Understanding Medicare Advantage (MA) Step Therapy

A Guide for Health Care Providers and Practice Administration

Example EYLEA® HD (aflibercept) Injection Step Therapy Issues and Applicable MA/HMO Plan Provisions[1,2]

Continuity of Care	Exception Requests
Issue: Step therapy requirements may disrupt ongoing EYLEA HD treatment. **Example scenario:** Patient is diagnosed and is receiving ongoing treatment with EYLEA HD injections. MA Plan discloses in the Annual Notice of Change and Evidence of Coverage documents that EYLEA HD injections may be subject to step therapy requirements to be effective during patients' ongoing treatment.	**Issue:** Provider requests an exception to the step therapy requirement. **Example scenario:** Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. MA Plan requires step therapy treatment protocol before approving EYLEA HD injections. Provider requests an exception to the step therapy requirement.
Title 42 Code of Federal Regulations Section 422.112(b) states...	**Title 42 Code of Federal Regulations Section 422.136 states...**
MA organizations offering coordinated care Plans must ensure continuity of care.	**Important Note: This Medicare Part C regulation requires Medicare Advantage Plans to follow Medicare Part D time frames for Medicare Part B drug coverage.** **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. **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. **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.
Title 42 Code of Federal Regulations Section 422.136(a)(1) states...	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.
Step therapy may be applied only to new prescriptions or administrations of Medicare Part B drugs for enrollees not actively receiving the affected medication. 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.	**Federal Register 84 Federal Regulations 23832 states...**
	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.
	Title 42 Code of Federal Regulations Section 423.568 states...
	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.
	Title 42 Code of Federal Regulations Section 423.578 states...
	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 and 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.

On the following page: Prompt Determination | Request for Additional Information | Appeals | Delayed Determination

EYLEA® HD (aflibercept) Injection 8 mg

EYLEA® HD
(aflibercept) Injection 8 mg

Example EYLEA HD Step Therapy Issues and Applicable MA/HMO Plan Provisions (cont'd)[1,2]

Prompt Determination

Issue: MA Plan must make a timely determination regarding provider's exception request.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. MA Plan requires step therapy treatment protocol before approving EYLEA HD injections.

Title 42 Code of Federal Regulations Section 422.566 states...

(d) ***Who must review organization determinations.*** If the MA organization expects to issue a partially or fully adverse medical necessity (or any substantively equivalent term used to describe the concept of medical necessity) decision based on the initial review of the request, the organization determination must be reviewed by a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria, before the MA organization issues the organization determination decision. The physician or health care professional reviewing the request need not, in all cases, be of the same specialty or subspecialty as the treating physician or other health care provider. The physician or other health care professional must have a current and unrestricted license to practice within the scope of his or her profession in a State, Territory, Commonwealth of the United States (that is, Puerto Rico), or the District of Columbia.

Title 42 Code of Federal Regulations Section 422.568 states...

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.

Title 42 Code of Federal Regulations Section 422.572 states...

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.

NOTE: MA Plans must always make determinations as expeditiously as the enrollee's health condition requires, regardless of time frames.

Title 42 Code of Federal Regulations Section 422.590 states...

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.

CMS Guidance Memo Dated August 7, 2018, page 4 states...

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.

Title 42 Code of Federal Regulations Section 423.568 states...

Time frame for requests for drug benefits. For an exceptions request, the Part D plan 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.

Title 42 Code of Federal Regulations Section 423.578 states...

When a Part D plan does not make a timely decision. If the Part D plan fails to make a decision on an exceptions request and provide notice of the decision within the time frame required under § 423.568(a) or § 423.572(a), as applicable, the failure constitutes an adverse coverage determination, and the Part D plan must forward the enrollee's request to the IRE within 24 hours of the expiration of the adjudication time frame.

Request for Additional Information

Issue: MA Plan requests additional information.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. MA Plan requires step therapy treatment protocol before approving EYLEA HD 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.

Title 42 Code of Federal Regulations Section 422.568 states...

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.

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.

Title 42 Code of Federal Regulations Section 422.572 states...

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.

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.

Appeals

Issue: Provider appeals MA Plan's denial.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. MA Plan requires step therapy treatment protocol before approving EYLEA HD injections. Provider requests an exception to the step therapy requirement. MA Plan denies provider's exception request. Provider appeals MA Plan's denial.

Title 42 Code of Federal Regulations Section 422.590 states...

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.

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.

Medicare Managed Care Manual, Chapter 13, Section 60.3 states...

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.

Standard: Preservice: **30 days**; postservice: **60 days**; Part B drugs: **7 days**.

Expedited: Part B drug requests cannot be expedited.

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**.

Medicare Managed Care Manual, Chapter 13, Section 50.12.1 states...

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.

Title 42 Code of Federal Regulations Section 422.582 states...

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.

Title 42 Code of Federal Regulations Section 422.590 states...

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.

Title 42 Code of Federal Regulations Section 422.582 states...

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.

Delayed Determination

Issue: MA delays making a postservice benefit determination.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. MA Plan requires a step therapy treatment protocol before approving EYLEA HD injections. Provider requests an exception to the step therapy protocol. MA delays making a postservice benefit determination.

Title 42 Code of Federal Regulations Section 422.520 states...

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).

All other claims from noncontracted providers must be paid or denied **within 60 calendar days** from the date of the request.

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.

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.

Medicare Managed Care Manual Chapter 4, Section 10.16, states...

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**.

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.

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

Implementation of MA Step Therapy—A Brief History[2,3]

August 7, 2018
Background

CMS announced that **starting January 1, 2019**, the agency would give MA plans the option of **applying step therapy requirements to Part B drugs**.

May 23, 2019
CMS Final Ruling

MA plans using step therapy to manage Part B drugs **must disclose that Part B drugs may be subject to step therapy requirements** in the plan's Annual Notice of Change and Evidence of Coverage documents provided each year to beneficiaries.

January 1, 2020
Effective Start Date

MA plans implementing step therapy have the option of offering **beneficiaries rewards and incentive programs that may be coupled with drug management program coordination**.

Savings from step therapy (additional supplemental benefits, lower premiums, or both) **must be reflected in the MA plan's pricing to beneficiaries** so that beneficiary requests are appropriately evaluated by MA plans.

Exceptions Continue to Be Available Today

If the requested drug is believed to be medically necessary, the provider should submit an oral or written statement supporting a request for an exception to the step therapy requirement. The supporting statement should indicate the basis for the exception request. CMS guidance provides the following examples:

The required drug...

- Has been ineffective in the treatment of the enrollee's disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence and the known relevant physical characteristics of the enrollee and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance, or
- Has caused or based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee, or
- Would not be as effective for the enrollee or would have adverse effects for the enrollee, or both

If an MA plan denies a beneficiary's request, then the beneficiary has the right to appeal. CMS should be monitoring appeals to ensure that beneficiary requests are appropriately evaluated by MA plans.

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.

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. To be codified at 42 CFR § 422 and § 423. Accessed April 4, 2024. https://www.federalregister.gov/documents/2019/05/23/2019-10521/modernizing-part-d-and-medicare-advantage-to-lower-drug-prices-and-reduce-out-of-pocket-expenses **3.** Verma S. Prior authorization and step therapy for Part B drugs in Medicare Advantage. Centers for Medicare & Medicaid Services. August 7, 2018. Accessed April 4, 2024. https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf

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