

## 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.

#### New York Insurance Code Section 4903 states...

- (b-1)** Plan will make a determination on a prior authorization and notify (by phone and in writing) the insured and the provider of the determination **within 3 business days** of receipt of the necessary information.
- (f)** If Plan renders an adverse determination without discussing the matter with the provider who recommended the service, procedure, or treatment under review, provider may request a reconsideration of the adverse determination. Reconsideration will occur **within 1 business day** of receipt of the request.
- (c-1)** A Plan shall grant a step therapy protocol override determination **within 72 hours** of the receipt of information that includes supporting rationale and documentation from a health care professional which demonstrates that:
- (1)** The required prescription drug or drugs is contraindicated or will likely cause an adverse reaction by or physical or mental harm to the insured; **(2)** The required prescription drug or drugs is expected to be ineffective based on the known clinical history and conditions of the insured and the insured's prescription drug regimen; **(3)** The insured has tried the required prescription drug or drugs while under their current or a previous health insurance or health benefit plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action and such prescription drug or drugs was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event; **(4)** The insured is stable on a prescription drug or drugs selected by their health care professional for the medical condition under consideration, provided that this shall not prevent a Plan from requiring an insured to try an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug or drugs; or **(5)** The required prescription drug or drugs is not in the best interest of the insured because it will likely cause a significant barrier to the insured's adherence to or compliance with the insured's plan of care, will likely worsen a comorbid condition of the insured, or will likely decrease the covered individual's ability to achieve or maintain reasonable functional ability in performing daily activities.
- (c-3) Effective April 20, 2025:** Upon a determination that the step therapy protocol should be overridden, the Plan shall authorize immediate coverage for the prescription drug prescribed by the insured's treating health care professional. Any approval of a step therapy protocol override determination request shall be honored until the lesser of either treatment duration based on current evidence-based treatment guidelines or 12 months following the date of the approval of the request or renewal of the insured's coverage.
- (e) (1)** Notice of an adverse determination made by a Plan shall be in writing and must include: **(i)** the reasons for the determination including the clinical rationale, if any; **(ii)** instructions on how to initiate standard appeals and expedited appeals pursuant to section 4904 and an external appeal pursuant to section 4914 of this article; **(iii)** notice of the availability, upon request of the insured, or the insured's designee, of the clinical review criteria relied upon to make such determination. Such notice shall also specify what, if any, additional necessary information must be provided to, or obtained by, the Plan in order to render a decision on the appeal; and **(iv)** for an adverse determination related to a step therapy protocol override request, information that includes the clinical review criteria relied upon to make such determination and any applicable alternative prescription drugs subject to the step therapy protocol of the Plan. **(2)** A Plan may provide notice of an adverse determination related to a step therapy protocol override determination electronically pursuant to subsection (i) of this section, including by electronic mail or through the health care plan's member portal and provider portal. An electronic notice of such an adverse determination may meet the requirements of subparagraph (iv) of paragraph one of this subsection by linking to information posted on the website of the health care plan.
- (g) Effective April 20, 2025:** Failure by the Plan to make a determination within the time periods prescribed in this section shall be deemed to be an adverse determination subject to appeal pursuant to section 4904 of this title, provided, however, that failure to meet such time periods for a step therapy protocol as defined in subsection (g-9) of section 4900 of this title or a step therapy protocol override determination pursuant to subsections (c-1), (c-2) and (c-3) of this section shall be deemed to be an override of the step therapy protocol. A Plan's failure to comply with any of the step therapy protocol requirements required in subsections 15 and 16 of section 4902 of this title shall be considered a basis for granting an override of the step therapy protocol, absent fraud.

#### New York Insurance Code Section 4902 states...

##### Effective April 20, 2025

- (15)** When establishing a step therapy protocol, a Plan shall ensure that the protocol cannot: **(i)** require a prescription drug that has not been approved by the United States Food and Drug Administration for the medical condition being treated and/or is not supported by current evidence-based guidelines for the medical condition being treated; **(ii)** require an insured to try and fail on more than two drugs within one therapeutic category before providing coverage to the insured for the prescribed drug; **(iii)** require the use of a step therapy-required drug for longer than 30 days or a duration of treatment supported by current evidence-based treatment guidelines appropriate to the specific disease state being treated; **(iv)** be imposed on an insured if a therapeutic equivalent to the prescribed drug is not available, or if the Plan has documentation that it has covered the drug for the enrollee within the past 365 days; **(v)** require a newly enrolled insured to repeat step therapy for a prescribed drug where that insured already completed step therapy for that drug under a prior plan, so long as the enrollee or provider submits information demonstrating completion of a step therapy protocol of the prior plan within the past 365 days; and **(vi)** be imposed on an insured for a prescribed drug that was previously approved for coverage by a plan for a specific medical condition after the insured's plan implements a formulary change or utilization management that impacts the coverage criteria for the prescribed drug until the approved override expires, unless a specifically identified and current evidence-based safety concern exists and a different therapeutic alternative drug exists.
- (16)** When establishing a step therapy protocol, a Plan shall ensure that the protocol accepts any written or electronic attestation submitted by the insured's health care professional as defined in section 4900 of this title stating that a required drug has failed as prima facie evidence that the required drug has failed.

On the following page:

Prompt Payment

Request for Additional Information

Filing Deadlines

Provider Appeals

This information is provided to you  
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➤ **Example EYLEA HD Claim Issues and Applicable State Provisions (cont'd)**

Prompt Payment	Request for Additional Information	Filing Deadlines	Provider Appeals
<p><b>Issue:</b> Plan delays timely payment pending medical necessity determination.</p> <p><b>Example scenario:</b> 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.</p> <p><b>New York Insurance Code Section 3224a states...</b></p> <p>Plan must pay paper claims <b>within 45 days</b> and electronic claims <b>within 30 days</b>. Failure to comply with these time frames may subject Plan to interest at a minimum 12% rate.</p> <p><b>New York Insurance Code Section 4905 states...</b></p> <p>If prior authorization has been received for a health care service, a Plan will not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used in the utilization review for procedures, treatment, and services delivered to the insured during the same course of treatment.</p>	<p><b>Issue:</b> Subsequent request for additional information.</p> <p><b>Example scenario:</b> Provider submits a claim for EYLEA HD reimbursement, but 31 days later, Plan indicates payment of claim is pending receipt of additional information.</p> <p><b>New York Insurance Code Section 3224a states...</b></p> <p>Plan must notify the policyholder, covered person, or health care provider in writing, and through the internet or other electronic means for claims submitted in that manner, <b>within 30 calendar days</b> of the receipt of the claim:</p> <ul style="list-style-type: none"> <li>• Whether the claim or bill has been denied or partially approved;</li> <li>• Which claim or medical payment that it is not obligated to pay, stating the specific reasons why it is not liable; and</li> <li>• To request all additional information needed to determine liability to pay the claim or make the health care payment</li> </ul>	<p><b>Issue:</b> Claim is past the filing deadline.</p> <p><b>Example scenario:</b> Provider timely submits an EYLEA HD claim. Plan denies the claim for being past the filing deadline.</p> <p><b>New York Insurance Code Section 3224a states...</b></p> <p>Provider must submit claim <b>within 120 days</b> after date of service for claim to be valid and enforceable against Plan. Provider and Plan may agree contractually to a different time period that is <b>not less than 90 days</b>.</p>	<p><b>Issue:</b> Provider appeals.</p> <p><b>Example scenario:</b> Provider wants to challenge Plan's denial or reduction of an EYLEA HD claim.</p> <p><b>New York Insurance Code Section 4903 states...</b></p> <p><b>Internal grievance:</b></p> <ul style="list-style-type: none"> <li>• Prospective review request must be filed <b>no later than 45 days</b></li> <li>• Plan must acknowledge <b>within 15 days</b> of filing</li> <li>• Determination <b>within 30 days</b> of receipt of all necessary information</li> </ul> <p>(e) Notice of an adverse determination made by a Plan shall be in writing and must include:</p> <p>(I) the reasons for the determination, including the clinical rationale, if any;</p> <p>(II) instructions on how to initiate standard appeals and expedited appeals pursuant to section 4904 and an external appeal pursuant to 4914 of this article; and</p> <p>(III) notice of the availability, upon request of the insured, or the insured's designee, of the clinical review criteria relied upon to make such determination. Such notice shall also specify what, if any, additional necessary information must be provided to, or obtained by, the Plan in order to render a decision on the appeal; and</p> <p>(IV) for an adverse determination related to a step therapy protocol override request, information that includes the clinical review criteria relied upon to make such determination and any applicable alternative prescription drugs subject to the step therapy protocol of the Plan.</p> <p><b>New York Insurance Code Section 4904 states...</b></p> <p><b>Internal grievance:</b></p> <ul style="list-style-type: none"> <li>• Retrospective review request must be filed <b>no later than 45 days</b></li> <li>• Plan must acknowledge <b>within 15 days</b> of filing</li> <li>• Determination <b>within 30 days</b> of receipt of all necessary information</li> <li>• Failure by the Plan to make a determination within the applicable time periods in this section <b>shall be deemed to be a reversal</b> of the Plan's adverse determination</li> </ul> <p><b>New York Insurance Code Section 4914 states...</b></p> <p><b>External review:</b></p> <ul style="list-style-type: none"> <li>• Insured has 120 days to request an external review of final adverse determination, but provider has only 60 days</li> <li>• The external appeal agent will have 30 days to make a determination</li> <li>• A \$50 fee may be charged to the provider by the Plan. The fee is to be refunded if the provider wins the appeal</li> <li>• If an insured's provider was acting as the insured's designee, payment for the external appeal shall be made by the Plan. The external appeal and any <b>designation shall be submitted on a standard form</b> developed by the superintendent in consultation with the Commissioner of Health</li> </ul> <p>Download designated form from the <a href="#">New York State Department of Financial Services website</a>.</p>

Complaints regarding these and other payer issues can be made to the [New York State Department of Financial Services website](#).



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