SENATE COMMITTEE ON HEALTH
Senator Akilah Weber Pierson, Chair

BILL NO: AB 1887
AUTHOR: Zbur
VERSION: May 20, 2026
HEARING DATE: July 1, 2026
CONSULTANT: Natalie Gehred

SUBJECT: Prescription drug coverage for rare diseases

SUMMARY: Requires prior authorization or utilization review for prescription drugs prescribed for the treatment of a rare disease to be complete within 30 days of the initial request by a provider. Requires approval of the prescription if the 30-day timeline is not met due to an unresolved decision or dispute. Prohibits step therapy for prescription drugs for the treatment of a rare disease if the drug is prescribed by a specialist with expertise in the condition or disease being treated and the specialist has determined the drug is medically necessary, unless a biosimilar, interchangeable biologic or generic is available.

Existing law:

1) Establishes the Department of Managed Health Care (DMHC) to regulate health plans under the Knox-Keene Health Care Service Plan Act of 1975 and the California Department of Insurance (CDI) to regulate health and other insurance. [HSC §1340, et seq. and INS §106, et seq.]

2) Requires health plans and insurers that perform utilization review (UR) or Utilization Management (UM) functions, or who delegate these functions to other contracting providers, to make decisions to approve, modify, or deny, a health service in a timely fashion appropriate for the enrollee's/insured's condition, as specified:
   a) Requires UR or UM decisions made before or during the provision of that service to be made within five business days from the receipt of the information reasonably necessary and requested to make the determination;
   b) Reduces this window to 72 hours if the enrollee/insured faces an imminent and serious threat to their health, including, but not limited to, the potential loss of life, limb, or other major bodily function, or if the normal timeframe for the decision-making process would be detrimental to their life or health or could jeopardize the enrollee's/insured's ability to regain maximum function;
   c) Requires a retrospective review decision to be communicated to the individual who received services, or to the individual's designee, within 30 days of the receipt of information that is reasonably necessary to make this determination; and,
   d) If a decision to approve, modify, or deny the request for authorization cannot be made within the timeframes specified in a) or b) due to specified reasons, requires the plan to notify the provider and the enrollee/insured of the additional information required and share the anticipated date on which a decision may be made. Requires the plan, upon receipt of all required information, to approve, modify, or deny the request for authorization within the timeframes specified in a) or b) above. [HSC §1367.01 and INS §10123.135]

3) Requires DMHC and CDI to require health plans and insurers to establish and maintain a prior authorization application programming interface for enrollees/insureds and contracted providers. [HSC §1374.196 and INS §10133.12]

4) Requires DMHC and CDI to jointly develop a uniform prior authorization form for coverage of prescription drugs. Requires a health plan or insurer to accept only a standardized prior authorization form or an electronic prior authorization process when requiring prior authorization for prescription drugs. [HSC §1367.241 and INS §10123.201]

5) Requires prior authorization or a step therapy exception to be deemed granted if a health plan or insurer fails to respond, within 72 hours upon the receipt of a completed form, or within 24 hours if exigent circumstances exist. Defines "exigent circumstances" as when an enrollee/insured is suffering from a health condition that may seriously jeopardize their life, health, or ability to regain maximum function, or when an enrollee/insured is undergoing a current course of treatment using a nonformulary drug. [HSC §1367.241 and INS §10123.191]

6) Authorizes a health plan or insurer or UR organization to require an enrollee/insured to try an AB-rated generic equivalent, biosimilar, or interchangeable biological product before providing coverage for the equivalent branded prescription. [HSC §1367.206 and INS §10123.201]

7) Requires a health plan or insurer to expeditiously grant a step therapy exception when a prescribing provider submits the necessary justification and clinical documentation supporting their determination that the required prescription drug is inconsistent with good professional practice for the provision of medically necessary covered services to the enrollee/insured, taking into consideration the enrollee's/insured's needs and medical history, along with the professional judgment of the provider. [HSC §1367.206 and INS §10123.201]

8) Excludes, from health plan or insurer prior authorization requirements, covered health care services that have been approved by the plan/insurer 90% or more times, as determined by DMHC or CDI after reporting and evaluation. Excludes outpatient drugs that are on tier three or tier four of a health plan or insurer's formulary, drugs or devices recommended for a use different from what the FDA has cleared or approved, experimental or investigational services, services prescribed for novel applications, or services provided through an out-of-network provider. Sunsets this law on January 1, 2034. [HSC §1367.025 and INS §10133.52]

This bill:

1) Prohibits a health plan or insurer from imposing step therapy for a drug approved by the federal Food and Drug Administration (FDA) for the treatment of a rare disease if the drug is prescribed by a specialist with expertise in the condition or disease being treated and the specialist has determined that the drug is medically necessary, unless a biosimilar, interchangeable biologic, or generic version of the drug is available. Defines "rare disease" as a disease that affects fewer than 200,000 people in the U.S.

2) Requires a health plan or insurer to complete prior authorization or other UR within 30 days upon the initial request for a prescription approved by the FDA for the treatment of a rare disease if the drug is prescribed by a specialist with expertise in the condition or disease being treated and the specialist has determined the drug is medically necessary, unless a biosimilar, interchangeable biologic, or generic version of the drug is available.

3) Requires the prior authorization or other UR to be immediately approved if, at the end of the 30-day period either: a decision to approve or deny the prior authorization or UR has not been made; or a dispute between the plan and provider or enrollee is ongoing.

4) Clarifies that these requirements do not affect the prior authorization timelines in existing law.

FISCAL EFFECT: According to the Assembly Committee on Appropriations:
The California Health Benefits Review Program (CHBRP) estimates premiums for health plans regulated by DMHC and offered in CalPERS would increase by $7.36 million per year, of which the state's share is about $3.4 million (General Fund). Premiums would also rise for CDI-regulated health insurance policies, the state's share of which would likely be in the low millions of dollars (General Fund).

The Legislative Analyst's Office recently warned of General Fund structural deficits of around $35 billion per year in fiscal year (FY) 2027-28 and ongoing.

CDI estimates costs of $12,000 in FY 2026-27, $26,000 in FY 2027-28, and $3,000 in FY 2028-29 and ongoing (Insurance Fund).

DMHC anticipates minor and absorbable costs.

CHBRP estimates this bill will increase total premiums for all payers by $147.8 million, including $88.7 million for employers, $25.2 million for employees in employer-sponsored insurance, and $26.6 million for individually purchased insurance

PRIOR VOTES:

Assembly Floor:	77 - 0
Assembly Appropriations Committee:	14 - 0
Assembly Health Committee:	15 - 0

COMMENTS:

1) *Author's statement.* According to the author, families living with rare diseases in California often spend years searching for a diagnosis and an effective treatment, only to be forced to "fail first" on less appropriate therapies or wait weeks or months for prior authorization from their health plan before they can start the one FDA-approved drug that can slow or stop their condition. These insurer-imposed delays are unnecessary when a specialist has prescribed an FDA approved therapy based on medical necessity, and in some cases they are reckless and life threatening. This bill removes these barriers by accelerating prior authorization and prohibiting step therapy for rare disease treatments, unless there is a generic or biosimilar alternative, thereby restoring treatment decisions to patients and their doctors. California is a global leader in rare disease research and innovation; this bill ensures that the people who rely on these breakthroughs can access them without bureaucratic obstacles, improving health outcomes and quality of life for some of our most vulnerable residents.

2) *Rare diseases and treatment.* According to the National Human Genome Research Institute (NHFRI), and as defined in the federal Food, Drug, and Cosmetic Act, rare diseases are those that affect fewer than 200,000 people in the U.S. There are over 7,000 rare diseases, according to the California Center for Rare Diseases at UCLA. Rare diseases are often

chronic, serious, and progressive in nature and can be life-threatening or life-limiting, including diseases like cystic fibrosis, Huntington's disease, Duchenne muscular dystrophy, phenylketonuria, and sickle cell disease. According to the NHGRI, about 80% of rare diseases are genetic, some of which can be identified early in California through the California Newborn Screening Program. Because many rare diseases are genetic, approximately 75% of rare diseases manifest during childhood, and 50% of patients with rare diseases are children, according to a 2025 review in *ACR Open Rheumatology*. However, according to the Rare Diseases Clinical Research Network, symptoms may not immediately appear even in diseases present from birth, and in some diseases, environmental factors may play a larger role.

The Orphan Drug Act of 1983 created an orphan drug designation that offers financial incentives for pharmaceutical manufacturers to invest in research and development for rare diseases, which, by definition, have a small market. According to a 2024 policy brief from the Congressional Research Service, since the enactment of the Orphan Drug Act, over 500 rare disease drugs have been approved. About 5% of rare diseases have an FDA-approved drug, according to a 2023 study in the *Orphanet Journal of Rare Diseases*, and up to 15% have least one promising drug candidate in the pipeline for treatment, diagnosis, or prevention.

3) *Prior authorization and step therapy in California.* Prior authorization is a form of UR or UM in which the payer grants permission for the use of the medication after the clinician prescribes it, before the patient can begin treatment. For prescription drugs, state-regulated health plans and insurers must use a standardized prior authorization form and decide requests within 72 hours (or 24 hours for urgent cases), or the request is automatically approved. If additional information is needed, the plan must notify the provider within those same timeframes or the request is deemed approved. Once the missing information is received, the 72- or 24-hour review period restarts. If no decision or request for more information is provided within the required timeframe, the prior authorization is approved for the full prescription, including refills. Denials must include notice to the provider and enrollee/insured of an external appeals process. Because rare disease drugs are specialty drugs, virtually all of them require prior authorization.

   Step therapy is a form of UR or UM in which the payer requires an ordered sequence of medications to be attempted before a different prescription medication is approved for a patient. For state-regulated insurance, step therapy is only allowed if there is more than one clinically appropriate drug available for treatment, and exceptions must be granted in situations where the required drug is contraindicated or expected to be ineffective based on the patient's clinical circumstances. As with prior authorization, step therapy exception decisions must be made within 72 hours for nonurgent requests (24 hours for exigent circumstances), or the request is deemed granted. CHBRP notes that because most treatable rare diseases only have a single FDA-labeled medication, step therapy is not typically used for rare diseases. California scores an "A" for step therapy on the state scorecard developed by the National Organization for Rare Diseases, which grades states on the step therapy exceptions process and timeline, categories of exceptions, and whether the state mandates that a step therapy protocol be based on clinical practice.

4) *Exemption from SB 306.* Concerns about prior authorization's effectiveness, administrative burden, and patient outcomes led the Legislature to passed SB 306 (Becker, Chapter 408, Statutes of 2025), which exempts health care services that have over 90% approval rates

from prior authorization by health plans and insurers. In July 2026, plans and insurers will begin reporting information to their regulators about prior authorization approval rates. DMHC and CDI will publish a list of services that receive prior authorization approval at least 90% of the time, and beginning January 1, 2028, health plans and insurers will no longer require prior authorizations for those services. Regulators are also required to publish a report on the impact of the elimination of prior authorization, including data on prior authorization requests and determinations, the volume of covered health care services subjected to prior authorization, administrative costs, timely access to care, enrollee/insured health outcomes, and data on reinstatements of prior authorization. SB 306 exempts a variety of services, including specialty outpatient drugs on Tier 4 of a drug formulary. Rare disease treatments are specialty drugs and therefore exempt from the SB 306 process.

5) *California Health Benefits Review Program (CHBRP) analysis.* AB 1996 (Thomson, Chapter 795, Statutes of 2002) requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996 and reviewed this bill. Key findings include:
   a) *Coverage impacts and enrollees covered*. CHBRP estimates that 13.8 million Californians (36.2% of the state) have CDI- and DMHC-regulated insurance subject to this bill. Medi-Cal managed care plans are excluded from this bill.
   b) *Medical effectiveness.* CHBRP did not find any literature on the impacts of UM on the use of prescription drugs for rare diseases. However, there is some evidence that UM leads to delays in access to prescription drugs to treat non-rare diseases. Based on five retrospective studies and one prospective cohort study for a variety of medical conditions and pharmaceutical classes, there is some evidence that prior authorization for prescription drug treatments of chronic diseases could cause delays in the initiation of prescription drug treatment ranging from an average of four to 44 days. Furthermore, there is some evidence from retrospective studies that UM for prescription drugs for non-rare diseases are related to unnecessary hospitalizations, emergency department visits, and increased morbidity resulting from delays in prescription drug treatments. Lastly, CHBRP found conflicting evidence on the impact of UM on denials of prescription drug treatments for non-rare diseases.
   c) *Utilization*. About 10% of those with health insurance subject to this bill have a rare disease, 82,000 of which are on a drug to treat the rare disease. CHBRP estimates that 10% of these enrollees/insureds start a new prescription in any given year, meaning that approximately 8,200 Californians would be affected by this bill (about 0.06% of most plans). From discussions with a clinical expert, CHBRP assumed that UM leads to a 60-day delay in access to all new rare disease treatment prescriptions for users. Therefore, the elimination of UM would remove the estimated 60-day delay in prescription initiation for new users, so that users starting new drugs would receive 12 months' worth of prescription fills (rather than 10) in the first year of this bill's enactment, resulting in 8,200 Californians with rare diseases starting 17,000 new prescriptions. This would increase utilization of small-molecule drugs by 4% for those drugs available at the pharmacy and by 8% for those administered by a physician. Utilization of biologics is estimated to increase by 2% for those available through either the pharmacy and 2% for those administered by a physician. No change in unit cost is estimated as a result of this bill.
   d) *Medi-Cal.* This bill does not apply to Medi-Cal plans.

e) *Impact on premiums.* Eliminating a 60-day delay for new rare disease prescriptions is estimated to increase total annual premiums by $148 million, with $96.1 million paid by employers and $51.7 million paid by enrollees/insureds. The $51.7 million paid by enrollees/insureds is comprised of $26.6 million paid by those in the individual market and $25.2 million paid by enrollees/insureds of group insurance. Average annual enrollee/insured premiums are estimated to increase by between $1.49 and $10.69, depending on the insurance market, with the largest increase in the individual market. In the long term, CHBRP expects utilization to grow after the first year of implementation as new drugs receive FDA approval, awareness of rare diseases improves, and diagnostic capabilities advance, which is likely to further increase premiums with increased utilization. However, some of this growth may be offset by the increased availability and use of biosimilar alternatives.

f) *Impact on cost sharing.* Because this bill is expected to provide two additional 30-day prescriptions per year for affected enrollees/insureds, cost-sharing for those taking those drugs will increase. The annual average cost-sharing for those with drugs subject to this bill is expected to increase by $900 to $1,200, depending on the insurance market, with the largest cost-sharing increases in the individual market.

g) *Essential health benefits (EHBs).* Because this bill does not require coverage for any additional prescription drugs, it does not exceed the current definition of EHBs in California.

h) *Public health.* CHBRP estimates no measurable population-level public health impacts of this bill due to the lack of rare-disease specific evidence in the literature regarding the impact of a 60-day delay in treatment on health outcomes and the possibility that people with rare diseases may receive other treatments for symptoms while awaiting approval for a medication subject to prior authorization. However, CHBRP suggests there are likely to be meaningful quality-of-life improvements for the individuals with rare diseases who would be able to access their treatments sooner, and for clinicians, patients, and families who would be able to avoid the administrative hassle of prior authorization or UM exceptions processes.

i) *Impact of recent amendments*. Although CHBRP predicts that this bill's recent amendments would decrease the bill's fiscal impact, they would likely delay access to prescription drugs. These delays could match or exceed current wait times, which would limit or reduce health and quality-of-life improvements at the person-level projected by CHBRP in its original analysis. All other portions of CHBRP's analysis remain relevant.

6) *Related legislation.* AB 1843 (Elhawary) would prohibit health plans and insurers from subjecting direct-acting antiviral drugs that are medically necessary for the treatment of hepatitis C to prior authorization. *AB 1843 is set for hearing on August 3, 2026 in the Senate Appropriations Committee.*

   AB 1970 (Harabedian) would prohibits health plans and insurers from imposing step therapy as a prerequisite to authorizing coverage of any prescription drug used for the treatment of a serious mental illness or substance use disorder. *AB 1970 passed thisCommittee by a vote of 9-0 on June 24, 2026*.

7) *Prior legislation.* SB 306 (Becker, Chapter 408, Statutes of 2025) excludes covered health care services that have been approved by the plan/insurer 90% or more times from health plan or insurer prior authorization requirements, as determined by DMHC or CDI after reporting and evaluation.

8) *Support.* The California Chronic Care Coalition (CCCC), the sponsors of this bill, share that many rare disease patients see an average of 17 providers over more than six years before receiving an accurate diagnosis, and the avoidable costs associated with those delays range from $86,000 to $517,000 per patient. The CCCC shares that only 4% to 6% of rare diseases have an FDA-approved treatment, and that these therapies are often the only meaningful option available to patients, making step therapy ill-suited to rare diseases. This bill stops prolonged review and step therapy requirements from standing between a patient and the treatment a specialist has already determined is medically necessary, while giving plans a fair window to act, protecting patients from indefinite limbo, and preserving UM where true alternatives exist. Other patient advocacy and disease research groups, including Rare Rising, the Neuropathy Action Foundation, Flok Health, EB Research Partnership, Cystic Fibrosis Research, Inc, AiArthritis, and Project Alive, agree that this bill offers a targeted solution to protect access to specialist-prescribed, FDA-approved therapies while allowing plans to apply UM controls in situations where true alternatives exist. They state that this bill will save lives, cut the hospitalization costs that dominate rare disease spending, and advance California's health equity goals by easing burdens on vulnerable families. Many groups share specific examples of difficulties accessing treatments. The Dravet Syndrome Foundation shares that Dravet Syndrome is among the 5% of rare diseases that have an FDA approved treatment, but access to the three approved medications is limited to specialty pharmacies and are often subject to prior authorization and step therapy requirements, which can result in increased seizure activity, emergency hospitalizations, and long-term impacts. The Hemophilia Foundation of Southern California shares that they have heard directly from families who have had to postpone or miss treatments while waiting for approvals—putting their health, mobility, and quality of life at risk. The ALS Association writes many patients continue to face significant barriers to accessing the first FDA-approved treatment targeting a rare and particularly aggressive form of ALS, including prior authorization delays, repeated requests for additional documentation, coverage denials, and lengthy appeals processes. Provider groups like the Psychiatric Physicians Alliance of California, Children's Specialty Care Coalition, and Alliance for Patient Access, among others, state that patients with rare diseases already endure prolonged diagnostic journeys and significant uncertainty. Once an effective therapy is identified, additional administrative delays can lead to disease progression, avoidable complications, and interruptions in care for patients. A provider from the National Association of Pediatric Nurse Practitioners states that it is frustrating to see their pediatric patients go weeks without enzyme replacement infusions due to delayed prior authorization. If patients miss too many doses, they must restart, and it can take anywhere between 4 to 18 months to get the patient back to their original maintenance dose. Cedars Sinai appreciates that this bill centers medical necessity and specialist expertise, ensuring that treatment decisions for complex rare conditions remain with the providers best equipped to manage them, and reduces administrative burden for both patients and providers. Many groups highlight the American Medical Association's survey that found that 93% of physicians reported patient care delays due to prior authorization, 91% stated that prior authorization negatively impacts clinical outcomes, and 34% reported serious adverse events tied to delays, including hospitalization, permanent disability, or death. Lastly, The Rare and Ready Coalition supports the bill but also asks the Committee to consider an amendment removing prior authorization requirements for patients age 18 and under.

9) *Opposition.* The Association of California Life and Health Insurance Companies (ACLHIC) and California Association of Health Plans (CAHP) oppose the $148 million projected increase in health insurance premiums, particularly given that health plans already cover these medications. They remind the Legislature that it has just passed a new and costly $1.5

billion Managed Care Organization Tax, which is expected to increase premiums by at least $100/year/person. With this expected increase, they urge careful consideration of the additional premium costs associated with this bill. They also oppose this bill's 30-day review period for prior authorization requests, arguing that because prior authorization requests for rare disease treatments are typically used as a verification tool rather than a mechanism to deny care, the language around automatic approval should be removed to avoid setting a precedent of preferential treatment for one class of expensive drugs. They also point out that because this bill does not require a provider's request to be complete or to include all clinically necessary information before the clock begins, it remains unclear whether the timeline resets if the request is denied, modified, appealed, or requires additional information, and therefore may not hold all parties equally accountable for ensuring patients receive safe and appropriate care. Although CAHP and ACLHIC appreciate the addition of language on biosimilars and generics, they point out that there are limited generic or biosimilar alternatives available for many rare disease drugs and that the language does not account for therapeutically equivalent options that may be the most appropriate choice. The ban on step therapy also restricts a plan or insurer's ability to manage formularies, as it could restrict their ability to offer lower-tier formulary alternatives before approving top-tier formulary drugs. The California Chamber of Commerce also opposes the bill due to the impacts on insurance premiums for employers and employees. They highlight that employer health care premiums are estimated to increase by over $96 million per year, and the largest increases will be seen in small-group (small businesses with fewer than 51 employees) and individual markets. These must also be viewed in the context of consistent increases year after year, partially due to benefit mandates. They share that the average premium for family coverage has increased 20% over the five years prior to the publication of the 2022 Kaiser Family Foundation Employer Health Benefits Survey.

10) *Policy comments.*
   a) A 30-day prior authorization clock that ends in automatic approval if decisions have not been made or disputes remain may unintentionally incentivize health plans to more often deny prior authorization requests, potentially increasing administrative burden by requiring patients and providers to appeal or initiate independent review.
   b) Current law requires health plans and insurers to provide coverage for at least one medication without step therapy for several categories of drugs, including those that reverse opioid overdose and medication assisted treatment for substance use disorder (HSC §1342.75). This framework preserves plans' and insurers' ability to require step therapy and prior authorization when there are multiple clinically effective treatments available.

11) *Amendments.* The Chair is requesting amendments to maintain consistency with other bills relating to restrictions on step therapy.

SUPPORT AND OPPOSITION:

Support: California Chronic Care Coalition (sponsor)
ALS Association
Alliance for Patient Access
Association for Creatine Deficiencies
Biocom California
Bleeding Disorders Council of California
Breathe California
Breathe Southern California

California Chronic Care Coalition
California Life Sciences Association
California Pharmacists Association
California Rheumatology Alliance
Cedars-Sinai
Children's Specialty Care Coalition
Chronic Disease Coalition
CSNK2A1 Foundation
Cure SMA
Cystic Fibrosis Research, Inc.
Dravet Syndrome Foundation
EB Research Partnership
Flok Health
Hemophilia Foundation of Southern California
Herrera & Company
Infusion Access Foundation
International Foundation for Autoimmune and Autoinflammatory Arthritis
International Pemphigus and Pemphigoid Foundation
Little Legs Big Heart Foundation
National Association of Pediatric Nurse Practitioners
National Ataxia Foundation
National Kidney Foundation
National Organization for Rare Disorders
National PKU Alliance
Neuropathy Action Foundation
Overcome Lupus
Project Alive
Psychiatric Physicians Alliance of California
Rare & Ready Coalition
RareRising
The EveryLife Foundation for Rare Diseases
TSC Alliance

Oppose: Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce

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