

Key Findings:

Analysis of California Senate Bill 746 Anticancer Medical Devices

Summary to the 2019–2020 California State Legislature, April 19, 2019



AT A GLANCE

The version of California Senate Bill (SB) 746 analyzed by CHBRP would require that health plans and policies effective on or after January 1, 2020, that cover chemotherapy or radiation therapy for the treatment of cancer also cover anticancer medical devices that meet definitions set forth in SB 746.

1. CHBRP estimates that, in 2020, all of the 24.5 million Californians enrolled in state-regulated health insurance will have insurance subject to SB 746.
2. **Benefit coverage.** Among enrollees that would be subject to SB 746, 91% have coverage for anticancer medical devices, which are categorized by health plans as durable medical equipment (DME). Because DME is already a covered benefit under California's definition of essential health benefits (EHBs), SB 746 would not require coverage for a new state benefit mandate that appears to exceed the definition of EHBs.
3. **Utilization.** It is estimated that there will be 56 adult enrollees with coverage subject to SB 746 using Optune® in the baseline year, and that utilization may increase by 10% (five users) postmandate.
4. **Expenditures.** The cost of Optune® is \$21,000 per user per month, and the average length of use is 5.2 months. It is estimated that SB 746 would increase total net annual expenditures by \$648,000 or 0.0004%.
5. **Medical effectiveness.** Adults with glioblastoma multiforme (GBM) using Optune® have increased overall survival and progression-free survival.
6. **Public health.** There is no projected measurable public health impact at the population level due to the small estimated increase in utilization.
7. **Long-term impacts.** The potential long-term impacts of SB 746 are unknown; larger impacts may occur in the long-term as more patients use the device and if the FDA approves more devices that are effective at treating cancer.

CONTEXT

CHBRP has identified only one anticancer medical device that meets the definitions in SB 746. This is based on CHBRP's review of the literature as well as consultation with experts at the FDA and academic institutions. This device is known as Optune® and is used in the treatment of a type of brain cancer called glioblastoma multiforme (GBM). This device was approved by the FDA to treat patients with recurrent GBM in 2011 and patients newly diagnosed with GBM in 2015.¹

Cancers of the brain and central nervous system (CNS) make up 1.35% of all cancers. GBM is the third most common of all brain and CNS tumors (14.7%) and accounts for 47.7% of malignant brain tumors. It is estimated that 2,530 new cases of brain and CNS cancer cases will be diagnosed in California in 2019, and of these, approximately 1,200 (47.7%) are GBM. The 5-year survival rate for those diagnosed with GBM is the lowest of any cancer of the brain or CNS at approximately 5.6%.

CHBRP's analysis discusses the impact of mandating coverage for Optune®, which is a battery-operated, wearable, portable device that uses four adhesive patches to deliver low-intensity tumor treating fields (TTFields) to the GBM tumor. These patches are connected to the device and applied to the patient's scalp. Although it is possible that other devices will be covered in the future, or that Optune® will be approved for the treatment of other types of cancer, for this analysis, CHBRP only describes current FDA-approved (as of March 2019) anticancer medical devices.

CHBRP has assumed that SB 746 would be applicable to all health plans regulated by the California Department of Managed Health Care (DMHC) (including Medi-Cal Managed Care Plans) and policies regulated by the California Department of Insurance (CDI) as of January 1, 2020.

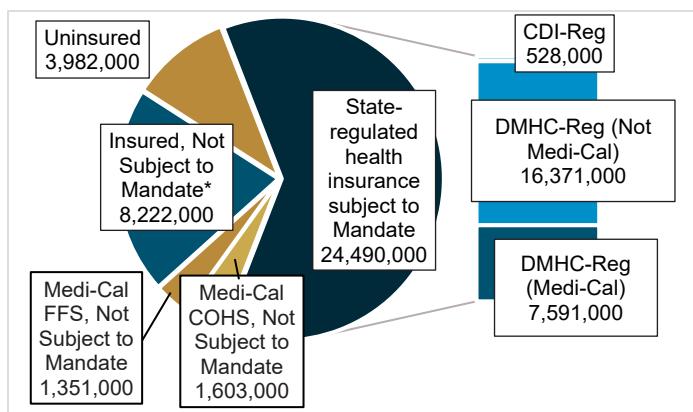
¹ Refer to CHBRP's full report for full citations and references.

BILL SUMMARY

SB 746 would require that health plans and policies effective on or after January 1, 2020, that cover chemotherapy or radiation therapy for the treatment of cancer also cover anticancer medical devices. The bill requires coverage of these medical devices only when the device has been approved by the FDA, is designed for use outside of a treatment facility, and is prescribed for the treatment of cancer based on medical necessity.

Figure A shows how many Californians have health insurance that would be subject to SB 746.

Figure A. Health Insurance in CA and SB 746



Source: California Health Benefits Review Program, 2019.

Notes: *Medicare beneficiaries, enrollees in self-insured products, etc.

IMPACTS

Benefit Coverage, Utilization, and Cost

As noted above, this analysis focused on the use of Optune® to treat GBM because it is the only anticancer device on the market today that meets the specifications of SB 746. According to the bill, “anticancer medical device” means a medical device, including component parts, services, and supplies necessary for the effective use of the device.

Benefit Coverage

Among current enrollees with health insurance that would be subject to SB 746, 91% have coverage for Optune®, as determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to

this survey represent 82% of enrollees with private market health insurance that can be subject to state mandates.

Health plans and policies that cover Optune® do so under the durable medical equipment (DME) benefit, and any cost-sharing requirements for DME, such as deductibles, copayments, and coinsurance, apply to Optune®.

Utilization

It is estimated that there will be 1,200 new cases (3.21 cases per 100,000 people) of GBM in California each year, with about 50% among adults aged 65 and over. SB 746 would not affect coverage for most older adults with GBM because most have coverage through the Medicare program, which is not subject to state benefit mandates.

Based on the age-adjusted incidence rate, CHBRP estimated that there will be 56 adult enrollees with coverage subject to SB 746 using Optune® in the baseline year. Even with insurance coverage for Optune®, patients may decide not to use it due to a variety of factors (e.g., not wanting to shave their head or wear a visible device, incompatibility with continuing to work), or providers may not offer it as a potential treatment.

Patients who live longer due to the use of Optune® may incur use of other services (e.g., chemotherapy), but CHBRP did not include those in the utilization and cost impact estimates due to limitations of current claims data.

Postmandate, it is estimated that the utilization of Optune® may increase 10% due to increased awareness and acceptance of the treatment by both providers and patients, which would result in five more users.

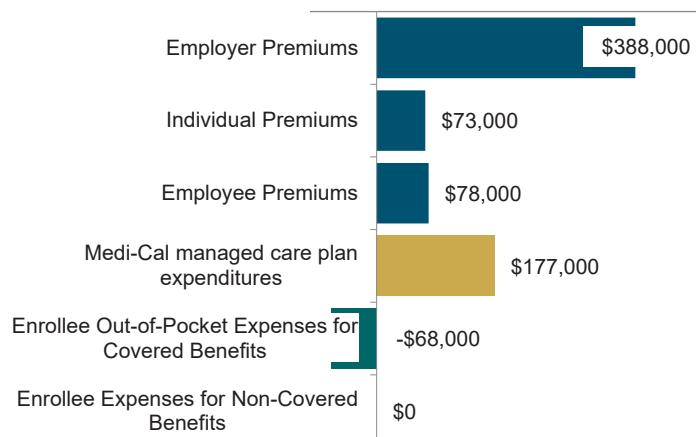
Expenditures

The cost of Optune® is \$21,000, with an average cost paid by health plans and insurers of \$18,624 per month per user, which includes component parts, services, and supplies necessary for the effective use of the device. The average length of Optune® use is 5.2 months. CHBRP estimates the average cost will be \$96,845 per user. SB 746 would increase total net annual expenditures by \$648,000 or 0.0004%. This is due to a \$717,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by an increase in enrollee expenses for covered and/or noncovered benefits. CHBRP projects no change to copayments or coinsurance for those with coverage but

does project an increase in the utilization of Optune® and therefore an increase in overall enrollee cost sharing. Expenditure impacts are shown in Figure B.

CHBRP does not project any cost offsets or savings in health care that would result postmandate since Optune® is used to complement other standard treatments.

Figure B. Expenditure Impacts of SB 746



Source: California Health Benefits Review Program, 2019.

Medi-Cal

CHBRP estimates there will be a \$177,000 increase in expenditures for the 7.6 million Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

CalPERS

CHBRP does not expect the impacts for CalPERS enrollees to be different from those for enrollees in other plans or policies.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP expects no measurable change in the number of uninsured persons due to the enactment of SB 746.

Medical Effectiveness

CHBRP's review of the literature focused on the following outcomes: (1) overall survival, (2) progression-free

survival, (3) quality of life and functional status, and (4) harms from the treatment.

CHBRP found a preponderance of evidence that adults with GBM receiving Optune® have increased overall survival (i.e., the length of time during which the GBM does not get worse) compared to those who receive standard care (e.g., active chemotherapy such as temozolomide [TMZ]). There is limited evidence that Optune® increases progression-free survival among people with newly diagnosed GBM. Findings regarding the effects of Optune® on functional status and quality of life are inconclusive. There is limited evidence that using Optune® does not lead to more frequent or severe harms than standard of care; skin irritation or reaction was the most common harm identified.

Public Health

Despite a preponderance of evidence that Optune® is medically effective, CHBRP projects no measurable public health impact at the population level due to the small estimated increase in utilization (i.e., five new users). However, SB 746 would likely yield increased length of life among the additional five enrollees who would use Optune® in the treatment of GBM.

Racial or ethnic disparities in the prevalence and treatment of GBM exist; however, CHBRP did not find evidence to suggest that SB 746 would impact utilization of Optune® differentially by race or ethnicity. Therefore, CHBRP projects no impact on racial or ethnic disparities related to GBM treatment and survival.

Long-Term Impacts

After the estimated increase in utilization in the first 12 months, there is no indication in the research literature that the trend of utilization and incidence rate of enrollees with GBM will change over time. Because of this, CHBRP assumes that the 10% increase projected for Year 1 will persist in Year 2. However, in the long term, it is possible that Optune® could be improved and be utilized more widely as the treatment becomes more normalized and patient acceptance increases.

There are several preliminary studies underway that assess the efficacy and safety of Optune® for other conditions and populations such as pediatric GBM, non-small cell lung cancer, pancreatic cancer, ovarian cancer,

and cancer that has metastasized in the brain from other locations. It is uncertain what impact Optune® could have on survival rates for these cancers. There also may be more anticancer medical devices that come to the market in the future. If either of these things happens, the overall utilization of anticancer devices will increase, along with cost.

The potential long-term impact of SB 746 is unknown, although it stands to reason that there is the potential for a larger impact in the long-term if the FDA approves Optune® to treat other cancers or approves other anticancer medical devices that are effective at treating cancer.

Essential Health Benefits (EHBs) and the Affordable Care Act

Anticancer medical devices are categorized by health plans as durable medical equipment (DME). Because DME is already a covered benefit under California's definition of EHBs, SB 746 would not require coverage for a new state benefit mandate that appears to exceed the definition of EHBs.