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.

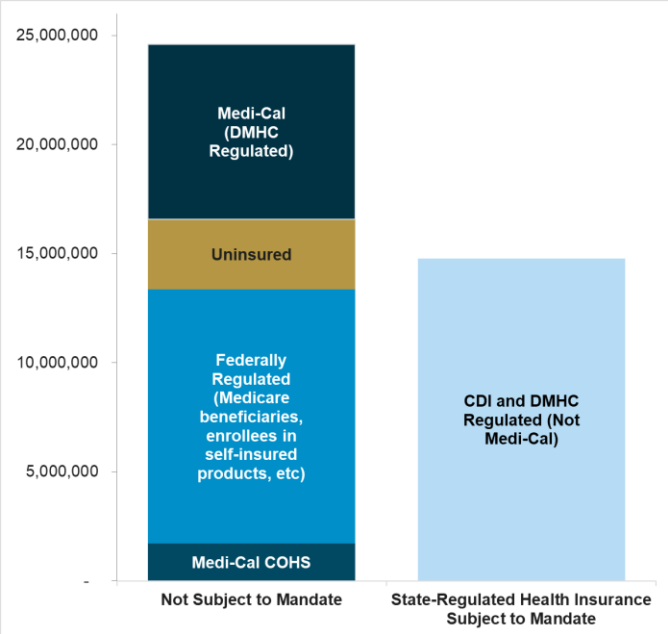
California law requires coverage of certain nonpharmacological therapies for pain management, including acupuncture and physical therapy. Both treatments are considered essential health benefits (EHBs) by the state. Existing law also requires health plans to provide coverage for appropriately prescribed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