Understanding Reimbursement Issues in California

A Guide for Health Care Providers and Practice Administration

California

Example EYLEA HD® (aflibercept) Injection Claim Issues and Applicable State Provisions

Prior Authorization

Issue: Plan delays prior authorization.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. Provider submits a request for prior authorization. Plan has not made a decision.

California Insurance Code Section 10123.191 states...

b) If a Plan or a contracted physician group fails to respond within 72 hours for nonurgent requests, and within 24 hours if exigent circumstances exist, upon receipt of a completed prior authorization request from a prescribing provider, the prior authorization request shall be deemed to have been granted.

(h) A Plan shall maintain a process for an external exception request review that complies with subdivision (c) of Section 156.122 of Title 45 of the Code of Federal Regulations.

California Insurance Code Section 10123.197 states...

(a) A request for an exception to a Plan's step therapy process for prescription drugs may be submitted in the same manner as a request for prior authorization for prescription drugs pursuant to Section 10123.191, and shall be treated in the same manner, and shall be responded to by the Plan in the same manner, as a request for prior authorization for prescription drugs.

Prior Authorization or Step Therapy Exception Form

California Health and Safety Code, Section 1367.206 states...

(a) If there is more than one drug that is clinically appropriate for the treatment of a medical condition, a Plan that provides coverage for prescription drugs may require step therapy.

- (b) A Plan shall expeditiously grant a request for a step therapy exception within the applicable time limit required by Section 1367.241 if a prescribing provider submits necessary justification and supporting clinical documentation supporting the provider's determination that the required prescription drug is inconsistent with good professional practice for provision of medically necessary covered services to the enrollee, taking into consideration the enrollee's needs and medical history, along with the professional judgment of the enrollee's provider. The basis of the provider's determination may include, but is not limited to, any of the following criteria:
- (1) The required prescription drug is contraindicated or is likely, or expected, to cause an adverse reaction or physical or mental harm to the enrollee in comparison to the requested prescription drug, based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- (2) The required prescription drug is expected to be ineffective based on the known clinical characteristics of the enrollee and the known characteristics and history of the enrollee's prescription drug regimen.
- (3) The enrollee has tried the required prescription drug while covered by their current or previous health coverage or Medicaid, and that prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse reaction. The Plan may require the submission of documentation demonstrating that the enrollee tried the required prescription drug before it was discontinued.
- (4) The required prescription drug is not clinically appropriate for the enrollee because the required drug is expected to do any of the following, as determined by the enrollee's prescribing provider:
- (A) Worsen a comorbid condition.
- (B) Decrease the capacity to maintain a reasonable functional ability in performing daily activities.
- (C) Pose a significant barrier to adherence to, or compliance with, the enrollee's drug regimen or plan of care.
- (5) The enrollee is stable on a prescription drug selected by the enrollee's prescribing provider for the medical condition under consideration while covered by their current or previous health coverage or Medicaid.
- (c) A health care provider or prescribing provider may 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 current utilization management processes.
- (d) An enrollee or the enrollee's designee or guardian may appeal a denial of an exception request for coverage of a nonformulary drug, prior authorization request, or step therapy exception request by filing a grievance under Section 1368.

 (e) (1) This section does not prohibit a health care provider from prescribing a prescription drug that is clinically appropriate.
- (2) This section does not prohibit a Plan or utilization review organization from requiring an enrollee to try an AB-rated generic equivalent, biosimilar, as defined in Section 262(i) (2) of Title 42 of the United States Code, or interchangeable biological product, as defined in Section 262(i) (3) of Title 42 of the United States Code, before providing coverage for the equivalent branded prescription drug.
- (3) Paragraph (2) does not prohibit or supersede a step therapy exception request as described in subdivision (b).

California Health and Safety Code 1367.01 states...

- (k) (1) A Plan, including a specialized health care service plan that uses an artificial intelligence, algorithm, or other software tool for the purpose of utilization review or utilization management functions, based in whole or in part on medical necessity, or that contracts with or otherwise works through an entity that uses an artificial intelligence, algorithm, or other software tool for the purpose of utilization review or utilization management functions, based in whole or in part on medical necessity, shall comply with this section and shall ensure all of the following:
- (A) The artificial intelligence, algorithm, or other software tool bases its determination on the following information, as applicable:
- (i) An enrollee's medical or other clinical history.
- (ii) Individual clinical circumstances as presented by the requesting provider.
- (iii) Other relevant clinical information contained in the enrollee's medical or other clinical record.

On the following pages:

Prior Authorization (cont'd)

Prompt Payment

Request for Additional Information

Filing Deadlines

Provider Appeals



Prior Authorization (cont'd)

California Health and Safety Code 1367.01 states (cont'd)...

- (B) The artificial intelligence, algorithm, or other software tool does not base its determination solely on a group dataset.
- (C) The artificial intelligence, algorithm, or other software tool's criteria and guidelines complies with this chapter, including, but not limited to, Section 1363.5 and applicable state and federal law.
- (D) The artificial intelligence, algorithm, or other software tool does not supplant health care provider decision making.
- (E) The use of the artificial intelligence, algorithm, or other software tool does not discriminate, directly or indirectly, against enrollees in violation of state or federal law.
- (F) The artificial intelligence, algorithm, or other software tool is fairly and equitably applied, including in accordance with any applicable regulations and guidance issued by the federal Department of Health and Human Services.
- (G) The artificial intelligence, algorithm, or other software tool is open to inspection for audit or compliance reviews by the department pursuant to Section 1381 and by the State Department of Health Care Services pursuant to applicable state and federal law.
- (H) Disclosures pertaining to the use and oversight of the artificial intelligence, algorithm, or other software tool are contained in the written policies and procedures, as required by subdivision (b).
- (1) The artificial intelligence, algorithm, or other software too's performance, use, and outcomes are periodically reviewed and revised to maximize accuracy and reliability.
- (J) Patient data is not used beyond its intended and stated purpose, consistent with the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code) and the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), as applicable.
- (K) The artificial intelligence, algorithm, or other software tool does not directly or indirectly cause harm to the enrollee.
- (2) Notwithstanding paragraph (1), the artificial intelligence, algorithm, or other software tool shall not deny, delay, or modify health care services based, in whole or in part, on medical necessity. A determination of medical necessity shall be made only by a licensed physician or a licensed health care professional competent to evaluate the specific clinical issues involved in the health care services requested by the provider, as provided in subdivision (e), by reviewing and considering the requesting provider's recommendation, the enrollee's medical or other clinical history, as applicable, and individual clinical circumstances.
- (3) For purposes of this subdivision, "artificial intelligence" means an engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments.
- (4) This subdivision shall apply to utilization review or utilization management functions that prospectively, retrospectively, or concurrently review requests for covered health care services.
- (5) A Plan subject to this subdivision shall comply with applicable federal rules and guidance issued by the federal Department of Health and Human Services regarding the use of artificial intelligence, algorithm, or other software tools. The department and the State Department of Health Care Services may issue guidance to implement this paragraph within one year of the adoption of federal rules or the issuance of guidance by the federal Department of Health and Human Services regarding the use of artificial intelligence, algorithm, or other software tools. Such guidance shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).
- (6) For purposes of implementing this subdivision, the department and the State Department of Health Care Services may enter into exclusive or nonexclusive contracts, or amend existing contracts, on a bid or negotiated basis. Contracts entered into or amended pursuant to this subdivision shall be exempt from Chapter 6 (commencing with Section 14825) of Part 5.5 of Division 3 of Title 2 of the Government Code, Section 19130 of the Government Code, and Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code, and shall be exempt from the review or approval of any division of the Department of General Services.
- (7) This subdivision applies to a Medi-Cal managed care plan only to the extent that the State Department of Health Care Services obtains any necessary federal approvals, and federal financial participation is not otherwise jeopardized.

 (I) The director shall review a Plan's compliance with this section as part of its periodic onsite medical survey of each plan undertaken pursuant to Section 1380, and shall include a discussion of compliance with this section as part of its report issued pursuant to that section.
- (m) This section shall not apply to decisions made for the care or treatment of the sick who depend upon prayer or spiritual means for healing in the practice of religion as set forth in subdivision (a) of Section 1270.
- (n) Nothing in this section shall cause a Plan to be defined as a health care provider for purposes of any provision of law, including, but not limited to, Section 6146 of the Business and Professions Code, Sections 33331 and 3333.2 of the Civil Code, and Sections 340.5.364. 425.13. 667.7 and 1295 of the Code of Civil Procedure.

California Health and Safety Code 1374.196 states...

- (a) Commencing January 1, 2027, or when final federal rules are implemented, whichever occurs later, the department shall require a health care service plan to establish and maintain the following application programming interfaces (API) for the benefit of enrollees and contracted providers, as applicable:
- (1) Patient access API.
- (2) Provider access API.
- (3) Paver-to-paver API.
- (4) Prior authorization API.
- (b) API described in subdivision (a) shall be in accordance with standards published in a final rule issued by the federal Centers for Medicare and Medicaid Services and published in the Federal Register, and shall align with federal effective dates, including enforcement delays and suspensions, issued by the federal Centers for Medicare and Medicaid Services.
- (c) (1) Until January 1, 2027, the director may issue guidance to plans regarding compliance with this section and that guidance shall not be subject to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code).
- (2) In developing the guidance under this subdivision, the department shall seek input from the State Department of Health Care Services.
- (d) This section does not limit existing requirements under this chapter, including, but not limited to, Section 1367.27.



Prompt Payment

Issue: Plan delays timely payment pending medical necessity determination.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. Provider submits a claim for EYLEA HD reimbursement, but 31 days later, claim is still pending medical necessity determination.

California Health and Safety Code Section 1371.35 states...

Effective UNTIL January 1, 2026

- (a) A Plan, including a specialized health care service plan, shall reimburse each complete claim, or portion thereof, whether in state or out of state, as soon as practical, but no later than 30 working days after receipt of the complete claim by the Plan, or if the Plan is a health maintenance organization, 45 working days after receipt of the complete claim by the Plan. However, a Plan may contest or deny a claim, or portion thereof, by notifying the claimant, in writing, that the claim is contested or denied, within 30 working days after receipt of the claim by the Plan, or if the Plan is a health maintenance organization, 45 working days after receipt of the claim by the Plan. The notice that a claim, or portion thereof, is contested shall identify the portion of the claim that is contested, by revenue code, and the specific information needed from the provider to reconsider the claim. The notice that a claim, or portion thereof, is denied shall identify the portion of the claim that is denied, by revenue code, and the specific reasons for the denial. A Plan may delay payment of an uncontested portion of a complete claim for reconsideration of a contested portion of that claim so long as the Plan pays those charges specified in subdivision (b).
- (b) If a complete claim, or portion thereof, that is neither contested nor denied, is not reimbursed by delivery to the claimant's address of record within the respective 30 or 45 working days after receipt, the Plan shall pay the greater of \$15 per year or interest at the rate of 15% per annum beginning with the first calendar day after the 30- or 45-working-day period. A Plan shall automatically include the \$15 per year or interest due in the payment made to the claimant, without requiring a request therefor.
- (c) For the purposes of this section, a claim, or portion thereof, is reasonably contested if the Plan has not received the completed claim. A paper claim from an institutional provider shall be deemed complete upon submission of a legible emergency department report and a completed UB 92 or other format adopted by the National Uniform Billing Committee, and reasonable relevant information requested by the Plan within 30 working days of receipt of the claim. An electronic claim from an institutional provider shall be deemed complete upon submission of an electronic equivalent to the UB 92 or other format adopted by the National Uniform Billing Committee, and reasonable relevant information requested by the Plan within 30 working days of receipt of the claim. However, if the Plan requests a copy of the emergency department report within the 30 working days after receipt of the electronic claim from the institutional provider, the Plan may also request additional reasonable relevant information within 30 working days of receipt of the emergency department report, at which time the claim shall be deemed complete. A claim from a professional provider shall be deemed complete upon submission of a completed HCFA 1500 or its electronic equivalent or other format adopted by the National Uniform Billing Committee, and reasonable relevant information requested by the plan within 30 working days of receipt of the claim. The provider shall provide the Plan reasonable relevant information within 10 working days of receipt of a written request that is clear and specific regarding the information sought. If, as a result of reviewing the reasonable relevant information, the Plan requires further information, the Plan shall have an additional 15 working days after receipt of the reasonable relevant information to request the further information, notwithstanding any time limit to the contrary in this section, at which time the claim shall be deemed complete.
- (d) This section shall not apply to claims about which there is evidence of fraud and misrepresentation, to eliqibility determinations, or in instances where the Plan has not been granted reasonable access to information under the provider's control. A Plan shall specify, in a written notice sent to the provider within the respective 30- or 45-working days of receipt of the claim, which, if any, of these exceptions applies to a claim.
- (e) If a claim or portion thereof is contested on the basis that the Plan has not received information reasonably necessary to determine paver liability for the claim or portion thereof, then the Plan shall have 30 working days or, if the Plan is a health maintenance organization, 45 working days after receipt of this additional information to complete reconsideration of the claim. If a claim, or portion thereof, undergoing reconsideration is not reimbursed by delivery to the claimant's address of record within the respective 30 or 45 working days after receipt of the additional information, the Plan shall pay the greater of \$15 per year or interest at the rate of 15% per annum beginning with the first calendar day after the 30-or 45-working-day period. A Plan shall automatically include the \$15 per year or interest due in the payment made to the claimant, without requiring a request therefor.
- (f) The obligation of the Plan to comply with this section shall not be deemed to be waived when the Plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services. This section shall not be construed to prevent a Plan from assigning, by a written contract, the responsibility to pay interest and late charges pursuant to this section to medical groups, independent practice associations, or other entities,
- (q) A Plan shall not delay payment on a claim from a physician or other provider to await the submission of a claim from a hospital or other provider, without citing specific rationale as to why the delay was necessary and providing a monthly update regarding the status of the claim and the Plan's actions to resolve the claim, to the provider that submitted the claim.
- (h) A Plan shall not request or require that a provider waive its rights pursuant to this section.
- (i) This section shall not apply to capitated payments.
- (i) This section shall apply only to claims for services rendered to a patient who was provided emergency services and care as defined in Section 1317.1 in the United States on or after September 1. 1999.
- (k) This section shall not be construed to affect the rights or obligations of any person pursuant to Section 1371.
- (I) This section shall not be construed to affect a written agreement, if any, of a provider to submit bills within a specified time period.
- (m) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.



Prompt Payment (cont'd)

California Health and Safety Code Section 1371.35 states (cont'd)...

Effective AFTER January 1, 2026

- (a) (1) A Plan, including a specialized health care service plan, shall reimburse a complete claim or portion thereof, whether in state or out of state, as soon as practicable, but **no later than 30 calendar days** after receipt of the claim by the Plan. If a claim or portion thereof does not meet the criteria for a complete claim or the criteria for coverage under the plan contract, a Plan shall notify the claimant, in writing, that the claim or portion thereof is contested or denied, as soon as practicable, but **no later than 30 calendar days** after receipt of the claim by the Plan.
- (2) The notice that a claim or portion thereof, is contested shall identify the portion of the claim that is contested, by procedure or revenue code, and the specific information needed from the provider to reconsider the claim, including any defect or impropriety or additional information needed to adjudicate the claim.
- (3) The notice that a claim or portion thereof, is denied shall identify the portion of the claim that is denied, by procedure or revenue code, and the specific reasons for the denial, including any defect or impropriety.
- (b) If a claim, or portion thereof, is not reimbursed by delivery to the claimant's address of record within 30 calendar days after receipt, the Plan shall pay interest at a rate of 15% per annum beginning with the first calendar day after the 30-calendar-day period. A Plan shall automatically include all interest that has accrued pursuant to this section in the payment made to the claimant, without requiring a request therefor. A plan failing to comply with this requirement shall pay the claimant the greater of an additional \$15 or a fee of 10% of the accrued interest.
- (c) For the purposes of this section, a claim, or portion thereof, is reasonably contested if the plan has not received the completed claim. A paper claim from an institutional provider shall be deemed complete upon submission of a legible emergency department report and a completed UB 92 or other format adopted by the National Uniform Billing Committee, and reasonable relevant information requested by the plan within 30 calendar days of receipt of the claim. However, if the Plan requests a copy of the emergency department report within the 30 calendar days after receipt of the electronic claim from the institutional provider, the Plan may also request additional reasonable relevant information within 30 calendar days of receipt of the emergency department report, at which time the claim shall be deemed complete. A claim from a professional provider shall be deemed complete upon submission of a completed HCFA 1500 or its electronic equivalent or other format adopted by the National Uniform Billing Committee, and reasonable relevant information requested by the Plan within 30 calendar days of receipt of the claim. The provider shall provide the plan reasonable relevant information within 10 working days of receipt of a written request that is clear and specific regarding the information, notwithstanding any time limit to the contrary in this section, at which time the claim shall be deemed complete.
- (d) This section shall not apply to claims about which there is evidence of fraud and misrepresentation, to eligibility determinations, or in instances where the plan has not been granted reasonable access to information under the provider's control. A Plan shall specify, in a written notice sent to the provider within 30 calendar days of receipt of the claim, which, if any, of these exceptions applies to a claim.
- (e) If a claim or portion thereof is contested on the basis that the plan has not received information reasonably necessary to determine payer liability for the claim or portion thereof, then the Plan shall have 30 calendar days after receipt of this additional information to complete reconsideration of the claim, or portion thereof, undergoing reconsideration is not reimbursed by delivery to the claimant's address of record within 30 calendar days after receipt of the additional information, the Plan shall pay interest at the rate of 15% per annum beginning with the first calendar day after the 30-calendar-day period. A Plan shall automatically include the interest due in the payment made to the claimant, without requiring a request therefor.
- (f) The obligation of the Plan to comply with this section shall not be deemed to be waived when the Plan requires its medical groups, independent practice associations, or other contracting entities to pay claims for covered services. This section shall not be construed to prevent a Plan from assigning, by a written contract, the responsibility to pay interest and late charges pursuant to this section to medical groups, independent practice associations, or other entities.
- (g) A Plan shall not delay payment on a claim from a physician or other provider to await the submission of a claim from a hospital or other provider, without citing specific rationale as to why the delay was necessary and providing a monthly update regarding the status of the claim and the Plan's actions to resolve the claim, to the provider that submitted the claim.
- (h) A Plan shall not request or require that a provider waive its rights pursuant to this section.
- (i) This section shall not apply to capitated payments.
- (j) This section shall apply only to claims for services rendered to a patient who was provided emergency services and care as defined in Section 1317.1 in the United States on or after September 1, 1999.
- (k) This section shall not be construed to affect the rights or obligations of any person pursuant to Section 1371.
- (I) This section shall not be construed to affect a written agreement, if any, of a provider to submit bills within a specified time period.
- (m) The department may issue compliance guidance and amend regulations for consistency with this section. The guidance and amendments shall not be subject to the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) until December 31, 2027.
- (n) This section shall become operative on January 1, 2026.



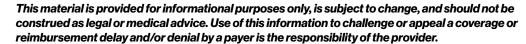
Request for Additional Information Filing Deadlines Provider Appeals Issue: Subsequent request for additional information. Issue: Claim is past the filing deadline. **Issue:** Provider appeals. **Example scenario:** Provider timely submits an EYLEA HD claim. Plan **Example scenario:** Provider submits a claim for EYLEA HD **Example scenario:** Provider wants to challenge Plan's denial or reduction of an reimbursement, but 31 days later. Plan indicates payment of claim is denies the claim for being past the filing deadline. FYI FAHD claim pending receipt of additional information. Title 28 California Code of Regulations Section 1300.71 states.... Title 28 California Code of Regulations Sections 1300.68 and 1300.68.01 state... California Health and Safety Code Section 1371.35 states... Neither Plan nor Plan's capitated provider that pays claims will impose a Internal appeal: A grievance system shall provide for a written acknowledgment within A provider's claim will be deemed complete upon submission of: deadline for receipt of a claim that is fewer than 90 days for contracted **5 calendar days** of receipt. The Plan's standard resolution, containing a written response A completed Centers for Medicare and Medicaid Services 1500 form (or providers and fewer than 180 days for noncontracted providers after the to the grievance, shall be sent to the complainant within 30 calendar days of receipt. its electronic equivalent or other format adopted by the National Uniform date of service, except as required by any state or federal law or regulation. The Plan's urgent care resolution, containing a written response to the grievance, shall be sent to the complainant within 3 calendar days of receipt. Billing Committee), and If Plan or Plan's capitated provider is not the primary payer under Reasonable, relevant information requested by Plan within 30 working coordination of benefits. Plan or Plan's capitated provider will not impose a For grievances involving delay, modification or denial of services based on a days of receiving the claim deadline for submitting supplemental or coordination of benefits claims to determination in whole or in part that the service is **not medically necessary**, the Plan The provider will provide Plan with reasonable, relevant information within any secondary payer that is fewer than 90 days from the date of payment shall include in its written response the reasons for its determination. The response 10 working days of receiving a written request that is clear and specific or date of contest, denial, or notice from the primary payer. shall clearly state the criteria, clinical guidelines, or medical policies used in reaching the regarding the information sought. If Plan requires further information as determination. "Date of receipt" means the working day when a claim, by physical or a result of reviewing the reasonable, relevant information, it will have an electronic means, is first delivered to either Plan's specified claims payment California Health and Safety Code Sections 1374.30 and 1374.33 state... additional 15 working days after receipt of the reasonable, relevant office, post office box, or designated claims processor or to Plan's capitated External appeal: An enrollee may apply to the department for an independent medical information to request the further information. provider for that claim. This definition will not affect the presumption of review of a decision to deny, modify, or delay health care services, based on a finding that receipt of mail set forth in Evidence Code Section 641 (see below). In the the disputed health care services are not medically necessary, within 6 months. situation where a claim is sent to the incorrect party, the date of receipt will Upon notice from the department that the health care service Plan's enrollee has applied be the working day when the claim, by physical or electronic means, is first delivered to the correct party responsible for adjudicating the claim. for an independent medical review, the Plan shall provide to the independent medical review organization all the documents within 3 business days of the Plan's receipt of the California Evidence Code Section 641 states... department's notice of a request by an enrollee for an independent review. A letter correctly addressed and properly mailed is presumed to have been The organization shall complete its review and make its determination in writing within received in the ordinary course of mail. **30 days** of the receipt of the application for review and supporting documentation, or within less time as prescribed by the director. If the disputed health care service has not been provided and the enrollee's provider or the department certifies in writing that an imminent and serious threat to the health of the enrollee may exist, including serious deterioration of the health of the enrollee, the analyses and determinations of the reviewers shall be expedited and **rendered within 3 days** of the receipt of the information. The enrollee shall pay no application or processing fees of any kind.

Complaints regarding these and other payer issues can be made to the <u>California Department of Managed Health Care website</u>.



 $\textbf{Visit NavigatingPayerChallenges.com for state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information and the state-specific and the state-speci$





EYLEA HD®
(aflibercept) Injection 8 mg

This information is provided to you