

Understanding Medicare Advantage (MA) Step Therapy

A Guide for Health Care Providers and Practice Administration

Example EYLEA® (afibercept) Injection Step Therapy Issues and Applicable MA/HMO Plan Provisions¹²

Continuity of Care	Exception Requests	Prompt Determination	Request for Additional Information	Appeals	Delayed Determination
<p>Issue: Step therapy requirements may disrupt ongoing EYLEA treatment.</p> <p>Example scenario: Patient is diagnosed and is receiving ongoing treatment with EYLEA injections. MA Plan discloses in the Annual Notice of Change and Evidence of Coverage documents that EYLEA injections may be subject to step therapy requirements to be effective during patients' ongoing treatment.</p> <p>Title 42 Code of Federal Regulations Section 422.112(b) states...</p> <p>MA organizations offering coordinated care Plans must ensure continuity of care.</p> <p>Title 42 Code of Federal Regulations Section 422.136(a)(1) states...</p> <p>Step therapy may be applied only to new prescriptions or administrations of Medicare Part B drugs for enrollees not actively receiving the affected medication.</p> <p>CMS has extended the lookback period to 365 days for MA Plans to determine whether a beneficiary has been actively taking a Medicare Part B drug and will be subject to step therapy. CMS = Centers for Medicare & Medicaid Services.</p>	<p>Issue: Provider requests an exception to the step therapy requirement.</p> <p>Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan requires step therapy treatment protocol before approving EYLEA injections. Provider requests an exception to the step therapy requirement.</p> <p>Title 42 Code of Federal Regulations Section 422.136 states...</p> <p>Important Note: This Medicare Part C regulation requires Medicare Advantage Plans to follow Medicare Part D time frames for Medicare Part B drug coverage.</p> <p>Time frame for requests for drug benefits. When a party makes a request for a drug benefit, the Part D Plan sponsor must notify the enrollee of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. For an exceptions request, the Part D Plan sponsor 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 physician's or other prescriber's supporting statement.</p> <p>Effect of failure to meet the adjudicatory time frames. If the Part D Plan sponsor fails to notify the enrollee of its determination in the appropriate time frame, the failure constitutes an adverse coverage determination, and the Plan sponsor must forward the enrollee's request to the Independent Review Entity (IRE) within 24 hours of the expiration of the adjudication time frame.</p> <p>Time frame for requests for payment. When a party makes a request for payment, the Part D Plan sponsor must notify the enrollee of its determination and make payment (when applicable) no later than 14 calendar days after receipt of the request.</p> <p>MA Plans must consider whether the inclusion of a particular Part B drug in a step therapy program has any therapeutic advantages in terms of safety and efficacy.</p> <p>Federal Register 84 Federal Regulations 23832 states...</p> <p>Effective January 1, 2020: CMS interprets the MA Plan's responsibility to provide all medically necessary covered services and items covered under the original Medicare program to mean that ineffectiveness or adverse effects of a treatment required in a step therapy program would be sufficient basis to grant an exemption or move an enrollee to a higher step in the protocol.</p> <p>Title 42 Code of Federal Regulations Section 423.568 states...</p> <p>Time frame for requests for drug benefits. For an exceptions request, the Part D Plan sponsor 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 physician's or other prescriber's supporting statement.</p> <p>Title 42 Code of Federal Regulations Section 423.578 states...</p> <p>When a Part D Plan sponsor does not make a timely decision. If the Part D Plan sponsor fails to make a decision on an exceptions request or provide notice of the decision within the time frame required under Section 423.568(a) or Section 423.572(a), as applicable, the failure constitutes an adverse coverage determination and the Part D Plan sponsor must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication time frame.</p>	<p>Issue: MA Plan must make a timely determination regarding provider's exception request.</p> <p>Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan requires step therapy treatment protocol before approving EYLEA injections.</p> <p>Title 42 Code of Federal Regulations Section 422.568 states...</p> <p>Requests for a Part B drug. 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 under the provisions of this section.</p> <p>Title 42 Code of Federal Regulations Section 422.572 states...</p> <p>For Medicare Part B drugs, an MA Plan must make its determination and notify the enrollee within 24 hours for expedited requests. This time period may not be extended.</p> <p>NOTE: MA Plans must always make determinations as expeditiously as the enrollee's health condition requires, regardless of time frames.</p> <p>Title 42 Code of Federal Regulations Section 422.590 states...</p> <p>Effect of failure to meet the adjudicatory time frames. If the MA organization makes a reconsidered determination that affirms, in whole or in part, 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. The organization must make reasonable and diligent efforts to assist in gathering and forwarding the information to the independent entity.</p> <p>CMS Guidance Memo Dated August 7, 2018, page 4 states...</p> <p>CMS recommends that MA Plans follow the rules governing Part D exceptions in 42 Code of Federal Regulations Section 423.578(b) and grant an exception whenever it determines that the drug is medically necessary and is a covered Part B drug.</p>	<p>Issue: MA Plan requests additional information.</p> <p>Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan requires step therapy treatment protocol before approving EYLEA injections. Provider requests an exception to the step therapy requirement. MA Plan makes a request for additional information in consideration of provider's exception request.</p> <p>Title 42 Code of Federal Regulations Section 422.568 states...</p> <p>If the MA organization fails to provide the enrollee with timely notice of an organization determination as specified in this section, this failure itself constitutes an adverse organization determination and may be appealed.</p> <p>NOTE: If additional information is requested, the MA organization is not excused from complying with the 72-hour standard time frame. Provider may seek an immediate appeal on delayed determinations. See Appeals column.</p> <p>Title 42 Code of Federal Regulations Section 422.572 states...</p> <p>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.</p> <p>NOTE: If additional information is requested, the MA organization is not excused from complying with the 24-hour expedited time frame. Provider may seek an immediate appeal on delayed determinations. See Appeals column.</p>	<p>Issue: Provider appeals MA Plan's denial.</p> <p>Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan requires step therapy treatment protocol before approving EYLEA injections. Provider requests an exception to the step therapy requirement. MA Plan denies provider's exception request. Provider appeals MA Plan's denial.</p> <p>Title 42 Code of Federal Regulations Section 422.590 states...</p> <p>Internal: Standard request Part B drugs: If the MA organization makes a reconsidered determination that affirms, in whole or in part, 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.</p> <p>Expedited request Part B drugs: An MA organization that approves a request for an expedited reconsideration must complete its reconsideration and give the enrollee (and the physician or other prescriber involved, as appropriate) notice of its decision as expeditiously as the enrollee's health condition requires but no later than 72 hours after receiving the request. This 72-hour period may not be extended under the provisions of this section.</p> <p>Medicare Managed Care Manual, Chapter 13, Section 60.3 states...</p> <p>External: The IRE must conduct the reconsideration as expeditiously as the enrollee's health condition requires, but not exceed the required time frames outlined below.</p> <p>Standard: Preservice: 30 days; postservice: 60 days; Part B drugs: 7 days.</p> <p>Expedited: Part B drug requests cannot be expedited.</p> <p>Failure to meet time frame for expedited reconsideration. If the MA organization fails to provide the enrollee with the results of its reconsideration within the time frames described, this failure constitutes an adverse reconsidered determination, and the MA organization must submit the file to the independent entity within 24 hours.</p> <p>Medicare Managed Care Manual, Chapter 13, Section 50.12.1 states...</p> <p>If CMS determines that the Plan has a pattern of not making appropriate efforts to forward information to the IRE, the Plan will be considered to be out of compliance with the terms of its Medicare contract and/or subject to intermediate sanctions in accordance with subpart O of 42 Code of Federal Regulations Part 422 or Part 423.</p> <p>Title 42 Code of Federal Regulations Section 422.582 states...</p> <p>Dismissals: The MA organization may dismiss a reconsideration request, either entirely or as to any stated issue, under certain circumstances. The MA organization's dismissal is binding unless the enrollee or other party requests review by the independent entity.</p> <p>Title 42 Code of Federal Regulations Section 422.590 states...</p> <p>Requests for review of a dismissal by the independent entity. 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.</p> <p>Title 42 Code of Federal Regulations Section 422.582 states...</p> <p>If good cause is established, the MA organization may vacate its dismissal of a request for an organization determination within 6 months from the date of the notice of dismissal.</p>	<p>Issue: MA delays making a postservice benefit determination.</p> <p>Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA injections. MA Plan requires a step therapy treatment protocol before approving EYLEA injections. Provider requests an exception to the step therapy protocol. MA delays making a postservice benefit determination.</p> <p>Title 42 Code of Federal Regulations Section 422.520 states...</p> <p>The contract between CMS and the MA organization must provide that the MA organization will pay 95% of the "clean claims" within 30 days of receipt if they are submitted by, or on behalf of, an enrollee of an MA private fee-for-service Plan or are claims for services that are not furnished under a written agreement between the organization and the provider. The MA organization must pay interest on clean claims that are not paid within 30 days in accordance with Sections 1816(c)(2)(B) and 1842(c)(2)(B).</p> <p>All other claims from noncontracted providers must be paid or denied within 60 calendar days from the date of the request.</p> <p>The term "clean claim" means a claim that has no defect or impropriety (including any lack of required substantiating documentation) or particular circumstance requiring special treatment that prevents timely payment from being made on the claim.</p> <p>The interest rate is determined by the US Treasury Department each January and July and may be accessed at http://fms.treas.gov/prompt/rates.html.</p> <p>Medicare Managed Care Manual Chapter 4, Section 10.16, states...</p> <p>Furthermore, if the Plan approved the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity.</p>

For more information about the MA Plan appeals process, go to <https://www.cms.gov/medicare/appeals-and-grievances/mmcag>.

Patients who want to file a complaint can find information at <https://www.medicare.gov/claims-appeals/file-a-complaint-grievance/filing-complaints-about-your-health-or-drug-plan>.



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References: 1. Data on file. Regeneron Pharmaceuticals, Inc. 2. Modernizing Part D and Medicare Advantage to lower drug prices and reduce out-of-pocket expenses. Fed Regist. 2019;84(100):23832-23884. <http://bit.ly/2KJVHCR>. Accessed March 3, 2023.

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