Understanding Medicare Advantage Plan/HMO

A Guide for Health Care Providers and Practice Administration

Medicare Advantage Plan/HMO

Example EYLEA® HD (aflibercept) Injection Claim Issues and Applicable Medicare Advantage Plan/HMO Provisions

Medical Necessity

Issue: Need to identify patient's MA plan, coverage and medical necessity.

Example scenario: Once patient is diagnosed, regional or local MA organization should be identified in order to confirm coverage criteria needed for medical necessity determinations.

Title 42 Code of Federal Regulations Section 422.101 states...

Except as specified in § 422.318 (for entitlement that begins or ends during a hospital stay) and § 422.320 (with respect to hospice care), each MA organization must meet the following requirements:

(a) Provide coverage of, by furnishing, arranging for, or making payment for, all services that are covered by Part A and Part B of Medicare (if the enrollee is entitled to benefits under both parts) or by Medicare Part B (if entitled only under Part B) and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees.

(b) Comply with:

1. Centers for Medicare & Medicaid Services (CMS) national coverage determinations;
2. General coverage and benefit conditions included in Traditional Medicare laws, unless superseded by laws applicable to MA plans. This includes criteria for determining whether an item or service is a benefit available under Traditional Medicare. For example, this includes payment criteria for inpatient admissions at 42 CFR 412.3, services and procedures that the Secretary designates as requiring inpatient care under 42 CFR 419.22(n), and requirements for payment of Skilled Nursing Facility (SNF) Care, Home Health Services under 42 CFR part 409, and Inpatient Rehabilitation Facilities (IRF) at 42 CFR 412.622(a)(3).
3. Written coverage decisions of local Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan. If an MA plan covers geographic areas encompassing more than one local coverage policy area, the MA organization offering such an MA plan may elect to apply to plan enrollees in all areas uniformly the coverage policy that is the most beneficial to MA enrollees. MA organizations that elect this option must notify CMS before selecting the area that has local coverage policies that are most beneficial to enrollees as follows:
   (i) An MA organization electing to adopt a uniform local coverage policy for a plan or plans must notify CMS at least 60 days before the date specified in § 422.254(a)(1), which is 60 days before the date bid amounts are due for the subsequent year. Such notice must identify the plan or plans and service area or services areas to which the uniform local coverage policy or policies will apply, the competing local coverage policies involved, and a justification explaining why the selected local coverage policy or policies are most beneficial to MA enrollees.
   (ii) CMS will review notices provided under paragraph (b)(3)(i) of this section, evaluate the selected local coverage policy or policies based on such factors as cost, access, geographic distribution of enrollees, and health status of enrollees, and notify the MA organization of its approval or denial of the selected uniform local coverage policy or policies.
4. Instead of applying rules in paragraph (b)(3)(ii) of this section, and to the extent it exercises this option, an organization offering an MA regional plan in an MA region that covers more than one local coverage policy area must uniformly apply all of the local coverage policy determinations that apply in the selected local coverage policy area in that MA region to all parts of that same MA region. The selection of the single local coverage policy area's local coverage policy determinations to apply throughout the MA region is at the discretion of the MA regional plan and is not subject to CMS pre-approval.
5. If an MA organization offering an MA local plan elects to exercise the option in paragraph (b)(3) of this section related to a local MA plan, or if an MA organization offering an MA regional plan elects to exercise the option in paragraph (b)(4) of this section related to an MA regional plan, then the MA organization must make information on the selected local coverage policy readily available, including through the Internet, to enrollees and health care providers.
6. MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature when coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs. Current, widely used treatment guidelines are those developed by organizations representing clinical medical specialties, and refers to guidelines for the treatment of specific diseases or conditions. Acceptable clinical literature includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to answer the relevant clinical question, or large systematic reviews or meta-analyses summarizing the literature of the specific clinical question.
   (i) ***Coverage criteria not fully established.*** Coverage criteria are not fully established when:
      (A) Additional, unspecified criteria are needed to interpret or supplement general provisions in order to determine medical necessity consistently. The MA organization must demonstrate that the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services;
      (B) NCDs or LCDs include flexibility that explicitly allows for coverage in circumstances beyond the specific indications that are listed in an NCD or LCD; or
      (C) There is an absence of any applicable Medicare statutes, regulations, NCDs or LCDs setting forth coverage criteria.
   (ii) ***Publicly accessible.*** For internal coverage policies, the MA organization must provide in a publicly accessible way the following:
      (A) The internal coverage criteria in use and a summary of evidence that was considered during the development of the internal coverage criteria used to make medical necessity determinations;
      (B) A list of the sources of such evidence; and
      (C) An explanation of the rationale that supports the adoption of the coverage criteria used to make a medical necessity determination. When coverage criteria are not fully established as described in paragraph (6)(i)(A), the MA organization must identify the general provisions that are being supplemented or interpreted and explain how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including from delayed or decreased access to items or services.

(c) Medical necessity determinations and special coverage provisions—

(1) ***Medical necessity determinations.***
   (i) MA organizations must make medical necessity determinations based on all of the following:
      (A) Coverage and benefit criteria as specified at paragraphs (b) and (c) of this section and may not deny coverage for basic benefits based on coverage criteria not specified in paragraph (b) or (c) of this section.
      (B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
      (C) The enrollee's medical history (eg, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
      (D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

Prior Authorization

Issue: Delay pending medical necessity determination.

Example scenario: Patient is diagnosed and meets medical necessity criteria for EYLEA HD injections. Provider submits a request for preservice authorization, but 15 days later, Medicare Advantage (MA) Plan has not made a decision.

Title 42 Code of Federal Regulations Section 422.136 states...

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 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 fails to notify the enrollee of its determination in the appropriate time frame, the failure constitutes an adverse coverage determination, and the Plan 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 422.138 states...

(a) ***Requirement.*** When a coordinated care plan, as specified in § 422.4(a)(iii) (including MSA network plans), uses prior authorization processes in connection with basic benefits or supplemental benefits, the MA organization must comply with the requirements in this section. (MA PFFS are not permitted to use prior authorization policies or "prior notification" policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the PFFS plan in advance that services will be furnished). Prior authorization processes include all policies and procedures used in prior authorization unless otherwise noted.

(b) ***Application.*** Prior authorization processes for coordinated care plans may only be used for one or more the following purposes:
   (1) To confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service; or
   (2) For basic benefits, to ensure an item or service is medically necessary based on standards specified in § 422.101(c)(1), or
   (3) For supplemental benefits, to ensure that the furnishing of a service or benefit is clinically appropriate.

(c) ***Effect of prior authorization or pre-service approval.*** If the MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at § 405.986 of this chapter) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. The definitions of the terms "reliable evidence" and "similar fault" in § 405.902 of this chapter apply to this provision.

42 Code of Federal Regulations Section 422.568 states...

Requests for a Part B drug: An MA 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 request. This 72-hour period may not be extended under the provisions of this section.

Prompt Payment

Issue: MA 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.

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

Deadline to pay a Medicare Part C claim is **30 days** from receipt of a clean claim* by MA Plan.

MA Plan must pay interest for the period beginning on the day after the required payment date and ending on the date the payment is made.

*Claim with no defect or impropriety (eg, lack of required substantiating documentation) or circumstance requiring special treatment that prevents timely payment from being made on the claim.

On the following page: Request for Additional Information | Filing Deadlines | Provider Appeals | Access to Services

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

Request for Additional Information	Filing Deadlines	Provider Appeals	Access to Services
Issue: Subsequent request for additional information. **Example scenario:** Provider submits a claim for EYLEA HD reimbursement, but 31 days later, MA Plan indicates payment of claim is pending receipt of additional information. **Medicare Managed Care Manual, Chapter 16A, Section 110 states…** A clean claim includes the minimum information necessary to adjudicate a claim, not to exceed the information required by Original Medicare. MA Plan must clearly identify the records, information, and documents it needs when requesting information from provider. If MA Plan does not obtain the requested information, it must make a decision **within the applicable time frame** based on the available clinical information. Provider's MA Plan contract may also address requests for additional information and related time frames.	**Issue:** Claim is past the filing deadline. **Example scenario:** Provider timely submits an EYLEA HD claim. MA Plan denies the claim for being past the filing deadline. **Title 42 Code of Federal Regulations Section 424.30 states…** Claims must be filed in all cases except when services are furnished on a prepaid capitation basis by an MA Organization. Claim filing deadlines may vary among MA Organizations. Provider should check the MA Organization contract for specific billing requirements.	**Issue:** Provider appeals. **Example scenario:** Provider wants to challenge MA Plan's denial or reduction of an EYLEA HD claim. **Title 42 Code of Federal Regulations Section 422.582 states…** If a Medicare Part C claim is denied as "noncovered" or "not medically necessary," provider should request a reconsideration† **within 60 calendar days** from the date the notice of denial or reduction is received. Once MA Plan receives the request, it must make a decision and notify provider **within:** • **30 days** for a standard request • **60 days** for a payment request A reconsideration resulting in a denial or reduction will automatically be advanced to an independent review **within:** • **30 days** for a standard review • **60 days** for a payment request Provider may appeal beyond reconsideration to an Administrative Law Judge and Medicare Appeals Council if the "amount in controversy" threshold is met. †Reconsideration is the second level of the appeals process under Medicare Part B; however, it is the first level of appeal under Medicare Part C. No specific CMS form is available. **Title 42 Code of Federal Regulations Section 422.590 states…** **Internal appeal:** **For a standard request for Part B drugs:** If the MA Plan 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 IRE contracted with CMS no later than **7 calendar days** from the date it receives the request for a standard reconsideration. **For an expedited request for Part B drugs:** An MA Plan that approves a request for 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 appeal:** 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 Plan 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 Plan must submit the file to the IRE 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…** The MA Plan may dismiss a reconsideration request, either entirely or as to any stated issue, under certain circumstances. The MA Plan's dismissal is binding **unless the enrollee or other party requests review** by the IRE. **Title 42 Code of Federal Regulations Section 422.590 states…** **Requests for review of a dismissal by the independent entity.** If the MA Plan dismisses a request for a reconsideration, the enrollee or other proper party has the right to request review of the dismissal by an IRE. A request for review of a dismissal must be filed in writing with the IRE **within 60 calendar days** from the date of the MA Plan's dismissal notice. **Title 42 Code of Federal Regulations Section 422.590 states…** If **good cause** is established, the MA Plan may vacate its dismissal of a request for an organization determination **within 6 months** from the date of the notice of dismissal.	**Issue:** Questions arise around additional providers and coverage for supplemental services. **Example scenario:** Provider needs information on others within the network that can provide supplemental covered services. **Title 42 Code of Federal Regulations Section 422.112 states…** (a) **Rules for coordinated care plans.** An MA organization that offers an MA coordinated care plan may specify the networks of providers from whom enrollees may obtain services if the MA organization ensures that all covered services, including supplemental services contracted for by (or on behalf of) the Medicare enrollee, are available and accessible under the plan. To accomplish this, the MA organization must meet the following requirements: (1) **Provider network.** (i) Maintain and monitor a network of appropriate providers that is supported by written agreements and is sufficient to provide adequate access to covered services to meet the needs of the population served. These providers are typically used in the network as primary care providers (PCPs), specialists, hospitals, skilled nursing facilities, home health agencies, ambulatory clinics, and other providers. The network must include providers that specialize in behavioral health services. (ii) **Exception:** MA regional plans, upon CMS pre-approval, can use methods other than written agreements to establish that access requirements are met. (iii) Arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. (b) **Continuity of care.** MA organizations offering coordinated care plans must ensure continuity of care and integration of services through arrangements with contracted providers that include: (8)(i) With respect to basic benefits, policies for using prior authorization that, at a minimum, include that for enrollees undergoing an active course of treatment: (A) Approval of a prior authorization request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider's recommendation; and (B) A minimum 90-day transition period for any active course(s) of treatment when an enrollee has enrolled in an MA plan after starting a course of treatment, even if the service is furnished by an out-of-network provider. This includes enrollees new to a plan and enrollees new to Medicare. The MA organization must not disrupt or require reauthorization for an active course of treatment for new plan enrollees for a period of at least 90 days. (ii) For purposes of this paragraph (b)(8), the following definitions apply: (A) ***Course of treatment*** means as a prescribed order or ordered course of treatment for a specific individual with a specific condition is outlined and decided upon ahead of time with the patient and provider. A course of treatment may but is not required to be part of a treatment plan. (B) ***Active course of treatment*** means a course of treatment in which a patient is actively seeing the provider and following the course of treatment.

- **Find information about MA Plan payment requirements in the Medicare Managed Care Manual at http://go.cms.gov/2FPvx00**
- **Access in-depth information about appeals and grievances, billing, coding, contracting, payments, and more by visiting CMS.gov and clicking on the Medicare tab**
- **To access an Appointment of Representative form, visit the CMS website at https://www.cms.gov/medicare/cms-forms/cms-forms/downloads/cms1696.pdf**

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

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Reference: Data on file. Regeneron Pharmaceuticals, Inc.

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

EYLEA® HD (aflibercept) Injection 8 mg