

Key Findings

Analysis of California Assembly Bill 620

Metabolic Disorders

Summary to the 2023–2024 California State Legislature, April 14, 2023



SUMMARY

The version of California Assembly Bill 620 analyzed by CHBRP would require health plans and policies to provide coverage for the testing and treatment of phenylketonuria (PKU) or other digestive and inherited metabolic disorders. This bill requires that coverage for treatment of these conditions include formulas and special food products that are part of a prescribed diet. AB 620 amends current law, which requires coverage for the testing and treatment of PKU only.

In 2024, the 22.8 million Californians enrolled in state-regulated health insurance will have insurance subject to, and potentially impacted by, AB 620. In addition to commercial enrollees, AB 620 would apply to more than 73% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 80% of Medi-Cal beneficiaries enrolled in plans regulated by the California Department of Managed Health Care (DMHC).

Benefit Coverage: At baseline, 152 commercial and CalPERS enrollees will use formula or special foods for other *inherited metabolic disorders*, 148 of which are covered by insurance and 4 that are not. Postmandate, 163 enrollees will use these products, all of which will be covered by insurance.

At baseline, 1,934 commercial and CalPERS enrollees will use formula or special foods for other *digestive disorders*, 431 of which are covered by insurance and 1,503 that are not. Postmandate, 5,185 enrollees will use these products, all of which will be covered by insurance.

At baseline, a total of 579 enrollees with other inherited metabolic disorders or digestive disorders who use formula and special food products have coverage. Postmandate, a total of 4,769 enrollees would have new benefit coverage for these products, including 1,507 enrollees using these products at baseline and an additional 3,262 enrollees who begin using these products due to the coverage expansion.

AB 620 does not exceed the definition of essential health benefits (EHBs) in California.

Medical Effectiveness: CHBRP found limited evidence that nutritional treatment is effective on induction and maintenance of remission in *Crohn's disease* and comparatively effective to standard treatment (i.e., drug therapy). There is insufficient evidence on the efficacy of nutritional treatment for *ulcerative colitis*. There is insufficient evidence on the efficacy of nutritional treatment for *inherited metabolic disorders*; treatment for these disorders is based on treatment guidelines.

Cost and Health Impacts¹: In 2024, AB 620 would increase total net annual expenditures by \$24,187,000 or 0.02% for enrollees with DMHC-regulated plans and California Department of Insurance (CDI)-regulated policies. This is primarily due to a \$26,928,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$2,741,000 decrease in enrollee expenses for covered and/or noncovered benefits.

At baseline, for enrollees with *inherited metabolic disorders*, the annual cost is \$6,369 for covered formulas and special food products and \$5,846 for noncovered formulas and special food products; for enrollees with *digestive disorders*, the annual cost is \$5,758 for covered formulas and special food products and \$2,619 for noncovered formulas and special food products. Postmandate, the 579 enrollees with these conditions who have coverage for formulas and special food products at baseline would experience no change in cost sharing. For the 1,507 enrollees using services at baseline for whom postmandate benefit coverage would be new, enrollees would experience an average decrease in out-of-pocket expenses for noncovered benefits of \$2,628.

Due to the limited number of enrollees impacted, CHBRP concludes that passage of AB 620 would have no measurable short-term or long-term public health impact.

¹ 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

A California law currently mandates coverage for the testing and treatment of phenylketonuria (PKU), which is a rare, but potentially serious, inherited disorder that causes an amino acid called phenylalanine to build up in the body. The law requires health plans and insurers to cover formula and special food products that are part of a prescribed diet deemed to be necessary for the treatment of PKU.² Newborns are screened for PKU soon after birth in the United States, and immediate treatment is needed to help prevent the development of serious physical or mental disabilities or to promote normal development and function. People with PKU, including babies, children, and adults, need to follow a diet that limits phenylalanine for the rest of their lives.

BILL SUMMARY

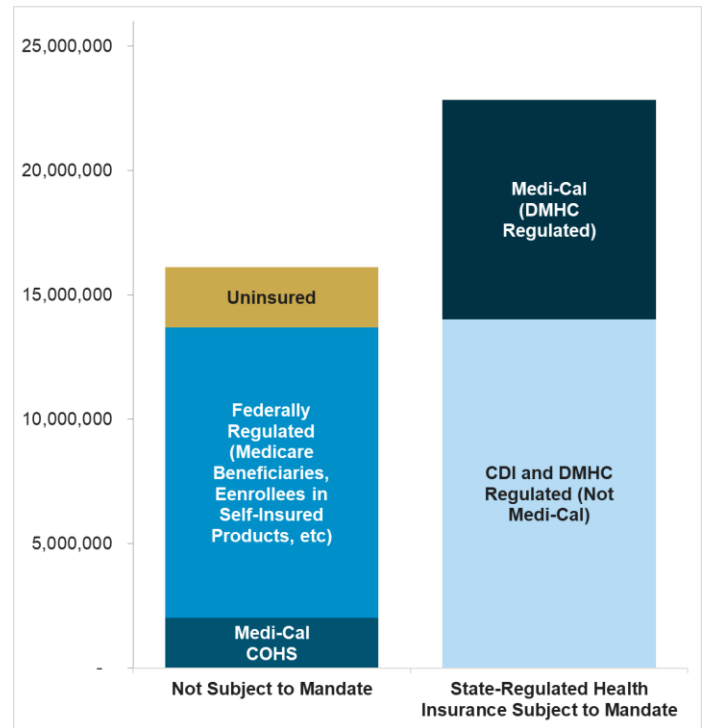
AB 620 would require a health care service plan contract or disability insurance policy that provides coverage for hospital, medical, or surgical expenses and is issued, amended, delivered, or renewed on and after January 1, 2024, to provide coverage for the testing and treatment of PKU or other digestive and inherited metabolic disorders. This bill amends current law, which requires coverage for the testing and treatment of PKU only.

AB 620 requires that coverage for treatment of these conditions include formulas and special food products that are part of a prescribed diet and managed by a health care professional in consultation with a physician who specializes in the treatment of these conditions and is authorized by the plan/insurer. It also requires that the diet is deemed medically necessary to avert the development of serious physical or mental disabilities or to promote normal development or function as a consequence of these conditions.

As is the case for the coverage of PKU currently, coverage is not required except to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet.

Figure A shows how many Californians have health insurance that would be subject to AB 620.

Figure A. Health Insurance in CA and AB 620



Source: California Health Benefits Review Program, 2023.

Key: CDI = California Department of Insurance; COHS = County Organized Health System; DMHC = Department of Managed Health Care.

IMPACTS

Benefit Coverage, Utilization, and Cost

Benefit Coverage

In addition to commercial enrollees, AB 620 would apply to more than 73% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 80% of Medi-Cal beneficiaries enrolled in California Department of Managed Health Care (DMHC)-regulated plans.

CHBRP assumed 100% of the commercial and CalPERS population enrolled in plans/policies subject to mandated offerings currently have coverage for tests and treatments for PKU or other digestive and inherited metabolic disorders. Based on the carrier survey responses, *tube feeding* is covered for 100% of enrollees with inherited metabolic disorders or digestive

² Refer to CHBRP's full report for citations and references.

disorders at baseline. There is no change to coverage of tube feeding postmandate.

Carriers have some coverage for formulas and special food products consumed *orally* for inherited metabolic disorders or digestive disorders; however, there are exceptions and limitations to when they are covered. Postmandate, all users have coverage for *oral* formulas and special food products for inherited metabolic and digestive disorders.

Utilization

CHBRP estimates 148 commercial and CalPERS enrollees will use formula or special foods for other *inherited metabolic disorders* that are covered by insurance and an additional 4 enrollees use them as a noncovered benefit at baseline. Postmandate, 163 enrollees will use formulas or special food products covered by insurance, including the 4 who used them at baseline and 11 additional enrollees who begin using them due to the coverage expansion.

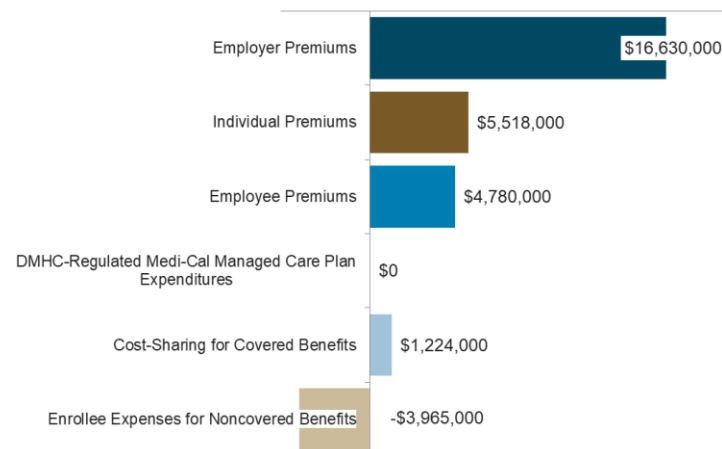
CHBRP estimates 431 commercial and CalPERS enrollees will use formula or special foods for other *digestive disorders* that are covered by insurance and an additional 1,503 enrollees use them as a noncovered benefit at baseline. Postmandate, 5,185 enrollees will use formulas or special food products covered by insurance, including the 1,503 who used them at baseline and 3,251 additional enrollees who begin using them due to the coverage expansion.

At baseline, a total of 579 enrollees with these conditions who use formula and special food products have coverage. Postmandate, a total of 4,769 enrollees would have new benefit coverage for these products, including 1,507 enrollees using these products at baseline and an additional 3,262 enrollees who begin using these products due to the coverage expansion.

Expenditures

AB 620 would increase total net annual expenditures by \$24,187,000, or 0.02%, for enrollees with DMHC-regulated plans and California Department of Insurance (CDI)-regulated policies. This is primarily due to a \$26,928,000 increase in total health insurance premiums paid by employers and enrollees for newly covered benefits, adjusted by a \$2,741,000 decrease in enrollee expenses for covered and/or noncovered benefits (see Figure B).

Figure B. Expenditure Impacts of AB 620



Source: California Health Benefits Review Program, 2023.

Changes in premiums as a result of AB 620 would vary by market segment, with increases ranging from 0.0227% to 0.0268%.

At baseline, for enrollees with *inherited metabolic disorders*, the annual cost is \$6,369 for covered formulas and special food products and \$5,846 for noncovered formulas and special food products; for enrollees with *digestive disorders*, the annual cost is \$5,758 for covered formulas and special food products and \$2,619 for noncovered formulas and special food products. Postmandate, the 579 enrollees with coverage for formulas and special food products at baseline would experience no change in cost sharing. For the 1,507 enrollees using services at baseline for whom postmandate benefit coverage would be new, enrollees would experience an average decrease in out-of-pocket expenses for noncovered benefits of \$2,628.

Medi-Cal

Based on the Medi-Cal Rx provider manual, Medi-Cal beneficiaries who have other inherited metabolic disorders or digestive disorders and are enrolled in DMHC-regulated plans have coverage for formulas and special foods through Medi-Cal Rx. CHBRP did not include them in this analysis.

CalPERS

For enrollees associated with CalPERS in DMHC-regulated plans, there would be a 0.0227% premium increase, or \$0.1579, per member per month (PMPM), due to AB 620.

Covered California – Individually Purchased

Within the individual DMHC-regulated market, health plans offered by Covered California would experience a 0.0263% premium increase, or \$0.1729 PMPM. Covered California individual market plans regulated by CDI would experience a 0.0280% increase in premiums, or \$0.1500 PMPM.

Number of Uninsured in California

Because the change in average premiums does not exceed 1% for any market segment, CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 620.

Medical Effectiveness

CHBRP found *limited evidence*³ from two Cochrane reviews that nutritional treatment is effective on induction and maintenance of remission in *Crohn's disease* and comparatively effective to standard treatment (i.e., drug therapy).

CHBRP found *insufficient evidence*⁴ from one systematic review on the efficacy of nutritional treatment for *ulcerative colitis*. Though the studies in the systematic review provide some evidence regarding the efficacy of nutritional treatment for ulcerative colitis, they were not specific to nutritional treatment alone, but to patients on an enteral nutrition diet and steroid therapy.

CHBRP found *insufficient evidence* on the efficacy of nutritional treatment for *inherited metabolic disorders*. No studies were found that examined the effectiveness of nutritional treatment for inherited metabolic disorders, and available evidence on treatment for these disorders are treatment guidelines based on expert opinion. Limiting factors that contribute to this evidence grade are the small number of individuals with these conditions, need for timely treatment, and ethical barriers to conducting other types of studies with this population.

Public Health

Due to the limited number of enrollees impacted, CHBRP concludes that passage of AB 620 would have

no measurable short-term or long-term public health impact.

- Although nutritional treatment for *inherited metabolic disorders* is supported by clinical guidelines, the change in utilization is small, and such disorders are rare.
- Although utilization of nutritional treatment for *digestive disorders* would increase, there is:
 - Limited evidence that this treatment is effective for inducing or maintaining remission compared to standard drug treatment for *Crohn's disease*.
 - Insufficient evidence on the effect of nutritional treatment for *ulcerative colitis*.

Due to no measurable public health impact, CHBRP concludes that AB 620 would also have no impact on disparities in health outcomes (by gender, race/ethnicity, sexual orientation/gender identity, or other determinants). It would also have no measurable long-term impact on public health, premature death, or societal economic losses.

Long-Term Impacts

CHBRP estimates utilization after the initial 12 months from the enactment of AB 620 would likely stay similar to utilization estimates during the first 12 months postmandate. Utilization changes may occur if new prescription medications or other advancements change the treatment options available for enrollees with digestive or other inherited metabolic disorders. Similarly, utilization may be greater than estimated if detection capabilities improve or overall prevalence increases such that more enrollees are diagnosed with digestive or other inherited metabolic disorders; however, CHBRP is unable to predict these types of changes. In addition, health care utilization may change if effective management of a condition through increased use of newly covered formulas and special food products allows enrollees with digestive or other inherited metabolic disorders to delay use of other treatments such as prescription medications and surgery.

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.

³ *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.

⁴ *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is

CHBRP estimates costs after the initial 12 months from the enactment of AB 620 are likely to remain similar in subsequent years; however, there may be cost offsets if increased use of newly covered formulas and special food products allows enrollees with digestive or other inherited metabolic disorders to delay use of other treatments such as prescription medications and surgery. CHBRP is unable to estimate these changes quantitatively due to the lack of data on long-term utilization and cost due to increased use of formulas and special food products.

Essential Health Benefits and the Affordable Care Act

AB 620 does not exceed the definition of essential health benefits (EHBs) in California because formula and special food products are considered durable medical equipment and would be encompassed within the “rehabilitative and habilitative services and devices” EHB benefit category.