California Health Benefits Review Program

Analysis of California Assembly Bill 620
Metabolic Disorders

A Report to the 2023–2024 California State Legislature

April 14, 2023

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Assembly Bill 620
Metabolic Disorders

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

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

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 Impacts[1]: 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

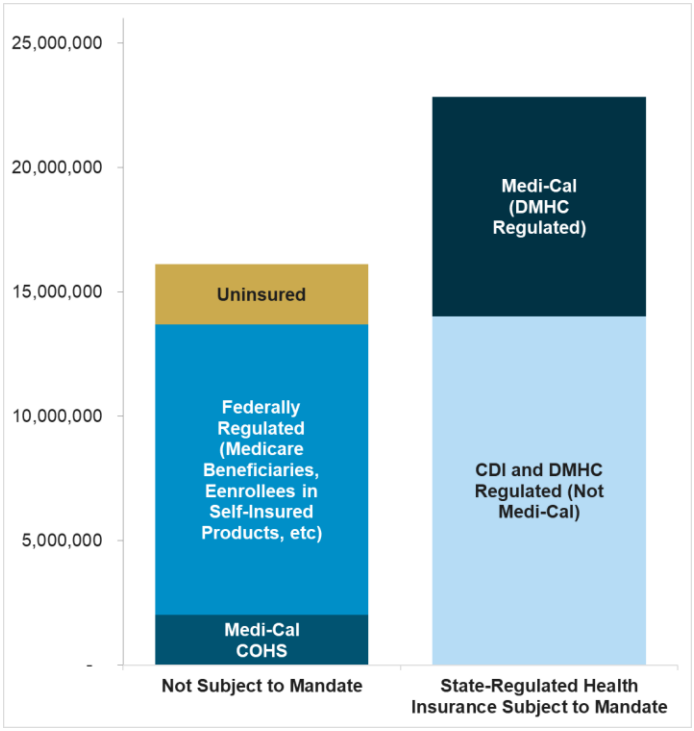
AB 620 would require a health care service plan contract or disability insurance policy that provides coverage for hospital, medical, or surgical expenses and is issued, amended, delivered, or renewed on and after January 1, 2024, to provide coverage for the testing and treatment of PKU *or other digestive 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.

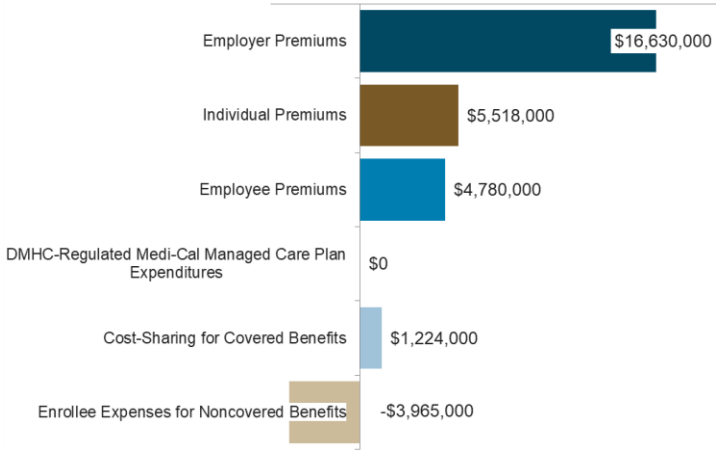
CHBRP estimates 431 commercial and CalPERS enrollees will use formula or special foods for other *digestive disorders* that are covered by insurance and an additional 1,503 enrollees use them as a noncovered benefit at baseline. Postmandate, 5,185 enrollees will use formulas or special food products 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.

[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 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.

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.

A Report to the California State Legislature

Analysis of California Assembly Bill 620 Metabolic Disorders

April 14, 2023

California Health Benefits Review Program
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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.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

Table 1. Impacts of AB 620 on Benefit Coverage, Utilization, and Cost, 2024

	Baseline (2024)	Postmandate Year 1 (2024)	Increase/ Decrease	Change Postmandate
Benefit coverage				
Total enrollees with health insurance subject to state-level benefit mandates (a)	22,842,000	22,842,000	0	0.00%
Total enrollees with health insurance subject to AB 620	22,842,000	22,842,000	0	0.00%
Percentage of enrollees with coverage for the testing and treatment of other digestive and inherited metabolic disorders	39%	100%	61%	159.07%
Number of enrollees with fully compliant coverage for the testing and treatment of other digestive and inherited metabolic disorders	8,817,000	22,842,000	14,025,000	159.07%
Utilization and unit cost				
Inherited metabolic disorders				
Covered formulas and special food products				
Number of enrollees using formulas and special food products	148	163	15	10.14%
Cost of formulas and special food products per enrollee per year	$6,369	$6,369	$0	0.00%
Enrollee cost-sharing	$510	$510	$0	0.00%
Noncovered formulas and special food products				
Number of enrollees using formulas and special food products	4	0	−4	−100.00%
Cost of formulas and special food products per enrollee per year	$5,846	$0	−$5,846	−100.00%
Enrollee cost of noncovered services	$5,846	$0	−$5,846	−100.00%
Digestive disorders				
Covered formulas and special food products				
Number of enrollees using formulas and special food products	431	5,185	4,754	1103.02%
Cost of formulas and special food products per enrollee per year	$5,758	$5,013	−$745	−12.93%
Enrollee cost-sharing	$783	$300	−$483	−61.72%
Noncovered formulas and special food products				
Number of enrollees using formulas and special food products	1,503	0	−1,503	−100.00%
Cost of formulas and special food products per enrollee per year	$2,619	$0	−$2,619	−100.00%
Enrollee cost of noncovered services	$2,619	$0	−$2,619	−100.00%
Expenditures				
Premiums				
Employer-sponsored (b)	$57,647,993,000	$57,663,224,000	$15,231,000	0.03%
CalPERS employer (c)	$6,158,262,000	$6,159,661,000	$1,399,000	0.02%
Medi-Cal (excludes COHS) (d)	$29,618,383,000	$29,618,383,000	$0	0.00%
Enrollee premiums				
Enrollees, individually purchased insurance	$21,229,233,000	$21,234,751,000	$5,518,000	0.03%

Outside Covered California	$4,867,955,000	$4,869,159,000	$1,204,000	0.02%
Through Covered California	$16,361,278,000	$16,365,592,000	$4,314,000	0.03%
Enrollees, group insurance (e)	$18,263,775,000	$18,268,555,000	$4,780,000	0.03%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copays, etc.)	$13,857,141,000	$13,858,365,000	$1,224,000	0.01%
Expenses for noncovered benefits (f) (g)	$3,965,000	$0	−$3,965,000	−100.00%
Total expenditures	$146,778,752,000	$146,802,939,000	$24,187,000	0.02%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[5]

(b) In some cases, a union or other organization. Excludes CalPERS.

(c) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents.

(d) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. In addition, CHBRP is estimating that there would be no increase for Medi-Cal beneficiaries enrolled in COHS managed care.

(e) Enrollee premium expenditures include contributions by enrollees to employer (or union or other organization)-sponsored health insurance, health insurance purchased through Covered California, and any contributions to enrollment through Medi-Cal to a DMHC-regulated plan.

(f) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(g) For covered benefits, such expenses would be eliminated, although enrollees with newly compliant benefit coverage might pay some expenses if benefit coverage is denied (through utilization management review).

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[5] For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[6] conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 620, Metabolic Disorders.

Bill-Specific Analysis of AB 620, Metabolic Disorders

Bill Language

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 phenylketonuria (PKU) or *other digestive and inherited metabolic disorders*. This bill amends current law, which requires coverage for the testing and treatment of PKU only.[7] 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, AB 620 states that 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. The terms "formula" and "special food product" are defined in the bill language. The full text of AB 620 can be found in Appendix A.

Relevant Populations

If enacted, AB 620 would apply to the health insurance of approximately 22,842,000 enrollees (58.6% of all Californians) who will have health insurance regulated by the state that may be subject to any state health benefit mandate law (see Table 2). This includes those who have commercial or CalPERS health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Although the bill does not specifically exempt Medi-Cal, it appears that these treatments are already covered under Medi-Cal.[8]

Table 2. Californians With State-Regulated Health Insurance Subject to AB 620

Type of Health Insurance	# of Enrollees in CA
Commercial plans regulated by DMHC and policies regulated by CDI	13,144,000
CalPERS plans regulated by DMHC	882,000
DMHC-regulated Medi-Cal managed care plans	8,817,000

Source: California Health Benefits Review Program, 2023.

Key: CDI = California Department of Insurance; DMHC = Department of Managed Health Care.

[6] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[7] Health and Safety Code (HSC) § 1374.56; Insurance Code (INS) § 10123.89.
[8] The Medi-Cal Rx Provider Manual, v 6.0, dated April 1, 2023, indicates that treatments for *PKU or other digestive and inherited metabolic disorders*, including formulas and special food products that are part of a prescribed diet, are covered benefits in Medi-Cal. Available at: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf.

As of January 1, 2022, outpatient prescription drugs are covered on a fee-for-service basis by the California Department of Health Care Services (DHCS) for all Medi-Cal beneficiaries.[9] Their pharmacy benefit is "carved out" of the coverage provided by Medi-Cal managed care plans, and so AB 620 would not be expected to impact their benefit coverage.[10]

Analytic Approach and Key Assumptions

CHBRP previously analyzed bill language, AB 163 (Coverage for Amino Acid–Based Elemental Formulas) in 2009[11] and AB 30 (Health Coverage: Inborn Errors of Metabolism) in 2007,[12] both of which were related to coverage of medical nutritional therapy including formula and special food products. Because these reports were completed 14 to 16 years ago, CHBRP conducted this analysis using literature and evidence from 2013 to the present.

Enrollees with an inherited metabolic disorder or digestive disorder who use formulas and special food products were categorized into the following four populations:

1) Enrollees with *inherited metabolic disorders* with formulas and special food products *fed via tube feeding*;

2) Enrollees with *digestive disorders* with formulas and special food products *fed via tube feeding*;

3) Enrollees with *inherited metabolic disorders* with formulas and special food products *consumed orally*; and

4) Enrollees with *digestive disorders* with formulas and special food products *consumed orally.*

Because it appears that formula and special food products administered via tube feeding are already covered, this analysis focuses primarily on those that are administered orally.

For this analysis, CHBRP considers the following to be the most common *digestive* diseases that may benefit from formula and special food products: inflammatory bowel disease (IBD) including Crohn's disease and ulcerative colitis, cystic fibrosis, eosinophilic enteritis, enteropathy, chronic pancreatitis, and intestinal malabsorption. *Inherited metabolic disorders* are individually rare and estimated to be about 1/3,000 individuals overall. Many of these are diagnosed through newborn screening, which is performed in order to initiate life- and brain-saving treatment early, before irreversible damage or death has occurred. These are often grouped into categories including: disorders of amino acid and protein metabolism (e.g., PKU, for which coverage of formula and special food products is already mandated), disorders of carbohydrate metabolism, and disorders of fatty acid oxidation metabolism.

CHBRP assumes that AB 620 is focused on chronic conditions that may benefit from formula and special food products and would exclude various acute digestive disorders.

If any of the assumptions listed above are incorrect, in particular, if the bill were to require coverage of formulas for acute conditions such as reflux, the cost impacts presented in this analysis may be significantly understated.

[9] For more on outpatient prescription drug coverage among Californians with state-regulated health insurance, see CHBRP's resource, *Pharmacy Benefit Coverage in State-Regulated Health Insurance*, available at https://chbrp.org/other_publications/index.php.
[10] DHCS, *All Plan Letter 22-012*, available at: https://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2022/APL22-012.pdf.
[11] CHBRP, *Analysis of Amino Acid–Based Elemental Formulas,* available at: https://www.chbrp.org/sites/default/files/bill-documents/AB163/ab163-FullReport.pdf.
[12] CHBRP, *Inborn Errors of Metabolism*, available at: https://www.chbrp.org/sites/default/files/bill-documents/AB30/ab30-FullReport.pdf.

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

One California law currently mandates coverage for the testing and treatment of PKU. It 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.[13]

Similar requirements in other states

The National Organization for Rare Disorders (NORD) publishes a state report card on coverage for medical nutrition. For people with *private* insurance, the 2022 NORD report card shows that 9 states mandate coverage for formula only, 27 states mandate coverage for medical nutrition more broadly, and 15 states do not mandate coverage. For people with *state-funded* insurance, 37 states mandate some degree of coverage for medical nutrition and 14 states do not mandate this coverage.[14]

New York law requires health insurers that cover prescription drugs to cover the cost of *enteral formulas* for home use, whether administered orally or via tube feeding, for which a physician or other licensed health care provider has issued a written order stating that the enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen.[15] The law lists specific diseases and disorders for which enteral formulas have been proven effective, including inherited diseases of amino acid or organic acid metabolism and Crohn's Disease. Introduced in 2023, New York Senate Bill 1234 would expand coverage and require health insurance policies that cover prescription drugs to include coverage for the cost of *enteral, infant, and baby formulas* subject to the same provisions as the current law.[16]

On March 22, 2023, the state of Virginia passed S 1399 that requires the state Bureau of Insurance to select a new essential health benefits benchmark plan for the 2025 plan year that includes coverage for formula and enteral nutrition products to be classified as “medicine” and to provide coverage for these products on the same terms and subject to the same conditions as for other medicines.[17] This legislation defines "inherited metabolic disorder" and "medically necessary formula and enteral nutrition products" and includes coverage for oral intake of these products.

In Massachusetts, proposed 2023 legislation (House Bill 1015) would require coverage for any active or retired employee of the commonwealth who is insured under the group insurance commission for the cost of enteral formulas for home use, whether administered orally or via tube feeding, for which a physician has issued a written order stating that the enteral formula is clearly medically necessary and has been proven effective as a disease-specific treatment regimen.[18] This bill includes a list of specific diseases for which enteral formulas have been proven effective, including amino acid disorders and Crohn’s disease.

[13] Health and Safety Code (HSC) §1374.56 and Insurance Code § 10123.89.
[14] National Organization for Rare Disorders, *State Report Card*, available at: https://rarediseases.org/policy-issues/medical-nutrition/.
[15] New York Consolidated Laws, Insurance Law – ISC § 4303. https://codes.findlaw.com/ny/insurance-law/isc-sect-4303.html.
[16] New York State Legislature, Senate Bill 1234. https://legiscan.com/NY/text/S01234/id/2631857.
[17] Virginia Senate Bill 1399. https://legiscan.com/VA/bill/SB1399/2023.
[18] The Commonwealth of Massachusetts. House Bill 1015. https://legiscan.com/MA/text/H1015/id/2742285.

Federal Policy Landscape

Affordable Care Act and essential health benefits

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. In California, nongrandfathered[19] individual and small-group health insurance are generally required to cover essential health benefits (EHBs).[20] In 2024, approximately 12.1% of all Californians will be enrolled in a plan or policy that must cover EHBs.[21]

AB 620 does not exceed the definition of 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.

Federal legislation and coverage

Federal legislation related to expanded medical nutrition therapy coverage under Medicare was introduced in the 2021-2022 session (S 1536[22] and HR 3108[23]) as the Medical Nutrition Therapy Act, although these bills were not signed into law. The Medical Nutrition Equity Act was also introduced in the 2021-2022 session (S 2013[24] and HR 3783[25]) and sought to expand coverage under Medicare, Medicaid, private health insurance, and other specified federal health care programs to include foods, vitamins, and individual amino acids that are medically necessary for the management of certain digestive and metabolic disorders and conditions; these bills also were not signed into law.

Medicare does not cover orally administered enteral nutrition products.[26] For certain conditions, Medicare does cover enteral nutrition products that are administered via tube feeding.[27]

[19] 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." Available at: www.healthcare.gov/glossary/grandfathered-health-plan.
[20] 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.
[21] See CHBRP's resource, *Sources of Health Insurance in California* and CHBRP's issue brief *California State Benefit Mandates and the Affordable Care Act's Essential Health Benefits*, both available at: https://chbrp.org/other_publications/index.php.
[22] US Congress Senate Bill 1536, available at: https://www.congress.gov/bill/117th-congress/senate-bill/1536/text
[23] US Congress House Bill 3108, available at: https://www.congress.gov/bill/117th-congress/house-bill/3108/text
[24] US Congress Senate Bill 2013, available at: https://www.congress.gov/bill/117th-congress/senate-bill/2013/text
[25] US Congress House Bill 3783, available at: https://www.congress.gov/bill/117th-congress/house-bill/3783/text
[26] Centers for Medicare & Medicaid Services. Enteral Nutrition - Policy Article. A58833. Available at: www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=58833. Accessed March 22, 2023.
[27] Centers for Medicare & Medicaid Services. Enteral Nutrition. L38955. Available at: www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38955. Accessed March 22, 2023.

BACKGROUND ON METABOLIC DISORDERS

As described in *Policy Context*, AB 620 would require plans and policies that provide coverage for hospital, medical, or surgical expenses to expand coverage from testing and treatment of phenylketonuria (PKU) only to testing and treatment of other digestive and inherited metabolic disorders. Coverage for treatment would include formulas and special food products that are part of a diet prescribed and managed by a health care professional who specializes in the treatment of these conditions. This section provides an overview of digestive and inherited metabolic disorders, disease prevalence, and testing and treatment of these conditions.

Metabolic Disorders

Inherited Metabolic Disorders

Inherited metabolic disorders are genetic disorders that affect an individual's ability to metabolize nutrients due to an enzymatic or transporter deficiency. Typically, these disorders are discussed in three main groups: disorders of amino acid and protein metabolism (e.g., PKU), disorders of carbohydrate metabolism (e.g., classic galactosemia), and disorders of fatty acid oxidation metabolism (e.g., medium-chain acyl-CoA dehydrogenase [MCAD] deficiency) (Boyer et al., 2015).

In most cases, inherited metabolic disorders, also referred to as inborn errors of metabolism, are present at birth and detected by newborn genetic screening, though some may be identified later as symptoms present (Ferreira et al., 2021). Left untreated, these disorders may result in developmental delays, intellectual disabilities, seizures, coma, or death. Severity of inherited metabolic disorders varies by disorder and how well a patient manages their nutritional needs.

Traditional therapies for inherited metabolic disorders include medication, dietary management, and nutritional supplements (Hoytema van Konijnenburg et al., 2021). Dietary management can include protein restriction, avoidance of fasting, special formulas, and food products manufactured specifically for these conditions (Boyer et al., 2015). Supplements can include amino acid compounds and B vitamins. Treatment varies by disorder and among individuals with a given disorder based on the severity of the deficiency. For some disorders, persons with severe deficiencies may need to take special formulas and supplements for their entire lives (Boyer et al., 2015).

Enteral nutrition refers to oral nutritional formulas or tube feeding that may supplement or replace dietary modifications in order to restore nutritional requirements (Balestrieri et al., 2020). Enteral nutrition involves delivery methods in which absorption occurs through the intestines; parenteral nutrition is delivered via the bloodstream using an intravenous tube (Crohn’s and Colitis Foundation, 2022).

Digestive Disorders

Digestive disorders are acute or chronic conditions affecting the digestive system which encompasses the gastrointestinal (GI) tract, liver, pancreas, and gallbladder (NIDDK, 2023). These conditions affect the body’s ability to absorb nutrients, which can result in mild to severe symptoms, disability, or death. Digestive disorders such as inflammatory bowel disease (IBD) typically develop, or are identified, in adolescence and early adulthood (Balestrieri et al., 2020), though it is possible for infants and children to be diagnosed with digestive disorders (NIDDK, 2023).

Current therapies for digestive disorders typically include use of medication, such as steroids, anti-inflammatories, immunosupressives, or biologics, along with dietary management (Cai et al., 2021). The primary concern with digestive disorders is that they may lead to malnutrition, which can occur by a variety of mechanisms: symptoms may result in reduced food intake, the body may not sufficiently absorb nutrients taken in orally, loss of nutrients after absorption (enteric nutrient loss), or increased nutritional

requirements due to inflammation (in the case of IBD). Mechanisms may also include medication or surgery. Consistent assessment of nutritional status and use of supportive nutritional therapy are critical in management of these disorders (Balestrieri et al., 2020; Mihai et al., 2013).

Metabolic Disorders Prevalence

The California Department of Health Care Services (DHCS) implements California's Newborn Screening (NBS) program, which screens for 33 core conditions recommended by the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).[28] These include, but are not limited to, inherited metabolic disorders. In California, approximately 1 in every 500 babies born will have a genetic disorder detected through the NBS panel (Feuchtbaum et al., 2012). Of these disorders, the most common amino acid and protein metabolism disorder is PKU (2.9 per 100,000 births), the most common carbohydrate metabolism disorder is 3-methylcrotonyl-CoA carboxylase def (2.9 per 100,000 births), and the most common fatty acid oxidation metabolism disorder is short-chain acyl-CoA dehydrogenase def (3.5 per 100,000 births). Overall, the most common metabolic disorder (categorized by the NBS program as an "other metabolic disorder") is duarte galactosemia (5.6 per 100,000 births) (Feuchtbaum et al., 2012). Table 3 shows prevalence for each of the three major inherited metabolic disorder categories reported by California's NBS program, and Table 4 shows prevalence in the United States for the two most common digestive disorders requiring nutritional therapies.

Table 3. Prevalence of Inherited Metabolic Disorders in California (2019)

Inherited Metabolic Disorders	Prevalence (per 100,000 births)
Amino acid and protein metabolism disorders	5.3
Carbohydrate metabolism disorders	5.6
Fatty acid oxidation metabolism disorders	7.2

Source: California Health Benefits Review Program, 2023; California Department of Public Health (CDPH), 2019.

Table 4. Prevalence of Digestive Disorders in the United States (2014)

Digestive Disorders	Prevalence
Crohn's disease	359,000
Ulcerative colitis	619,000

Source: California Health Benefits Review Program, 2023; National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), 2014.

Disparities[29] in Metabolic Disorders and Treatment

Disparities are noticeable and preventable or modifiable differences between groups of people. Health insurance benefit mandates or related legislation may impact disparities. Where intersections between

[28] Established under Section 1111 of the Public Health Service (PHS) Act, 42 U.S.C. 300b-10, as amended in the Newborn Screening Saves Lives Act of 2008.
[29] 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).

health insurance benefit mandates and social determinants or systemic factors exist, CHBRP describes relevant literature.

CHBRP found literature identifying disparities by race or ethnicity, sex or gender, geography, and income.

Race or Ethnicity

Multiple recent systematic reviews have examined peer-reviewed studies for racial or ethnic differences in digestive disorders, primarily for IBD. Until recently, IBD was considered a disease predominantly affecting White individuals (Afzali and Cross, 2016; Barnes et al., 2021). There is now increasing awareness and research into the epidemiology of IBD in non-White patients, and these studies are finding that incidence and prevalence in non-White populations is increasing (Afzali and Cross, 2016).

One systematic review of 40 studies found inequities by race in health care access and utilization for IBD, utilization of medical and surgical therapy, and disease perceptions and knowledge (Sewell and Velayos, 2013). IBD care involves frequent visits to specialists, and studies have long shown inequalities in access to – and utilization of – health care services among underrepresented groups, which may exacerbate negative outcomes in these populations. Additionally, Sewell and Velayos identified two large nationally representative studies that indicated clear differences in surgical care by race; for example, African American patients were 54% less likely to undergo colectomy for ulcerative colitis than were White patients, whereas Hispanic patients were 26% less likely. These findings were supported by more than 10 other studies of varying scope and sample sizes. These differences were not limited to surgical interventions – seven studies identified race-based differences in treatment with immunomodulators and infliximab, suggestive of disparities in access to or utilization of these therapies. Finally, two studies included in the systematic review that examined race and disease perceptions and knowledge found that African American patients had less disease-specific knowledge and perceived greater intrusiveness of IBD on their lives compared to White patients, whereas Hispanic patients also had less disease-specific knowledge than White patients had.

Racial differences in rates of surgery and surgical outcomes for patients with IBD are mixed (Barnes et al., 2021). Some studies have shown no difference in IBD-related surgeries by race, whereas others have indicated a greater need for Crohn's disease surgery among African American and Hispanic patients. Studies also found in nationally representative samples that African American patients have worse outcomes after undergoing IBD-related surgery, including greater complications, increased risk of death and serious morbidity, and longer hospital admissions (Barnes et al., 2021; Booth et al., 2022).

In the literature that CHBRP identified, the authors call for more research on IBD in non-White populations to better quantify trends in prevalence, disparities in health care delivery and outcomes, and IBD phenotypes in order to modify the disparities observed (Afzali and Cross, 2016; Barnes et al., 2021; Booth et al., 2022; Sewell and Velayos, 2013).

Sex or Gender[30]

CHBRP found one review article examining gender differences for inherited metabolic disorders and digestive disorders. Sweezey and Ratijen (2014) examined factors related to cystic fibrosis and concluded that female gender was associated with poorer morbidity and mortality and that gender differences exist for disease progression, including nutritional status. The mechanisms involved in this are a source of some disagreement among experts, though the authors encourage future research in this area to explore novel interventions for hormonal involvement. Although sex or gender is not a modifiable difference, increasing female participation in cystic fibrosis research is one way to better understand these differences and close this gap.

[30] 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, 2019).

Geography

A recent systematic review (Booth et al., 2022), a meta-analysis (Song et al., 2019), and an umbrella review of meta-analyses (Piovani et al., 2019) were identified that evaluated geographic factors related to IBD. Living conditions during childhood and urban living environments resulted in increased risk for IBD. Booth et al. (2022) concluded that surgical disparities exist based on sociologic and structural factors. Crohn's disease and ulcerative colitis are chronic diseases with intermittent periods of flare and remission, and they require access to specialists, appropriate therapies, and frequent follow-up visits, which may be limited for more rural populations, to ensure positive outcomes (Barnes et al., 2021).

Income

Poor health contributes to reduced income, creating a negative feedback loop (Khullar and Chokshi, 2018). This is a longstanding trend in health outcomes. Oates and Schechter (2016) found that for cystic fibrosis patients, socioeconomic status (SES) was inversely related such that those with lower SES had higher mortality and morbidity. Those with lower SES also had poorer health outcomes (both for lung function and nutritional status) than those of higher SES. This inequality was apparent even in infancy. For the example of cystic fibrosis, income may play a role in these disparities by reducing access to the required high-fat, high-protein foods, and nutritional supplements required for management of the disease (Oates and Schechter, 2016). These may be costly and are likely less affordable to lower income families.

Barriers to Treatment of Metabolic Disorders

Although insurance coverage has been found be a predictor of referral for surgery (Afzali and Cross, 2016) and ability to afford treatment and subspecialty care (Barnes et al., 2021), barriers to treatment of metabolic disorders unrelated to insurance coverage exist. Boyer and colleagues (2015) highlight that tolerance to specialty diets varies widely between patients even for the same condition and can also vary for the same patient at different life stages. This means that management of these diseases requires lifelong monitoring and access to care. Additionally, compliance with specialty diets is a limiting factor in both children and adults (Stepien et al., 2019). In the literature that CHBRP found, these barriers, along with disparities highlighted above, result in additional complications in management of these metabolic disorders.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 620 would expand coverage for testing and treatment of phenylketonuria (PKU) only to PKU and other digestive and inherited metabolic disorders. Coverage for treatment would include formulas and special food products that are part of a diet prescribed and managed by a health care professional who specializes in the treatment of these conditions. Additional information on digestive and metabolic disorders is included in the *Background* section. The medical effectiveness review summarizes findings from evidence[31] on nutritional treatment for digestive and inherited metabolic disorders.

Research Approach and Methods

The search was limited to abstracts of studies published in English. The search was limited to studies published from 2013 to present. CHBRP relied on two Cochrane reviews published in 2018 for findings related to Crohn's disease. Of the 247 articles found in the literature review, 22 were reviewed for potential inclusion in this report on AB 620, and a total of 3 articles (the two Cochrane reviews and one systematic review) were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on oral enteral nutrition, were narrative reviews and did not report findings from clinical research studies or were of poor quality. 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.

Studies of PKU and enteral nutrition via tube feeding were omitted from the medical effectiveness review because of existing coverage for these conditions and treatments.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[32] 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. What is the effectiveness of nutritional treatment (formula and special food products) for *digestive disorders*?

    a. How effective is nutritional treatment for treatment of digestive disorders compared to standard treatments (i.e., drug treatments)?

2. What is the effectiveness of nutritional treatment (formula and special food products) for *inherited metabolic disorders*?

Methodological Considerations

The analysis of nutritional treatment for digestive disorders will focus on chronic conditions, as noted in the *Policy Context* section (refer to "Analytic Approach and Key Assumptions"). The literature on this topic

[31] 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 in the *Medical Effectiveness Analysis and Research Approach* document (available at: www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis 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.

[32] 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 www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis.

focuses on IBD, including Crohn's disease and ulcerative colitis. Though there may be other, less common, digestive conditions for which nutritional treatment is of interest, this review will focus on these primary conditions.

The literature on nutritional treatment for inherited metabolic disorders is sparse. Most studies on this topic focus on PKU or tube feeding, for which there is already mandated coverage, and are case studies of individual patients, case series of small groups of patients, or surveys of clinicians regarding the treatments they prescribe. The lack of a rigorous literature base on nutritional treatment for inherited metabolic disorders is due to several ethical barriers to conducting randomized controlled trials on this population, including the medical necessity to provide timely treatment to this population and the potentially fatal consequences of withholding treatment. Additionally, the small number of individuals with these conditions makes it difficult to recruit a sufficient number of subjects to conduct prospective studies. Though inherited metabolic disorders cover a wide range of conditions, they are very rare as a whole, with incidence rates for many individual inherited metabolic disorders of less than 5 in 100,000 infants (see *Background* for prevalence rates in California). However, the lack of controlled studies on treatment of inherited metabolic disorders does not indicate a lack of scientific basis for treatment. Unlike many other conditions, inherited metabolic disorders are single-cause conditions amenable to causal therapies, and the mechanisms of metabolizing nutrients are well understood. For these reasons, this medical effectiveness review will rely primarily on available clinical practice and treatment guidelines.

Outcomes Assessed

The primary outcomes of interest for the effect of nutritional treatment on *digestive conditions* are disease remission (obtaining and maintaining) and prevention of relapse (symptom re-occurrence). Secondary outcomes include quality of life, growth metrics (i.e., height and weight), and adverse events (e.g., disease progression, symptom severity, complications).

The primary outcome associated with nutritional treatment of inherited metabolic disorders is proper growth and development (including both physical and cognitive functioning).

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of nutritional treatment, provided orally as formula or special food product, for digestive and inherited metabolic disorders as addressed by AB 620. 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 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.

Effectiveness of Nutritional Treatment (Formula and Special Food Products) for *Digestive Disorders*

CHBRP identified two Cochrane reviews and one systematic review that examined the effectiveness of nutritional treatment for digestive conditions. These reviews focus specifically on Crohn's disease and ulcerative colitis.

A Cochrane review by Akobeng et al. (2018) evaluated the efficacy of enteral nutrition (i.e., oral nutritional formulas) for the maintenance of remission in Crohn's disease. Studies that compared enteral nutrition with no intervention, placebo, or any other treatment were reviewed, and four RCTs were selected that met the inclusion criteria. Of these four studies, each used different comparison groups: (1) compared two different types of enteral nutrition diets (n = 33); (2) compared a half enteral nutrition diet to a free diet (n = 51); (3) compared an enteral nutrition diet to 6-mercaptopurine (an immunosuppressive drug) or a no treatment control group; and (4) compared an enteral nutrition diet to mesalamine (a nonsteroidal anti-inflammatory). The results of the studies could not be pooled due to the differences in comparison groups and the way outcomes were assessed; therefore, the results of each study were assessed independently. The review determined the certainty of evidence for the primary outcome (relapse) provided in the included studies as very low (three studies) or low (one study) based on the GRADE (Grading of Recommendations, Assessment, Development, and Evaluations) criteria (Guyatt et al., 2008; Schünemann et al., 2011).

> The study that compared two different types of enteral nutrition diets (elemental vs. polymeric) found no significant difference in remission rates at 12 months. For participants in the elemental diet group, 58% (11/19) had experienced a relapse compared to 57% (8/14) of participants in the polymeric diet group. This study did not report on any secondary outcomes (Verma et al., 2001).
>
> Participants who received half of their total daily caloric intake as enteral nutrition were found to have a significantly lower chance of relapse at 12 months compared to participants who were in the free diet group. For participants in the enteral nutrition group, 35% (9/26) had experienced a relapse compared to 64% (16/25) of participants in the free diet group. This study reported no differences in weight change between the two diet groups and no adverse events in either group (Takagi et al., 2006).
>
> The study that compared an enteral nutrition diet to 6-mercaptopurine (6-MP) found no significant difference between the two groups in remission rates at 12 months. For participants in the enteral nutrition group, 38% (12/32) experienced a relapse compared to 23% (7/30) of participants in the 6-MP group. Adverse events were reported in both groups. In the enteral nutrition diet group, one participant required surgery due to worsening Crohn's disease. In the 6-MP group, four adverse events were noted, including liver injury (two participants), hair loss (one participant), and surgery due to an abscess (one participant) (Hanai et al., 2012).
>
> Lastly, no significant difference was found in remission rates at 6 months between an enteral nutrition diet and mesalamine. For participants in the enteral nutrition group, 42% (18/43) had experienced a relapse compared to 55% (22/40) of participants in the mesalamine group. For the

secondary outcomes reported in this study, weight gain was reported to be higher in the enteral nutrition group than the mesalamine group (Triantafillidis et al., 2010).

Another Cochrane review by Narula et al. (2018) evaluated the effectiveness of an exclusive enteral nutrition diet for induction of remission in Crohn's disease. It is important to note that the studies in this review included enteral therapy delivered via nasogastric feeding tubes and orally. Ten studies were identified that compared enteral nutrition to steroid therapy. This included a meta-analysis of eight trials (n = 409 participants) in which no significant difference was found in remission rates. For participants in the enteral nutrition group, 55% (111/223) achieved remission compared to 72% (133/186) of participants in the steroid therapy group.

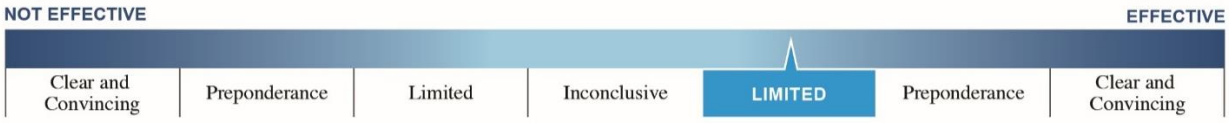
A subgroup analysis by age was performed to examine remission rates separately for adults and children. The results of the subgroup analysis showed a significant difference in remission rates for adults, such that higher remission rates were found for those receiving steroid therapy (73%) compared to enteral nutrition (45%). The opposite result was found for children, such that significantly higher remission rates were found for those receiving enteral nutrition (83%) compared to steroid therapy (61%).

Adverse events and withdraw rates were also compared across the two groups. No difference in the rate of adverse events was found; however, participants receiving enteral nutrition treatment were more likely to withdraw from trials due to adverse events than participants receiving steroid therapy. The most common reason for study withdrawal was an inability to tolerate (unpalatable due to taste or smell) the enteral nutrition diet. The authors rated the quality of evidence for all outcomes as very low, based on the GRADE criteria.

A systematic review by Marsh et al. (2022) examined the effect of dietary management approaches in the treatment of ulcerative colitis. The review included eight randomized control trials and two retrospective analyses. These studies compared different methods of dietary management, including enteral nutrition (EN), total parenteral nutrition (TPN), elimination diets, and standard oral diets. Patients were also receiving steroid therapy as the primary treatment in all studies. Of relevance to this analysis, four studies examined the effects of EN or TPN to a standard oral diet and found no difference in remission rates or disease progression (i.e., need for a colectomy) between patients who received an enteral nutrition diet compared to a standard oral diet. The authors assessed the quality of evidence on the GRADE criteria, and rated these four studies as low to very low due to small sample sizes and methodological flaws.

Summary of findings regarding nutritional treatment for Crohn's disease: There is limited evidence 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).

Figure 1. Effectiveness of Nutritional Treatment for Crohn's Disease



Summary of findings regarding nutritional treatment for ulcerative colitis: There is insufficient evidence from one systematic review on the efficacy of nutritional treatment for ulcerative colitis. Though the studies presented above in the systematic review (Marsh et al., 2022) 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. A grading of insufficient evidence does not indicate that there is no effect, but rather means that the effect is unknown.

Figure 2. Effectiveness of Nutritional Treatment for Ulcerative Colitis

Effectiveness of Nutritional Treatment (Formula and Special Food Products) for *Inherited Metabolic Disorders*

CHBRP identified no studies that examined the effectiveness of nutritional treatment for inherited metabolic disorders, as discussed in the *Methodological Considerations*. This section provides an overview of the treatment for inherited metabolic disorders based on available review articles, treatment guidelines (see Table 5), and recommendations.

Inherited metabolic disorders are genetic disorders that affect an individual's ability to metabolize nutrients due to an enzymatic or transporter deficiency. These deficient enzymes may result in deficiency of compounds that may be needed for proper growth and development or result in the accumulation of a toxic chemical that is harmful. Left untreated, these disorders can result in severe intellectual disability, irreversible neurologic damage, or death A review article by Boyer et al. (2015) outlines the nutritional management for inherited metabolic disorders as consisting of two basic principles. The first principle in management of these disorders is to reduce the concentrations of the nutrients that result in toxic buildup, through dietary restriction. The second principle of management is to provide the deficient nutrients for normal growth and development, through dietary supplements. Treatment guidelines for these conditions reflect a consensus that this therapy must be maintained throughout the lifespan (Häberle et al., 2012; Huemer et al., 2015; Singh et al., 2005). The majority of these guidelines used methodologies established by the Scottish Intercollegiate Guideline Network (SIGN) and Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) (Guyatt et al., 2008; Harbour and Miller, 2001). These recommendations are rated as Grade D, given that the evidence is primarily based on expert opinion (Häberle et al., 2012; Technical Expert[33]).

Table 5. Nutritional Treatment Guidelines for the Most Prevalent Inherited Metabolic Disorders

Type of Disorder	Primary Treatment Guidelines
Amino acid and protein metabolism disorders	
Amino acid disorders	Strict dietary control intake of the offending amino acid; diet includes only prescribed amounts of medical foods, specialized formula, typical formula, and low-protein foods; supplements of a specific vitamin cofactor, carnitine, and specific amino acid supplements may also be required.
Organic acid disorders	Strict dietary control intake of the offending organic acid precursor; diet includes only prescribed amounts of medical foods, specialized formula, typical formula, and low-protein foods; supplements of a specific vitamin cofactor, carnitine, and specific amino acid supplements may also be required.
Urea cycle disorders	Strict dietary control of offending amino acids; specialized formula that limits excessive nitrogen intake by providing only essential amino acids; supplements of a specific vitamin

[33] Personal communication with Renata C. Gallagher, MD, PhD, Medical Director, Metabolism Clinic, UCSF Health, April 2023.

	cofactor, carnitine, and specific amino acid supplements may also be required.
Carbohydrate metabolism disorders	Dietary restriction limiting any toxic sugars; providing regular glucose and glucose polymers via specialized formulas.
Fatty acid oxidation metabolism disorders	Dietary restriction limiting fat intake and supplying alternative fat as orally administered medium-chain triglyceride–enriched formula or as a supplement.

Source: California Health Benefits Review Program, 2023.

Summary of findings regarding nutritional treatment for inherited metabolic disorders: There is *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. A grade of *insufficient evidence*, in this case, is not an evaluation of the effectiveness of the treatment guidelines, but rather an assessment that the effect is not measurable.

Figure 3. Effectiveness of Nutritional Treatment for Inherited Metabolic Disorders

Summary of Findings

CHBRP found *limited evidence* from two Cochrane reviews on the effect of nutritional treatment for Crohn's disease. The studies in these reviews provided *limited evidence* on the efficacy of enteral nutrition treatment for inducing and maintaining remission in patients with Crohn's disease and when compared to standard drug treatment. CHBRP found *insufficient evidence* on the effect of nutritional treatment for ulcerative colitis. The low quality of the studies included in the reviews contributed to the gradings provided in this medical effectiveness analysis. Methodological flaws in study designs, small sample sizes, concurrent drug therapy, inconsistency in outcomes reporting and comparison groups, and differences in prescribed nutritional interventions, result in a literature base that is not as rigorous, thereby limiting the certainty of conclusions drawn from the evidence.

CHBRP found *insufficient evidence* on the effect of nutritional treatment for inherited metabolic disorders. The clinical practice guidelines that are available for treatment of these conditions are based primarily on expert opinion and provided *insufficient evidence* on the efficacy of nutritional treatment for inherited metabolic disorders. There are several limitations that contribute to the lack of evidence for treatment of these conditions, including the small number of individuals with these conditions, need for timely treatment, and ethical barriers to conducting randomized controlled trials with this population. The current guidelines for treatment of these conditions reflect expert consensus on nutritional treatment for these conditions, and there are significant risks associated with withholding or delaying treatment in this population, including physical and mental developmental delays, internal injuries, or death. A grade of *insufficient evidence* in this case is not an evaluation of the effectiveness of the treatment guidelines, but rather an assessment that the effect is not measurable.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 620 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) to extend coverage of formulas and special foods from phenylketonuria (PKU) only to other inherited metabolic and digestive disorders.

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 DMHC-regulated plans.[34] As noted in the *Policy Context* section, AB 620 would impact these CalPERS enrollees. Although the bill applies to Medi-Cal beneficiaries, CHBRP assumed that 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 and did not include them in this analysis.

This section reports the potential incremental impacts of AB 620 on estimated baseline benefit coverage, utilization, and overall cost.

Analytic Approach and Key Assumptions

There are multiple inherited metabolic or digestive disorders that could fall under the purview of AB 620. CHBRP analyzed the inherited metabolic disorders collectively although rates of formula and special food product use would likely differ by condition.

CHBRP identified seven *digestive disorders* that would have formula and special food product use, including cystic fibrosis, Crohn's disease, ulcerative colitis, eosinophilic enteritis, enteropathy, chronic pancreatitis, and intestinal malabsorption. CHBRP assumed that enrollees with any of these seven conditions who use formula and special food products collectively account for 85% of total enrollees with a digestive condition who use formula or special food products.

Enrollees with an inherited metabolic disorder or digestive disorder who use formulas and special food products were categorized into the following four populations:

1) Enrollees with *inherited metabolic disorders* with formulas and special food products *fed via tube feeding*;

2) Enrollees with *digestive disorders* with formulas and special food products *fed via tube feeding*;

3) Enrollees with *inherited metabolic disorders* with formulas and special food products *consumed orally*; and

4) Enrollees with *digestive disorders* with formulas and special food products *consumed orally.*

AB 620 does not require coverage for formulas and special food products except to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet. CHBRP assumes the administration of a benefit being tied to such a benchmark would be burdensome and **assumes coverage of the full cost of formulas and special food products and not only the portion that exceeds the cost of a normal diet.**

[34] For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

CHBRP did not include infants with reflux in this analysis. If AB 620 were to require coverage of formulas for acute conditions such as reflux, the cost impacts presented in this analysis may be significantly understated.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

Baseline and Postmandate Benefit Coverage

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.[35]

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 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.

Baseline and Postmandate Utilization

CHBRP estimates 148 commercial and CalPERS enrollees will use formula or special foods for other *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.

Baseline and Postmandate Per-Unit Cost

The annual cost of formulas and special food products for enrollees with *inherited metabolic disorders* is $6,369 for covered formulas and special food products, and $5,846 for noncovered formulas and special food products at baseline. The annual cost of formulas and special food products for enrollees with *digestive disorders* is $5,758 for covered formulas and special food products, and $2,619 for noncovered formulas and special food product at baseline.

[35] The Medi-Cal Rx Provider Manual, v 6.0, dated April 1, 2023, indicates that treatments for *PKU or other digestive and inherited metabolic disorders*, including formulas and special food products that are part of a prescribed diet, are covered benefits in Medi-Cal. Available at: https://medi-calrx.dhcs.ca.gov/cms/medicalrx/static-assets/documents/provider/forms-and-information/manuals/Medi-Cal_Rx_Provider_Manual.pdf.

CHBRP assumes per user cost of formulas and special food products will not change as a result of AB 620. However, due to the projected change in the mix of digestive conditions for enrollees using covered formulas and special food products, the average cost of formulas and special food products per enrollee per year is projected to decrease from $5,758 to $5,013.

Baseline and Postmandate Expenditures

Table 6 and Table 7 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

AB 620 would increase total net annual expenditures by $24,187,000 or 0.02% for enrollees with DMHC-regulated plans and 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.

Premiums

Changes in premiums as a result of AB 620 would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 6, and Table 7) with health insurance that would be subject to AB 620.

In the DMHC-regulated commercial plans, the largest premium increase (0.0268%) would occur for the small-group market, whereas the individual market would face the smallest premium increase (0.0261%). Within the individual DMHC-regulated market, health plans offered by Covered California would experience a 0.0263% premium increase.

Among CDI-regulated commercial plans, the largest premium increase would be for the individual market (0.0245%), and the smallest would occur for the small-group market (0.0227%). Covered California individual market plans regulated by CDI would experience a 0.0280% increase in premiums. For enrollees associated with CalPERS in DMHC-regulated plans, there would be a 0.0227% premium increase due to AB 620.

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there will be no impact because formulas and special food products are covered by Medi-Cal Rx which is not DMHC-regulated.

Enrollee Expenses

AB 620–related changes in cost sharing for covered benefits (deductibles, copays, etc.) and out-of-pocket expenses for noncovered benefits would vary by market segment. Note that such changes are related to the number of enrollees (see Table 1, Table 6, and Table 7) with health insurance that would be subject to AB 620 expected to use the relevant treatments during the year after enactment.

CHBRP projects no change to copayments or coinsurance rates but does project an increase in utilization of formulas and special food products and therefore an increase in enrollee cost sharing.

It is possible that some enrollees have incurred expenses related to formulas and special food products for which coverage was denied, but CHBRP cannot estimate the frequency with which such situations occur and so cannot offer a calculation of impact.

In the DMHC-regulated commercial plans, the largest enrollee cost-sharing increase, $0.0190 PMPM, would occur for the individual market, whereas the large-group market would face the smallest cost-

sharing increase, $0.0021 PMPM. Within the individual DMHC-regulated market, health plans offered by Covered California would experience a $0.0176 PMPM cost-sharing increase.

In the CDI-regulated commercial plans, the largest enrollee cost-sharing increase, $0.0274 PMPM, would occur for the individual market, whereas the large-group market would face the smallest cost-sharing increase, $0.0035 PMPM. Within the individual CDI-regulated market, health plans offered by Covered California would experience a $0.0359 PMPM cost-sharing increase.

For enrollees associated with CalPERS in DMHC-regulated plans, there would be a $0.0021 PMPM cost-sharing increase due to AB 620.

For Medi-Cal beneficiaries enrolled in DMHC-regulated plans, there will be no impact because formulas and special food products are covered by Medi-Cal Rx, which is not DMHC-regulated.

Average enrollee out-of-pocket expenses per user

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. CHBRP estimates are based on claims data and may underestimate the cost savings for enrollees due to carriers' ability to negotiate discounted rates that are unavailable to patients and their families.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1, Table 6, and Table 7), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 620.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 620.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

This subsection estimates the extent to which lack of (or insufficient) benefit coverage prompts enrollees to seek care from public programs or other payers, including charities, or other state departments (e.g., Department of Education for autism).

In general, CHBRP assumes that enrollees who do not have benefit coverage pay for treatments/services directly (e.g., self-pay). However, in some cases, those noncovered benefits may be provided by public programs or by other, alternative sources.

If CHBRP is unable to provide a quantifiable estimate, then qualitative statements regarding potential shifts may be made as long as there is evidence that public or private entities are currently paying for services for enrollees who do not have coverage for the mandate service/benefit.

Table 6. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	*Medi-Cal (excludes COHS) (c)*		*Large Group*	*Small Group*	*Individual*	**Total**
					Under 65	*65+*				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to AB 620	7,780,000	2,212,000	2,618,000	882,000	0	0	371,000	35,000	127,000	14,025,000
Premiums										
Average portion of premium paid by employer (e)	$473.17	$417.10	$0.00	$581.85	$254.61	$543.16	$490.57	$517.32	$0.00	$93,424,638,000
Average portion of premium paid by enrollee	$122.17	$180.13	$645.33	$113.49	$0.00	$0.00	$180.61	$168.99	$626.90	$39,493,007,000
Total premium	**$595.34**	**$597.23**	**$645.33**	**$695.34**	**$254.61**	**$543.16**	**$671.18**	**$686.31**	**$626.90**	**$132,917,645,000**
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$40.98	$127.06	$168.73	$49.17	$0.00	$0.00	$99.22	$184.48	$208.51	$13,857,141,000
Expenses for noncovered benefits (f)	$0.02	$0.03	$0.03	$0.02	$0.00	$0.00	$0.02	$0.03	$0.03	$3,965,000
Total expenditures	**$636.35**	**$724.32**	**$814.09**	**$744.53**	**$254.61**	**$543.16**	**$770.42**	**$870.82**	**$835.43**	**$146,778,751,000**

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and non-grandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.1% are state retirees, state employees, or their dependents.

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[36]

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[36] For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

Table 7. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2024

	DMHC-Regulated						CDI-Regulated			
	Commercial Plans (by Market) (a)			Publicly Funded Plans			Commercial Policies (by Market) (a)			
	Large Group	*Small Group*	*Individual*	*CalPERS (b)*	*Medi-Cal (excludes COHS) (c)*		*Large Group*	*Small Group*	*Individual*	**Total**
					Under 65	*65+*				
Enrollee counts										
Total enrollees in plans/policies subject to state mandates (d)	7,780,000	2,212,000	2,618,000	882,000	8,043,000	774,000	371,000	35,000	127,000	22,842,000
Total enrollees in plans/policies subject to AB 620	7,780,000	2,212,000	2,618,000	882,000	0	0	371,000	35,000	127,000	14,025,000
Premiums										
Average portion of premium paid by employer (e)	$0.1254	$0.1119	$0.0000	$0.1322	$0.0000	$0.0000	$0.1140	$0.1177	$0.0000	$16,630,000
Average portion of premium paid by enrollee	$0.0324	$0.0483	$0.1682	$0.0258	$0.0000	$0.0000	$0.0420	$0.0384	$0.1533	$10,299,000
Total premium	$0.1577	$0.1602	$0.1682	$0.1579	$0.0000	$0.0000	$0.1560	$0.1561	$0.1533	$26,929,000
Enrollee expenses										
Cost sharing for covered benefits (deductibles, copays, etc.)	$0.0021	$0.0132	$0.0190	$0.0021	$0.0000	$0.0000	$0.0035	$0.0205	$0.0274	$1,225,000
Expenses for noncovered benefits (f)	−$0.0219	−$0.0252	−$0.0274	−$0.0220	$0.0000	$0.0000	−$0.0221	−$0.0279	−$0.0299	−$3,965,000
Total expenditures	$0.1379	$0.1482	$0.1597	$0.1381	$0.0000	$0.0000	$0.1374	$0.1487	$0.1509	$24,188,000
Percent change										
Premiums	0.0265%	0.0268%	0.0261%	0.0227%	0.0000%	0.0000%	0.0232%	0.0227%	0.0245%	0.0203%
Total expenditures	0.0217%	0.0205%	0.0196%	0.0185%	0.0000%	0.0000%	0.0178%	0.0171%	0.0181%	0.0165%

Source: California Health Benefits Review Program, 2023.

Notes: (a) Includes enrollees with grandfathered and non-grandfathered health insurance acquired outside or through Covered California (the state's health insurance marketplace).

(b) Includes only CalPERS enrollees in DMHC-regulated plans. Approximately 51.71are state retirees, state employees, or their dependents.

(c) Includes only Medi-Cal beneficiaries enrolled in DMHC-regulated plans. Includes those who are also Medicare beneficiaries.

(d) Enrollees in plans and policies regulated by DMHC or CDI. Includes those associated with Covered California, CalPERS, or Medi-Cal.[37]

(e) In some cases, a union or other organization – or Medi-Cal for its beneficiaries.

(f) Includes only those expenses that are paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS = California Public Employees' Retirement System; CDI = California Department of Insurance; COHS = County Organized Health Systems; DMHC = Department of Managed Health Care.

[37] For more detail, see CHBRP's resource, *Sources of Health Insurance in California*, available at: http://chbrp.org/other_publications/index.php.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 620 would mandate coverage of testing and treatment of phenylketonuria (PKU) or other digestive and inherited metabolic disorders.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[38] of AB 620 on nutritional treatment for proper growth and development for inherited metabolic disorders, and for inducing and maintaining remission and prevention of relapse of digestive disorders, on potential disparities, barriers, and harms.

Estimated Public Health Outcomes

Measurable health outcomes relevant to AB 620 include proper growth and development for inherited metabolic disorders, and inducing and maintaining remission and prevention of relapse of digestive disorders.

As presented in *Medical Effectiveness*, there was insufficient evidence on the effect of nutritional treatment for *inherited metabolic disorders*. There was limited evidence on the effect of nutritional treatment of Crohn's disease for inducing and maintaining remission compared to standard drug treatment, and insufficient evidence on the effect of nutritional treatment for ulcerative colitis.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, CHBRP estimates that, postmandate,163 enrollees will use formulas or special food products for *other metabolic disorders*, and 5,185 enrollees will use formulas or special food products for *digestive disorders*. Additionally, for 1,507 enrollees who currently use these treatments and would have this as an additional benefit coverage postmandate, the average decrease in annual out-of-pocket expenses per enrollee would be $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:

- 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.
- Although utilization of nutritional treatment for *digestive disorders* would increase, there is 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.

Although CHBRP projects no measurable public health impact due to the findings described above, at the person-level, enrollees with inherited metabolic disorders or digestive disorders prescribed formulas or food products consumed orally would have out-of-pocket costs reduced on average by $2,628. This reduced financial burden could affect enrollees utilizing these treatments positively, though CHBRP is not able to project quantitative impacts. However, as discussed in the *Background* section, these person-level impacts may depend on the tolerance of and compliance with the nutritional treatment or drug treatment

[38] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

for the enrollee. Person-level impacts may also depend on access to professional monitoring of nutritional deficiencies.

Potential Harms From AB 620

When data are available, CHBRP estimates the marginal change in relevant harms associated with interventions affected by the proposed mandate. In the case of AB 620, as discussed in *Medical Effectiveness,* CHBRP found limited evidence on the effect of nutritional treatment for Crohn's disease in inducing and maintaining remission compared to standard drug treatment, and insufficient evidence on the effect of nutritional treatment for ulcerative colitis. Based on these findings, if nutritional treatment for these *digestive disorders* were to increase, there may be a lack of efficacy for this treatment as compared to drug treatment.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 620, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization 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.

Cost Impacts

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.

APPENDIX A TEXT OF BILL ANALYZED

On February 14, 2023, the California Assembly Committee on Health requested that CHBRP analyze AB 620, as introduced on February 9, 2023.

ASSEMBLY BILL **NO. 620**

Introduced by Assembly Member Connolly

February 09, 2023

An act to amend Section 1374.56 of the Health and Safety Code, and to amend Section 10123.89 of the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 620, as introduced, Connolly. Health care coverage for metabolic disorders.

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 disability insurers, including health insurers, by the Department of Insurance. Existing law requires a health care service plan contract and disability insurance policy that provides coverage for hospital, medical, or surgical expenses and is issued, amended, delivered, or renewed on and after July 1, 2000, to provide coverage for the testing and treatment of phenylketonuria, including coverage for the formulas and special food products that are part of a prescribed diet, as specified.

This bill would require a health care service plan contract and 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 other digestive and inherited metabolic disorders. Because a violation of the bill’s requirements by a health care service plan would be a crime, the 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 1374.56 of the Health and Safety Code is amended to read:

1374.56. (a) On and after ~~July 1, 2000,~~ *January 1, 2024*, every health care service plan contract, except a specialized health care service plan contract, issued, amended, delivered, or renewed in this state that provides coverage for hospital, medical, or surgical expenses shall provide coverage for the testing and treatment of phenylketonuria (PKU) *or other digestive and inherited metabolic disorders* under the terms and conditions of the plan contract.

(b) Coverage for treatment of ~~phenylketonuria (PKU)~~ *PKU or other digestive and inherited metabolic disorders* shall include those formulas and special food products that are part of a diet prescribed by a licensed physician and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease *or other digestive and inherited metabolic disorders* and who participates in or is authorized by the plan, provided 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 ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.*

(c) Coverage pursuant to this section 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.

(d) For purposes of this section, the following definitions shall apply:

(1) "Formula" means an enteral product or enteral products for use at home that are prescribed by a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments, as medically necessary for the treatment of ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.*

(2) "Special food product" means a food product that is both of the following:

(A) Prescribed by a physician or nurse practitioner for the treatment of ~~phenylketonuria (PKU)~~ *PKU or other digestive and inherited metabolic disorders* and is consistent with the recommendations and best practices of qualified health professionals with expertise germane to, and experience in the treatment and care of, ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.* It does not include a food that is naturally low in protein, but may include a food product that is specially formulated to have less than one gram of protein per serving.

(B) Used in place of normal food products, such as grocery store foods, used by the general population.

SEC. 2. Section 10123.89 of the Insurance Code is amended to read:

10123.89. (a) On and after ~~July 1, 2000,~~ *January 1, 2024*, every policy of disability insurance issued, amended, delivered, or renewed in this state that provides coverage for hospital, medical,

or surgical expenses shall provide coverage for the testing and treatment of phenylketonuria (PKU) *or other digestive and inherited metabolic disorders* under the terms and conditions of the policy.

(b) Coverage for treatment of ~~phenylketonuria (PKU)~~ *PKU or other digestive and inherited metabolic disorders* shall include those formulas and special food products that are part of a diet prescribed by a licensed physician and managed by a health care professional in consultation with a physician who specializes in the treatment of metabolic disease *or other digestive and inherited metabolic disorders* and who participates in or is authorized by the insurer, provided 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 ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.*

(c) Coverage pursuant to this section is not required except to the extent that the cost of necessary formulas and special food products exceeds the cost of a normal diet.

(d) For purposes of this section, the following definitions shall apply:

(1) "Formula" means an enteral product or enteral products for use at home that are prescribed by a physician or nurse practitioner, or ordered by a registered dietician upon referral by a health care provider authorized to prescribe dietary treatments, as medically necessary for the treatment of ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.*

(2) "Special food product" means a food product that is both of the following:

(A) Prescribed by a physician or nurse practitioner for the treatment of ~~phenylketonuria (PKU)~~ *PKU or other digestive and inherited metabolic disorders* and is consistent with the recommendations and best practices of qualified health professionals with expertise germane to, and experience in the treatment and care of, ~~phenylketonuria (PKU).~~ *PKU or other digestive and inherited metabolic disorders.* It does not include a food that is naturally low in protein, but may include a food product that is specially formulated to have less than one gram of protein per serving.

(B) Used in place of normal food products, such as grocery store foods, used by the general population.

(e) This section shall not apply to vision-only, dental-only, accident-only, specified disease, hospital indemnity, Medicare supplement, long-term care, or disability income insurance, except that for accident only, specified disease, or hospital indemnity coverage, coverage for benefits under this section shall apply to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or contract. ~~Nothing in this section shall be construed as imposing~~ *This section does not impose* a new benefit mandate on accident only, specified disease, or hospital indemnity insurance.

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 the effects of nutritional treatment (provided orally as formula or special food product) for digestive and inherited metabolic disorders were identified through searches of PubMed (MEDLINE), Cochrane Library, Embase, and CINAHL. Websites maintained by the following organizations were also searched: National Institutes of Health (NIH), the Scottish Intercollegiate Guidelines Network (SIGN), the National Organization for Rare Disorders (NORD), and the Crohn's and Colitis Foundation. The search was limited to abstracts of studies published in English. The search was limited to studies published from 2013 to present. CHBRP relied on two Cochrane reviews published in 2018 for findings related to Crohn's disease. Studies of PKU and enteral nutrition via tube feeding were omitted from the medical effectiveness review because of existing coverage for these conditions and treatments.

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 247 articles, of which 22 were reviewed for inclusion in this report. A total of three articles (two Cochrane reviews and one systematic review) were included in the medical effectiveness review for AB 620. The other articles were eliminated because they did not focus on oral enteral nutrition, were narrative reviews and did not report findings from clinical research studies, or were of poor quality.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead considers 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*.[39] 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;*

[39] Available at: www.chbrp.org/about/analysis-methodology/medical-effectiveness-analysis.

- *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 (* indicates truncation of word stem)

Searches employed the following formula: Condition x Treatment x Outcomes

Condition:

Digestive disorders

Inflammatory bowel disease (IBD)

Crohn's disease

Ulcerative colitis

Inherited metabolic disorders

Amino acid metabolism*

Urea cycle*

Maple syrup urine disease

Treatment:

Prescribed dietary therapy

Specialized nutrition

Nutritional therapy

Specialized formula

Specialized food products

Enteral nutrition (EN)

Comparison Treatments:

Normal diet

Free diet

Corticosteroids

Steroid therapy

Biologics

Outcomes:

Disease management

*Remission

*Relapse

Symptom control

Quality of life

Growth

Development

Healthcare utilization

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[40] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[41]

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

CHBRP surveyed DHMC- and CDI-regulated insurance carriers, as well as CalPERS carriers, and received four commercial responses and seven CalPERS responses. Responses to this survey represented 82% of the commercial market.

For this analysis, CHBRP relied on CPT codes to identify services related to AB 620.

Analysis-Specific Caveats and Assumptions

Methodology and Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated insurance plans, CDI-regulated policies, and CalPERS plans subject to the requirements of the Knox-Keene Health Care Service Plan Act.
- Based on coverage documents from the California Department of Health Care Services (DHCS), we assumed that all Medi-Cal plans, including Medi-Cal managed care plans regulated by the DMHC, have coverage of testing, treatment, formula, and special food products for PKU or other digestive and inherited metabolic disorders.
- 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.
- CHBRP identified 4 populations that would be affected by AB 620:
    - Enrollees with *inherited metabolic disorders* with formulas and special food products *fed via tube feeding;*
    - Enrollees with *digestive disorders* with formulas and special food products *fed via tube feeding;*

[40] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[41] See method documents posted at https://www.chbrp.org/about/analysis-methodology/cost-impact-analysis; in particular, see *Cost Analyses: Data Sources, Caveats, and Assumptions*.

  - Enrollees with *inherited metabolic disorders* with formulas and special food products *consumed orally;* and
  - Enrollees with *digestive disorders* with formulas and special food products *consumed orally*.

- Based on the carrier survey responses, tube feeding is fully covered for both inherited metabolic disorders and digestive disorders at baseline. 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.
- AB 620 does not require coverage for formulas and special food products except to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet. CHBRP assumes the administration of a benefit being tied to such a benchmark would be burdensome and assumes coverage of the full cost of formulas and special food products, and not only the portion that exceeds the cost of a normal diet. This results in a more conservative impact for AB 620.

Methodology and Assumptions for Baseline and Postmandate Utilization

Inherited metabolic disorder and digestive disorder identification

- Enrollees with inherited metabolic disorders or digestive disorders were identified in Milliman's proprietary 2021 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD). The data was limited to California commercial enrollees and split into 0-1, 2-17, 18-64, and 65+-year age groups.
- Enrollees with *inherited metabolic disorders* were identified as having one of the following ICD 10 diagnosis codes on non-laboratory and non-radiology claims on three separate dates. CHBRP required three separate dates to identify enrollees who were actively managing their condition under the care of a physician as these enrollees may be users of special food products or formulas.
  - E701, E7020, E7021, E7029, E7040, E7041, E7049, E705, E708, E7081, E7089, E709, E710, E71110, E71111, E71118, E71120, E71121, E71128, E7119, E712, E7130, E71310, E71311, E71312, E71313, E71314, E71318, E7132, E7139, E7140, E7141, E7142, E7143, E71440, E71448, E7150, E71510, E71511, E71518, E71520, E71521, E71522, E71528, E71529, E7210, E7211, E7212, E7219, E7220, E7221, E7222, E7223, E7229, E723, E724, E7250, E7251, E7252, E7253, E7259, E728, E7281, E7289, E729, E7410, E7411, E7412, E7419, E7420, E7421, E7429, E8840, E8841, E8842, E8849.
- Enrollees with *digestive disorders* were identified as having one of following seven conditions that affect the gastrointestinal tract using ICD 10 codes appearing on non-laboratory and non-radiology claims on three separate days in the following hierarchal order:
  - Cystic fibrosis: E8411, E8419, E848, E849.
  - Crohn's disease: K5000, K50011, K50012, K50013, K50014, K50018, K50019, K5010, K50111, K50112, K50113, K50114, K50118, K50119, K5080, K50811, K50812, K50813, K50814, K50818, K50819, K5090, K50911, K50912, K50913, K50914, K50918, K50919.
  - Ulcerative colitis: K5100, K51011, K51012, K51013, K51014, K51018, K51019, K5180, K51811, K51812, K51813, K51814, K51818, K51819, K5190, K51911, K51912, K51913, K51914, K51918, K51919.

- Eosinophilic enteritis: K200, K5281, K5282.
- Enteropathy: C862, K522, K5221, K5222, K5229.
- Chronic pancreatitis: K860, K861, K8681, Q453, Z90410, Z90411.
- Intestinal malabsorption: K904, K9049, K9089, K909, K912.

Formulas and special food products identification

- Of the enrollees with an inherited metabolic disorder or digestive disorder, enrollees receiving formulas and special food products through tube feeding were identified using the following:
  - CPT codes: B4034, B4035, B4036, B4081, B4082, B4083, B4087, B4088, B9000, B9002, B9998, Q9994, S9340, S9341, S9342, S9343.[42]
  - ICD 10 diagnosis codes: Z931, Z4659.
- Of the enrollees with an inherited metabolic disorder or digestive disorder, enrollees receiving formulas and special food products orally were identified using the following CPT codes:
  - B4036, B4081, B4082, B4083, B4087, B4088, B4100, B4102, B4103, B4104, B4105, B4149, B4150, B4152, B4153, B4154, B4155, B4157, B4158, B4159, B4160, B4161, B4162, B9000, B9002, B9998, Q9994, S9340, S9341, S9342, S9343, S9432, S9433, S9434, S9435.[43]
- Outpatient pharmacy claims were examined for prescriptions in the Enteral Feeding Supply, Infant Food, Nutritional Supplements, Tube Feeding, and Infant Supplies therapeutic drug classes, but very few were found and not included in this analysis due to credibility issues.

Formulas and special food products utilization – metabolic disorders

- CHBRP assumed the 2021 CHSD utilization rate of formulas and special food products consumed orally for enrollees with inherited metabolic disorders is the utilization rate of formulas and special food products covered by insurance at baseline.
- The utilization rate was trended from 2021 to 2024 using 0% annualized trend.
- Based on physician review of the coverage limitations identified in the carrier survey, CHBRP assumed 90% of the conditions requiring utilization of formulas and special food products for inherited metabolic disorders are covered at baseline.[44] CHBRP assumed the utilization rate of formulas and special food products covered by insurance at postmandate is 10% greater than the utilization rate at baseline.
- Of the additional 10% utilization covered by insurance postmandate, CHBRP assumed a portion of the enrollees would purchase the formulas and special food products as a noncovered benefit at baseline. Using Milliman's Health Cost Guidelines utilization adjustment factors and the price differential between the full price and cost sharing only portion of formulas and special food products, CHBRP determined the portion of enrollees who purchased the formulas and special food products as a noncovered benefit at baseline.

[42] CPT copyright 2023 American Medical Association. All rights reserved.
[43] CPT copyright 2023 American Medical Association. All rights reserved.
[44] Communication with Dr. Carol Bazell, March 14, 2023.

Formulas and special food products utilization – digestive disorders

- CHBRP assumed the 2021 CHSD utilization rate of formulas and special food products consumed orally for enrollees with digestive disorders is the utilization rate of formulas and special food products covered by insurance at baseline.
- The utilization rate was trended from 2021 to 2024 using 0% annualized trend.
- CHBRP assumed the total postmandate utilization rate of formula and special food products (including tube fed utilization) for enrollees with digestive disorders is 25% (for ages 0-1 and ages 2-17 years) or 15% (for ages 18-64 and 65+ years).[45] Enrollees under age 18 years are assumed to have a higher utilization rate than adults due to failure to grow. The postmandate utilization rate of formula and special food products consumed orally is the total assumed utilization rate above (15% or 25% depending on age) net the tube-fed utilization.
- If the utilization rate of formula and special food products for enrollees is greater than the assumed postmandate utilization rate, CHBRP assumed the formula and special food products for that condition are fully covered at baseline.
- Of the additional utilization covered by insurance postmandate, CHBRP assumed a portion of the enrollees would purchase the formulas and special food products as a noncovered benefit at baseline. Using Milliman's Health Cost Guidelines utilization adjustment factors and the price differential between the full price and cost-sharing–only portion of formulas and special food products, CHBRP determined the portion of enrollees who purchased the formulas and special food products as a noncovered benefit at baseline.
- CHBRP assumed only 85% of enrollees with digestive disorders using formulas and special food products were identified by the seven digestive disorders modeled.[46] The utilization rates were increased accordingly at baseline and postmandate.

Methodology and Assumptions for Baseline and Postmandate Cost

- CHBRP calculated the average allowed cost of formulas and special food products per user based on the 2021 CHSD data.
    - The data was limited to California commercial enrollees and split into 0-1, 2-17, 18-64, and 65+ year age groups.
    - Average allowed costs per user were developed separately for inherited metabolic disorders and each of the seven digestive disorders listed above by age group.
- Allowed costs per user were trended using 3.50% trend.
- CHBRP assumed the cost of formulas and special food products per user with digestive disorders in the ages 0-2 year range is equal to the cost of formulas and special food products per user with digestive disorders in the 2-17 year range, due to credibility issues. Similarly, the cost of formulas and special food products for digestive disorders in the age 18-64 and 65+ year ranges with credibility issues were set to costs in the age 2-17 and 18-64 year ranges, respectively.
- CHBRP assumed the average cost per user of formula and special food products for the digestive conditions not captured by the seven digestive disorders above was equal to the average cost per user captured by the seven digestive disorders.

[45] Ibid.
[46] Ibid.

- For enrollees without coverage for formulas and special food products at baseline, CHBRP assumed the cost per user of formulas and special food products was equal to the cost per user of formulas and special food products covered by insurance.
- CHBRP did not assume a change in the average cost per user for formula or special food products postmandate.
- AB 620 does not require coverage for formulas and special food products except to the extent that the cost of the necessary formulas and special food products exceeds the cost of a normal diet. CHBRP assumes the administration of a benefit being tied to such a benchmark would be burdensome and assumes coverage of the full cost of formulas and special food products and not only the portion that exceeds the cost of a normal diet. This results in a more conservative impact for AB 620.

Methodology and Assumptions for Baseline and Postmandate Cost Sharing

- The paid-to-allowed ratio for the cost of formulas and special food products for inherited metabolic disorders and each of the seven digestive disorders was calculated using the 2021 CHSD data. The paid-to-allowed ratio was adjusted to reflect the plan benefit differentials by line of business.
- For enrollees with coverage for formulas and special food products at baseline and postmandate, one minus the line of business adjusted paid-to-allowed ratio was multiplied by the average per user cost of formulas and special food products per user to calculate the average cost sharing for enrollees with coverage for formulas and special food products consumed orally.
- CHBRP assumed enrollees without coverage for formulas and special food products at baseline pay the full average cost per user.

Differences between the estimates and actual amounts depend on the extent to which future experience conforms to the assumptions made in this analysis. It is almost certain that actual experience will not conform exactly to the assumptions used in this analysis. Actual amounts will differ from projected amounts to the extent that actual experience is better or worse than expected.

Determining Public Demand for the Proposed Mandate

CHBRP reviews public demand for benefits by comparing the benefits provided by self-insured health plans or policies (which are not regulated by the DMHC or CDI and therefore not subject to state-level mandates) with the benefits that are provided by plans or policies that would be subject to the mandate.

Among publicly funded self-insured health insurance policies, the preferred provider organization (PPO) plans offered by CalPERS have the largest number of enrollees. The CalPERS PPOs currently provide benefit coverage similar to what is available through group health insurance plans and policies that would be subject to the mandate.

To further investigate public demand, CHBRP used the bill-specific coverage survey to ask plans and insurers who act as third-party administrators for (non-CalPERS) self-insured group health insurance programs whether the relevant benefit coverage differed from what is offered in group market plans or policies that would be subject to the mandate. The responses indicated that there were no substantive differences.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 620 would have a substantially different impact on utilization of either the tests, treatments, or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of AB 620 would be substantially the same as the impacts in the first year (see Table 1). Minor changes to utilization and expenditures are due to population changes between the first year postmandate and the second year postmandate.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

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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Danielle Casteel, MA, of the University of California, San Diego, prepared the medical effectiveness analysis. Naomi Hillery, MPH, of the University of California, San Diego, prepared the public health impact analysis. Penny Coppernoll-Blach, MS, of the University of California, San Diego, conducted the literature search. Casey Hammer, FSA, MAAA, and Norman Yu of Milliman, provided actuarial analysis. Todd Gilmer, PhD, of the University of California, San Diego, reviewed the cost impact analysis. Renata C. Gallagher, MD, PhD, Medical Director, Metabolism Clinic, of UCSF Health, provided expert input on the analytic approach. Karen Shore, PhD, CHBRP contractor prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and a member of the CHBRP Faculty Task Force, Sara McMenamin, PhD, of the University of California, San Diego, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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