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).

On the following page: Prompt Payment | Request for Additional Information | Filing Deadlines | Provider Appeals

Example EYLEA HD Claim Issues and Applicable State Provisions (cont'd)

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...

Plan will reimburse a 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 or, if Plan is a health maintenance organization, **no later than 45 working days** after receipt of the complete claim.

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, Plan will 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.

Request for Additional Information

Issue: Subsequent request for additional information.

Example scenario: Provider submits a claim for EYLEA HD reimbursement, but 31 days later, Plan indicates payment of claim is pending receipt of additional information.

California Health and Safety Code Section 1371.35 states...

A provider's claim will be deemed complete upon submission of:

- A completed Centers for Medicare and Medicaid Services 1500 form (or its electronic equivalent or other format adopted by the National Uniform Billing Committee), and
- Reasonable, relevant information requested by Plan **within 30 working days** of receiving the claim

The provider will provide Plan with reasonable, relevant information **within 10 working days** of receiving a written request that is clear and specific regarding the information sought. If Plan requires further information as a result of reviewing the reasonable, relevant information, it will have **an additional 15 working days** after receipt of the reasonable, relevant information to request the further information.

Filing Deadlines

Issue: Claim is past the filing deadline.

Example scenario: Provider timely submits an EYLEA HD claim. Plan denies the claim for being past the filing deadline.

Title 28 California Code of Regulations Section 1300.71 states....

Neither Plan nor Plan's capitated provider that pays claims will impose a deadline for receipt of a claim that is **fewer than 90 days** for contracted providers and **fewer than 180 days** for noncontracted providers after the date of service, except as required by any state or federal law or regulation.

If Plan or Plan's capitated provider is not the primary payer under coordination of benefits, Plan or Plan's capitated provider will not impose a deadline for submitting supplemental or coordination of benefits claims to any secondary payer that is **fewer than 90 days** from the date of payment or date of contest, denial, or notice from the primary payer.

"Date of receipt" means the working day when a claim, by physical or electronic means, is first delivered to either Plan's specified claims payment office, post office box, or designated claims processor or to Plan's capitated provider for that claim. This definition will not affect the presumption of receipt of mail set forth in Evidence Code Section 641 (see below). In the situation where a claim is sent to the incorrect party, the date of receipt will be the working day when the claim, by physical or electronic means, is first delivered to the correct party responsible for adjudicating the claim.

California Evidence Code Section 641 states...

A letter correctly addressed and properly mailed is presumed to have been received in the ordinary course of mail.

Provider Appeals

Issue: Provider appeals.

Example scenario: Provider wants to challenge Plan's denial or reduction of an EYLEA HD claim.

Title 28 California Code of Regulations Sections 1300.68 and 1300.68.01 state...

Internal appeal: A grievance system shall provide for a written acknowledgment **within 5 calendar days** of receipt. The Plan's standard resolution, containing a written response to the grievance, shall be sent to the complainant **within 30 calendar days** of receipt. 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.

For grievances involving delay, modification or denial of services based on a determination in whole or in part that the service is **not medically necessary**, the Plan shall include in its written response the reasons for its determination. The response shall clearly state the criteria, clinical guidelines, or medical policies used in reaching the determination.

California Health and Safety Code Sections 1374.30 and 1374.33 state...

External appeal: An enrollee may apply to the department for an independent medical review of a decision to deny, modify, or delay health care services, based on a finding that the disputed health care services are not medically necessary, **within 6 months**.

Upon notice from the department that the health care service Plan's enrollee has applied 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 department's notice of a request by an enrollee for an independent review.

The organization shall complete its review and make its determination in writing **within 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 California Department of Managed Health Care website.

Visit NavigatingPayerChallenges.com for state-specific and federal legislation or contact your Reimbursement Business Manager (RBM) for more information

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This material is provided for informational purposes only, is subject to change, and should not be construed as legal or medical advice. Use of this information to challenge or appeal a coverage or reimbursement delay and/or denial by a payer is the responsibility of the provider.

Reference: Data on file. Regeneron Pharmaceuticals, Inc.

This information is provided to you by Regeneron, the maker of

EYLEA® HD (aflibercept) Injection 8 mg