Measures Pain intensity, interference, or both?
Brief Headache Screen (BHS) [299]	2003	Adults with headaches, migraines, or headache medication overuse	Outpatient: Primary Care	Chronic: Headache/ Migraines	4 items, with 3 supplemental questions	Maizels and Houle [258]	No	No	Both
Defense and Veterans Pain Rating Scale (DVPRS)[300]	2013	Adults with self-reported pain	Outpatient; VA; Inpatient: Military Facilities	Chronic, Cancer, Post-Surgical, Acute	5 items	Buckenmaier III et al. [301]	Yes	No	Both
McGill Pain Questionnaire[302]	2009	Adults with self-reported pain, including acute and chronic pain	Outpatient	Chronic and Acute	22 items	Dworkin et al. [261]	Yes	Yes	Pain Intensity
Pain, Enjoyment of Life, and General Activity (PEG) Scale[303]	2009	Adults with chronic pain	Outpatient: VA, Primary Care, Ambulatory Clinic	Chronic: Musculo-skeletal, General	3 items	Krebs et al. [262]	No	No	Both

(continued)

[299] https://doi.org/10.1111/j.1526-4610.2007.00946.x
[300] https://doi.org/10.1093/pm/pny135
[301] https://doi.org/10.1111/j.1526-4637.2012.01516.x
[302] https://doi.org/10.1016/j.jpain.2015.01.012
[303] https://doi.org/10.1007/s11606-009-0981-1

Pain Screening Tools (continued)

Tool	Year Validated	Population	Health Setting	Pain Type	Tool Length	Tool Creator	Available in Spanish?	Can be self-administered?	Measures Pain intensity, interference, or both?
PROMIS Pain Intensity[304]	2020	Adults experiencing chronic pain	Clinical and Community Research Sites	Chronic	3 items	Cella et al. [305]	Yes	Yes	Pain Intensity
PROMIS Pain Interference[306]	2010	Adults experiencing chronic or cancer pain	Clinical and Community Research Sites	Chronic, Cancer	41 items	Amtmann et al. [265]	Yes	Yes	Pain Interference
STarT Back Screening Tool (SBT)[307;308;309]	2008	Adults with low back pain	Outpatient: Physical Therapy Clinics, Outpatient Clinics	Chronic: Low Back Pain, Musculo-skeletal	9 items, 5-10 minutes	Hill et al.[310]	Yes	No	Both

[304] https://www.healthmeasures.net/index.php?option=com_instruments&view=measure&id=3379&Itemid=992
[305] https://doi.org/10.1016/j.jval.2019.02.004
[306] https://doi.org/10.1016/j.pain.2010.04.025
[307] https://doi.org/10.2522/ptj.20120207
[308] https://doi.org/10.2522/ptj.20100109
[309] https://doi.org/10.2522/ptj.20150377
[310] https://doi.org/10.1002/art.23563

SUD and Substance Misuse Screening Tools

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
Alcohol, Smoking and Substance Involvement Screening Test (ASSIST)[311;312;313;314;315;316]	2002	All adults 18+	Outpatient: Federally Qualified Health Centers, Primary Care, VA; Workers' Compensation Clinic; Inpatient: Substance Use Treatment Facilities	Alcohol, Tobacco, Drugs	8 items	WHO ASSIST Working Group[270]	Yes	No
Current Opioid Misuse Measure (COMM)[273;317]	2007	Adults who take opioids for chronic pain	Outpatient: Specialty Clinic; Workers' Compensation Clinic	Opioids	17 items	Butler et al.[318]	No	Yes
Alcohol Use Disorders Identification Test	1987	All adults 18+	Outpatient: Primary Care, Federally Qualified Health Centers, Internal Medicine Clinic, General Internal Medicine,	Alcohol	10 items	Saunders et al.[279]	Yes	Yes

311 https://doi.org/10.1046/j.1360-0443.2002.00185.x
312 https://doi.org/10.1097/adm.0000000000000246
313 https://doi.org/10.1016/j.drugalcdep.2016.05.030
314 https://doi.org/10.3109/10826084.2011.629705
315 https://doi.org/10.1080/08897077.2011.562732
316 https://doi.org/10.1016/j.drugalcdep.2016.03.029
317 https://doi.org/10.1111/pme.12403
318 https://doi.org/10.1016/j.pain.2007.01.014

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
(AUDIT)[319;320;321;322;323;324;325;326;327;328;329]								
Alcohol Use Disorders Identification Test Consumption Questions (AUDIT-C)[280;281;282;283;287;330;331;332]	1998	All adults 18+	Outpatient: Primary Care, VA, Federally Qualified Health Centers, General Internal Medicine	Alcohol	3 items	Bush et al.[333]	Yes	Yes
Cut-Annoyed-Guilty-Eye (CAGE)[284;287;334]	1984	All adults 18+	Outpatient: General Internal Medicine, VA	Alcohol	4 items	Ewing[293]	Yes	Yes

319 https://doi.org/10.1016/j.mcna.2017.03.011
320 https://doi.org/10.1111/j.1360-0443.1993.tb02093.x
321 https://doi.org/10.1186/1940-0640-9-2
322 https://doi.org/10.1016/j.addbeh.2010.12.023
323 https://doi.org/10.1016/j.drugalcdep.2009.11.009
324 https://doi.org/10.7326/0003-4819-159-3-201308060-00652
325 https://doi.org/10.1016/j.pop.2010.11.007
326 https://doi.org/10.1007/s11414-017-9576-5
327 https://doi.org/10.1016/j.pop.2016.01.008
328 https://doi.org/10.1016/j.alcohol.2013.07.001
329 https://doi.org/10.1097/jhq.0000000000000069
330 https://doi.org/10.1080/00221341.2011.630941
331 https://doi.org/10.1186/s13722-017-0100-2
332 https://doi.org/10.1007/s11606-010-1509-4
333 https://doi.org/10.1001/archinte.158.16.1789
334 https://doi.org/10.1001/jama.1984.03350140051025

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
CAGE Adapted to Include Drugs (CAGE-AID)[335;336]	1998	All adults 18+	Outpatient: Primary Care	Alcohol, Drugs	4 items	Brown et al.[337]	No	Yes
Drug Abuse Screen Test (DAST-10)[338]	1982	All adults 18+	Outpatient: Primary Care	Drugs	10 items	Skinner[339]	Yes	Yes

(continued)

SUD and Substance Misuse Screening Tools (continued)

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
DAST-2[340]	2017	All adults 18+	Outpatient: VA	Drugs	2 items	Tier et al.[299]	No	Yes
DUDIT[341]	2005	All adults 18+	Outpatient; Residential Drug and Alcohol Treatment Programs	Drugs	11 items	Berman et al.[342]	Yes	Yes
Opioid Risk Tool (ORT)[343]	2005	Adults who are or may be prescribed opioids	Pain Clinic	Opioids	5 items	Webster & Webster[302]	No	Yes

335 https://doi.org/10.1016/j.pop.2010.11.007
336 https://doi.org/10.1016/j.pop.2016.01.008
337 https://doi.org/10.1006/pmed.1997.0250
338 https://doi.org/10.1016/j.amjmed.2012.11.031
339 https://doi.org/10.1016/0306-4603(82)90005-3
340 https://doi.org/10.1016/j.addbeh.2017.06.008
341 https://doi.org/10.1016/j.addbeh.2011.07.030
342 https://doi.org/10.1159/000081413
343 https://doi.org/10.1111/j.1526-4637.2005.00072.x

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
Global Appraisal of Individual Needs (GAIN) assessment instruments (I, SS, Q-3)	1993	Adolescents, adults	Outpatient: various providers	All SUD	4-131 items	Dennis et al..[344]	Yes	Yes
Single Item Screening Question (SISQ)[345;346;347;348;349;350;351]	2009	All adults 18+	Outpatient: Primary Care; Inpatient: Psychiatric Consultation; Internal Medicine Clinics	Alcohol, Drugs	1 item	Smith et al.[307]	No	Yes
Screen of Drug Use (SoDU)[352;353;354;355]	2015	All adults 18+	Outpatient: VA	Opioids, Cannabis, Other Drugs	2 items	Tiet et al.[312]	No	Yes
Substance Use Brief Screen (SUBS)[356]	2015	All adults 18-64	Outpatient: Primary Care	Drugs, Alcohol, Tobacco	4 items	McNeely et al.[314]	No	Yes

[344] https://gaincc.org/about/#:~:text=Dr.,movement%20toward%20evidence%2Dbased%20practice.
[345] https://doi.org/10.1080/08897077.2011.562732
[346] https://doi.org/10.7326/0003-4819-159-3-201308060-00652
[347] https://doi.org/10.1097/jhq.0000000000000069
[348] https://doi.org/10.1016/j.amjmed.2012.11.031
[349] https://doi.org/10.1001/archinternmed.2010.140
[350] https://doi.org/10.1016/j.psym.2011.01.041
[351] https://doi.org/10.1007/s11606-015-3391-6
[352] https://doi.org/10.1016/j.addbeh.2019.02.010
[353] https://doi.org/10.1016/j.drugalcdep.2019.01.044
[354] https://doi.org/10.1001/jamainternmed.2015.2438
[355] https://doi.org/10.1016/j.addbeh.2020.106614
[356] https://doi.org/10.1016/j.amjmed.2015.02.007

Tool	Year Validated	Population	Health Setting	Substance Type	Tool Length	Tool Creator	Available in Spanish?	Can be Self-Administered?
Tobacco, Alcohol, Prescription Medication, and Other Substance Use, Screening Tool (TAPS)[357]	2016	All adults 18+	Outpatient: Primary Care	Tobacco, Alcohol, Prescription Medication, Other Substances	4 items	Wu et al.[315]	Yes	Yes
Short Michigan Alcohol Screening Test–Geriatric Version (SMAST-G)[358]	1992	All adults 50+	Inpatient: Rehabilitation Program	Alcohol	10 items	Blow et al.[359]	Yes	Yes

[357] https://doi.org/10.1016/j.cct.2016.07.013

[358] https://doi.org/10.1111/j.1530-0277.2009.00987.x

[359] Blow, F. C., Brower, K. J., Schulenberg, J. E., Demo-Dananberg, L. M., Young, J. P., & Beresford, T. P. (1992). The Michigan Alcoholism Screening Test – Geriatric Version (MAST-G): A new elderly-specific screening instrument. *Alcoholism: Clinical and Experimental Research*, *16*, 372.

APPENDIX D
ABBREVIATED COMPREHENSIVE PAIN TREATMENT LIST

Pain Treatment Category	Treatment	Simplified coverage - Yes (Y), Partial (P), No (N)	If covered, NCD, LCD, or neither	Included in AHRQ review?
CAM	Actipatch	N		N
CAM	Acupressure	N		Y
CAM	Acupuncture	Partial	NCD	Y
CAM	Alexander technique	N		Y
CAM	Aroma therapy	N		N
CAM	Art and music therapy	N		N
CAM	Balneotherapy	N		N
CAM	Chelation therapy	N		N
CAM	Chiropractic services	P	LCD	Y
CAM	Cold and heat therapy	P	LCD	Y
CAM	Colonic hydrotherapy	N		N
CAM	Color therapy	N		N
CAM	Continuous passive motion machine	P	NCD	N
CAM	Cranial osteopathy	P	LCD	N
CAM	Craniosacral therapy	N		N
CAM	Cupping	N		N
CAM	Dance/movement therapy	N		N
CAM	Dry needling	P	NCD	Y
CAM	Equine therapy	N		N
CAM	Feldenkrais	P	LCD	N
CAM	Fitness programs, gym benefits	N		N
CAM	Floatation therapy	N		N
CAM	Gyrotonics	P		N
CAM	Hydrotherapy	P	LCD	N
CAM	Lymph drainage	P	LCD	N
CAM	Massage therapy	P	LCD	Y
CAM	Meditation including transcendental medication	N		N
CAM	Mirror therapy	N		N
CAM	Mud therapy	N		N
CAM	Music therapy	P		N
CAM	Myofascial release	P		Y
CAM	Osteopathic manipulation	P	LCD	N
CAM	Peer support services	N		N
CAM	Pilates	N		N
CAM	Postural retraining	P	LCD	N
CAM	Qigong	N		Y
CAM	Recreational therapy	N		N
CAM	Reflexology	N		N
CAM	Reiki	N		N
CAM	Spirituality	N		N
CAM	Tai chi	N		N
CAM	Therapeutic exercise	P	LCD	Y
CAM	Trigger point therapy	P	LCD	N
CAM	Visceral manipulation	N		N
CAM	Yoga	N		Y

Pain Treatment Category	Treatment	Simplified coverage - Yes (Y), Partial (P), No (N)	If covered, NCD, LCD, or neither	Included in AHRQ review?
CAM	Zero balancing	N		N
CAM	Pet therapy	N		N
CAM	Salt therapy	N		N
CAM	Thermotherapy (heat therapy)	N		Y
Pharmacotherapy	Intravenous Immunoglobulin (IVIG)	Y		N
Pharmacotherapy	Intravenous infusion of anesthetics (ketamine, lidocaine)/Implanted targeted intrathecal drug delivery systems	Y		N
Pharmacotherapy	Diazepam	N		N
Pharmacotherapy	Carbamazepine	N		N
Pharmacotherapy	Gabapentin	N		Y
Pharmacotherapy	Oxcarbazepine	N		Y
Pharmacotherapy	Phenytoin	N		N
Pharmacotherapy	Pregabalin	N		Y
Pharmacotherapy	Topiramate	N		N
Pharmacotherapy	Zonisamide	N		N
Pharmacotherapy	Amitriptyline	N		N
Pharmacotherapy	Desvenlafaxine	N		N
Pharmacotherapy	Duloxetine	N		Y
Pharmacotherapy	Imipramine/desipramine	N		N
Pharmacotherapy	Nortripytyline	N		N
Pharmacotherapy	Venlafaxine	N		N
Pharmacotherapy	Local anesthetics and topicals	P	Neither	Y
Pharmacotherapy	Muscle relaxants	P	Neither	N
Pharmacotherapy	Aspirin	N		N
Pharmacotherapy	NSAIDS	P	Neither	Y
Pharmacotherapy	N-type calcium channel blocker	N		N
Pharmacotherapy	Buprenorphine	Y		N
Pharmacotherapy	Butorphanol	Y		N
Pharmacotherapy	Codeine	N		N
Pharmacotherapy	Fentanyl	Y		N
Pharmacotherapy	Hydrocodone	N		N
Pharmacotherapy	Hydromorphone	Y		N
Pharmacotherapy	Levorphanol	Y		N
Pharmacotherapy	Meperidine	Y		N
Pharmacotherapy	Methadone	Y		N
Pharmacotherapy	Morphine	Y		N
Pharmacotherapy	Nalbuphine	Y		N
Pharmacotherapy	Oxycodone	N		N
Pharmacotherapy	Oxymorphone	Y		N
Pharmacotherapy	Tapendatol	N		N
Pharmacotherapy	Tramadol	N		N
Pharmacotherapy	Acetaminophen	P		Y
Pharmacotherapy	Cannabidiol/CBD oil products	N		Y
Pharmacotherapy	Cannabinoids, multiple administration routes	N		N
Pharmacotherapy	Corticosteroids	Y		N
Pharmacotherapy	Ketamine	P	LCD	N
Pharmacotherapy	Snake venom	N		N
Pharmacotherapy	Spider venom peptides	N		N

Pain Treatment Category	Treatment	Simplified coverage - Yes (Y), Partial (P), No (N)	If covered, NCD, LCD, or neither	Included in AHRQ review?
Procedure	Botulinum toxin injections (Botox)	P	LCD	N
Procedure	Destruction by neurolytic agent of the interdigital nerve of the foot—Morton's Neuroma only	P	LCD	N
Procedure	Epidural steroid injections (ESIs)	P	LCD	N
Procedure	Facet joint nerve block and denervation injection	P	LCD	N
Procedure	Glucocorticoid injection	P	LCD	N
Procedure	Hyaluronic acid injection	P	LCD	N
Procedure	Intradiscal and facet joint platelet rich plasma	P	NCD	N
Procedure	Joint injections (corticosteroid. Can also include corticosteroid + local anesthesia)	P	LCD	N
Procedure	Medial branch block	P	LCD	N
Procedure	Nerve blockade for the treatment of chronic pain and neuropathy	P	LCD	N
Procedure	Peripheral nerve injections (peripheral nerve blocks)	P	LCD	N
Procedure	Sphenopalatine block	P	LCD	N
Procedure	Sympathetic nerve blocks (SNBs)	P	LCD	N
Procedure	Trigger point injections (dry needling or injection of local anesthesia)	P	LCD	N
Procedure	Chemical neurolysis	N		N
Procedure	Cryoneuroablation (Cryoneurolysis, Cryoablation)	N		N
Procedure	Radiofrequency ablation	P	LCD	N
Procedure	Deep brain stimulation	P	NCD	N
Procedure	Dorsal root ganglion stimulation	P	NCD	N
Procedure	High-frequency impulse therapy	N		N
Procedure	Intrathecal Medication Pumps	P	LCD	N
Procedure	Peripheral nerve and peripheral nerve field stimulation	P	LCD	N
Procedure	Pulsed electrical & electromagnetic stimulation devices	P	LCD	N
Procedure	Spinal cord stimulation (implant)	P	LCD	N
Procedure	Vagus nerve stimulation	N		N
Procedure	Arthrocentesis	N		N
Procedure	Bracing	Y	Neither	N
Procedure	Cold laser	N		Y
Procedure	Cooled or pulsed radio-frequency denervation	N		N
Procedure	Cranial Electro-therapy Stimulation (CES)	N		Y
Procedure	Cryotherapy, whole body	N		N
Procedure	Decompression (traction units, tilt tables)	P	NCD or LCD depending on search term used	Y
Procedure	Deep oscillation therapy	N		N
Procedure	Electrical nerve stimulators	P	NCD	N
Procedure	External trigeminal nerve stimulation	P	NCD	N
Procedure	Functional electrical stimulation	P	LCD	N
Procedure	Home oxygen for cluster headache	P	NCD	N

Pain Treatment Category	Treatment	Simplified coverage - Yes (Y), Partial (P), No (N)	If covered, NCD, LCD, or neither	Included in AHRQ review?
Procedure	Hyaluronan acid therapies for knee osteoarthritis, Viscosupplementation	P	LCD	N
Procedure	Hyperbaric oxygen therapy	Y	NCD	N
Procedure	Induced lesions of nerve tracts	Y	NCD	N
Procedure	Infrared light therapy	N		N
Procedure	Injections - Tendons, Ligaments, Ganglion Cysts, Tunnel Syndromes, Morton's Neuroma	P	LCD	N
Procedure	Interferential Current Stimulation	N		N
Procedure	Interspinous Process Spacer Devices	N		N
Procedure	Intradiscal methylene blue	N		N
Procedure	Intradiscal ozone	N		N
Procedure	Intradiscal stem cells	N		N
Procedure	Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions	P	LCD	N
Procedure	Microcurrent stimulation devices (MENS)	N		N
Procedure	Minimally-invasive Surgical (MIS) Fusion of the Sacroiliac (SI) Joint	P	LCD	N
Procedure	Neuromuscular electrical stimulation devices (NEMS), open/closed loop	N		N
Procedure	Neurostimulators for headache	P	LCD	Y
Procedure	Occipital stimulation	P	LCD	N
Procedure	Percutaneous electric nerve stimulation (PENS)	N		N
Procedure	Percutaneous image-guided lumbar decompression for Lumbar Spinal Stenosis	P	NCD	N
Procedure	Percutaneous neuromodulation therapy	P	NCD	N
Procedure	Physical therapy	P	LCD	N
Procedure	Piriformis injection (local anesthetic, corticosteroid, and/or botulinum toxin)	Y	Neither	N
Procedure	Platelet-rich plasma injections	P	LCD	N
Procedure	Prolotherapy	N		N
Procedure	Radiation therapy, palliative	N		N
Procedure	Reduction Mammaplasty	P	LCD	N
Procedure	Regenerative/ adult autologous stem cell therapy (stem cell transplantation)	P	NCD	N
Procedure	Scrambler therapy	N		N
Procedure	Therapeutic ultrasound (TU)	P	LCD	Y
Procedure	Thermal intradiscal procedures (e.g. intervertebral disc annuloplasty or transdiscal biaculoplasty)	N		N
Procedure	Total Joint Arthoplasty	P	LCD	N
Procedure	Traction	P	NCD/LCD depending on condition being treated	N
Procedure	Transcutaneous electric nerve stimulation (TENS)	P	NCD	Y
Procedure	Transcutaneous electrical modulation pain reprocessing (TEMPR)	N		Y
Procedure	Vertebral augmentation (including vertebroplasty and kyphoplasty)	P	LCD	N

Pain Treatment Category	Treatment	Simplified coverage - Yes (Y), Partial (P), No (N)	If covered, NCD, LCD, or neither	Included in AHRQ review?
Procedure	Vertebral axial decompression	N		N
Psychotherapy	Biofeedback	P	NCD	N
Psychotherapy	Cognitive behavioral therapy (CBT)	Y		Y
Psychotherapy	Hypnotherapy (Hypnosis)	P	LCD	Y
Psychotherapy	Psychological and neuropsychological testing and evaluation to diagnose illness	P	LCD	N
Psychotherapy	Acceptance and commitment therapy (ACT)	N		Y
Psychotherapy	Behavioral health integration - Integration of behavioral health services with medical care	P	Neither	N
Psychotherapy	Behavioral therapy (BT)	Y		Y
Psychotherapy	Central nervous system assessment (part of psychotherapy)	P		N
Psychotherapy	Dialectical behavioral therapy (DBT)	Y		N
Psychotherapy	Emotional awareness and expression therapy (EAET)	N		N
Psychotherapy	Family counseling	P	NCD	N
Psychotherapy	Guided imagery/graded motor imagery	N		N
Psychotherapy	Health and behavior assessment (part of psychotherapy)	P	LCD	N
Psychotherapy	Mindfulness-based stress reduction (MBSR)	N		Y
Psychotherapy	Obesity counseling	P	NCD	N
Psychotherapy	Occupational therapy	P	LCD	Y
Psychotherapy	Outpatient mental health treatment	P	NCD	N
Psychotherapy	Psychiatric therapeutic procedures	P	LCD	N
Psychotherapy	Psychotherapy (individual and group)	P	LCD	N
Psychotherapy	Relaxation therapy (relaxation training)	N		N
Psychotherapy	Virtual reality therapy	N		N
Supplemental	Alcohol misuse screening	P	NCD	N
Supplemental	Bismuth subsalicylate	N		N
Supplemental	Buprenorphine/ naloxone	N		N
Supplemental	Clonidine	Y		N
Supplemental	Depression screening	Y	NCD	N
Supplemental	Dicyclomine	Y		N
Supplemental	Drug screen testing (urine)	P	LCD	N
Supplemental	Lofexidine	N		N
Supplemental	Loperamide	N		N
Supplemental	Medication for Opioid Use Disorder (MOUD)	Y		N
Supplemental	Naloxone	Y		N
Supplemental	Naltrexone	Y		N
Supplemental	Ondansetron	Y		N
Supplemental	Prochlorperazine	Y		N
Supplemental	Promethazine	Y		N
Supplemental	Screening, brief intervention, and referral to treatment services (SBIRT)	Y	Neither	N
Supplemental	Topical menthol/ methylsalicilate	N		N
Supplemental	Trazodone	N		N