Date of Hearing: April 21, 2026

ASSEMBLY COMMITTEE ON HEALTH
Mia Bonta, Chair
AB 1887 (Zbur) – As Amended March 26, 2026

SUBJECT: Prescription drug coverage for rare diseases.

SUMMARY: Prohibits prior authorization (PA), step therapy, or any other utilization review (UR) for a federal Food and Drug Administration (FDA) approved drug approved 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 generic, biosimilar, or interchangeable biosimilar 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 (Knox-Keene Act) and California Department of Insurance (CDI) to regulate health and other insurance. [Health & Safety Code (HSC) § 1340, *et seq.* and Insurance Code (INS) § 106, *et seq.*]

2) Establishes California's essential health benefits (EHBs) benchmark under the Patient Protection and Affordable Care Act (ACA) as the Kaiser Small Group Health Maintenance Organization, establishes existing California health insurance mandates, and the 10 ACA mandated benefits, including prescription drug coverage. [HSC § 1367.005 and INS § 10112.27]

3) Defines "basic health care services" as all of the following:

    a) Physician services, including consultation and referral;

    b) Hospital inpatient services and ambulatory care services;

    c) Diagnostic laboratory and therapeutic radiologic services;

    d) Home health services;

    e) Preventive health services;

    f) Emergency health care services, including ambulance and ambulance transport services and out-of-area coverage. Basic health care services includes ambulance and ambulance transport services provided through the 911 emergency response system; and,

    g) Hospice care, as specified. [HSC § 1345 and INS § 10112.281]

4) Requires the criteria or guidelines used by health plans and insurers, or any entities with which plans or insurers contract for UR or utilization management (UM) functions, to determine whether to authorize, modify, or deny health care services to:

    a) Be developed with involvement from actively practicing health care providers;

b) Be consistent with sound clinical principles and processes;

c) Be evaluated, and updated if necessary, at least annually;

d) If used as the basis of a decision to modify, delay, or deny services in a specified case under review, be disclosed to the provider and the enrollee or insured in that specified case; and,

e) Be available to the public upon request. [HSC § 1363.5 and INS § 10123.135]

5) Requires health plans and disability insurers and any contracted entity that performs UR or UM functions, prospectively, retrospectively, or concurrently, based on medical necessity requests to comply with specified requirements. [HSC § 1367.01 and INS § 10123.135]

6) Requires decisions to approve, modify, or deny, based on medical necessity, requests by providers prior to, or concurrent with the provision of health care services to be made in a timely fashion that does not to exceed five business days from the health plan or health insurer's receipt of the information reasonably necessary and requested by the plan to make the determination. Requires, in cases where the review is retrospective, the 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 be communicated to the provider in a manner that is consistent with current law. [HSC § 1367.01 and INS § 10123.135]

7) Requires decisions to approve, modify, or deny requests by providers prior to, or concurrent with, the provision of health care services, to be made in a timely fashion appropriate for the nature of the enrollee or insured's condition, not to exceed 72 hours when an individual's condition is such that they face 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 the normal timeframe for the decision-making process would be detrimental to the enrollee's life or health or could jeopardize the enrollee's ability to regain maximum function, after the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. [HSC § 1367.01 and INS § 10123.135]

8) Authorizes a health care provider or prescribing provider, enrollee, insured, or their designee or guardian to appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request consistent with the plan's or insurer's current UM process. [HSC § 1367.206 and INS § 10123.201]

9) Prohibits a health plan or insurer from subjecting antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including PrEP or PEP, to PA or step therapy. Permits a health plan or insurer not to cover all of the therapeutically equivalent versions without PA or step therapy, if at least one therapeutically equivalent version is covered without PA or step therapy, if the FDA has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV. Limits coverage to a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber. [HSC § 1342.74 and INS § 10123.1933]

10) Excludes from health plan and insurer PA requirements specified covered health care service that have been approved by the plan or insurer 90% or more times as determined by DMHC

and CDI after health plan and insurer reporting and evaluation by DMHC and CDI. [HSC § 1367.025 and INS § 10133.52]

11) Establishes the California Health Care Quality and Affordability Act, which creates the Office of Health Care Affordability (OHCA) within the Department of Health Care Access and Information (HCAI). Identifies OHCA's three primary responsibilities: managing spending targets, monitoring system performance, and assessing market consolidation. Requires OHCA to collect, analyze, and publicly report data on total health care expenditures, and enforce spending targets set by a Health Care Affordability Board (Board). [HSC § 127500, *et seq*.]

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** 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 PA from their health plan before they can start the one FDA-approved drug that can slow or stop their condition. The author states that 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. The author continues that this bill removes these barriers by prohibiting PA, step therapy, and other UR for FDA-approved medications used to treat rare diseases, unless there is a generic or biosimilar alternative, thereby restoring treatment decisions to patients and their doctors. The author concludes that 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) **BACKGROUND**. Rare diseases are medical disorders, illnesses, or conditions that affect a relatively small number of individuals. According to the National Institutes of Health and the Orphan Drug Act, rare diseases are those that affect fewer than 200,000 people in the United States. Rare diseases are often chronic, serious, and progressive diseases that are life-threatening or life-limiting. Signs of rare diseases are often present at birth or in childhood, although there is a subset of rare diseases that do not appear until adulthood. Rare diseases can affect any organ system and might affect multiple body systems. Approximately 80% of rare diseases are caused by genetic mutations and may be inherited but can also be new mutations. Rare diseases may also be caused by infections or environmental factors. There are an estimated 5,000 to over 10,000 rare diseases in the United States. It is estimated that 1 in 10 Californians, or close to 4 million Californians, are living with a rare disease, based on national estimates. Only 5% of the 5,000 to 10,000 rare diseases currently have FDA-approved drugs indicated for their treatment. The time to receive a correct diagnosis of a rare disease can vary widely, with 4 to 5 years as the average.

   a) **California Health Benefits Review Program (CHBRP).** CHBRP was created in response to AB 1996 (Thomson), Chapter 795, Statutes of 2002, which 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. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on EHBs, and

legislation that impacts health insurance benefit designs, cost-sharing, premiums, and other health insurance topics to CHBRP's purview. CHBRP reviewed this bill and included the following impact estimates in their analysis:

i) **Premium & enrollee out-of-pocket increases.** Premiums paid by employers and enrollees would increase upon enaction of this bill by an estimated $148 million. Individual annual premium impacts range from $1.49 to $10.69 depending on market segment. The average annual enrollee premium impact for users is $1.90 for large-group, $3.80 for small-group, $10.69 for individual market, and $1.49 for CalPERS enrollees. This premium increase applies to all enrollees regardless of whether they use the new benefit. Annual expenses for those using drugs subject to this bill, including cost sharing and noncovered expenses, would increase by between $900 and $1,200. Over time, utilization of FDA-approved drugs for rare diseases is likely to increase as new drugs are developed and receive FDA approval. These factors would contribute toward increases in premiums.

ii) **UM and access to care.** CHBRP found there is not enough research on the impact of UM on access to rare-disease drugs. Based on existing literature and discussion with content experts, CHBRP determined that PA is typically the only type of UM used when reviewing access to coverage for FDA-approved drugs for rare-diseases. In studies of non-rare diseases, CHBRP found some evidence that PA results in delays for initiation of prescription drug treatments. CHBRP found that PA leads to a 60-day delay in access to all new prescriptions for users, i.e., individuals with rare diseases starting an FDA-approved drug. The 60-day delay estimate reflects clinical expert opinion from a specialist in rare metabolic diseases with extensive experience managing UM requirements for this patient population. Unlike other studies reviewed, which examined UM delays in more common conditions over shorter timeframes, rare disease PA processes are typically more burdensome, often requiring detailed diagnostic documentation, genetic testing results, and specialist attestation, justifying a longer timeline than observed for other treatments.

iii) **Public health impacts.** CHRBP determined that this bill would produce no measurable public health impact at the population level. However, this bill could yield health and quality-of-life improvements at the person-level, such as faster access to medications, potential reductions in unnecessary health care utilization while awaiting PA for medications, and reduced stress and administrative burden for patients, their families, and their clinicians by removing PA requirements.

b) **UM and UR.** UM and UR are processes used by health plans to evaluate and manage the use of health care services. UR can occur prospectively, retrospectively, or concurrently and a plan can approve, modify, delay or deny in whole or in part a request based on its medical necessity. PA is a UR technique used by health plans that requires patients to obtain approval of a service or medication before care is provided. PA is intended to allow plans to evaluate whether care that has been prescribed is medically necessary for purposes of coverage. PA is one type of UM tool that's used by health plans, along with others such as concurrent review and step therapy, to control costs, limit unnecessary care, and evaluate safety and appropriateness of a service.

c) **Growing consumer premiums and affordability concerns.** Over the last two decades, significant federal policy changes have reshaped the health insurance landscape in California, expanding coverage, increasing affordability, and strengthening consumer protections for millions of residents. These policies drove historic reductions in the uninsured rate and provided greater stability for families, providers, and health systems across the state. These gains, however, are under threat as the expiration and rollback of key federal supports, combined with broader economic uncertainty and rising health care costs, risk reversing hard-won progress and increasing the number of Californians who are struggling to access affordable health care. According to the California Health Care Foundation 2026 Health Policy Survey (CHCF Survey), half of Californians (51%) reported that their health care expenses have increased faster than their incomes, and a vast majority (71%) are experiencing financial strain due to health care costs. About 6 in 10 Californians overall (59%), and 70% of Californians with low incomes, say they skipped or postponed care due to cost in the past year. Nearly half of Californians (47%) say it is "very" or "somewhat" difficult to afford health care.

   i) **Covered California.** Covered California is the state's ACA marketplace where small-businesses and individuals can directly purchase coverage. Over 90% of Covered California enrollees receive some combination of state and federal subsidies to afford their premiums. However, the expiration of federal enhanced premium tax credits at the end of 2025 is creating stark affordability concerns. Covered California estimates that about 1.7 million Californians will see significant increases to their costs in 2026; on average, enrollees will notice 97% increases to their monthly health insurance premiums. As of February, Covered California estimated a 3% decrease in enrollment overall, with a 32% decrease in new enrollments compared to 2025. One-third of enrollees are opting for lower-cost Bronze plans, compared to 25% in 2025, and 75% of renewals who switched plans downgraded to Bronze-level coverage. About 14% of previous enrollees cancelled their plans, and for those making over 400% of the federal poverty level (FPL), policy termination rates are double what they were in 2025 (22% up from 11%). CHBRP's analysis showed this bill has the highest premium impacts in the Covered California individual and small-group markets.

   ii) **Employer coverage**. For those on employer-based individual and family plans, the California Health Benefits Survey found that the average total premium for family coverage in California has increased by 24% since 2022 – rapidly outpacing the national rates of inflation (12%) and wages (14%). This continues a 20-year trend: according to the UC Labor Center, family health care premiums for private-sector workers have grown by 129% since 2005, faster than the state's median household income (94%) and the inflation rate (69%). Because health insurance is part of an employee's total compensation plan, higher premiums cut into employee wage increases and other benefits.

d) **OHCA cost targets.** OHCA was established in 2022 in response to widespread cost-related access challenges across California. OHCA collects, analyzes, and publicly reports data on total health care expenditures and enforces spending targets. OHCA's spending targets are intended to reduce excess spending and slow health care spending growth. In April of 2024, OHCA approved a statewide cost growth target of 3.5% starting in 2025 and phasing down to 3% by 2029. Health care entities, including health

plans and insurers, are subject to the statewide spending target and are subject to progressive enforcement if the entity's costs exceed the target. Some entities have raised concerns that new legislative insurance mandates will make it difficult for them to meet the established cost growth target.

Current law does not explicitly require OHCA to adjust the cost growth targets based on changes to state policy, such as insurance mandates, that may increase spending. However, it does require OHCA to consider state benefit mandates in its development and enforcement of cost growth targets. Specifically, when establishing cost growth target methodology, OHCA is required to review relevant state policy changes impacting covered benefits, provider reimbursement, and costs, among other factors. In addition, in enforcing cost growth targets, OHCA is required to consider factors that contribute to spending in excess of the applicable target, and the extent to which each entity has control over the applicable components of its cost target.

3) **SUPPORT.** The California Chronic Care Coalition (CCCC) is sponsoring this bill, stating that many rare disease patients, especially children, experience years-long "diagnostic odysseys," seeing an average of 17 providers over more than six years before receiving an accurate diagnosis. CCCC continues that during those years alone, avoidable medical and productivity costs attributable to delayed diagnosis range from approximately $86,000 to $517,000 per patient. CCCC notes that when a rare disease is finally identified and an FDA-approved therapy exists, UM protocols that delay or deny access effectively extend this costly odyssey at the very point when patients are poised to benefit from appropriate treatment. CCCC argues that economic evidence strongly supports moving cost control "upstream" by ensuring timely access to appropriate treatment for rare disease patients rather than relying on downstream spending from preventable complications. CCCC cites a national study of 379 prevalent rare diseases that estimated the total economic burden at $997 billion annually, including $449 billion in direct medical costs, $437 billion in productivity losses, and substantial non-medical and uncovered costs. CCCC states that on a per-patient basis, the average annual economic burden for a person with a rare disease is roughly $266,000—ten times higher than the $26,000 per-patient burden associated with common diseases. CCCC argues that direct medical costs alone are three to five times higher for rare disease patients than for the general population, with hospital inpatient care and outpatient visits accounting for nearly half of those costs. CCCC continues that California's health policy framework emphasizes equity, quality, and measurable reductions in health disparities. CCCC argues that rare disease patients—especially children, communities of color, rural residents, non-English speakers, and families with limited resources—face disproportionate challenges navigating PA and step therapy appeals, compounding the inequities they already experience. CCCC concludes that by eliminating these barriers for a narrowly defined set of FDA-approved rare disease treatments, this bill advances California's equity goals and ensures that access is driven by clinical need rather than by a family's capacity to navigate insurance bureaucracy.

4) **OPPOSITION.** The California Association of Health Plans (CAHP) and Association of California Life and Health Insurance Companies (ACLHIC) are strongly opposed to any legislation that will increase premiums for Californians – especially at a time when health care affordability remains a critical concern. CAHP and ACLHIC urge members to vote no on this bill due to its astronomical impact to premiums. CAHP and ACLHIC note that UM is not an arbitrary practice, it ensures patients get the appropriate treatment, at the right time,

for the most affordable price. CAHP and ACLHIC continue that this bill seeks to remove *all* utilization management practices for drugs used to treat rare diseases – which due to their complex formulation to target small populations, range in costs between hundreds of thousands of dollars to millions of dollars. CAHP and ACLHIC state that under this bill plans would have to offer blanket coverage for all new drugs used to treat rare diseases that enter the market (regardless of their efficacy or cost) and be restricted in their abilities to manage formularies and provide appropriate coverage of high-priced drugs. CAHP and ACLHIC appreciate the provision on biosimilars, but state it is important to note that because these conditions are rare, it's likely that many of them are only treated by a biologic and do not have a biosimilar available. CAHP and ACLHIC continue that the legislature has spent the past year discussing policies to address the rising cost of healthcare – with a specific focus on health care premiums. CAHP and ACLHIC conclude by reminding the legislature that mandates have a direct correlation to premium increases for Californians and urge careful and consistent consideration of this individual proposal's impact and the cumulative impact of healthcare mandates.

5) **RELATED LEGISLATION.** AB 1843 (Elhawary) would prohibit a health plan or health insurer from subjecting direct-acting antiviral drugs that are medically necessary for the treatment of hepatitis C to PA, as specified. AB 1843 is currently pending in the Assembly Health Committee.

6) **PREVIOUS LEGISLATION.**

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

   b) AB 384 (Connolly) of 2025, would have prohibited a health plan, health insurer, or Medi-Cal from requiring PA for an individual to be admitted to medically necessary 24-hour inpatient settings for mental health and substance use disorders (SUDs) and for any medically necessary health care services provided to an individual while admitted for that care. AB 384 was held on the Assembly Appropriations Committee suspense file.

   c) AB 510 (Addis) of 2025, would have required, upon request, an appeal or grievance regarding a decision by a health plan or health insurer delaying, denying, or modifying a health care service based in whole or in part on medical necessity, to be reviewed by a peer physician or health care professional of the same or similar specialty as the requesting provider. AB 510 was held on the Assembly Appropriations Committee suspense file.

   d) AB 512 (Harabedian) of 2025, would have required health plan and health insurer decisions based on medical necessity to approve, modify, or deny requests by providers prior to the provision of health care services to enrollees to be made in a timely fashion appropriate for the nature of the enrollee's condition, not to exceed 48 hours for standard requests, or 24 hours for urgent requests, from the plan's receipt of the information reasonably necessary and requested by the plan to make the determination. AB 512 was vetoed by Governor Newsom, who said in part:

"I strongly support the goal of improving the PA process. Accordingly, I recently signed SB 306 (Becker), which seeks to ensure that enrollees receive timely responses to requests for care by taking a holistic approach to improve the PA process. Under this new law, health plans and health insurers are required to submit data to DMHC and CDI, respectively, regarding the types of health care services subject to PA requirements. The departments must analyze the data and then issue a list of services that should not be subject to a PA requirement by 2027."

e) AB 539 (Schiavo) of 2025, would have required a PA for a health care service to remain valid for a period of at least one year from the date of approval. AB 539 is a two-year bill in the Senate Health Committee.

f) AB 574 (Mark González) of 2025, would have prohibited a health plan or health insurer that provides coverage for physical therapy (PT) from requiring PA for the initial 12 treatment visits for a new condition for PT. For a recurring condition, this bill would have allowed a health plan or insurer to impose PA if the individual seeks care within 180 days of their last physical therapy intervention for that condition. AB 574 was vetoed by Governor Newsom whose veto message was similar to that of AB 512.

g) AB 669 (Haney) of 2025, would have prohibited concurrent or retrospective review of medical necessity for the first 28 days of in-network inpatient SUD stay. Would have prohibited concurrent or retrospective review of medical necessity of in-network outpatient SUD visits. Would have prohibited retrospective review of medical necessity for the first 28 days of in-network intensive outpatient or partial hospitalization SUD services, as specified. Would have prohibited PA for in-network coverage of medically necessary outpatient prescription drugs to treat SUD. AB 669 was held on the Senate Appropriations Committee suspense file.

h) SB 516 (Skinner) of 2024, would have required DMHC and CDI, by July 1, 2025, to issue instructions, including a standard reporting template, to health plans and insurers to report specified information, including all covered health care services, items, and supplies subject to PA. SB 516 was not heard in the Assembly Health Committee.

i) SB 598 (Skinner) of 2023, would have prohibited a health plan or insurer from requiring a contracted health professional to complete or obtain a PA for any covered health care services if the plan or insurer approved or would have approved not less than 90% of the PA requests they submitted in the most recent completed one-year contracted period. SB 598 was held on suspense in the Assembly Appropriations Committee.

j) SB 250 (Pan) of 2022 was similar to SB 598 and was held on suspense in the Assembly Appropriations Committee.

k) AB 1880 (Arambula) of 2022, would have required a health plan or insurer's UM process to ensure that an appeal of a denial, is reviewed by a clinical peer, as specified. Would have defined clinical peer as a physician or other health professional who holds an unrestricted license or certification from any state and whose practice is in the same or a similar specialty as the medical condition, procedures, or treatment under review. AB 1880 was vetoed by Governor Newsom who stated in part:

"Health plans and health insurers should make every effort to streamline UM processes and reduce barriers to all medically necessary care. However, the bill's requirements, which are limited to denied authorizations for prescription drugs, are duplicative of California's existing independent medical review requirements, which provide enrollees, insureds, and their designated representatives with the opportunity to request an external review from an independent provider. I encourage the Legislature to pursue options that leverage existing requirements and resources, rather than creating duplicative new processes."

7) **POLICY COMMENTS.** As detailed in the background section of this analysis, health insurance premiums are skyrocketing due to federal policy changes and disinvestments. These increasing costs are putting immense pressure on the pockets of millions of Californians and pushing many to abandon coverage altogether. This committee has held two informational hearings on this topic this year already where firsthand stories of these impacts were shared. A Promotora from the Central Valley shared stories of her clients dropping coverage and having to drive to Mexico to purchase essential prescriptions. She also shared how she had to drop her comprehensive health plan for a minimum coverage plan in order to afford her monthly premium and coverage for her newborn daughter. A health insurance agent from rural northern California testified about the 300-400% premium increases her clients are seeing, which is leading them to enroll in less-comprehensive coverage that doesn't provide meaningful access to care. She shared an example of a client who was subject to a $6,000 deductible for a mammogram – despite paying hundreds of dollars a month for her insurance coverage. A retired veteran from Colusa County testified about premiums for himself and his wife jumping from $540 a month to nearly $4,000 a month from 2025 to 2026. A cost that is more than double his monthly mortgage, and one he simply cannot afford on his fixed income.

   These stories represent the current reality for millions of people across the state. This Legislature must thoroughly consider the impact of policies, such as those under this bill, that will significantly impact premiums at a time when there isn't room for consumers to bear more monthly costs. It's important to note that **prescription drugs to treat rare diseases are already covered**. This bill does not expand access to those medications. What this bill does is remove a health plan's ability to review a prescribed drug before approving it under PA. What that does is ensure that .06% of patients will receive their medication 30-60 days faster than they normally would, improving access for that small population.

   What the Legislature must decide is, during this incredibly difficult time in our health care system, if that shortened timeline is worth raising costs by nearly $150 million for the 99.04% of other Californians who won't see a benefit and are already struggling to maintain the basic care they have.

REGISTERED SUPPORT / OPPOSITION:

Support

California Chronic Care Coalition (sponsor)
AiArthritis
Alliance for Patient Access
American Kidney Fund
Association for Creatine Deficiencies

Biocom
Bleeding Disorders Council of California
California Life Sciences Association
California Pharmacists Association
California Rheumatology Alliance
Cedars-Sinai
Central Coast Oncology & Hematology
Children's Specialty Care Coalition
Chronic Disease Coalition
Csnk2a1 Foundation
Cure Sma
Cystic Fibrosis Research, INC. (CFRI)
Dravet Syndrome Foundation
Eb Research Partnership
EveryLife Foundation for Rare Diseases
Flok Health
Hemophilia Foundation of Southern California
Herrera & Company
Iga Nephropathy Foundation
International Pemphigus and Pemphigoid Foundation
National Health Law Program
National Kidney Foundation Serving Northern California, Northern Nevada, Oregon, Washington and Alaska
National Pku Alliance
Nephcure
Neuropathy Action Foundation
NW Rare Disease Coalition
Project Alive
Psychiatric Physicians Alliance of California (PPAC)
Rare & Ready Coalition
TSC Alliance
U.S. Pain Foundation

Opposition

Association of California Life & Health Insurance Companies
California Association of Health Plans
California Chamber of Commerce
California Small Business Association

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