# Understanding the Medicare Appeals Process

## A Guide for Health Care Providers and Practice Administration

**Example EYLEA® (aflibercept) Injection Medicare Appeals Issues and Applicable Part B and Part C Provisions**

### Medicare Part B:

| Initial Determination | Level 1 Redetermination | Level 2 Reconsideration |
|---|---|---|
| **Issue:** Delay pending medically necessary determination.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. Medicare Administrative Contractor (MAC) must make a determination that the injections are medically necessary. | **Issue:** EYLEA deemed not medically necessary.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MAC determines that the injections are not medically necessary or within clinical guidelines. | **Issue:** EYLEA deemed not medically necessary.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MAC reviewed medical necessity and upheld the decision of the Level 1 redetermination. |
| **Section 1862(a)(1)(A) of Social Security Act states...** | **42 Code of Federal Regulations (CFR) Section 405.942 states...** | **42 CFR Section 405.960 states...** |
| The Social Security Act requires payment for items or services that are reasonable and necessary without the need for preservice authorization.<br>Medicare coverage and payment for items and services depend on a determination that an item or service:<br>• Falls within a benefit category<br>• Is not specifically excluded from coverage<br>• Is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member | Any request for redetermination must be filed **within 120 calendar days** from the date a party receives the notice of the initial determination.<br>**42 CFR Section 405.950 states...**<br>The contractor mails, or otherwise transmits, written notice of the redetermination or dismissal to the parties to the redetermination at their last known addresses **within 60 calendar days** of the date the contractor receives a timely filed request for redetermination. | A person or entity that is a party to a redetermination made by a contractor and is dissatisfied with that determination may request a reconsideration by a Qualified Independent Contractor (QIC) regardless of the amount in controversy.<br>**42 CFR Section 405.962 states...**<br>Any request for a reconsideration must be filed **within 180 calendar days** from the date the party receives the notice of the redetermination.<br>**42 CFR Section 405.962 states...**<br>Time frame for making a reconsideration: **Within 60 calendar days** of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination. |

### Medicare Part C:

| Initial Determination | Level 1 Reconsideration | Level 2 Reconsideration |
|---|---|---|
| **Issue:** Delay pending medically necessary determination.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. Medicare Advantage (MA) Plan must make an initial determination that the injections are medically necessary. | **Issue:** EYLEA deemed not medically necessary.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan determines that the injections are not medically necessary or within clinical guidelines. | **Issue:** EYLEA deemed not medically necessary upon reconsideration.<br>**Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan reviewed medical necessity and either upheld the decision of the Level 1 reconsideration or dismissed the Level 1 reconsideration request made by provider. |
| **42 CFR Section 422.568 states...** | **42 CFR Section 422.582 states...** | **42 CFR Section 422.590 states...** |
| An MA organization must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but **no later than 72 hours** after receipt of the request. This 72-hour period may not be extended.<br>**42 CFR Section 422.572 states...**<br>If the MA organization fails to provide the enrollee with timely notice of an expedited organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed. | A request for reconsideration must be filed **within 60 calendar days** from the date of the notice of the organization determination.<br>The MA organization dismisses a reconsideration request, either entirely or as to any stated issue.<br>**42 CFR Section 422.590 states...**<br>When the issue is the MA organization's denial of coverage based on a lack of medical necessity (or any substantively equivalent term used to describe the concept of medical necessity), the reconsidered determination must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue. | If the MA organization makes a reconsidered determination that affirms its adverse organization determination, it must prepare a written explanation and send the case file to the independent entity contracted with CMS **no later than 7 calendar days** from the date it receives the request for a standard reconsideration.<br>If the MA organization dismisses a request for a reconsideration, the enrollee or other proper party has the right to request review of the dismissal by the independent entity. A request for review of a dismissal must be filed in writing with the independent entity **within 60 calendar days** from the date of the MA organization's dismissal notice. |

**For more information about the Medicare appeals and grievance process, go to https://www.cms.gov/medicare/appeals-and-grievances/mmcag.**

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

REGENERON


777 Old Saw Mill River Road, Tarrytown, NY 10591
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**Reference:** Data on file. Regeneron Pharmaceuticals, Inc.

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

EYLEA® (aflibercept) Injection