California Health Benefits Review Program

Analysis of California Assembly Bill 2585 Health Care Coverage: Nonpharmacological Pain Management Treatment

A Report to the 2021–2022 California State Legislature

April 16, 2022

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 2585 Health Care Coverage: Nonpharmacological Pain Management Treatment

Summary to the 2021–2022 California State Legislature, April 16, 2022

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Assembly Bill 2585 analyzed by CHBRP would **authorize, but not mandate**, coverage for nonpharmacological pain management treatment (NPMT). The bill defines NPMT as pain management treatment without the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain.

If enacted, AB 2585 would apply to the health insurance of enrollees in Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated policies, exempting Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Benefit Coverage: At baseline, CHBRP estimates 100% of enrollees with health insurance subject to AB 2585 have coverage for instrument-based NPMTs if determined medically necessary[1] by the health plan/policy, and 0% have coverage for behavioral-based NPMTs. Because AB 2585 is not a mandate, the bill does not to exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: CHBRP investigated three categories of NPMTs: nonpharmacological restorative treatments, interventional pain management, and behavioral-based approaches. CHBRP considers the first two categories instrument-based NPMTs and the third as behavioral-based NPMT. CHBRP cannot draw a single overall conclusion regarding the effectiveness of all NPMTs. Instead, CHBRP draws separate conclusions regarding each type of NPMT for health outcomes, quality of life outcomes, and use of prescription pain medications. CHBRP also reviews the evidence of harms associated with each type of NPMT.

For nonpharmacological restorative treatments, evidence regarding the effects of transcutaneous electrical nerve stimulation (TENS) on pain intensity, quality of life, and use of opioid pain medication is largely inconclusive,[2] and there is insufficient evidence[3] to assess the effects of percutaneous electrical nerve stimulation (PENS).

For interventional pain management, there is a preponderance of evidence that spinal cord stimulation (SCS) is more effective than studied alternatives at relieving pain and improving quality of life, and limited evidence that interspinous process devices (IPDs) and peripheral nerve stimulation (PNS) are more effective than comparators. There is a preponderance of evidence that radiofrequency ablation (RFA) is associated with greater reduction in pain. The effects of SCS on use of opioid pain medication is inconclusive, and the impact of IPDs on opioid pain medication use is insufficient. There is limited evidence that PNS and RFA do not affect consumption of opioid pain medication.

There is insufficient evidence regarding the effects of RelieVRx (formerly EaseVRx), the only FDA-approved behavioral health approach for treating pain, on pain intensity, quality of life, and use of opioid pain medication.

Potential Harms: The evidence identified by CHBRP suggests that nonpharmacological restorative therapies for alleviating pain are not associated with severe harms.

For interventional pain management NPMTs, CHBRP found that SCS is associated with severe harms including death, nerve damage, sustained muscle weakness, lung injury, and serious infection, and with a high rate of explantation. There is limited evidence that IPD is associated with severe harms. There is a preponderance of evidence that IPD is associated with a higher risk of reoperation relative to other surgical interventions.

There is insufficient evidence to assess whether use of RelieVRx is associated with severe harms.

Cost and Health Impacts[4]: Due to the lack of mandate of AB 2585, CHBRP assumes health plans and policies would not change existing coverage of NPMTs as authorized under AB 2585, thus CHBRP estimates no fiscal impact due to the enactment of this bill.

[1] Refer to CHBRP's issue brief on medical necessity at: https://files4.1.revize.com/chbrpnew/Medical%20Necessity%20FINAL%20120321.pdf.

[2] *Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

[3] *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

[4] Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by.

CONTEXT

Pain is defined as actual or potential tissue damage that is associated with an unpleasant sensory and/or emotional experience.[5] Pain has a complex categorization system, often classified by length of time and connection of tissue injury. Common classifications of pain include acute and chronic. The prevalence of pain remains a pervasive public health issue in the United States. Despite this, current data on the incidence and prevalence of pain are inconsistent or incomplete.

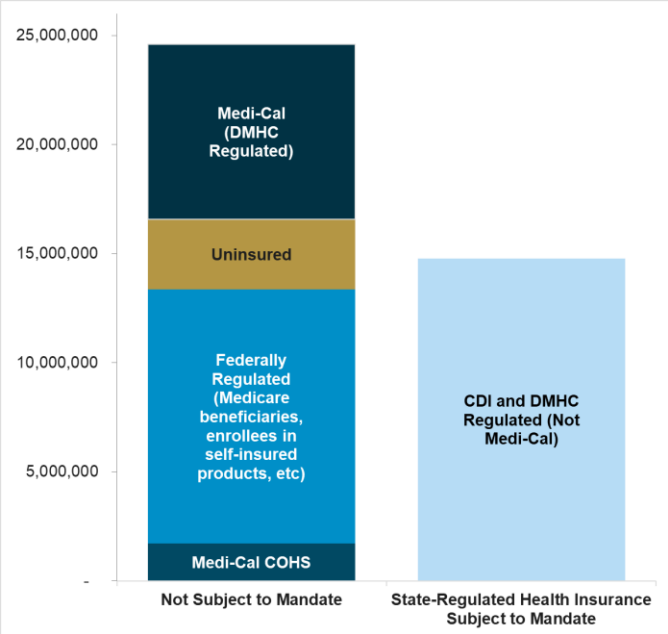
California law requires coverage of certain nonpharmacological therapies for pain management, including acupuncture and physical therapy. Both treatments are considered essential health benefits (EHBs) by the state. Existing law also requires health plans to provide coverage for appropriately prescribed pain management medications for terminally ill patients.

In response to the ongoing opioid epidemic, the U.S. Department of Health and Human Services in collaboration with the U.S. Department of Defense and the U.S. Department of Veteran Affairs with the Office of National Drug Control Policy convened a Pain Management Best Practices Inter-Agency Task Force (Task Force) to address acute and chronic pain. As part of the Task Force's mandate, a list of recommendations for best practices for managing acute and chronic pain were developed. Per the Task Force's report on Pain Management Best Practices, the five main approaches to treating and managing pain include: (1) pharmacological (comprising nonopioid and opioid medications); (2) restorative; (3) interventional (comprising pharmacological and nonpharmacological approaches); (4) behavioral health; and (5) complementary and integrative health approaches. With an emphasis on the development of an effective pain treatment plan post-patient evaluation, the Task Force recommends a multimodal and patient-centered approach to treating and managing acute or chronic pain. CHBRP considers the second and third categories instrument-based NPMTs and the fourth as behavioral-based NPMT.

BILL SUMMARY

AB 2585 would authorize, but not mandate, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatments (NPMTs). The bill defines NPMT as pain management treatment without the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain. Figure A notes how many Californians have health insurance that would be subject to AB 2585.

Figure A. Health Insurance in CA and AB 1930



Source: California Health Benefits Review Program, 2022.

CHBRP defined "behavioral-based therapy" as a therapeutic approach using a medical device that primarily focuses on the use of cognitive behavioral therapy (CBT) or other psychotherapy. "Instrument-based therapy" was defined as a therapeutic approach that uses a medical device.

Due to the language of AB 2585, this analysis focuses on only those instruments and therapies that are approved by the FDA as pain management treatment without the use of medication. FDA-approved devices and treatments that deliver any quantity of pain medication or drug to the patient to reduce pain, such as intrathecal pumps and steroid injections, were excluded from the analysis. CBT and other psychotherapy that may be delivered by means other than a device (e.g., in-person or via telehealth) were also excluded.

For the purposes of this analysis, CHBRP considered the following NPMTs:

Nonpharmacological restorative therapies

- Transcutaneous electrical nerve stimulation (TENS)
- Percutaneous electric nerve stimulation (PENS)

[5] Refer to CHBRP's full report for full citations and references.

Interventional pain management

- Interspinous process devices (IPD)
- Peripheral nerve stimulation (PNS)
- Radiofrequency ablation (RFA)
- Spinal cord stimulation (SCS)

Behavioral health approaches

- RelieVRx (formerly EaseVRx) virtual reality

IMPACTS

Benefit Coverage, Utilization, and Cost

AB 2585 does not mandate coverage of NPMTs, thus CHBRP estimates no fiscal impact due to the enactment of this bill. In its analysis, CHBRP presents a qualitative discussion of issues surrounding benefit coverage and costs of NPMTs without making any estimates or assumptions regarding utilization and its change in the first year post-enactment

Benefit Coverage

CHBRP estimates 100% of enrollees with health insurance subject to AB 2585 currently have coverage for instrument-based NPMTs if deemed medically necessary by the enrollee's health plan or policy. How these devices are covered depends on the nature of the device in question. NPMTs that meet the definition of durable medical equipment (DME) appropriate for use in the home, such as TENS units, are covered under the supplemental DME benefit for eligible enrollees, when determined medically necessary by the plan/policy.

No enrollees currently have coverage for behavioral-based NPMTs. CHBRP identified virtual reality as the only behavioral-based NPMT for which the FDA recently granted approval (in November of 2021).

Medical Effectiveness

CHBRP cannot draw a single overall conclusion regarding the effectiveness of all NPMTs. Each of the three types of NPMTs discussed in the medical effectiveness review use different mechanisms of action to address pain and the amount and strength of evidence varies widely across NPMTs. In addition, low back pain is the only type of pain for which studies of all three types of NPMTs have been conducted. For these reasons, CHBRP draws separate conclusions regarding each type of NPMT for health outcomes, quality-of-life outcomes, and use of prescription pain medications.

CHBRP also reviews the evidence of harms associated with each type of NPMT.

For nonpharmacological restorative treatments, evidence regarding the effects of TENS on pain intensity, quality of life, and use of opioid pain medication is largely inconclusive,[6] and there is insufficient evidence[7] to assess the effects of PENS.

For interventional pain management, there is a preponderance of evidence[8] that SCS is more effective at relieving pain and improving quality of life than the treatments to which they have been compared, and limited evidence[9] that IPD and PNS are more effective than comparators. There is a preponderance of evidence that RFA is more effective than comparators at relieving pain and limited evidence that it improves quality of life. Evidence regarding the effects of SCS on use of opioid pain medication is inconclusive. Evidence regarding the impact of IPD on opioid pain medication use is insufficient. There is limited evidence that PNS and RFA do not affect consumption of opioid pain medication.

There is insufficient evidence regarding the effects of RelieVRx, the only FDA-approved behavioral health approach for treating pain, on pain intensity, quality of life, and use of opioid pain medication.

Potential Harms

The evidence identified by CHBRP suggests that nonpharmacological restorative therapies for alleviating pain are not associated with severe harms.

For interventional pain management NPMTs, CHBRP found that SCS is associated with severe harms including death, nerve damage, sustained muscle weakness, lung injury, and serious infection, and with a high rate of explantation. There is limited evidence that IPD is associated with severe harms including interspinous spacer fracture, coronary ischemia, respiratory distress, hematoma, and death due to pulmonary edema. There is a preponderance of

[6] *Inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.
[7] *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.
[8] *Preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.
[9] *Limited evidence* indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

evidence that IPD is associated with a higher risk of reoperation relative to other surgical interventions.

There is insufficient evidence to assess whether use of RelieVRx is associated with severe harms.

Public Health

Despite evidence that suggests that some forms of NPMT are medically effective (SCS, RFA), CHBRP estimates AB 2585 would produce no public health impact due to no projected change in coverage or utilization.

Long-Term Impacts

Given CHBRP estimates no cost impacts due to AB 2585, CHBRP does not anticipate any long-term impacts from the bill.

Although data are inconclusive regarding the ability of NPMTs to help discontinuation of opioids, there is a growing interest in this topic with studies underway given the recognized need to address the high proportion of individuals who use opioids for chronic pain. Please note that the absence of evidence is not “evidence of no effect,” and it is possible that an impact on NPMTs on opioid use – desirable or undesirable – could result, but current evidence is insufficient to inform an estimate. The results of future clinical studies and development of newer technologies may impact the role of NPMT in the treatment of pain and as alternatives to opioids in the long term.

Essential Health Benefits and the Affordable Care Act

AB 2585 would not result in new benefit coverage that exceeds the definition of EHBs in California.

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April 16, 2022

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The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[10] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 2585, Nonpharmacological Pain Management Treatment.

Bill-Specific Analysis of AB 2585, Nonpharmacological Pain Management Treatment

Bill Language

AB 2585 would **authorize, but not mandate,** Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatment (NPMT). The bill defines NPMT as pain management treatment without the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain. The full text of AB 2585 can be found in Appendix A.

Relevant Populations

If enacted, AB 2585 would apply to the health insurance of approximately 14.8 million enrollees (37.6% of all Californians). This represents 65% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by DMHC or CDI. If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, exempting Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

Because AB 2585 specifies "group and individual" plans and policies, the health insurance of Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 2585's requirements.[11]

Analytic Approach and Key Assumptions

Existing law does not prohibit DMHC-regulated health plans or CDI-regulated insurers from covering NPMT of their own accord. AB 2585 is not a mandate to do so. Due to the permissive language of AB 2585, CHBRP assumes health plans and policies would not elect to provide additional coverage as authorized under AB 2585. As such, the traditional CHBRP cost model was not employed for this analysis. Instead, this analysis provides estimates of baseline coverage and costs of NPMTs.

Because AB 2585 does not require coverage for NPMTs, this analysis assumes that health plans and policies will continue to operate per the status quo, and therefore, there will be no changes to benefit coverage, utilization, or fiscal impacts made based on this legislation.

CHBRP's analysis focuses on the background of pain management and recent literature of existing technologies that may qualify as NPMTs.

[10] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[11] Personal communication, W. White, California Department of Health Care Services, March 2020.

CHBRP uses the following terms throughout the analysis:

- **Behavioral-based therapy**: a therapeutic approach that uses a medical device and primarily focuses on the use of cognitive behavioral therapy (CBT) or other psychotherapy.
- **Instrument-based therapy**: a therapeutic approach that uses a medical device.
- **Nonpharmacological pain management treatment (NPMT**): refers to the definition described in AB 2585, that is, FDA-approved behavioral-based or instrument-based pain management treatments without the use of medication.
- **Nonpharmacological therapies for pain management**: current treatments for pain that may or may not be approved by the FDA.

Due to the language of AB 2585, this analysis focuses on only those instruments and therapies that are approved by the FDA as pain management treatment without the use of medication. FDA-approved devices and treatments that deliver any quantity of pain medication or drug to the patient to reduce pain, such as intrathecal pumps and steroid injections, were excluded from the analysis. CBT and other psychotherapy that may be delivered by means other than a device (e.g., in-person or via telehealth) were also excluded from the analysis because AB 2585 addresses only coverage for FDA-approved devices; it does not address coverage for these therapies.

The FDA categorizes medical devices into three different classes based on risk, with Class 1 devices having the lowest risk and Class 3 having the highest. Approval of devices to go to market depends on classification. Class 1 and 2 devices generally need to be classified as “FDA-cleared” prior to going to market. Class 3 devices must obtain classification as “FDA-approved” prior to marketing a new device. Nonpharmacological therapies for pain management may be classified as a Class 1, 2, or 3 medical device. Given this nuance, CHBRP assumed a broad interpretation of being “approved by the FDA” to include devices classified as either FDA-cleared or FDA-approved.

For the purposes of this analysis, CHBRP considered the following NPMTs:

Nonpharmacological restorative therapies

- Transcutaneous electrical nerve stimulation (TENS)
- Percutaneous electric nerve stimulation (PENS)

Interventional pain management

- Interspinous process devices (IPDs)
- Peripheral nerve stimulation (PNS)
- Radiofrequency ablation (RFA)
- Spinal cord stimulation (SCS)

Behavioral health approaches

- RelieVRx (formerly EaseVRx) virtual reality

CHBRP approached this analysis in the context of using NPMT as a clinically indicated alternative to opioids rather than solely for their efficacy in the treatment and management of pain. The Centers for

Disease Control and Prevention (CDC) states that 91 Americans die each day from an opioid overdose. In 2017, the opioid crisis was officially declared a public health emergency (CDC, 2021). Since the early 2000s, there have been increased efforts to curb the use of opioids through various strategies. Thus, CHBRP selected to focus its analysis on the impact AB 2585 would have in meeting the goal of curbing the use of opioids, in addition to determining the medical effectiveness of available NPMTs.

Interaction With Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

Pain management treatment

California has two primary laws concerned with pain. The first is the Pain Patient's Bill of Rights,[12] which relates primarily to opiate therapy. It provides patients with the option to request or reject the use of any or all modalities in order to relieve their severe chronic intractable pain (SCIP). It also allows patient suffering from SCIP to choose opiate medications to relieve pain prior to having an invasive medical procedure. A patient's physician has the authority to refuse to prescribe the opiate medication, but must inform the patient that there are other physicians who treat pain and whose methods include the use of opiates. The second law is the California Intractable Pain Treatment (CIPT) Act,[13] which authorizes physicians and surgeons to prescribe, dispense, or administer "dangerous drugs or prescription controlled substances" for the treatment of pain or a condition causing pain, including intractable pain. The CIPT Act exempts physicians and surgeons from undergoing disciplinary action for prescribing, dispensing, or administering dangerous drugs or prescription controlled substances when done in accordance with state law.

Existing law requires coverage of certain nonpharmacological therapies for pain management, including acupuncture and physical therapy. Both treatments are considered essential health benefits in the state of California.[14] Existing law also requires health plans to provide coverage for appropriately prescribed pain management medications for terminally ill patients.[15]

Similar requirements in other states

At least one other state has passed legislation related to nonpharmacological therapies for pain management. In 2021, Colorado passed legislation requiring health plans to align cost sharing for nonpharmacological pain treatment with that of primary care visits for nonpreventive services for at least six visits of physical therapy, occupational therapy, chiropractic care, or acupuncture.[16]

Several states have recently introduced legislation regarding nonpharmacological therapies for pain management. Legislation introduced in Rhode Island would require the development of an educational pamphlet on the use of opioid alternatives for the treatment of pain, and to inform patients about the availability of opioid alternatives for pain treatment and their advantages and disadvantages.[17] Massachusetts and Florida also introduced bills that would require their health departments to publish

[12] HSC Section 124961.
[13] BPC Section 2241.5.
[14] HSC Section 1367.005; INS Section 10112.27.
[15] HSC Section 1367.215.
[16] Colorado House Bill 1276.
[17] Rhode Island House Bill 7131 and Senate Bill 2611.

educational opioid alternative pamphlets/materials for pain treatment.[18] A Wisconsin bill would prohibit prior authorization for the first 12 physical therapy visits and any nonpharmacological management of pain provided through care related to physical therapy.[19] A New Hampshire bill would require the Department of Health and Human Services to create a voluntary nonopioid directive form for nonopioid pain treatment. It would also require health plans to provide coverage for evidence-based nonopioid pain treatment, including, but not limited to, yoga, chiropractic care, osteopathic manipulation, and acupuncture, and prohibit cost sharing from exceeding that for primary care visits.[20] Finally, Pennsylvania introduced legislation that would require health plans to provide coverage for evidence-based nonopioid pain management care, including, but not limited to, acupuncture, chiropractic care, massage therapy, occupational therapy, osteopathic manipulation, and physical therapy.[21]

No other states have introduced or passed legislation regarding coverage of NPMTs, as defined by AB 2585.

Federal Policy Landscape

Federal Legislation

In recent years, the federal government has passed multiple laws intended to address the country's opioid epidemic. In 2016, both the Comprehensive Addiction and Recovery Act (CARA) and the 21st Century Cures Act (Cures Act) were enacted. CARA focused primarily on public health and law enforcement strategies, whereas the Cures Act emphasized medical innovation, funding, and addressing mental health and substance use activities. In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act was signed into law.

The SUPPORT for Patients and Communities Act is a broad law that includes measures to address law enforcement, public health, opioid production and distribution, public education, access to opioid addiction treatment services, and health care financing and coverage. Part of the legislation required the U.S. Health and Human Services Agency to convene stakeholders to "address the challenges and barriers of developing nonaddictive medical products intended to treat acute or chronic pain or addiction" and publish guidance addressing these challenges. In response, the FDA recently published draft guidance to accompany development of nonopioid analgesics for acute pain lasting up to 30 days (FDA, 2022a). The law also directed the Centers for Medicare & Medicaid Services (CMS) to issue guidance to states, or update existing guidance documents, on items and services that may be provided in state Medicaid programs for non-opioid treatment and management of pain. The 2019 guidance published by CMS acknowledged the proven efficacy of exercise therapy, physical therapy, and cognitive behavioral therapy for chronic pain. It also pointed to state's option to provide coverage for acupuncture, massage therapy, chiropractic care, cognitive behavioral therapy, physical therapy, or other Medicaid-coverable services (CMS, 2019). AB 2585, if enacted, would not impact benefit coverage for Medi-Cal beneficiaries.

No legislation regarding the use of NPMT is currently pending at the federal level.

Guidelines and best practices

The FDA recently updated its opioid analgesic Risk Evaluation and Mitigation Strategy (REMS) blueprint for health care providers involved in the treatment and monitoring of patients with pain. The blueprint includes general principles for nonpharmacological approaches and pharmacological analgesic therapies, but does not recommend one approach over the other. For nonpharmacological treatment, the FDA states health care providers should be educated about the range of treatment options available and their

[18] Massachusetts House Bill 2219 of 2021; Florida House Bill 725.
[19] Wisconsin Senate Bill 972 and Assembly Bill 972.
[20] New Hampshire House Bill 247.
[21] Pennsylvania House Bill 916.

appropriate use within a multidisciplinary approach to pain management. In addition, the blueprint warns health care providers of the variability in evidence for various methods to support their utility in pain management (FDA, 2018).

In 2019, a report was published by the Pain Management Best Practices Inter-Agency Task Force (Task Force) on best practices for pain management. The Task Force was convened by the U.S. Department of Health and Human Services in conjunction with the U.S. Department of Defense and the U.S. Department of Veterans Affairs with the Office of National Drug Control Policy to address acute and chronic pain amidst the ongoing opioid crisis in the United States. See the *Background* section for more details on the findings of the report.

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 2585 may interact with requirements of the ACA as presently exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[22,23]

Essential Health Benefits

In California, nongrandfathered[24] individual and small-group health insurance is generally required to cover essential health benefits (EHBs).[25] In 2023, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs. [26]

States may require state-regulated health insurance to offer benefits that exceed EHBs.[27,28,29] Should California do so, the state could be required to defray the cost of additionally mandated benefits for enrollees in health plans or policies purchased through Covered California, the state's health insurance marketplace. However, state benefit mandates specifying provider types, cost sharing, or other details of existing benefit coverage would not meet the definition of state benefit mandates that could exceed EHBs,[30] and CHBRP is unaware of any state mandate passed into law that has been determined to

[22] The ACA requires nongrandfathered small-group and individual market health insurance – including, but not limited to, qualified health plans (QHPs) sold in Covered California – to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.

[23] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.

[24] A grandfathered health plan is "a group health plan that was created – or an individual health insurance policy that was purchased – on or before March 23, 2010. Plans or policies may lose their 'grandfathered' status if they make certain significant changes that reduce benefits or increase costs to consumers." Accessed at: www.healthcare.gov/glossary/grandfathered-health-plan.

[25] For more detail, see CHBRP's issue brief, *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, available at https://chbrp.org/other_publications/index.php.

[26] See CHBRP's resource, *Estimates of Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits: An Update and Overview of New Federal Regulations*, both available at https://chbrp.org/other_publications/index.php.

[27] ACA Section 1311(d)(3).

[28] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.

[29] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.

[30] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.

exceed EHBs. AB 2585 does not require coverage for a new state benefit mandate, therefore the bill does not exceed the definition of EHBs in California.

BACKGROUND ON PAIN MANAGEMENT TREATMENT

As noted in the *Policy Context*, AB 2585 would authorize, but not mandate, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatment (NPMT). This bill defines NPMT as pain management treatment *without* the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain.

This background section provides information related to pain and its classifications, common pain conditions, and approaches to managing pain, including pharmacological and NPMT to provide context for the consideration of the *Medical Effectiveness*; *Benefit Coverage, Utilization, and Cost Impact*; and *Public Health Impacts* sections. U.S. population-based prevalence rates for the most common pain conditions, as well as chronic pain and high-impact chronic pain, are also provided. California-specific data related to the rate of prescribed opioids and rate of prescription opioid overdose deaths are also included. Specific NPMT and related outcomes are provided in the *Medical Effectiveness* section.

Pain Classifications and Common Pain Conditions

Per the International Association for the Study of Pain (IASP), pain is defined as actual or potential tissue damage that is associated with an unpleasant sensory and/or emotional experience (IASP, 2020). Pain has a complex categorization system, often classified by length of time and connection of tissue injury (Tick et al., 2018). Common classifications of pain include acute and chronic (Tick et al., 2018). Acute pain typically has sudden onset and occurs for a shorter duration of time with an identifiable cause (Tick et al., 2018). By contrast, chronic pain often has no identifiable cause and persists for a minimum of 3 months (Tick et al., 2018). High-impact chronic pain is a type of chronic pain that can restrict or substantially interrupt daily activities such as working outside the home or engaging in household chores (NIH, 2018). Pain can also be identified by the pathological process (e.g., cancer pain, post-operative pain) (Tick et al., 2018). It is important to note that many of these pain categories can coexist and overlap (Tick et al., 2018). For example, cancer pain can be categorized as acute or chronic pain (Tick et al., 2018).

Common chronic pain conditions include low back pain (LBP), neck pain, osteoarthritis (OA), and migraines (Tick et al, 2018). The most common cause of LBP is nonspecific (i.e., no evident pathology) and can be influenced by posture, activity, or the time of day (Wong et al., 2017). LBP can also occur as a result of an injury to a muscle (strain) or ligament (sprain) and can range in intensity from a dull, persistent ache to a sharp and severe pain (NIH, 2020). If left untreated, LBP can lead to neuropathic pain symptoms (Baron et al., 2016). Neck pain can be categorized as neuropathic or nonneuropathic (Cohen and Hooten, 2017). Whereas nonneuropathic neck pain is classified as nonspecific, neuropathic neck pain symptoms are attributable to a nerve injury (Cohen and Hooten, 2017). OA is a degenerative joint disease that occurs most often in the hands, hips, and knees, which can be characterized by pain/aching, stiffness, decreased mobility, and/or swelling in the affected area (CDC, 2020). Migraines are a common and debilitating condition characterized by intense pulsing or throbbing localized in one region of the head and can be coupled with nausea and/or sensitivity to light and sound (NIH, 2019a; CDC, 2022).

Prevalence of Pain in the United States

The prevalence of pain remains a pervasive public health issue in the United States (Tick et al., 2018). Despite this, current data on the incidence and prevalence of pain are inconsistent or incomplete (IOM, 2011). Per the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)), there is no standardization of methods to assess pain, definitions, or key survey questions related to pain across

population-based surveys or within agencies (IOM, 2011).[31] Furthermore, in a majority of cases, pain-related questions in national population-based surveys target adults only (IOM, 2011). CHBRP is able to report on U.S. population-based pain-related survey data conducted by the National Center for Health Statistics (NCHS) via the National Health Interview Survey (NHIS). This includes data on a 3-month period prevalence of common pain conditions, chronic pain, and high-impact chronic pain among U.S. adults in 2019 (Lucas et al., 2021; Zelaya et al., 2020).

Prevalence of Common Pain Conditions in the United States

The following table (Table 1) identifies a 3-month period prevalence of common pain conditions among U.S. adults by select sociodemographic characteristics (age, gender, race/ethnicity, and family income) in 2019. According to the 2019 NHIS, approximately 59% of U.S. adults aged 18 years and over experienced pain of any kind regardless of body region in the past 3 months (Lucas et al., 2021). Furthermore, back pain was the most prevalent pain condition with 39.0% reporting back pain within the past 3 months, followed by lower limb pain at 36.5%, and upper limb pain at 30.7% (see Table 1).

Table 1. Period Prevalence of Any Back, Lower Limb, and/or Upper Limb Pain in the Past 3 Months Among Adults in the United States, 2019

Sociodemographic Characteristic	Pain Condition		
	Back Pain [(a)]	Lower Limb (Hips, Knees, or Feet) [(b)]	Upper Limbs (Hands, Arms, or Shoulders) [(c)]
All respondents [(d)]	39.0%	36.5%	30.7%
Age, years			
18-29	28.4%	21.0%	16.2%
30-44	35.2%	28.8%	24.1%
45-64	44.3%	43.4%	37.9%
65 and over	46.6%	50.3%	42.0%
Gender			
Male	37.2%	33.5%	29.0%
Female	40.6%	39.2%	32.3%
Race/ethnicity			
Hispanic	31.2%	27.4%	24.4%
Non-Hispanic White	42.7%	40.1%	33.4%
Non-Hispanic Black	35.8%	36.6%	28.6%

[31] Founded in 1970, the National Academy of Medicine (NAM) was formerly called the Institute of Medicine until 2015 (NAM. 2022).

Non-Hispanic Asian	24.5%	20.6%	21.0%
Family income			
Less than 100% FPL	44.8%	42.1%	37.1%
100%--199% FPL	40.6%	37.9%	33.0%
200% or more FPL	37.6%	35.2%	29.1%

Source: U.S. Department of Health and Human Services (DHHS). National Center for Health Statistics, National Health Interview Survey, 2019 as reported in Lucas and colleagues (2021).

Note: (a) Back pain is based on responses of "a little," "a lot," or somewhere between "a little and a lot" to a question asking how much pain they had in their back in the past 3 months.

(b) Lower limb pain is based on responses of "a little," "a lot," or somewhere between "a little and a lot" to a question asking how much pain they had in their hips, knees, or feet in the past 3 months.

(c) Upper limb pain is based on responses "a little," "a lot," or somewhere between "a little and a lot" to a question asking how much pain they had in their hands, arms, or shoulders in the past 3 months.

(d) All respondents were over the age of 18 years.

Key: FPL = Federal Poverty Level.

Prevalence of Chronic Pain and High Impact Chronic Pain in the United States

The following table (Table 2) identifies a 3-month period prevalence of chronic pain and high-impact pain among U.S. adults by select sociodemographic characteristics (age, gender, race/ethnicity, and urbanization level) in 2019. Per the 2019 NHIS, the overall prevalence of chronic pain was 20.4%, and the prevalence of high-impact chronic pain was 7.4% – which frequently limits life or other activities of daily living such as work within the past 3 months (Zelaya et al., 2020). Data from the NHIS indicate that the percentage of U.S. adults with chronic or high-impact chronic pain increased with age as well as among those who lived in more rural areas (see Table 2) (Zelaya et al., 2020). Furthermore, data indicate that women were more likely to have chronic and high-impact chronic pain in comparison to men, respectively (see Table 2) (Zelaya et al., 2020).

Table 2. Period Prevalence of Chronic Pain and High-Impact Chronic Pain in the Past 3 Months Among Adults in the United States, 2019

Sociodemographic Characteristic	Type of Pain	
	Chronic Pain [b]	High Impact Chronic Pain [c]
All respondents [a]	20.4%	7.4%
Age, years		
18-29	8.5%	2.2%
30-44	14.6%	4.4%
45-64	25.8%	10.3%
65 and over	30.8%	11.8%
Gender		

Male	19.0%	6.3%
Female	21.7%	8.5%
Race/ethnicity		
Hispanic	13.0%	5.3%
Non-Hispanic White	23.6%	8.4%
Non-Hispanic Black	19.3%	7.4%
Non-Hispanic Asian	6.8%	2.2%
Urbanization level [(d)]		
Large central metro	16.4%	6.1%
Large fringe metro	18.0%	6.4%
Medium and small metro	22.8%	8.0%
Rural	28.1%	10.9%

Source: U.S. Department of Health and Human Services (DHHS). National Center for Health Statistics, National Health Interview Survey, 2019 as reported in Zelaya and colleagues (2020).

Note: (a) All respondents were over the age of 18 years.

(b) Chronic pain is based on responses from “most days” or “every day” to the following question: “In the past 3 months, how often do you have pain? Would you say never, some days, most days, or every day?”

(c) High impact chronic pain is defined as adults who have chronic pain and who responded “most days” or “every day” to the following question: “Over the past 3 months, how often did your pain limit your life or work activities? Would you say never, some days, most days, or every day?”

(d) Counties were classified into urbanization levels based on the 2013 NCHS Urban-Rural Classification Schemes for Counties.

Clinical Guidelines for Treating Specific Pain Conditions

CHBRP is unaware of clinical guidelines related to the treatment and management of acute and chronic pain overall. However, clinical guidelines exist for the treatment and management of specific pain conditions (e.g., low back pain) (NASS, 2020; Qaseem et al., 2017). For example, the American College of Physicians (ACP) Clinical Guidelines consist of three recommendations specific to treating low back pain (Qaseem et al., 2017). Specific to patients suffering from acute or subacute low back pain, the ACP recommends nonpharmacological treatment with superficial heat, massage, acupuncture, or spinal manipulation (Recommendation 1) (Qaseem et al., 2017). Nonsteroidal anti-inflammatory drugs (NSAIDs) or muscle relaxants may be prescribed if pharmacological treatment is desired (Qaseem et al., 2017). For treatment of chronic low back pain, it is recommended that clinicians and patients opt for nonpharmacological treatment prior to using pharmacological treatment (Recommendation 2) (Qaseem et al., 2017). Examples of nonpharmacological treatments include: exercise, multidisciplinary rehabilitation, mindfulness-based stress reduction, acupuncture, tai chi, yoga, biofeedback therapy, spinal manipulation, cognitive behavioral therapy, low-level laser therapy, operant therapy, or progressive relaxation (Qaseem et al., 2017). Lastly, if chronic low back pain patients do not obtain adequate relief from nonpharmacological treatment, then clinicians should consider NSAIDs as first-line therapy, or tramadol or duloxetine as second-line therapy (Recommendation 3) (Qaseem et al., 2017). Prescription opioids should only be considered if a patient has failed the aforementioned step therapy (Qaseem et al., 2017).

Patients experiencing low back pain – whether acute, subacute, or chronic – should be advised to remain active as tolerated (Qaseem et al., 2017).

Treatment Approaches to Management of Pain

In the early 1990s, the United States saw a dramatic increase in the prescription of opioids to treat cancer, end-of-life care, and episodic acute pain (Tick et al., 2018). Underlying factors contributing to this increase in prescription opioids included: (1) the alleged undertreatment of noncancer pain; (2) ongoing promotion of opioids to treat undertreated pain by pain specialists and patient advocacy groups; (3) targeted efforts by large pharmaceutical companies; and (4) regulatory interventions by governmental organizations (Bernard et al., 2018, Lyden and Binswanger, 2019; Manchikanti et al., 2012). The use of prescription opioids were intended to be part of a multimodal approach to pain management; however, increased prescription of opioids contributed to the widespread misuse of prescription and non-prescription opioids – resulting in the first wave of opioid overdose deaths in 1999 (Bernard et al., 2018; CDC, 2021; DHHS, 2021).[32] In response to the ongoing opioid epidemic, the U.S. Department of Health and Human Services (DHHS) in collaboration with the U.S. Department of Defense and the U.S. Department of Veteran Affairs with the Office of National Drug Control Policy convened a Pain Management Best Practices Inter-Agency Task Force (Task Force) to address acute and chronic pain (DHHS, 2019). As part of the Task Force's mandate, a list of recommendations for best practices for managing acute and chronic pain were developed (DHHS, 2019). Per the Task Force's report on Pain Management Best Practices, the five main approaches to treating and managing pain include: (1) pharmacological (comprised of nonopioid and opioid medications); (2) restorative; (3) interventional (comprising pharmacological and nonpharmacological approaches); (4) behavioral health; and (5) complementary and integrative health approaches (DHHS, 2019). With an emphasis on the development of an effective pain treatment plan post-patient evaluation, the Task Force recommends a multimodal and patient-centered approach to treating and managing acute or chronic pain (DHHS, 2019).

Pharmacological Approaches to Managing Pain

Pharmacological approaches to managing pain include two broad categories: nonopioid and prescription opioid medications (DHHS, 2019). Nonopioid medications used to manage acute or chronic pain are composed of a broad class of drugs and may be available over the counter or via prescription. Common nonopioid medications include: acetaminophen, NSAIDs (nonsteroidal anti-inflammatory drugs), anticonvulsants (i.e., medications to treat neuropathic or neurological disorders), antidepressants, and musculoskeletal relaxant agents (DHHS, 2019; Tick et al., 2018). Prescription opioid medications are a controlled substance group of analgesics (i.e., pain relief drugs) that are often used to treat acute, cancer-related, and, at times, chronic pain (DHHS, 2019). Common prescription opioids include: hydrocodone, codeine, oxycodone, methadone, morphine, and fentanyl (DHHS, 2019). Due to their varying range in potency, opioids are associated with numerous side effects such as: physical dependence, tolerance, constipation, sleepiness, nausea, vomiting, irritability, itching, respiratory depression, and/or mortality (DHHS, 2019).

Clinical guidelines for prescribing opioids to treat pain

Given the increases in opioid misuse and related overdoses over the past 30 years, several agencies (Veteran's Administration/Department of Defense, the U.S. Centers for Disease Control and Prevention, and the American Society of Interventional Pain Physicians) have developed clinical practice guidelines in recent years to ensure the appropriate use and administration of opioids for pain management (DHHS, 2019). Per the 2016 CDC Guideline for Prescribing Opioids for Chronic Pain, when determining whether to initiate or continue prescription opioids for chronic pain, clinicians should consider opioid therapy only if

[32] Over the past 2 decades, the United States has continued to face an opioid epidemic resulting in two subsequent waves of overdose deaths due to specific opioid drugs: (1) the rise of heroin opioid overdose deaths in 2010 (Wave 2), and more recently (2) the rise of synthetic opioid overdose deaths – largely due to fentanyl – in 2013 (Wave 3) (CDC, 2021).

expected benefits for both pain and function are anticipated to outweigh potential patient risks (CDC, 2016). However, it is important to note that nonpharmacological therapy and nonopioid therapy are preferred treatments for chronic pain (CDC, 2016). Furthermore, prior to initiating an opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if the risks exceed the benefits (CDC, 2016).

Use of prescription opioids to treat pain in California

Despite the ongoing U.S. opioid epidemic and recent uptick in drug overdoses due to the COVID-19 pandemic, some progress has been made related to the prescription opioid epidemic in California. (CHCF, 2021; 2022). Over the past decade, California has decreased its rate of prescribed opioids by 45%, from 606.8 per 1,000 in 2010 to 333.3 per 1,000 in 2020 (CDPH, 2022). Moreover, the rate of prescription opioid overdose (excluding synthetics[33]) deaths has decreased by 22%, from 3.7 per 100,000 in 2010 to 2.9 per 100,000 in 2020 (CDPH, 2022). It is important to note that of the more than 1,900 overdose deaths due to any type of opioid in 2010, nearly three-quarters of deaths (74%) were due to prescription opioids overdose (excluding synthetics) (CDPH, 2022). Interestingly, of the 5,500 Californian overdose deaths due to any type of opioid in 2020, approximately one-fifth of deaths (22%) were due to prescription opioid overdose (excluding synthetics) (CDPH, 2022). California's progress in reducing the use of prescription opioids to treat pain over the years can be attributed in part to the implementation of several efforts, including a prescription drug monitoring program; mass dissemination of opioid prescribing guidelines; and expanded access to medication-assisted treatment for opioid use disorder (CHCF, 2022).

Restorative Approaches to Managing Pain

As part of a multimodal treatment plan, nonpharmacological restorative therapies can also be used to manage acute and chronic pain (DHHS, 2019). Common restorative approaches to managing pain include: physical therapy, occupational therapy, physiotherapy, therapeutic exercise, and other treatments such as transcutaneous electric nerve stimulation (TENS), percutaneous electrical nerve stimulation (PENS), massage therapy, superficial cold or heat therapy, and therapeutic ultrasound (DHHS, 2019; FDA, 2022b). FDA-approved nonpharmacological restorative therapies for pain relief include two medical devices: (1) TENS devices that apply electrical currents via skin-surface electrodes; and (2) PENS devices that apply electrical currents via minimally invasive needle electrodes to directly target nerve tissue (FDA, 2022b; Vance et al., 2015).

Interventional Approaches to Managing Pain

Interventional pain management is defined as a subspecialty of pain medicine that can diagnose and treat pain using minimally invasive procedures to reduce pain and reliance on oral pharmacotherapies (DHHS, 2019). Most pain management specialists offer interventional therapies for acute and chronic pain as part of a multimodal approach to pain management (DHHS, 2019). Interventional therapies are typically conducted in a health care setting, ranging from a primary care setting to a more specialized setting depending on the degree of complexity and invasiveness (DHHS, 2019). Common interventional approaches include epidural steroid injections, facet joint nerve block and denervation injection, cryoneuroablation, radiofrequency ablation, peripheral nerve injections, sympathetic nerve blocks, neuromodulation, intrathecal medication pumps, vertebral augmentation, trigger points, joint injections, interspinous process devices, and regenerative/adult autologous stem cell therapy (DHHS, 2019).

[33] Unlike naturally occurring opioids (e.g., morphine, codeine), which are derived from a variety of poppy plants, synthetic opioids (e.g., fentanyl, methadone) are substances that are synthesized in a laboratory (DEA, 2020). In the late 1970s and 1980s, illicit synthetic opioids – which are often more potent than morphine and heroin – began to emerge and led to an in increase in drug trafficking and abuse of illicit synthetic opioids (DEA, 2020). As of 2013, there has been a resurgence in increased trafficking and abuse of illicit synthetic opioids (DEA, 2020).

To provide alternatives to pharmacological approaches to treatment of pain, the FDA has approved several interventional pain management medical devices:

1. Interspinous process devices (IPD): IPDs are spacers implanted between adjacent spinal processes to reduce compression of nerves during spinal extension. IPDs are commonly used to treat low back and leg pain (e.g., lumbar spinal stenosis) (DHHS, 2019; Pintauro et al., 2017);

2. Spinal cord stimulators (SCS): SCS are implanted devices that deliver low levels of electrical impulses directly into the spinal cord to relieve low back and/or lower extremity pain (DHHS, 2019; FDA, 2021b);

3. Peripheral nerve stimulators (PNS): PNS are implanted devices that deliver low levels of electrical impulses directly to nerves located *outside* of the spinal cord (i.e., peripheral nerves) to treat chronic pain conditions (DHHS, 2019; Nayak and Banik, 2018); and

4. Radiofrequency ablation (RFA) devices: RFA devices are used to create lesions/burns in nerves to block pain signals via the insertion of needles delivering continuous or pulse high-voltage electrical currents for treatment of chronic pain conditions (DHHS, 2019; Kapural and Mekhail, 2001).

Behavioral Health Approaches to Managing Pain

Over the years, clinicians have increasingly recognized the connection between pain perception and psychological wellbeing (DHHS, 2019). If left untreated, patients with chronic pain are at increased risk for psychological distress, increased stress and anxiety, and physical inactivity (DHHS, 2019). Behavioral health interventions can play an important role in reducing psychological distress and disability due to pain (DHHS, 2019). Common nonpharmacological behavioral health approaches include: behavioral therapy, cognitive behavioral therapy, acceptance and commitment therapy, mindfulness-based stress reduction, emotional awareness and expression therapy, biofeedback, and relaxation training/hypnotherapy (DHHS, 2019).

In recent years, emerging technologies have prompted researchers to conduct pain reduction research studies using immersive virtual reality (VR) (Garcia et al., 2021a). Immersive VR provides patients with an interactive audio and visual experience via a headset (Sarkar et al., 2021). The intention of VR is to reduce pain through distraction, relaxation, and mindfulness (Sarkar et al., 2021). In November of 2021, the FDA approved the first prescription-use immersive VR system (RelieVRx) – intended for use in a home setting – that applies cognitive behavioral therapy and other behavioral health approaches to reduce low back pain (FDA, 2021a).

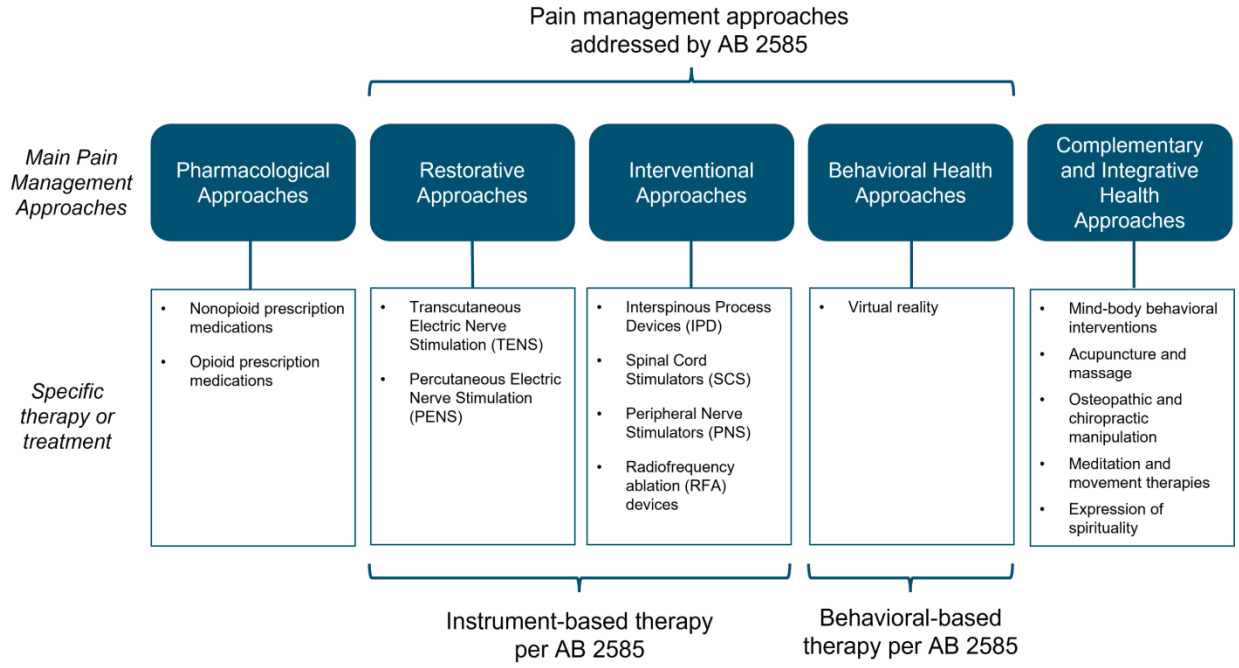
Complementary and Integrative Health Approaches to Managing Pain

Clinicians are also encouraged to consider complementary and integrative health approaches for pain management as part of a multimodal approach to treating patients with acute or chronic pain (DHHS, 2019). Common nonpharmacological complementary and integrative health approaches include: mind–body behavioral interventions, acupuncture and massage, osteopathic and chiropractic manipulation (i.e., manually guided intervention), meditation and movement therapies such as yoga and tai-chi, and expression of spirituality (DHHS, 2019). It is important to note that there are no FDA-approved complementary and integrative health approaches to pain management because these approaches are not subject to FDA regulation.

Pain Management Approaches and AB 2585

A summary of the pain management approaches described in the Task Force's report and their relation to the pain management therapies addressed by AB 2585 can be found in Figure 1.

Figure 1. Pain Management Approaches and Interaction With AB 2585.



Source: California Health Benefits Review Program, 2022.

Barriers to Accessing Nonpharmacological Therapies for Pain Management

Numerous barriers have been identified in accessing nonpharmacological therapies for pain management, including factors related to the patient, health care provider, and health care system (Becker et al., 2017; DHHS, 2019). Patient barriers to accessing nonpharmacological therapies for pain management include: limited resources (e.g., financial or transportation); inadequate or nonexistent health insurance coverage; lack of time needed to schedule and attend appointments; lack of knowledge and awareness regarding available nonpharmacological therapies for pain management; lack of trust in health care providers; fear of pain exacerbation due to increased physical activity; and lack of motivation or interest in nonpharmacological therapies (Becker et al., 2017; DHHS, 2019). Per the Pain Management Best Practices, barriers to accessing nonpharmacological therapies for pain management related to health care providers include: health care provider underestimation of patients' reported level of pain (i.e., unconscious biases); current health care workforce shortages – especially among behavioral and pain management specialists; and lack of research on and/or awareness of novel and effective approaches to pain care (DHHS, 2019). Finally, DHHS (2019) identified cost and reimbursement issues specific to the health care system as barriers to accessing nonpharmacological therapies for pain management.

Disparities[34] and Social Determinants of Health[35] in Chronic Pain

Per statute, CHBRP includes discussion of disparities and social determinants of health (SDoH) as it relates to chronic pain. Disparities are noticeable and preventable differences between groups of people.

[34] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).
[35] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from CDC, 2014; Healthy People 2020, 2019).

Social determinants of health (SDoH) include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography, etc.). CHBRP found literature identifying disparities and SDOH in pain by race/ethnicity, sex/gender, age, socioeconomic status, geographic location, and access to care/management of pain. Research shows that poor health – such as chronic pain – contributes to reduced income, creating a negative feedback loop (Khullar and Chokshi, 2018).

Disparities and SDoH in Pain

Race or ethnicity

Racial and ethnic disparities in the prevalence of chronic pain are well documented (Janevic et al., 2017; Yang et al., 2022). In two studies using data from a nationally representative Health and Retirement Study, researchers found that despite Whites generally reporting a similar or higher overall prevalence of chronic pain compared to other race/ethnicities, Blacks and Latinos were more likely to report greater pain severity/intensity (Javenic et al., 2017; Yang et al., 2022). Furthermore, researchers found that Blacks reported significantly higher levels of pain-related interference related to conducting activities of daily living in comparison to Whites (Yang et al., 2022). Factors related to disparities in pain among Blacks, Latinos, Asians, and American Indians/Alaska Natives racial/ethnic groups include: increased likelihood for having poor health and chronic conditions; increased exposure to environmental and geographic challenges; inadequate access to health care and insurance coverage; and socioeconomic disadvantages (see summary on socioeconomic status below) (IOM, 2011; Javenic et al., 2017).

Sex or gender[36]

A number of studies have reported greater pain prevalence among women relative to men (Bartley and Fillingim, 2013; Leresche, 2011; Templeton, 2020). For example, researchers found that rates of common musculoskeletal pain conditions (e.g., OA, fibromyalgia, migraines, and LBP) were substantially higher among women than men (Leresche, 2011; Templeton, 2020). Factors contributing to these differences in pain prevalence include: (1) gender-based differences such as psychosocial differences in coping strategies and social norms; and (2) sex-based differences in pain mechanisms (Leresche, 2011). For example, studies have found that anatomical differences in pain-signaling pathways and the influence of sex hormones have contributed to sex-based differences in pain perception (Templeton, 2020).

Age

Difficulties in estimating pain prevalence and receipt of care for pain among children are well documented (IOM, 2011; Manworren and Stinson, 2016; Ramira et al., 2016). Children who are not of speaking age or have a cognitive impairment are at high risk for having their pain underestimated and/or undertreated (Manworren and Stinson, 2016). Extensive literature has found that health disparities in children are associated with racial/ethnic diversity and other economic disadvantages (Cheng et al., 2015).

The elderly population (i.e., 65 years of age and older) experiences pain at a disproportionate rate compared to other age groups (Jones et al., 2016; Kaye et al., 2010). According to Jones and colleagues (2016), approximately two thirds of U.S. adults aged 65 and up reported experiencing some type of chronic pain. The literature shows that pain may be underreported in elderly groups due to the belief that pain is an anticipated part of aging (Jones et al., 2016; Kaye et al., 2010). Additionally, some elderly patients may lack the cognitive reserve to verbalize and/or identify that they are experiencing pain (Dentino et al., 2017).

[36] CHBRP uses the National Institutes of Health (NIH) distinction between “sex” and “gender”: “‘Sex’ refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. ‘Gender’ refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time.” (NIH, 2019b).

Socioeconomic status (i.e., income and education)

Socioeconomic status (SES) is defined as an individual's or population's position within a social structure and is typically measured as a combination of education, income, and/or occupation (Winkleby et al., 1992). Studies have indicated an association between low SES and the prevalence of chronic pain (Booher, 2019; Grol-Prokopczyk, 2017; Janevic et al., 2017). Data from a nationally representative Health and Retirement Study found that the impact of pain generally decreased with increasing education (Janevic et al., 2017). Furthermore, researchers found that nearly half of all adults experiencing chronic pain within the lowest wealth quartile (i.e., assets <$16,000) reported that their pain contributed to their financial hardship (Janevic et al., 2017). Risk factors associated with low SES and the prevalence of pain include: having an increased likelihood of poor health; having a higher prevalence of mood disorders and history of trauma; and having an increased likelihood of employment in a high-risk occupation (Janevic et al., 2017).

Geography

Disparities in the prevalence of pain via geographic region have also been noted. Several studies have found a higher prevalence of chronic pain among adults living in rural areas than in urban areas (Dahlhamer et al., 2018; Rafferty et al., 2021; Suntai et al., 2020). In a study examining Behavioral Risk Factor Surveillance Survey data from a chronic pain module in 2018, Rafferty and colleagues (2021) found that suburban and rural residents were significantly less likely to report the use of nonpharmacological therapies for pain management and were less likely to receive multiple treatments for chronic pain in comparison to urban residents (Rafferty et al., 2021). Contributing factors to geographic disparities in pain prevalence among rural populations include having higher rates of employment in high-risk occupations; having higher rates of senior populations who are at increased risk for chronic pain; and having reduced access to health care providers and transportation (Rafferty et al., 2021; Suntai et al., 2020).

Accessing care and treatment for pain

Disparities in accessing care and treatment for pain exist among people who have been historically, economically, and socially marginalized (Craig et al., 2020). In particular, disparities for vulnerable racial/ethnic groups occur at the individual, provider, and societal level (Mossey, 2011). Factors contributing to limited access to care and management of pain among Blacks, Latinos, Asian Americans, and American Indians and Alaska Natives include: inadequate health insurance coverage; language and/or communication barriers; medical mistrust; stigma; provider bias (both conscious and unconscious); limited cultural competency among providers; and provider undertreatment of pain (Craig et al., 2020; De Ruddere and Craig, 2016; IOM, 2011). Additionally, access to care is often compounded by other risk factors among vulnerable racial/ethnic groups such as having economic, environmental, and geographic challenges (Craig et al., 2020).

Societal Impact of Pain in the United States

The presence of chronic pain in the United States has direct and indirect economic and societal costs. Gaskin and Richards (2012) estimated that the total financial cost of pain to society was equal to a range of $560 to $635 billion in 2010 dollars. Translated into 2022 dollars, the total financial cost of pain inclusive of indirect and direct costs equates to a range of $720 to $819 billion. This calculation consists of the following range of direct and indirect costs in 2022 dollars: incremental costs of health care ($336.5 to 386.7 billion), days of work missed ($14.9 to $16.3 billon), hours of work lost ($122.7 to $124.4 billion), and lower wages ($245.7 to $291.8 billion). Please note, the societal impact discussed here is relevant to a broader population than AB 2585 impacts, which would affect the health insurance of a subset of Californians (see *Policy Context*). See the *Benefit Coverage, Utilization, and Cost Impacts* section for estimates of direct cost impacts for the specific population targeted by AB 2585.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2585 would authorize, but not mandate, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatment (NPMT), which this bill defines as any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain. Additional information on diseases/conditions is included in the *Background* section. The medical effectiveness review assesses findings from evidence[37] on the following NPMTs:

Nonpharmacological restorative therapies

- Transcutaneous electrical nerve stimulation (TENS)
- Percutaneous electrical nerve stimulation (PENS)

Interventional pain management

- Interspinous process devices (IPD)
- Peripheral nerve stimulation (PNS)
- Radiofrequency ablation (RFA)
- Spinal cord stimulation (SCS)

Behavioral health approaches

- RelieVRx virtual reality

Nonpharmacological restorative therapies and interventional pain management are instrument-based NPMTs. RelieVRx virtual reality is the only behavioral therapy NPMT approved by the FDA. Please note that this analysis uses the terminology from the source material cited, which refers to the original name for RelieVRx virtual reality, EaseVRx.

Research Approach and Methods

Studies of NPMTs were identified through searches of PubMed, the Cochrane Library, Web of Science, Embase, and Scopus. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), PubMed Health, and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English. The search was limited to studies published between 2010 to present. Of the 798 articles found in the literature review, 50 were reviewed for potential inclusion in this report on AB 2585. Our content expert identified an additional 11 studies which were also reviewed for potential inclusion. A total of 39 studies were included in the medical effectiveness review for this report. Some of these studies were meta-analyses or systematic reviews

[37] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

than synthesized findings from multiple studies. The other articles were eliminated because they did not focus on NPMTs, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

The medical effectiveness review was limited to randomized controlled trials (RCTs) because these types of studies provide the strongest evidence of the impact of an intervention on outcomes of interest. Where available, CHBRP relied on systematic reviews and meta-analyses of RCTs because they synthesize findings from multiple RCTs.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[38] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. How does the use of NPMTs impact health-related outcomes for patients?
2. Does use of NPMTs impact quality of life and pain interference with activity (for example, interference with walking or performing work-related tasks)?
3. Is there any evidence that NPMTs reduce utilization of prescription opioids for pain management?
4. What harms are associated with NPMTs?

Methodological Considerations

Many of the RCTs had small sample sizes that limited their ability to detect statistically significant differences between people treated with NPMTs and people who received other interventions.

Some studies only examined the effects of NPMTs on outcomes immediately after treatment or shortly thereafter and did not assess whether these NPMTs improved outcomes over multiple months or years. This is a major limitation of chronic pain studies because treatments for chronic pain need to be effective over the long term to improve quality of life and reduce use of pain medication.

In some studies, people in the control group did not receive a sham version of the NPMT (e.g., an inactive TENS device). Findings from studies in which the control group does not receive a sham version of the NPMT may overstate the effect of the device because they do not control for the effect of a participant's belief that the device will reduce their pain or improve other outcomes (i.e., the placebo effect). Lack of an appropriate sham control may also falsely present an effect favoring the NPMT when in fact there is no effect. Participant blinding with a sham treatment is therefore essential in clinical trials for pain management to ascertain the true effect of the NPMT.

Some studies, particularly studies of interventional pain management devices, compared an NPMT to another treatment. Findings from these studies cannot be compared directly to studies that compared an NPMT to a sham intervention or no intervention. Instead, they offer evidence of the effectiveness of an NPMT relative to other treatments for a disease or condition.

Some of the studies included in the review are single-blinded or open-label clinical trials, which may introduce bias. In a double-blinded study, researchers and participants are unaware of the treatment

[38] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

assignments. In RCTs for pain management, the research team may consist of the clinicians performing the intervention, the investigators conducting the follow-up assessments, statisticians, data analysts, and study coordinators, etc. In single-blinded trials, either the participant or the research team is unaware of the treatment assignment. In open-label clinical trials, neither the research team nor the participant is blinded to the treatment assignment. Because some NPMTs require surgery to implant a device, it is infeasible for the clinician performing the procedure to be blinded to treatment assignments. However, it is feasible to blind the patient and the investigators conducting follow-up assessments, and blinding these persons provides stronger evidence of the effectiveness of NPMTs.

Not all studies reported on clinical significance. This is a major limitation because a finding may be statistically significant (i.e., the observed difference in the samples is deemed to be suggestive of a true difference in the population), but not be clinically significant (i.e., the observed difference in the samples is deemed large enough to be meaningful to people who receive an intervention or to health professionals) (Ranganathan et al., 2015). There are several guidelines available for assessing clinical significance, one of which is the Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT) recommendations. The IMMPACT recommendations offer guidance for interpreting clinical importance (significance) in chronic pain trials. Using a 0 to 10 numerical rating scale (NRS), a 10% to 20% decrease is considered minimally important, a ≥30% decrease is moderately important, and a ≥50% decrease is substantially important (Dworkin et al., 2008).

Outcomes Assessed

The medical effectiveness review assessed the impact of NPMTs on three types of outcomes:

- Health outcomes related to pain (e.g., intensity of pain)[39]
- Quality-of-life outcomes (e.g., interference of pain on activity and quality of life as measured by the EuroQol-5 Dimension or Brief Pain Inventory – Short Form)[40]
- Use of prescription pain medications

The medical effectiveness review also assessed evidence regarding harms associated with FDA-approved NPMTs.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of NPMTs for which AB 2585 would authorize coverage. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the

[39] Several instruments are used to assess self-reported pain intensity. Two common ones are the numerical rating scale (NRS) and the visual analog scale (VAS). Haefeli and Elfering (2006) offer the following descriptions of the NRS and VAS instruments. The NRS presents patients with a scale (usually 0-10, 0-20, or 0-100) and asks them to identify the number that best matches their pain intensity. Typically, zero correlates with "no pain," and the upper limit correlates with "worst pain ever possible." The VAS is a line where patients are asked to indicate their pain level – the lower limit denotes "no pain at all," and the upper limit correlates with "pain as bad as it could be." Pain intensity is measured as the distance (usually in millimeters or centimeters) between "no pain" and the patient-identified pain level.

[40] To facilitate the comparison of findings across studies, quality of life findings are reported for studies that used either the EuroQol-5 Dimension (EQ-5D) or Brief Pain Inventory – Short Form (BPI-sf). The EQ-5D assesses health-related quality of life across five self-reported dimensions (mobility, self-care, usual activities, pain and discomfort, and anxiety and depression). The BPI-sf evaluates self-reported pain and its impact on daily functioning.

strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms are included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

Clear and convincing evidence indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

Insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

More information is available in Appendix B.

CHBRP cannot draw a single overall conclusion regarding the effectiveness of all NPMTs. Each of the three types of NPMTs discussed in the medical effectiveness review use different mechanisms of action to address pain and the strength and amount of evidence varies substantially across NPMTs. For these reasons, CHBRP draws separate conclusions regarding each type of NPMT for health outcomes, quality of life outcomes, and use of prescription pain medications. CHBRP also reviews the evidence of harms associated with each type of NPMT.

Nonpharmacological Restorative Therapies

Transcutaneous electrical nerve stimulation (TENS) – chronic pain

Findings from studies of the effects of TENS on chronic pain are assessed separately from findings regarding its effects on acute pain due to differences in these two types of pain.

Impact on health-related outcomes

Gibson et al. (2019) synthesized eight systematic reviews covering 51 TENS-related RCTs for chronic pain. This synthesis included studies that assessed TENS versus sham TENS, TENS versus usual care or no treatment, TENS combined with another intervention versus that intervention alone, comparisons of different types of TENS, and TENS delivered with different frequencies. One systematic review (Gibson et al., 2017) reported that TENS was associated with a greater reduction in pain intensity for neuropathic pain than sham TENS (difference in means [MD] = −1.58 [95% confidence interval (CI) −2.08 to −1.09, $p < 0.001$]). Another systematic review (Rutjes et al., 2009) evaluated TENS versus sham studies and TENS versus no intervention studies for knee osteoarthritis. Results from the pooled analysis by Rutjes et al. (2009) indicated that TENS reduced pain intensity more than sham TENS or no intervention (standardized mean difference [SMD] = −0.85 [95% CI −1.36 to −0.34, $p = 0.001$]). However, Gibson et al. (2019) noted that it may have been inappropriate to pool data from sham TENS studies with data from

studies with no intervention because the two treatments are inherently different and likely had different effect sizes. The remaining six studies were not reviewed any further due to inadequate data.

Newberry et al. (2017) conducted a systematic review of the effectiveness of multiple nonsurgical treatments for osteoarthritis of the knee, including TENS. The authors identified four RCTs that compared TENS to sham TENS. A meta-analysis of findings from these RCTs found that receipt of TENS was associated with short-term (4 to 6 weeks post-treatment) reduction in pain intensity (SMD = −0.31 [95% CI −0.56 to −0.06]). Two of the four RCTs examined medium term effects (4 to 6 months post-treatment) on pain intensity and found no statistically significant difference between people who received TENS and people who received sham TENS.

Martimbianco et al. (2019) performed a systematic review of seven RCTs that assessed the impact of TENS on chronic neck pain. Two of the included studies assessed TENS versus sham TENS with outcomes measured at short-term and intermediate-term follow-ups. Short-term follow-ups were defined as more than 1 day and up to 3 months post-treatment. Intermediate-term follow-ups were defined as more than 3 months and up to 1 year post-treatment. The first study did not find a difference in pain reduction for TENS versus sham TENS (MD = −0.10 [95% CI −0.97 to 0.77]) (Sahin et al., 2011). Similarly, Maayah and Al-Jarrah (2010) also did not find a difference in pain reduction at short-term follow-up for TENS versus sham TENS (risk ratio (RR) = 1.57 [95% CI 0.84 to 2.92]). Three studies assessed TENS combined with another intervention (infrared, trapezium stretching, and exercise) versus that intervention alone. Chiu et al. (2005) concluded that there was little to no difference in pain reduction at the short-term (MD = 0.40 [95% CI −0.27 to 1.07]) or intermediate-term (MD = −0.21 [95% CI −0.92 to 0.50]) follow-ups for TENS plus infrared versus infrared treatment alone. Azatcam et al. (2016) observed a difference at the short-term (MD = −0.78 [95% CI −1.34 to −0.22]) and intermediate-term (MD = −1.17 [95% CI −1.67 to −0.67]) follow-ups, suggesting that TENS plus trapezius stretching is more effective at reducing pain than trapezius stretching alone. Yesil et al. (2018)[41] determined little to no difference at the short-term follow-up (MD = −0.65 [95% CI −1.36 to 0.06]) for TENS plus exercise versus exercise alone.

Sawant et al. (2015) analyzed four studies in a systematic review of TENS treatments for managing pain associated with multiple sclerosis. One of these studies (Chitsaz et al. (2009) compared TENS versus Nortriptyline (an antidepressant and nerve pain medication) for upper extremity pain and found no difference in efficacy between the two treatments (SMD = −0.49 [95% CI −1.00 to 0.03, $p > 0.05$]).

Zhou et al. (2018) conducted an RCT comparing the efficacy of three different interventions: neuromuscular electrical stimulation (NMES), TENS, and routine rehabilitation (control) on hemiplegic shoulder pain. All participants received routine rehabilitation. After 4 weeks of treatment, the mean self-reported pain intensity scores in the NMES, TENS, and control groups reduced by 2.03, 1.44, and 0.61 points, respectively. Differences between the groups were statistically significant ($p < 0.001$) after 4 weeks, but not at week 2 (halfway through treatment) and week 8 (4 weeks after treatment).

Jamison et al. (2019) assessed high-frequency TENS (hfTENS) versus treatment as usual (control) in an RCT for low back pain. Given that the study had no active comparator group (e.g., a sham or placebo group), participants and the research team were not blinded. After 6 weeks of treatment, the hfTENS group experienced lower “worst” pain scores than the control group ($p < 0.025$) and after 3 months, the hfTENS group experienced less pain intensity compared to the control group (average pain intensity score: 4.0 [standard deviation (SD) = 2.5] versus 5.7 [SD = 1.9], $p < 0.01$).

Peacock et al. (2019) compared three treatments in an open-label RCT of TENS for chronic musculoskeletal pain: Tennant Biomodulator devices (which use biofeedback electrical stimulation), traditional Chinese acupuncture, and TENS. All groups also received usual care. Between baseline and the end of the 6-week treatment, all participants exhibited a 16% decrease in pain. No statistical differences were observed between the three treatments at the end of treatment or at the 1-month follow-

[41] Findings from Yesil et al. (2018) have been published in multiple articles; citations can be found in Martimbianco et al. (2019).

up. This study of active duty and retired military personnel experienced a high attrition rate of 27%, which limits confidence in the study's findings.

He et al. (2021) examined TENS versus sham TENS for pain related to pancreatic cancer in a participant-blinded RCT. The TENS group experienced less pain across different time points after treatment. Compared to baseline, the mean percentage change in self-reported pain was −77.9% [95% CI −79.0% to −76.9%] right after treatment, −37.9% [95% CI −40.3% to −35.5%] after 1 hour, −27.1% [95% CI −29.0% to −25.1%] after 2 hours, and −8.3% [95% CI −10.8% to −5.7%] after 3 hours. By contrast, the sham TENS group experienced increased pain at 1, 2, and 3 hours after treatment. Compared to baseline, the mean percentage change in self-reported pain was −25.3% [95% CI −26.7% to −24.0%] right after treatment, 26.2% [95% CI 23.7% to 28.3%] after 1 hour, 98.7% [95% CI 95.1% to 102.3%] after 2 hours, and 128.1% [95% CI 124.6% to 131.7%] after 3 hours. The mean percentage changes in self-reported pain at 1, 2, 3, and 4 weeks after treatment did not differ between the two groups.

Impact on quality of life

The systematic review by Newberry et al. (2017) included three RCTs that compared the effects of TENS versus sham TENS on function scores of people with osteoarthritis on the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC). The function subscale of the WOMAC measures ability to perform activities of daily living, such as standing, walking, and climbing stairs. None of the three RCTs found statistically significant differences in effects on function in the short term (4 to 6 weeks post-treatment) or medium term (4 to 6 months post-treatment).

Jamison et al. (2019) observed less pain-related interference (for example, with general activity and walking ability) in the hfTENS group than the treatment-as-usual control group. After 3 months, the hfTENS group reported a mean average interference rating of 3.2 [SD = 3.0], whereas the control group reported a rating of 5.4 [SD = 2.3] ($p < 0.01$).

Impact on utilization of prescription opioids for pain management

Martimbianco et al. (2019) detected no differences between the TENS and control groups in regard to pain medication consumption.

Jamison et al. (2019) noted a decrease in prescription pain medication use in both the hfTENS and control groups; however, there were no between-group differences.

He et al. (2021) found an increase in morphine use from baseline for both the TENS group and control group but no statistically significant differences between the two groups at 1 week, 2 weeks, 3 weeks, or 4 weeks post-treatment.

Harms

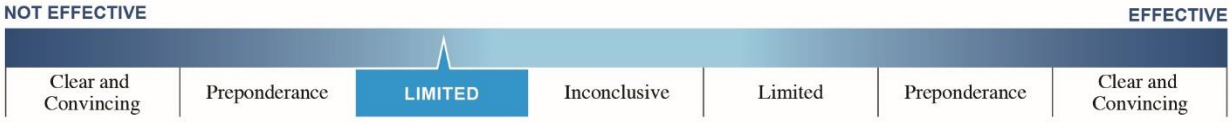
Zhou et al. (2018), Peacock et al. (2019), and He et al. (2021) all reported that participants in their studies did not experience any adverse events.

Summary of findings regarding transcutaneous electrical nerve stimulation for chronic pain: There is inconclusive evidence from four systematic reviews and four RCTs regarding the impact of TENS on chronic pain. There is inconclusive evidence from one systematic review and one RCT regarding the impact of TENS on quality of life among people with chronic pain. There is limited evidence from one systematic review and two RCTs that TENS does not affect consumption of pain medication. Studies that examined adverse events associated with use of TENS for chronic pain reported no harms.

Figure 2. Impact of TENS on Chronic Pain Relief

Figure 3. Impact of TENS for Chronic Pain on Quality of Life

Figure 3. Impact of TENS for Chronic Pain on Utilization of Prescription Opioids for Pain Management



Transcutaneous electrical nerve stimulation (TENS) – acute pain

Impact on health-related outcomes

Zhu et al. (2017) evaluated six RCTs in a systematic review and meta-analysis of TENS for relieving pain associated with total knee arthroplasty (knee replacement surgery). In a meta-analysis of two studies that compared self-reported pain intensity scores during the 24 hours after surgery, the TENS group reported significantly lower pain intensity scores compared to the control group (SMD = −0.47 [95% CI −0.87 to −0.08, p = 0.02). In a separate meta-analysis of two studies that measured self-reported pain intensity scores and active range of motion at 2 weeks after surgery, the TENS group had significantly greater range of knee motion compared to the control group (SMD = 0.37 [95% CI 0.06 to 0.68, p = 0.02]). However, there was no statistically significant difference in pain intensity between the TENS group and the control group.

Elboim-Gabyzon et al. (2019) examined TENS versus sham TENS after hip fracture surgery in a double-blinded RCT. All participants also received standard rehabilitation care. The TENS group reported less pain while walking compared to the sham TENS group after 5 days of treatment. Between days 2 and 5 of treatment, the TENS group experienced a mean pain intensity reduction of 2.55 [SD = 1.37, p < 0.0001], and the sham TENS group experienced a reduction of 1.06 (SD = 1.11, p < 0.0001). The difference in pain intensity reduction between the two groups was statistically significant (p < 0.0011). Participants were also asked to participate in a walking test on postoperative day 5 where their walking distance in a 2-minute walk test was measured. The active TENS group walked a statistically significant longer distance than the sham TENS group (9.36 [SD = 3.81] versus 6.83 [SD = 3.59], respectively, p = 0.02). (Units were not provided for the walking distances in the 2-minute walk test.) A six-point functional ambulation classification (FAC) tool was used to assess mobility; the highest score (5) indicates greatest independent mobility. The TENS group exhibited greater improvements in mobility between postoperative days 2 and 5 compared to the sham TENS group (1.43 points [SD = 0.66] versus 1.06 points [SD = 0.54], respectively, p = 0.04). Participants were also tested on their ability to sit and stand five times – no differences were observed between the two groups.

Engen et al. (2016) piloted a RCT to determine the efficacy of TENS combined with opioid administration versus opioids alone following video-assisted thoracoscopy. Pain was measured hourly for 48 hours; no statistically significant difference was detected among the TENS group and the opioids alone group.

Husch et al. (2020) conducted a double-blinded RCT comparing TENS, sham TENS, and conventional physiotherapy alone (control) 48 hours after thoracotomy. All participants received conventional physiotherapy. The authors found no statistically significant differences in pain intensity across the three groups.

Mahure et al. (2017) compared the impact of TENS versus sham (placebo) TENS for pain related to arthroscopic rotator cuff repair in a double-blinded RCT. All patients also received Percocet (oxycodone/acetaminophen) for use as "rescue pain pills." Mean self-reported pain scores were lower for the TENS group than the sham TENS group throughout the first week after surgery. Statistically significant between-group differences were observed at 12 hours after surgery (3.1 [SD = 3.6] for the TENS group versus 5.8 [SD = 4.4] for the sham TENS group, p = 0.047) and 7 days after surgery (3.6 [SD = 2.1] for the TENS group versus 5.8 [SD = 1.2] for the sham TENS group, p = 0.008). Statistically significant differences between the two groups were not observed at the other time points (24, 36, and 48 hours, and 3, 4, 5, and 6 days after surgery).

Ozturk et al. (2016) conducted an RCT assessing three treatments for postoperative pain after cardiac surgery: parasternal block, intermittent TENS, and morphine infusions only (control); all patients had access to morphine infusions after surgery via intravenous patient-controlled analgesia (PCA) pumps. The parasternal block group had significantly lower self-reported mean pain intensity scores than both the TENS group and the control group at 4, 5, 6, 7, and 8 hours after surgery ($p < 0.001$), but there were no significant differences at 12 or 24 hours. Self-reported pain intensity scores were lower in the TENS group than the control group for all time points, but differences were not statistically significant. This study noted that the investigators who followed up with patients were blinded to the treatment assignments.

Impact on quality of life

CHBRP did not identify any studies that reported on the impact of TENS for acute pain on quality of life.

Impact on utilization of prescription opioids for pain management

Zhu et al. (2017) performed a meta-analysis of two studies that assessed morphine consumption in the 24 hours after total knee arthroplasty and found that morphine use was significantly lower in the TENS group than the control group during this period (SMD = −0.81 [95% CI −1.44 to −0.18, p = 0.012).

Engen et al. (2016) found no statistically significant difference in change in consumption of oral morphine equivalents (OMEs) between the group that received TENS plus opioids and the group that received only opioids at 48 hours post-treatment.

Husch et al. (2020) reported no differences in analgesic medication use between the TENS, sham TENS, and control groups (acetaminophen p = 0.742; dipyrone p = 0.445; tramadol p = 0.706; morphine p = 0.564) between 24 hours and 48 hours after thoracotomy.

Mahure et al. (2017) observed statistically significant differences in Percocet consumption between the TENS group and sham TENS group 48 hours after the procedure (12.8 Percocet tablets [SD = 4.7] versus 17.2 Percocet tablets [SD = 6.3] respectively, p = 0.020) as well as 7 days after the procedure (25.2 Percocet tablets [SD = 10.0] versus 33.8 Percocet tablets [SD = 14.3], respectively, p = 0.037). In this study, Percocet was provided to patients as "rescue pain pills."

As previously mentioned, all patients in the Ozturk et al. (2016) study were offered morphine infusions after surgery through intravenous PCA pumps. At 24 hours post-surgery, the control group self-administered more morphine doses (52.4 mg [SD = 23.1]) than the TENS group (37.0 mg [SD = 15.2]) and parasternal block group (26.5 mg [SD = 13.3]). The parasternal block group used significantly less morphine than the TENS and control groups ($p < 0.001$), and the TENS group used significantly less morphine than the control group ($p < 0.001$).

Harms

Mahure et al. (2017) observed no machine-related complications in either the TENS group or sham TENS group in their study of pain associated with arthroscopic rotator cuff repair procedures.

Ozturk et al. (2016) reported no side effects related to local anesthesia or opioids, and there were no statistical differences in wound complications between the parasternal block, TENS, and control groups.

Summary of findings regarding transcutaneous electrical nerve stimulation for acute pain: There is inconclusive evidence from one systematic review and five RCTs regarding the impact of TENS on acute pain following medical procedures. There is insufficient evidence on the impact of utilizing TENS for acute pain on quality of life. There is inconclusive evidence from one systematic review and four RCTs that TENS for acute pain has an impact on use of prescription pain medication. There is insufficient evidence of harms associated with use of TENS to treat acute pain.

Figure 4. Impact of TENS on Acute Pain Relief

Figure 5. Impact of TENS for Acute Pain on Quality of Life

Figure 6. Impact of TENS for Acute Pain on Utilization of Prescription Opioids for Pain Management

Percutaneous electrical nerve stimulation (PENS)

Impact on health-related outcomes

Miao et al. (2018) conducted a double-blinded RCT assessing the effectiveness of percutaneous neuromuscular electrical stimulation (PNMES) versus sham PNMES (control) for treating neck pain in participants with cervical spondylosis. From baseline through the end of the 12-week treatment and 4-week follow-up, the PNMES group exhibited greater decreases in mean pain intensity compared to the control group. The PNMES group reported pain intensity scores of 6.1 [SD = 1.5] at baseline, 1.3 [SD = 0.5] after 12 weeks of treatment, and 1.6 [SD = 0.7] at the 4-week follow-up. The control group reported pain intensity scores of 6.3 [SD = 1.6] at baseline, 3.8 [SD = 1.7] after 12 weeks of treatment, and 4.0 [SD = 1.9] at the 4-week follow-up. Between-group differences were statistically significant after 12 weeks of treatment and the 4-week follow-up ($p < 0.01$ for both time periods). The Miao et al. (2018) study also observed statistically significant increases in the mean range of motion (ROM) of the cervical spine for the PNMES group compared to the control group at the end of the 12-week treatment and 4-week follow-up.

Six types of movement were observed: flexion, extension, right bending, left bending, right rotation, and left rotation. For both groups, ROM progressively improved from baseline to the end of the 12-week treatment and 4-week follow-up. Between-group differences across the six types of movement were statistically significant after 12 weeks of treatment and the 4-week follow-up ($p < 0.01$ for all types of movement).

Impact on quality of life

CHBRP did not identify any studies that reported findings regarding the impact of PENS on quality of life.

Impact on utilization of prescription opioids for pain management

CHBRP did not identify any studies that reported findings regarding the impact of PENS on use of prescription opioids.

Harms

Miao et al. (2018) did not report any harms for either the PENS group or control group.

Summary of findings regarding PENS: There is insufficient evidence from one RCT regarding the effects of PENS on pain intensity, quality of life, or use of prescription pain medication. There is insufficient evidence of harms associated with use of PENS to treat pain.

Figure 7. Impact of PENS on Pain Relief

Figure 8. Impact of PENS on Quality of Life

Figure 9. Impact of PENS on Utilization of Prescription Opioids for Pain Management

Interventional Pain Management

Interspinous process devices (IPD)

The literature uses several terms to refer to interspinous process devices, including interspinous spacers and interspinous process spacer device implants.

Impact on health-related outcomes

Zaina et al. (2016) synthesized five RCTs that compared surgical versus nonsurgical interventions for lumbar spinal stenosis. One RCT (Zucherman et al., 2004[42]) examined the differences in symptom severity and physical function between participants who received an interspinous spacer versus participants who received usual nonsurgical treatment. Interspinous spacers were found to be more efficacious than usual treatment at the 6-week, 6-month, and 1-year follow-ups.

Machado et al. (2016) analyzed 24 RCTS published in 39 research articles or abstracts in a systematic review of interspinous spacers versus other surgical procedures for lumbar spinal stenosis. Three trials (Lønne et al., 2015a, 2015b; Moojen et al., 2013; Strömqvist et al., 2013[43]) compared interspinous spacers with conventional bony decompression and observed no differences in pain reduction between the two procedures in the short term (MD = −0.93 [95% CI −9.86 to 8.00]) or long term (MD = −0.55 [95% CI −8.08 to 6.99]. Two trials (Azzazi et al., 2010; Davis et al., 2013[44]) examined interspinous spacers and bony decompression combined with fusion – no difference in pain reduction was observed at the long-term follow-up (MD = 5.35 [95% CI −1.18 to 11.88]). Machado and colleagues (2016) classified trials with follow-up periods <12 months after intervention as short-term studies, and trials with follow-up times 12 months or more after intervention as long-term studies.

Wei et al. (2021) conducted a systematic review and meta-analysis of 34 RCTs assessing the efficacy of different interventions for lumbar spinal stenosis. IPD implants were compared with minimally invasive decompression, laminectomy/laminotomy, and decompression combined with fusion. All surgical procedures, including IPDs, were determined to be significantly more efficacious at reducing pain than nonsurgical interventions in the short-term and long-term. The authors did not define short term and long term. IPDs ranked last in a comparison of seven different surgical interventions' ability to yield the greatest short-term change in pain. That is, IPDs had a 1% chance of yielding the greatest short-term change in pain compared with the other six surgical interventions assessed (decompression, decompression plus fusion, minimally invasive decompression, endoscopic decompression, laminectomy, and laminotomy).

Schenck et al. (2021) presented data on a 5-year–long RCT comparing IPD implantation with conventional bony decompression for treatment of intermittent neurogenic claudication due to lumbar spinal stenosis. Patients and the nurses who observed the patients postintervention were blinded through the 1-year follow-up, but it is unclear whether they remained blinded through the 5-year follow-up. At 260 weeks, the IPD group experienced less back and leg pain intensity than the bony decompression group; the between-group difference was statistically significant for back pain (p = 0.02), but not leg pain (0.12).

Impact on quality of life

One study in the Machado et al. (2016) systematic review found no statistically significant difference in quality of life after interspinous spacer implantation versus bony decompression for lumbar spinal stenosis (Lønne et al., 2015). Another study on interspinous spacers and bony decompression combined with fusion also found no statistically significant difference between these two treatments (Davis et al. 2013).

Impact on utilization of prescription opioids for pain management

CHBRP did not identify any studies that reported on the impact of IPDs on utilization of prescription opioids.

[42] Findings from Zucherman et al. (2004) have been published in multiple articles; citations can be found in Zaina et al. (2016).
[43] Findings from Lønne et al. (2015) and Moojen et al. (2013) have been published in multiple articles. Citations for these articles can be found in Machado et al. (2016).
[44] Findings from Davis et al. (2013) have been published in multiple articles; citations can be found in Machado et al. (2016).

Harms

The Zucherman et al. (2004) study assessed in the Zaina et al. (2016) systematic review determined that 11% of those who received an interspinous spacer experienced side effects such as interspinous spacer fracture, coronary ischemia (reduced blood flow through the coronary arteries), respiratory distress syndrome, hematoma (localized bleeding outside a blood vessel), and death due to pulmonary edema (excess fluid in the lungs).

Machado et al. (2016) observed that compared to patients receiving bony decompression, patients receiving interspinous spacers required a longer operation time (MD = 39.11 minutes [95% CI 19.43 minutes to 58.78 minutes]) and had a higher risk of reoperation (RR = 3.95 [95% CI 2.12 to 7.37]). There were no differences in length of hospital stay (MD = 0.51 days [95% CI -0.58 days to 1.60 days]) and in perioperative blood loss (MD = 144.00 mL [95% CI −209.74 mL to 497.74 mL]) between the two groups. By contrast, compared to patients receiving interspinous spacers, patients receiving bony decompression plus fusion required a longer operation time (MD = 78.91 minutes [95% CI 30.16 minutes to 127.65 minutes] and longer hospital stays (MD = 1.58 days [95% CI 0.90 days to 2.27 days]), in addition to greater perioperative blood loss (MD = 238.90 mL [95% CI 182.66 mL to 295.14 mL]). There were no differences in risk of reoperation (RR = 0.70 [95% CI 0.32 to 1.51]).

Wei et al. (2021) evaluated the probability of complications among eight surgical interventions for lumbar spinal stenosis: split spinous process decompression, laminectomy, decompression plus fusion, laminotomy, minimally invasive decompression, IPDs, decompression, and endoscopic decompression. IPDs ranked sixth (2% chance of complication among all eight surgical interventions). In regard to the probability of having the highest reoperation rate among the same eight surgical interventions, IPDs ranked first (64% chance of reoperation among all eight surgical interventions).

Schenck et al. (2021) determined that post-surgery complications were minor. However, the IPD group had a 29% reoperation rate 2 years after the initial implantation compared to 13% of the bony decompression group (p = 0.04). In the IPD reoperation group, the IPD was explanted and participants received bony decompression.

Summary of findings regarding interspinous process devices: There is limited evidence from one systematic review that IPD and other surgical interventions are associated with greater reduction in pain than nonsurgical interventions. There is a preponderance of evidence from two systematic reviews and one RCT that IPD is not associated with greater reduction in pain relative to other surgical interventions. There is limited evidence from one systematic review that IPD is not associated with greater improvement in quality of life. There is insufficient evidence regarding the impact of IPDs on utilization of prescription opioids. There is limited evidence that IPD is associated with severe harms including interspinous spacer fracture, coronary ischemia, respiratory distress, hematoma, and death due to pulmonary edema. There is a preponderance of evidence that IPD is associated with a higher risk of reoperation relative to other surgical interventions.

Figure 10. Impact of IPDs and Other Surgical Interventions on Pain Relief Compared to Nonsurgical Interventions

Figure 11. Impact of IPDs on Pain Relief Compared to Other Surgical Interventions

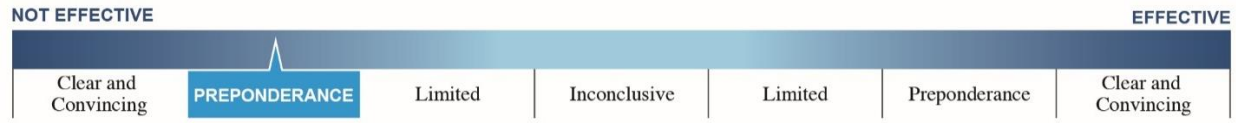


Figure 12. Impact of IPDs on Quality of Life

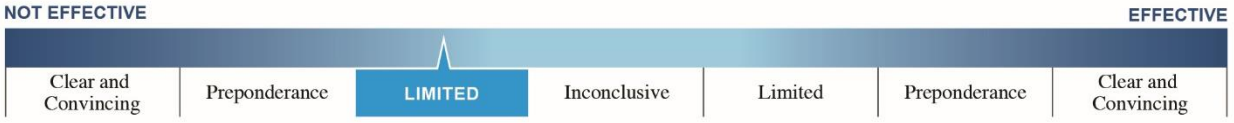


Figure 13. Impact of IPDs on Utilization of Prescription Opioids for Pain Management

Spinal cord stimulation (SCS)

Impact on health-related outcomes

O'Connell et al. (2021) synthesized 15 published studies and 20 ongoing studies in a systematic review of RCTs evaluating SCS covering a range of chronic conditions such as failed back surgery syndrome, low back pain, and neuropathic pain. The systematic review included studies that compared 1) implanted SCS interventions versus sham stimulation, no treatment, or usual care, and 2) SCS interventions combined with another treatment versus that treatment alone (medical management or physical therapy). O'Connell et al. (2021) performed a meta-analysis of six studies that compared SCS versus sham SCS within 1-month after intervention. They found that SCS was associated with a greater reduction in pain intensity than sham SCS (MD = −8.73 [95% CI −15.67 to −1.78], p = 0.005). In another meta-analysis of three studies that assessed SCS combined with another intervention versus that intervention alone, O'Connell et al. (2021) found that combining SCS with another intervention was associated with a greater reduction in pain than the other intervention alone at the 1-month follow-up (MD = −37.41 [95% CI −46.39 to −28.42], p < 0.001). A separate meta-analysis of five studies that evaluated SCS combined with another intervention versus that intervention alone revealed an observed effect for pain intensity reduction favoring receipt of SCS combined with another intervention at the 6-month follow-up (MD = −31.22 [95% CI −47.34 to −15.10], p < 0.001). One study (Kemler et al., 2000) examined SCS combined with another intervention versus that intervention alone with a 5-year follow-up. There was no effect for either group (MD = −7.00 [95% CI −24.76 to 10.76], p = 0.44).[45]

Duarte et al. (2020) performed a systematic review of eight RCTs comparing SCS with sham SCS and placebos (i.e., inactive device and difference in one or more study procedures) for treatment of neuropathic pain. Compared to the two types of control groups, participants receiving SCS experienced greater reductions in pain intensity (pooled MD = −1.15 [95% CI −1.75 to −0.55], p = 0.001). When assessing SCS versus sham SCS and SCS versus placebos, there was a larger treatment effect observed in studies employing placebos (pooled MD = −1.88 [95% CI −2.77 to −0.98], p = 0.008) compared to studies that employed sham SCS (pooled MD = −0.34 [95% CI −1.04 to 0.36], p = 0.287).

[45] Findings from Kemler et al. (2000) have been published in multiple articles; citations can be found in O'Connell et al. (2021).

Petersen et al. (2021) compared the effects of conventional medical management (CMM) with 10-kHz high-frequency SCS combined with CMM on painful diabetic neuropathy in an open-label RCT. A greater proportion of people in the 10-kHz SCS + CMM group experienced ≥50% pain relief than in the CMM-only group (79% versus 5% [95% CI 64.2% to 83.0%], $p < 0.001$) at the 3-month follow-up. Between baseline and the 6-month follow-up, 2% of the 10-kHz SCS + CMM group reported worsening pain compared to 52% of the CMM group.

Turner et al. (2010) conducted a prospective cohort study of participants with chronic back and leg pain associated with failed back surgery syndrome. Participants were grouped based on whether they had previously received SCS treatment (SCS group); a pain clinic evaluation, but not SCS (pain clinic group); or neither a pain clinic evaluation nor SCS (usual care group). At the 6-month follow-up, a greater proportion of the SCS group (18%) experienced a ≥50% relief in leg pain compared to the pain clinic group (5%, $p = 0.09$) and the usual care group (3%, $p = 0.02$). No statistically significant differences were observed at the 12-month or 24-month follow-ups.

Impact on quality of life

As previously mentioned, the O'Connell et al. (2021) systematic review examined the impact of SCS versus sham SCS and SCS combined with another intervention versus that intervention alone. Findings from a meta-analysis of two studies that compared SCS to sham SCS suggest that there was no statistically significant difference in health-related quality of life. Other studies included in the O'Connell et al. (2021) systematic review evaluated SCS combined with another intervention versus that intervention alone at different follow-up periods: short term (one study), medium term (five studies), and long term (one study). Short term was defined as within 1 month of surgery, medium term as 3 to 8 months following surgery, and long term as 1 year or more after surgery. The short-term follow-up study (de Vos et al., 2014) found that SCS had a positive effect on health-related quality of life (MD = 17 [95% CI 5.74 to 28.26]. O'Connell et al. (2021) performed a meta-analysis of the five medium-term follow-up studies and found a positive effect of SCS on health-related quality of life (SMD = 0.73 [95% CI 0.46 to 0.99], $p < 0.001$). The long-term follow-up study (Kemler et al., 2000) found no difference between groups at the 5-year follow-up (MD = −0.09 [95% CI −0.74 to 0.56]).[46]

Petersen et al. (2021) observed a statistically significant 16-point [95% CI 11.3 points to 20.5 points] mean increase in health-related quality of life scores for the10-kHz SCS + CMM group ($p < 0.001$) but no statistically significant change in the CMM group. The mean health-related quality-of-life score for the CMM group decreased from 0.630 [95% CI 0.600 to 0.660] at baseline to 0.599 [95% CI 0.566 to 0.632] at the 6-month follow-up. By contrast, the mean health-related quality-of-life score for the 10-kHz SCS + CMM group increased from 0.636 [95% CI 0.604 to 0.668] at baseline to 0.765 [95% CI 0.737 to 0.793] at the 6-month follow-up ($p < 0.001$).

Impact on utilization of prescription opioids for pain management

O'Connell et al. (2021) conducted a pooled analysis of two studies that assessed the effects of SCS combined with another intervention versus that intervention alone on pain medication use. At the 6-month follow-up, there was some indication that use of different analgesics reduced in the SCS group; however, evidence was evaluated as either very low-certainty or low-certainty due to potential bias from study design limitations, imprecision, and inconsistency. The PROCESS study found that 15.4% of the SCS group and 2.1% of the control group stopped using opioids at the 6-month follow-up but found no clear evidence of between-group differences in morphine consumption at the low range (MD = −28.60 mg [95% CI −102.65 mg to 45.45 mg]) or high range (−48.20 mg [95% CI −140.57 mg to 44.17 mg]) (Kumar et al., 2005).

[46] It should be noted that although some of these studies did not use either the EQ-5D or BPI-sf to assess quality of life (e.g., one study used the McGill Pain Questionnaire and another used the SF-36 Physical Component Score), they were included in this report because the data was pooled together with data from studies that did use the EQ-5D instrument. For more information about the instruments used to assess quality of life, please refer to footnote 30 on page 18.

Pollard et al. (2019) conducted a systematic review and meta-analysis of five RCTs that compared conventional SCS to medical therapy and high-frequency SCS for chronic back and/or limb pain. Four studies compared conventional SCS to medical therapy. In one pooled analysis of three studies, the SCS group had higher odds of decreasing use of opioids compared to the medical therapy group (OR = 8.60 [95% CI 1.93 to 38.30]). In another pooled analysis of two studies, the SCS group had greater reductions in mean medication dose than the medical therapy group (pooled weighted mean difference [WMD] = −1.97 [95% CI −3.67 to −0.27]). One study (Kapural et al., 2015) compared the effects of conventional SCS versus high-frequency SCS on reducing opioid use after 12 months and found no statistical difference between the two groups despite a greater proportion of the high-frequency SCS group reducing opioid use compared to the conventional SCS group (34% versus 26%; OR = 1.43 [95% CI 0.74 to 2.78]).

Turner et al. (2010) found that compared to the SCS group (12%), the pain clinic group (34%, p = 0.04) and usual care group (27%, p = 0.17) consumed more opioids at 6 months. No between-group differences were detected at 12 and 24 months.

Vu et al. (2022) conducted a retrospective cohort study to assess the effects of SCS versus no SCS on opioid use for postlaminectomy syndrome (PLS). Although the SCS group had a higher average of opioid use 1 year before implantation compared to the non-SCS group 1 year before PLS index date (4.3 [SD = 8.5] versus 4.1 [SD = 9.3], p < 0.001), the SCS group had a lower average of opioid use 3 to 15 months after implantation than the non-SCS group 3 to 15 months post-index date (3.8 [SD = 8.2] versus 4.0 [SD = 9.4], p = 0.006).

Harms

O'Connell et al. (2021) reported the following potential complications for SCS: electrode wire malfunction and migration, infection, and additional surgery to repair implanted SCS units. Serious complications of SCS treatment can include nerve damage, chronic muscle fatigue, lung injury, serious infection, extended hospital stays, SCS devices breaking through the skin barrier, and death.

Pollard et al. (2019) observed that serious neurological-related complications were rare. There was one death related to hematoma. Adverse events associated with SCS included pain and discomfort experienced at the implant site and lead migration.

Petersen et al. (2021) did not identify any adverse events related to the study for the CMM group. The 10-kHz SCS + CMM group reported 18 adverse events among 14 different patients. Explantations due to infection occurred in 2% of the 10-kHz SCS + CMM group.

Turner et al. (2010) found that 16% of the SCS group had an adverse event, including increased back or leg pain, fluid leakage at the implant site, and severe headache. One participant experienced a life-threatening infection of the epidural space around the spinal cord that required surgery. Among the 27 patients who received a permanent SCS implantation, 15% experienced an infection, 19% had chronic pain where the stimulator was implanted, and 11% had another biological complication in the 18 months after permanent implant. There were seven reoperations within the 18 months – one reoperation to shift the pulse generator due to pain, four reoperations because of lead migration, and two reoperations to both shift the pulse generator and because of lead migration. In addition, five participants opted to have the permanent SCS device explanted – four explantations due to inadequate pain relief and one explantation because of infection.

Summary of findings regarding spinal cord stimulation: There is a preponderance of evidence from two systematic reviews, one RCT, and one prospective cohort study that SCS is more effective than sham SCS for reducing pain intensity, and that combining SCS with other interventions is associated with greater reduction in pain intensity than other interventions alone. There is a preponderance of evidence from one systematic review and one RCT that SCS is associated with a greater improvement with quality of life. There is inconclusive evidence from two systematic reviews, one prospective cohort study, and one retrospective cohort study that SCS is associated with greater reductions in opioid medication use. SCS is associated with severe harms including death, nerve damage, sustained muscle weakness, lung injury, and serious infection. SCS is also associated with a high rate of explantation.

Figure 14. Impact of SCS on Pain Relief

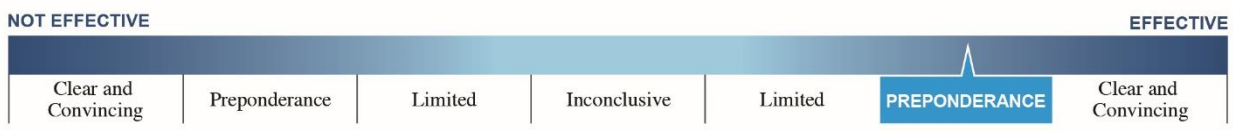


Figure 15. Impact of SCS on Quality of Life

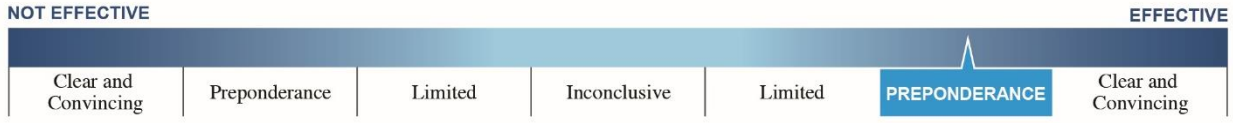


Figure 16. Impact of SCS on Utilization of Prescription Opioids for Pain Management

Peripheral nerve stimulation (PNS)

Impact on health-related outcomes

Deer et al. (2016) conducted a randomized, double-blinded, partial-crossover study to assess the effectiveness of PNS treatment combined with pain medications compared to pain medication alone (control) in treating neuropathic pain. Between baseline and 3 months of treatment, the PNS group experienced a 27.2% reduction in average pain and the control group experienced a 2.3% reduction ($p < 0.0001$). Approximately 38% of the PNS group and 10% of the control group achieved at least a 30% reduction in average pain and no increase in pain medication dosage ($p = 0.0048$).

Eldabe et al. (2019) used the PNS technique subcutaneous nerve stimulation (SQS) to compare SQS and optimized medical management (OMM) versus to OMM alone for back pain due to failed back surgery syndrome in an open-label RCT. Between baseline and the 6-month follow-up, the SQS + OMM group experienced an average 45.6% [SD = 32.1] reduction in back pain intensity while the OMM group experienced an average 0.3% [SD = 21.1] reduction ($p < 0.0001$). Between baseline and the 9-month follow-up, the SQS + OMM group experienced an average 47.0% [SD = 32.3] reduction in back pain intensity, whereas the OMM group experienced an average 2.5% [SD = 22.9] reduction ($p < 0.0001$). In addition, at the 6-month follow-up, 26.8% of the SQS + OMM group experienced ≥50% reduction in back pain intensity compared to 1.7% of the OMM group ($p = 0.0002$). At the 9-month follow-up, 33.9% of the

SQS + OMM group experienced ≥50% reduction in back pain intensity compared to 1.7% of the OMM group ($p < 0.0001$).

Gilmore et al. (2019) examined the effect of PNS on chronic neuropathic postamputation pain in a randomized, double-blinded, partial-crossover study. Compared to the sham PNS group, a larger proportion of the PNS therapy group reported a ≥50% reduction in average postamputation pain during the first 4 weeks of treatment (14% versus 58% respectively, $p = 0.037$). After 4 weeks of treatment, the sham PNS group crossed over, and both groups received active PNS for 4 additional weeks. After 8 weeks of treatment, 67% of the PNS therapy group experienced a ≥50% reduction in average postamputation pain, compared to the 14% of the sham PNS group at the end of week 4 ($p = 0.014$). There was no observed change in the sham PNS crossover group; that is, the proportion of participants experiencing a ≥50% reduction in average postamputation pain after crossing over and receiving PNS therapy for 4 weeks remained 14%. The PNS therapy group experienced statistically significant ≥50% reductions in average postamputation pain each month between 3 and 6 months post-treatment.

Wilson et al. (2014) assessed the efficacy of PNS versus usual care for chronic shoulder pain after stroke in an assessor-blinded pilot RCT. The mean pain rating for the PNS group decreased from 7.5 [SD = 0.7] at baseline to 3.2 [SD = 0.7] at 10 weeks and 3.0 [SD = 0.7] at 16 weeks. The mean pain rating for the usual care group decreased from 7.6 [SD = 0.7] at baseline to 6.1 [SD = 0.8] at 10 weeks and 6.1 [SD = 0.8] at 16 weeks. The between-group difference at 10 weeks (2.9, 95% CI 0.8 to 5.0) and 16 weeks (3.1, 95% CI 1.0 to 5.2) were both statistically significant.

Impact on quality of life

Eldabe et al. (2019) observed a statistically significant difference in mean increase in quality of life for the SQS + OMM group (0.19 [SD = 0.25]) compared to the OMM group (−0.01 [SD = 0.15]) between baseline and the 9-month follow-up ($p = 0.0003$).

In the Gilmore et al. (2019) study, 80% of the PNS therapy group experienced ≥50% reductions in pain interference after 8 weeks of stimulation therapy compared with 15% of the placebo group after the initial 4 weeks of no stimulation ($p = 0.003$).

The Wilson et al. (2014) study found no statistically significant difference in mean pain interference ratings between the PNS group and the usual care group.

Impact on utilization of prescription opioids for pain management

The Deer et al. (2016) study observed no statistically significant differences in medication dose between the PNS group and control group ($p = 0.608$). Following treatment, medication use remained unchanged for 97.8% of the PNS group and 95.9% of the control group.

The Gilmore et al. (2019) study found no statistically significant difference in the average daily morphine equivalent dose (MED) for the PNS therapy group and the sham PNS group at 4 weeks and 18 weeks follow-up.

Harms

Deer et al. (2016) did not identify any serious adverse events associated with the PNS devices in either the PNS group or the control group throughout the trial and full 1-year follow-up. All adverse events were minor – details of those minor adverse events were not detailed in the publication.

There were 103 events reported in the SQS + OMM group of the Eldabe et al. (2019) study and 90 in the OMM group for a total of 193 events – 178 were categorized as adverse events and the remaining 15 were attributed to device deficiencies. Among the 80 implantations throughout the study (SQS + OMM

and OMM groups), there were four infections from the device or implantation, three lead fractures, and two lead dislocations or migrations.

In the Gilmore et al. (2019) study, there were 22 reported study-related events (none were considered serious). Skin irritation or redness was reported at the implantation site (seven cases), electrode adhesion site (four cases), and bandage site (four cases). In addition, there were five cases of reported pain due to the device implantation or during stimulation, one case of pruritus at the electrode adhesion site, one case of pruritus under the supporting belt, and one case of fatigue. Of these 22 reported study-related events, 96% were categorized as mild, 4% as moderate, none as severe.

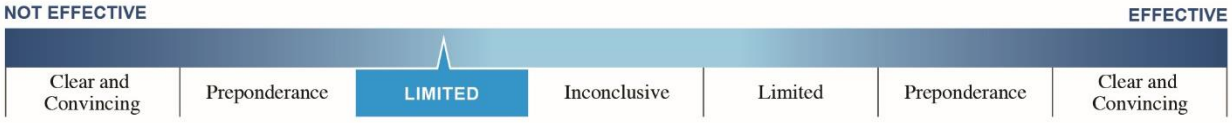
In the Wilson et al. (2014) study, 13 participants received an implantation. There was one case of re-implantation due to dislodgement, three cases where an electrode fragment was retained, six cases of pruritus at the electrode or bandage site, and two cases of reported pain after implantation.

Summary of findings regarding peripheral nerve stimulation: There is limited evidence from four RCTs that PNS is associated with greater reduction in pain relative to treatments to which it was compared. There is limited evidence from three RCTs that PNS is associated with greater reduction in interference of pain with activity and with greater improvement in quality of life. There is limited evidence from two RCTs that PNS does not reduce use of prescription pain medications. There is limited evidence that PNS is not associated with major harms.

Figure 17. Impact of PNS on Pain Relief

Figure 18. Impact of PNS on Quality of Life

Figure 19. Impact of PNS on Utilization of Prescription Opioids for Pain Management



Radiofrequency ablation (RFA)

Impact on health-related outcomes

Ajrawat et al. (2020) synthesized 13 RCTs, 2 nonrandomized comparative studies, and 18 noncomparative cohort studies in a systematic review of 33 studies that used radiofrequency (RF) to treat osteoarthritis-related knee pain. Only 10 of the 33 studies explicitly stated the criteria for determining pain intensity reduction. Six comparative studies reported that 65.5% of the RF group and 19.3% of the control group experienced >50% pain relief. The comparison treatments included RF with no neurotomy (Choi et al., 2011); intra-articular (IA) corticosteroid (Davis et al., 2018; Yuan et al., 2016); unipolar pulsed RF (Gulec et al., 2017); no nerve block with cooled RF (McCormick et al., 2018); and nerve block (Ikeuchi et al., 2011).

Amr et al. (2018) compared bilateral splanchnic nerve block at T10 and T11 using RFA (RFA group) versus bilateral splanchnic nerve block at T11 using alcohol (alcohol group) in a RCT. Participants and the clinician who performed the follow-up assessments were blinded to the treatment assignments; it is unclear whether the clinicians who performed the procedures were blinded. Compared to baseline, both the RFA group and the alcohol group reported decreased pain intensity at 30 minutes post-intervention ($p < 0.001$ for both groups), which remained unchanged at the 3-month follow-up for the RFA group. The decrease in pain intensity was not sustained for the alcohol group at the 3-month follow-up.

Bang et al. (2019) conducted an RCT to assess the impact of endoscopic ultrasound-guided celiac plexus neurolysis (EUS-CPN) versus EUS-guided radiofrequency ablation (EUS-RFA) for abdominal pain related to pancreatic cancer. Participants and the investigators who performed the follow-up assessments were blinded to the treatment assignments; the clinicians who performed the procedures were not blinded. At the 4-week follow-up, the RFA group had significantly lower self-reported pain intensity scores than the CPN group (30.1 versus 57.3, $p = 0.002$).

Khalil et al. (2019) examined RFA of the basivertebral nerve versus standard care for the treatment of chronic low back pain in an open-label RCT. In analyses that adjusted for self-reported pain intensity scores at baseline, the mean changes in self-reported pain intensity at 3 months were −3.46 in the RFA group and −1.02 in the standard care group ($p < 0.001$).

Orgera et al. (2014) ran a single-blinded RCT investigating RFA combined with vertebroplasty versus vertebroplasty alone for treating patients with multiple myeloma. Although self-reported intensity decreased for both groups, there was no statistically significant difference in scores between the two groups at 24 hours ($p = 0.33$) or 6 weeks ($p = 0.29$).

Patel et al. (2012) investigated cooled RF versus sham RF for chronic sacroiliac joint pain in a double-blinded, partial crossover RCT. There was no statistical difference between the cooled RF and sham RF groups at the 1-month follow-up ($p = 0.160$). Mean self-reported pain intensity at the 3-month follow-up compared to baseline was significantly greater ($p < 0.035$) for the for the cooled RF group (−2.4 [SD = 2.7]) than the sham RF group (−0.8 [SD = 2.4]).

Patel performed a follow-up study in 2016. Participants in the sham RF group were offered the opportunity to crossover after 3 months. In the original cooled RF group, the mean self-reported pain intensity score significantly decreased from 5.9 [SD = 1.2] at baseline to 3.2 [SD = 2.6] at the 12-month follow-up ($p < 0.0001$). In the crossover cooled RF group, the mean self-reported pain intensity score significantly decreased from 5.8 [SD = 1.3] at baseline to 3.3 [SD = 2.1] 6 months following crossover ($p = 0.0003$).

Walega et al. (2019) explored the effects of RFA versus sham RFA administered 2 to 6 weeks prior to total knee arthroplasty in a randomized, double-blinded, sham-controlled clinical trial. Both the RFA group and the sham RFA group experienced no treatment effect on postoperative pain at any of the follow-up points (48 hours and 1, 3, and 6 months after total knee arthroplasty).

Impact on quality of life

Amr et al. (2018) observed statistically significant ($p < 0.001$) improvements in quality-of-life scores from baseline for the RFA group between 1 and 12 weeks postintervention and between 2 and 8 weeks postintervention for the alcohol group. The alcohol group had significantly higher quality-of-life scores every week between 1 and 12 weeks postintervention, except at the 2-week follow-up.

In analyses that adjusted for quality-of-life scores at baseline, Khalil et al. (2019) observed a statistically significant difference (0.1668 [95% CI 0.1193 to 0.2144], $p <0.001$) in the mean changes in quality-of-life scores for the RFA group 0.1803 [95% CI 0.1469 to 0.2137] and the standard care group 0.0135 [95% CI −0.0203 to 0.0472] at 3 months.

Impact on utilization of prescription opioids for pain management

Amr et al. (2018) observed a significant decrease in morphine sulfate tablet (MST) use for both the RFA group and the alcohol group ($p < 0.001$) between baseline and 24 hours after intervention. Compared to baseline, the average MST use decreased significantly from 1-day postintervention to 12-weeks postintervention for the RF group and from 1-day postintervention to 2-weeks postintervention for the alcohol group, with no statistically significantly decreases after the second week.

Bang et al. (2019) found that opioid analgesic consumption was higher in the RFA group (112.7 mg) compared to the CPN group (105.4 mg) 4 weeks after intervention, but the difference between the two groups was not significant ($p = 0.583$).

Khalil et al. (2019) observed that 35.3% of the RFA group and 28.3% of the standard care group used opioid pain medications at baseline ($p = 0.529$). There was no significant difference in opioid reduction for either group at 3 months.

Orgera et al. (2014) found that medication consumption decreased significantly following the procedure and at 6 weeks for both the RFA + vertebroplasty group and vertebroplasty only group, but there was no statistically significant difference between the two groups.

There were no differences in opioid use between the RFA group and sham RFA group in the Walega et al. (2019) study at any of the follow-up points (48 hours and 1, 3, and 6 months after surgery).

Harms

Among the 33 studies in the Ajrawat et al. (2020) systematic review, 29 studies evaluated adverse events. Of those 29 studies, 20 (69%) indicated no adverse events associated with RF treatments. The remaining 9 studies (31%) reported minor localized adverse events.

Amr et al. (2018) reported no major complications for either the RFA group or the alcohol group. Both groups experienced diarrhea, hypotension, as well as pain from the injection and in the back, but differences were not statistically significant between the groups ($p = 0.28$).

Bang et al. (2019) observed no adverse events during the procedure. At 48 hours after the procedure, one participant experienced diarrhea, one had a fever, one felt nauseous and/or vomited, and two experienced an increase in abdominal pain in the CPN group. Four participants felt nauseous and/or vomited, and one experienced an increase in abdominal pain in the RFA group. No significant difference in the occurrence of procedure-related side effects were detected between the two groups (35.7% for CPN versus 41.7% for RFA, $p = 0.999$).

Khalil et al. (2019) identified 22 reports of adverse events, 15 of which were among 13 RFA participants. None of these adverse events were device-related – 10 were related to the procedure (e.g., pain from the incision, urinary retention, and lateral femoral cutaneous neuropraxia). One participant experienced back pain in a new location, and seven participants experienced leg pain or paresthesia. There were no reports of broken devices, fractures, or infections.

Orgera et al. (2014) found no major complications, although two patients died from causes unrelated to the study. Two patients from the RFA + vertebroplasty group and seven patients in the vertebroplasty only group experienced extraosseous cement leakage after vertebroplasty. Three participants experienced opioid toxicity after the procedure but recovered.

Patel et al. (2012) found no serious complications. Some participants experienced soreness or numbness at the RFA introducer site in the 2 weeks after treatment.

No adverse events related to the trial were reported in the Walega et al. (2019) study on RFA administration prior to total knee arthroplasty.

Summary of findings regarding radiofrequency ablation: There is a preponderance of evidence from one systematic review, six RCTs, and one follow-up study that receipt of RFA is associated with greater reduction in pain relative to the treatments to which it has been compared. There is limited evidence from two RCTs that receipt of RFA is associated with greater improvement in quality of life. There is limited evidence from five RCTs that receipt of RFA does not affect use of opioid pain medication. A preponderance of evidence suggests that RFA is not associated with major adverse events.

Figure 20. Impact of RFA on Pain Relief

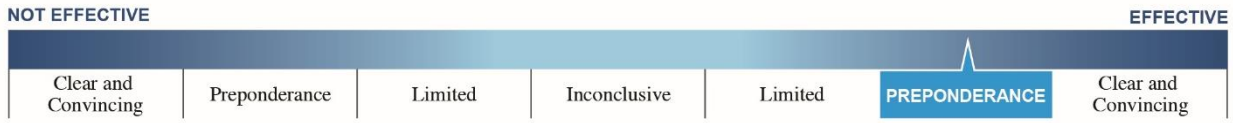
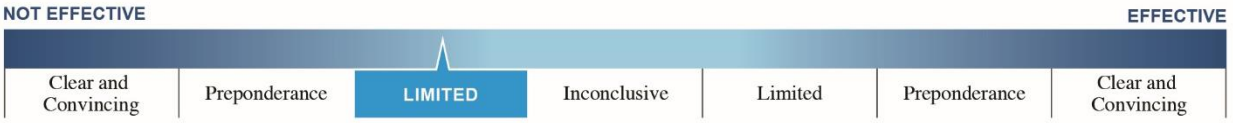


Figure 21. Impact of RFA on Quality of Life

Figure 22. Impact of RFA on Utilization of Prescription Opioids for Pain Management



Behavioral Health Approaches

RelieVRx (formerly EaseVRx)

Impact on health-related outcomes

Garcia et al. (2021a) conducted an 8-week randomized control trial to assess the efficacy of EaseVRx, an interactive, immersive multimodal, skills-based, pain self-management VR program delivered through a VR headset. The study compared EaseVRx to sham VR, where participants were given a VR headset that displayed footage of nature with neutral music. The average pain intensity by the end of the 8-week study period was lower for the EaseVRx group than the sham VR group (2.9 versus 4.0, respectively, $p < 0.001$). Although pain intensity reduced over time for both groups, the EaseVRx group experienced a greater reduction in pain intensity than the sham VR group over the 8-week study period (42.8% versus 25.1%, respectively). Approximately 65% of the EaseVRx group and 40% of the Sham VR group experienced at least a 30% decrease in pain intensity and 46% of the EaseVRx group and 26% of the sham VR group experienced at least a 50% decrease. Study participants and the statisticians performing the data analyses were blinded to the treatment assignments.

Garcia et al. (2021b) followed up with participants at 3 months post-treatment to continue examining the efficacy of EaseVRx versus sham VR for chronic lower back pain. Treatment assignments were revealed to the statisticians but not participants. After 3 months, the EaseVRx group still had lower pain intensity

than the sham VR group (3.7 versus 4.5, respectively, p = 0.0017). The EaseVRx group experienced a 30.3% reduction in pain intensity and the sham VR group experienced a 15.8% reduction. Approximately 46.8% of the EaseVRx group and 31.2% of the sham VR group experienced at least a 30% decrease in pain intensity and 36.4% of the EaseVRx group and 16.9% of the sham VR group experienced at least a 50% decrease. This suggests that the effect observed after the 8-week treatment was sustained through the 3-month post-treatment period.

Impact on quality of life

At the end of the 8-week Garcia et al. (2021a) study, the EaseVRx group reported lower pain interference with activity than the sham VR group (2.7 versus 3.8, respectively, p = 0.004). Both groups experienced a reduction in pain interference, but the EaseVRx group experienced a greater reduction in pain interference with activity compared to the sham VR group (51.6% versus 32.4%, respectively). Approximately 71% of the EaseVRx group and 57% of the sham VR group experienced at least a 30% decrease in pain interference with activity and 56% of the EaseVRx group experienced at least a 50% decrease. The percentage of sham VR participants experiencing at least a 50% decrease was not reported.

At 3 months post-treatment, Garcia et al. (2021b) found that the EaseVRx group continued to experience lower pain interference with activity compared to the sham VR group (3.7 versus 4.7, respectively, p = 0.0004). The EaseVRx group experienced a 36.6% reduction in pain interference with activity, and the sham VR group experienced a 15.7% reduction. Approximately 54.5% of the EaseVRx group and 36.4% of the sham VR group experienced at least a 30% decrease in pain interference with activity and 40.3% of the EaseVRx group and 20.8% of the sham VR group experienced at least a 50% decrease. These findings suggest that the effect observed after the 8-week treatment was sustained through the 3-month post-treatment period.

Impact on utilization of prescription opioids for pain management

In the 8-week Garcia et al. (2021a) study, neither the EaseVRx group nor the sham VR group had a significant change in morphine milligram equivalent (MME) dosage between baseline and the end of the 8-week follow-up. The EaseVRx group reported a significant reduction in self-reported over-the-counter (OTC) analgesic medication use; 61 participants used OTC analgesics at baseline compared to 50 participants at 8 weeks post-treatment (p = 0.01). The sham VR group did not have a significant change; 55 participants used OTC analgesics at baseline compared to 56 participants at 8 weeks post-treatment.

Garcia et al. (2021b) detected no significant changes between the two groups' self-reported prescription opioid and OTC analgesics use at the 3-month follow-up.

Harms

The only adverse event reported during the 8-week Garcia et al. (2021a) study was cybersickness, a form of motion sickness or nausea associated with VR use.

Summary of findings regarding EaseVRx: There is insufficient evidence from one RCT and one follow-up study that EaseVRx is associated with greater reduction in pain and interference of pain with activity compared to sham VR among people with chronic low back pain. There is also insufficient evidence that EaseVRx does not affect use of prescription opioids and OTC analgesics 3 months after completion of treatment. Evidence from one RCT suggests that EaseVRx is not associated with severe harms.

Figure 23. Impact of EaseVRx on Pain Relief

Figure 24. Impact of EaseVRx on Pain Interference With Activity

Figure 25. Impact of EaseVRx on Utilization of Prescription Opioids for Pain Management

Summary of Findings

CHBRP cannot draw a single overall conclusion regarding the effectiveness of all NPMTs. Each of the three types of NPMTs discussed in the *Medical Effectiveness* review use different mechanisms of action to address pain and the amount and strength of evidence regarding effectiveness varies widely across NPMTs. In addition, low back pain is the only type of pain for which studies of all three types of NPMTs have been conducted. For these reasons, CHBRP draws separate conclusions regarding each type of NPMT.

- For nonpharmacological restorative treatments, evidence regarding the effects of TENS on pain intensity, quality of life, and use of opioid pain medication is largely inconclusive and there is insufficient evidence to assess the effects of PENS.

- For interventional pain management, there is a preponderance of evidence that SCS is more effective at relieving pain and improving quality of life than the treatments to which they have been compared, and limited evidence that IPD and PNS are more effective than comparators. There is a preponderance of evidence that RFA is associated with greater reduction in pain and limited evidence that RFA improves quality of life. Evidence regarding the effects of SCS on use of opioid pain medication is inconclusive. Evidence regarding the impact of IPD on opioid pain medication use is insufficient. There is limited evidence that PNS and RFA do not affect consumption of opioid pain medication.

- There is insufficient evidence regarding the effects of RelieVRx, the only FDA-approved behavioral health approach for treating pain, on pain intensity, quality of life, and use of opioid pain medication.

- The evidence identified by CHBRP suggests that nonpharmacological restorative therapies for alleviating pain are not associated with severe harms. There is insufficient evidence to assess whether use of RelieVRx is associated with severe harms. For interventional pain management NPMTs, CHBRP found that SCS is associated with severe harms including death, nerve damage, sustained muscle weakness, lung injury, and serious infection, and with a high rate of

explantation. There is limited evidence that IPD is associated with severe harms including interspinous spacer fracture, coronary ischemia, respiratory distress, hematoma, and death due to pulmonary edema. There is a preponderance of evidence that IPD is associated with a higher risk of reoperation relative to other surgical interventions.

A summary of CHBRP's conclusions for each type of NPMT and for each of the three types of outcomes assessed can be found in Table 3.

Table 3. Summary of Evidence of Medical Effectiveness of NPMTs

Type of NPMT	Pain Intensity	Quality of Life/Pain Interference With Activity	Use of Opioid Pain Medication
Nonpharmacological restorative therapies			
Transcutaneous electrical nerve stimulation (TENS)	Inconclusive evidence of effects on chronic pain. Inconclusive evidence of effects on acute pain.	Inconclusive evidence of effects among people with chronic pain. Insufficient evidence of effects among people with acute pain.	Limited evidence of no impact among people with chronic pain. Inconclusive evidence of impact among people with acute pain.
Percutaneous electrical nerve stimulation (PENS)	Insufficient evidence	Insufficient evidence	Insufficient evidence
Interventional pain management			
Interspinous process devices (IPD)	Limited evidence that IPD is more effective than non-surgical interventions for lumbar spinal stenosis. Preponderance of evidence that IPD is not more effective than other surgical procedures for lumbar spinal stenosis.	Limited evidence that IPD is not associated with improvement in quality of life.	Insufficient evidence
Spinal cord stimulation (SCS)	Preponderance of evidence that SCS is associated with greater pain relief than sham SCS and that combining SCS with other interventions is more effective than other interventions alone.	Preponderance of evidence that SCS is associated with a greater improvement with quality of life.	Inconclusive evidence that SCS is associated with greater reductions in opioid medication use.
Peripheral nerve stimulation (PNS)	Limited evidence that PNS is associated with greater reduction in pain than comparators.	Limited evidence that PNS is associated with greater improvement in quality of life than comparators.	Limited evidence of no impact.
Radiofrequency ablation (RFA)	Preponderance of evidence that receipt of RFA is associated with greater reduction in pain relative to the treatments to which it has been compared.	Limited evidence suggests that RFA is associated with better quality of life relative to the treatments to which it has been compared.	Limited evidence that RFA does not affect use of opioid pain medication.
Behavioral health approaches			
RelieVRx	Insufficient evidence	Insufficient evidence	Insufficient evidence

Source: California Health Benefits Review Program, 2022.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2585 would authorize, not mandate, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatment (NPMT). The bill defines NPMT as pain management treatment without the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain.

If enacted, AB 2585 would apply to the health insurance of approximately 14.8 million enrollees. This represents about 65% of the 22.8 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by DMHC or CDI. If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies. Medi-Cal beneficiaries enrolled in DMHC-regulated plans would not be subject to AB 2585's requirements.[47]

Analytic Approach and Key Assumptions

- AB 2585 does not mandate coverage of NPMTs, thus CHBRP estimates no fiscal impact due to the enactment of this bill. As mentioned in the *Policy Context* section, due to the permissive language of AB 2585, CHBRP assumes health plans and policies would not elect to provide additional coverage as authorized under AB 2585

- CHBRP presents here a qualitative discussion of issues surrounding benefit coverage and costs of NPMTs without making any estimates or assumptions regarding utilization and its change in the first year post-enactment because CHBRP expects no coverage or utilization change due to the bill (thus, no fiscal impact).

Benefit Coverage of NPMTs

CHBRP queried health plans and policies in California to determine baseline benefit coverage of NPMTs. Responses to this survey represent 65% of enrollees with private market health insurance that is subject to state mandates. All queried plans and policies stated that enrollees with health insurance subject to AB 2585 have coverage for *instrument-based NPMTs* if determined medically necessary[48] by the health plan/policy. How these devices are covered depends on the nature of the device in question. For example, surgically implanted instruments, such as spinal cord stimulators, may be covered under the base Prosthetic and Orthotic benefit for all enrollees when determined medically necessary by the plan/policy. NPMTs that meet the definition of durable medical equipment[49] (DME) appropriate for use in the home, such as TENS units, are covered under the supplemental DME benefit for eligible enrollees, when determined medically necessary by the plan/policy.

CHBRP's queried plans and policies reported either not being aware of *behavioral-based NPMTs* or not providing coverage. CHBRP identified virtual reality as the only behavioral-based NPMT for which the FDA recently granted approval (in November of 2021). Current Procedural Terminology (CPT) codes are not yet established for this device. Lack or dearth of coverage and reimbursement for virtual reality is a recognized barrier to wider adoption (Sarkar et al., 2021; Vincent et al., 2021).

[47] Personal communication, W. White, California Department of Health Care Services, March 2020.
[48] Refer to CHBRP's issue brief on medical necessity at: https://files4.1.revize.com/chbrpnew/Medical%20Necessity%20FINAL%20120321.pdf.
[49] California Code of Regulations, Title 22, Section 51321.

Utilization management

Benefit coverage of NPMTs is largely dependent of medical necessity determinations. Medical necessity reviews require providers to submit documentation regarding their patient's diagnosis and the procedure to be performed or device to be used, and tend to require more detail on the severity of the diagnosis, other interventions previously tried, risks of not performing the procedure or using the device, and the frequency of the use of the device or procedure. The prospective review of medical necessity is what is often referred to as prior authorization. Prior authorization and other limits are used widely in pain management. These utilization management criteria vary across plans and payer types and are considered a barrier to care for nonpharmacological therapies for pain management, according to a recent study of different types of health plans (Heyward et al., 2018). Health plan coverage policies are not recommendations for treatment and differ from clinical treatment guidelines, though such guidelines often form the basis of a health plan's coverage policy for a certain device or technology. Health plan and policy medical reviewers exercise clinical judgement and have discretion in making individual coverage determinations.

CHBRP estimates 100% of enrollees with health insurance subject to AB 2585 currently have coverage for instrument-based NPMTs if deemed medically necessary by the enrollee's health plan or policy, and none have coverage for behavioral-based NPMTs. CHBRP estimates no fiscal impact due to AB 2585.

Costs of NPMTs

As discussed in the *Background* section, NPMTs range from noninvasive restorative (e.g., TENS, PENS) and behavioral treatments (e.g., virtual reality) to invasive interventional treatments (e.g., IPDs, SCS, PNS, and RFA).

Table 4 includes estimated costs of NPMTs. The cost of each of these treatments requires the consideration of not only the cost of the device itself but the entirety of the service or procedure associated with the medical treatment. Thus, costs might vary considerably by enrollee or situation. Costs may also vary for noninvasive devices depending on the setting, for instance whether a TENS unit is used at home by the patient themselves or at a clinical setting by a provider.

Table 4. Cost estimates for NPMTs

NPMT	Device and/or Procedure	Estimated Cost [(a)]
Restorative devices		
Transcutaneous electric nerve stimulation (TENS)	Device only; can be used at home or might be used by clinician in office	Approx. $30 to $300 for at-home device over the counter (cost may be even higher for more advanced devices); no estimate available for in-office use
Percutaneous electrical nerve stimulation (PENS)	Full cost of service performed by clinician	No estimate available, no CPT code established
Behavioral devices		
Virtual reality (RelieVRx)	Device and program; can be used at home or by clinician	No estimate available, no CPT code established
Interventional devices		
Interspinous process devices (IPD)	Full cost of service, including device implantation	$11,000 to $13,000 (CPT code 22869: Insertion of interlaminar/interspinous process stabilization/distraction device)
Peripheral nerve stimulators (PNS)	Full cost of service, including device implantation	$5,000 to $6,000 (CPT code 64555: percutaneous implantation of neurostimulator electrode array; peripheral nerve)
Radiofrequency (RF) ablation	Full cost of service	$1,000 to $2,000 (CPT code 64635: destruction by neurolytic agent, paravertebral facet joint nerve(s))
Spinal cord stimulation (SCS)	Full cost of service, including device implantation	$17,620 to $21,340 (CPT 63655: laminectomy for implantation of neurostimulator electrodes)

Source: California Health Benefits Review Program, 2022.

(a) Cost estimates are from Medicare.gov's procedure price lookup tool for the major CPT code associated with the procedure, total costs for the CPT code is based on national averages, available at: www.medicare.gov/procedure-price-lookup/. This cost likely does not reflect the total average cost of a procedure when multiple codes are used for reimbursement. If the device/procedure is covered, enrollee out-of-pocket costs typically consist of copay or coinsurance on the amount.

Key: CPT = Current Procedural Terminology.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 2585 would authorize, but not mandate, Department of Managed Health Care (DMHC)-regulated plans and California Department of Insurance (CDI)-regulated insurers to cover nonpharmacological pain management treatment (NPMT). This bill defines NPMT as pain management treatment *without* the use of medication that includes any U.S. Food and Drug Administration (FDA)-approved behavioral or instrument-based therapy intended to manage or treat pain. This section estimates the short-term public health impact[50] of AB 2585 on NPMT and potential reduction in disparities.

Estimated Public Health Outcomes

As presented in *Medical Effectiveness*, there is broad variation in the amount and strength of the evidence related to NPMTs on health outcomes, quality of life outcomes, use of prescription pain medications, and harms.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, it is not anticipated that AB 2585 would result in a change in benefit coverage or utilization of NPMTs. For this reason, CHBRP concludes that AB 2585 would have no impact on public health outcomes. For this reason, CHBRP also concludes that AB 2585 would have no impact on disparities in health outcomes overall or by race/ethnicity, sex/gender, age, socioeconomic status (SES), geographic location, and access to care/management of pain. It also would have no impact on premature death and societal economic losses.

Despite evidence that suggests that some forms of NPMT are medically effective for specific outcomes, CHBRP estimates AB 2585 would produce no public health impact due to no projected change in coverage or utilization.

Impact on Disparities[51]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in pain exist by race/ethnicity, sex/gender, age, SES, geographic location, and access to care/management of pain. CHBRP estimates AB 2585 would not change the identified disparities by race/ethnicity, sex/gender, age, SES, geographic location, and access to care/management of pain disparities because CHBRP does not expect that AB 2585 would change coverage or utilization.

Disparities in the prevalence and treatment of pain exist, however, CHBRP did not find evidence to suggest that AB 2585 would impact utilization of NPMTs differentially by race/ethnicity, sex/gender, age, socioeconomic status, or geographic location. Therefore, CHBRP estimates AB 2585 would produce no impact on these disparities related to pain treatment and clinical outcomes.

[50] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.
[51] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

LONG-TERM IMPACTS

Given CHBRP estimates no cost impacts due to AB 2585, CHBRP does not anticipate any long-term impact of AB 2585, which CHBRP defines as impacts occurring beyond the first 12 months after implementation.

As described in the *Background* section, there is growing interest in encouraging the use of NPMTs in multimodal chronic pain treatment with the intention of reducing reliance on opioids for the treatment of chronic pain (DHHS, 2019). As determined in the *Medical Effectiveness* section, clinical studies on NPMTs and use of pain medication require additional research. However, there is a growing interest in this topic with studies underway, given the recognized need to address the high proportion of individuals who use opioids for chronic pain (DHHS, 2019). Please note that the absence of evidence is not "evidence of no effect" and it is possible that an impact on NPMTs on opioid use – desirable or undesirable – could result, but current evidence is insufficient to inform an estimate. The results of future clinical studies and development of newer technologies may impact the role of NPMT in the treatment of pain and as alternatives to opioids in the long term.

APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2022, the California Assembly Committee on Health requested that CHBRP analyze AB 2528.

ASSEMBLY BILL **NO. 2585**

Introduced by Assembly Member McCarty

February 18, 2022

An act to add Section 1367.218 to the Health and Safety Code, and to add Section 10126.7 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 2585, as introduced, McCarty. Health care coverage: nonpharmacological pain management treatment.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. These provisions require specified services and drugs to be covered by various health care services plans and health insurers.

This bill would permit an individual or group health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2023, that covers hospital, medical, or surgical expenses to provide coverage for nonpharmacological pain management treatment, as defined. Because a willful violation of these provisions by a health care service plan is a crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.218 is added to the Health and Safety Code, to read:

1367.218. (a) An individual or group health care service plan contract issued, amended, or renewed on or after January 1, 2023, that covers hospital, medical, or surgical expenses, may provide coverage for nonpharmacological pain management treatment.

(b) For the purposes of this section, "nonpharmacological pain management treatment" is pain management treatment without the use of medication that includes any behavioral or instrument-based therapy approved by the federal Food and Drug Administration intended for the use of managing or treating pain.

SEC. 2. Section 10126.7 is added to the Insurance Code, to read:

10126.7. (a) An individual or group disability insurance policy issued, amended, or renewed on after January 1, 2023, that provides coverage for hospital, medical, or surgical benefits may provide coverage for nonpharmacological pain management treatment.

(b) For the purposes of this section, "nonpharmacological pain management treatment" is pain management treatment without the use of medication that includes any behavioral or instrument-based therapy approved by the federal Food and Drug Administration intended for the use of managing or treating pain.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of FDA-approved NPMTs were identified through searches of PubMed, the Cochrane Library, Web of Science, Embase, and Scopus. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), PubMed Health, and the Scottish Intercollegiate Guideline Network.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Medical Effectiveness Review

The medical effectiveness literature review returned abstracts for 798 articles, of which 50 were reviewed for inclusion in this report. Our content expert identified an additional 11 studies which were also reviewed for potential inclusion. A total of 39 studies were included in the medical effectiveness review for AB 2585.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's Medical Effectiveness Analysis Research Approach. To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence; and*
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical

effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms

Searches employed the following formula: Condition * Treatment * ME Outcome

Condition:

Acute pain

Chronic pain

Treatment:

FDA-approved behavioral or instrument-based pain management therapy

FDA-approved therapies/treatments for pain management

Virtual reality (VR) immersive treatment for pain management

Implantable neurostimulators

Electrical nerve stimulators

Electrical pulse simulators

Peripheral nerve stimulators

Radiofrequency ablation

Devices:

AppliedVR EaseVRx/RelieVRx

Senza Spinal Cord Stimulation System

AlphaStim

Cephaly

Neuralace

Cymedica IntelliHab

Quell by Neurometrix

Sprint PNS

StimRouter by Bioness

ProClaim XR by Abbott

Nerivio Midra by Theranica

Medical Effectiveness Outcomes:

Symptom reduction/changes in self-reported pain

Pain intensity

Physical function

Interference of pain with activity

Interference of pain with mood

User satisfaction

Changes in prescription opioid use

Quality of life

APPENDIX C INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by the sponsors of AB 2585 in March 2022.

Szalavitz M. What the Opioid Crisis Took From People in Pain. New York Times. Guest Essay. March 7, 2022. Available at: www.nytimes.com/2022/03/07/opinion/opioid-crisis-pain-victims.html.

Submitted information is available upon request. For information on the processes for submitting information to CHBRP for review and consideration please visit: www.chbrp.org/requests.html.

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The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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