



Medicare Advantage and CMS rules for Prior Authorization

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Agenda



- ▶ Goals of Medicare Advantage (MA) regulatory changes in prior authorization
- ▶ Changes to MA prior authorization regulations starting in 2024, and across administrations
- ▶ Finalized and proposed CMS policies across MA, Medicaid, and QHPs in federally facilitated marketplaces related to interoperability and prior authorization
- ▶ Discussion/ questions

Disclaimer



This presentation is only meant to explain in general terms current federal policy and should not be interpreted as specific guidance for organizations related to compliance with federal statute or CMS regulations

MA regulatory changes went into effect in 2024



- ▶ To make MA prior authorization “no more restrictive” than Traditional Medicare
- ▶ To promote transparency in criteria used to determine medical necessity, and ensure that they were evidence-based
- ▶ To ensure proper processes are followed for utilization management

MA regulatory changes went into effect in 2024



- ▶ MA organizations must comply with Traditional Medicare **coverage criteria**:
 - ▶ CMS's national coverage determinations (NCDs) and local coverage determinations (LCDs)
 - ▶ Coverage and benefit conditions under Traditional Medicare laws

- ▶ What about when coverage criteria are not fully established?

National Coverage Determination (NCD)

Computed Tomography

220.1

Tracking Information

Publication Number

100-3

Manual Section Number

220.1

Manual Section Title

Computed Tomography

Version Number

2

Effective Date of this Version

03/12/2008

Implementation Date

07/28/2008

MA regulatory changes starting in 2024



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.

In these circumstances, the MA organization can create their own **internal** coverage criteria, but...

MA Internal Coverage Criteria requirements



The internal coverage criteria must be **publicly accessible** and based on **current evidence in widely used treatment guidelines** or **clinical literature**

Current, widely-used treatment guidelines: 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.

MA Internal Coverage Criteria requirements



The following have to be publicly accessible:

- (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, 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.

MA Utilization Management (UM) processes (2024)



- ▶ MA plans must establish a UM committee to annually review all UM policies and procedures, including for the use of prior authorization, and ensure consistency with NCDs and LCD
- ▶ Requires that a denial based on a medical necessity 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 service at issue
- ▶ Approval of a prior auth request for a course of treatment must be valid for as long as medically reasonable and necessary to avoid disruptions in care in accordance with the coverage criteria, patient's medical history, and treating provider's recommendation.
- ▶ 90 day transition period when an enrollee currently undergoing treatment switches to a new MA plan, during which the MA plan may not require prior authorization for the active course of treatment

MA 2026 changes (between administrations)



- ▶ Proposed new public accessibility criteria
 - ▶ Internal coverage criteria web page clearly displayed in the footer of the website
 - ▶ Available free of charge, without establishing user account or password or submitting personally identifying information
 - ▶ Machine-readable and available in the root directory of the website domain
- ▶ Proposed **and finalized** provision that restricted MA plans' ability to reopen and modify previously approved inpatient hospital decision on the basis of information gathered after the approval. Only able to reopen an approved admission for obvious error or fraud (started 2026).

MA UM Health Equity Provisions



- ▶ April 2024 final rule (went into effect in 2025): MA plans must:
 - ▶ Incorporate a person with expertise in health equity on the UM Committee
 - ▶ Conduct an annual health equity analysis on the use of prior authorization, which must examine the impact of prior authorization at the plan level, on enrollees with one or more social risk factors, and make the analyses public. Subsequent proposal in Nov 2024 would disaggregate by service but was not finalized by next administration.
- ▶ April 2026 final rule (goes into effect in 2027) these provisions are **repealed**

CMS multipayer interoperability and prior authorization rules



- ▶ Finalized January 2024, rule, that goes into effect in 2026 (some provisions) and 2027 (other provisions). This rule related to **prior authorization of services** and *excluded pharmacy services*.
- ▶ Applies to:
 - ▶ Medicare Advantage organizations
 - ▶ State Medicaid and CHIP FFS programs
 - ▶ Medicaid and CHIP Managed Care Organizations
 - ▶ Qualified Health Plans on the Federally Facilitated Exchanges (**Maryland does not have a Federally Facilitated Exchange so these federal rules do not apply to MD QHPs**)
- ▶ **Newly proposed rule on April 10, that *extends many of same policies to pharmacy services***

CMS multipayer interoperability and prior authorization rules



- ▶ **Prior authorization decision timeframes:** Impacted payors send prior authorization decisions within **72 hours** for **expedited** requests and **7 days for standard** (non-urgent) requests
- ▶ Beginning in 2026, impacted payors must provide a specific reason for denied prior authorization requests for non-drug items and services.
- ▶ **Newly proposed to go into effect Oct 1, 2027 for drugs:**
 - ▶ **No later than 24 hours** after receiving prior authorization request for Medicaid and CHIP MCOs.
 - ▶ **No later than 72 hours** after standard prior authorization requests and **no later than 24 hours** for expedited prior authorization requests for QHP on Federally Facilitated Exchanges.
 - ▶ **Beginning Oct 1, 2027**, impacted payors must provide specific reason for denied drugs

CMS multipayer interoperability and prior authorization rules



- ▶ **Public reporting** of prior authorization metrics (started March 2026 for non-drug items and services and **proposed for drugs March 2028**) on plan websites:
 - ▶ A list of all items, services, **and drugs** that require prior authorization
 - ▶ The percentage of standard prior authorization requests that were approved*
 - ▶ The percentage of standard prior authorization requests that were denied*
 - ▶ The percentage of standard prior authorization requests that were approved after appeal*
 - ▶ The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved*

* = Aggregated across all items and services

CMS multipayer interoperability and prior authorization rules



- ▶ **Public reporting** of prior authorization metrics (continued):
 - ▶ The percentage of expedited prior authorization requests that were approved*
 - ▶ The percentage of expedited prior authorization requests that were denied*
 - ▶ The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations*
 - ▶ The average and median time that elapsed between the submission of a request and a decision by the payer, plan, or issuer, for expedited prior authorizations, aggregated for all items and services*

* = Aggregated across all items and services

Newly proposed to include numeric counts of numerators/ denominators in addition to percentages

CMS multipayor interoperability and prior authorization rules



- ▶ Rules also advance several Application programming interfaces (APIs) to improve data flow and transparency
- ▶ **Patient Access API** adds prior authorization information
- ▶ **Provider Access API** sharing claim and encounter data, USCDI data elements, specific prior authorization information
- ▶ **Payer-to-Payer API** sharing claims and encounter data, USCDI data elements, specific prior authorization information
- ▶ **Prior authorization API** that is populated with a list of covered items and services, documentation requirements for approval, and PA request and response. **Proposed to include drugs covered under a medical benefit October 1, 2027.**

CMS multipayer interoperability and prior authorization rules



- ▶ Newly proposed that impacted payers support electronic prior authorization for drugs covered under a pharmacy benefit, and support the National Council for Prescription Drug Programs standards beginning Oct 1, 2027
- ▶ This would allow providers to query formularies, determine real-time coverage information, and exchange prior authorization requests and decisions for drugs

High-level differences for discussion



- ▶ Public accessibility of medical necessity criteria outside of MA
- ▶ Slight differences in clinical evidence requirements between MD statute and MA
- ▶ Interoperability and prior auth rules for MD QHPs (since MD is not a federally-facilitated marketplace) including prior auth metric reporting
- ▶ Health equity provisions were different than MD state requirements but were subsequently repealed
- ▶ Others?



Appendix

References for further information



- ▶ [2024 MA and Part D Final Rule](#)
- ▶ [2026 MA and Part D Proposed Rule](#)
- ▶ [2026 MA and Part D Final Rule](#)
- ▶ [2024 Interoperability and Prior Auth Final Rule](#)
- ▶ [April 2026 Interoperability and Prior Auth Proposed Rule](#)

References for further information



- ▶ MHCC released proposed updates to regulations for electronic prior authorization (similar to the interoperability rules) with comments due June 1st

Clinical evidence standards in MD law



(11) certification by the private review agent that the criteria and standards to be used in conducting utilization review are generally recognized by health care providers practicing in the relevant clinical specialties and are:

- (i) objective;
- (ii) clinically valid;
- (iii) reflected in published peer-reviewed scientific studies and medical literature;
- (iv) developed by:
 1. a nonprofit health care provider professional medical or clinical specialty society, including through the use of patient placement criteria and clinical practice guidelines; or
 2. for criteria not within the scope of a nonprofit health care provider professional medical or clinical specialty society, an organization that works directly with health care providers in the same specialty for the designated criteria who are employed or engaged within the organization or outside the organization to develop the clinical criteria, if the organization:
 - A. does not receive direct payments based on the outcome of the utilization review; and
 - B. demonstrates that its clinical criteria are consistent with criteria and standards generally recognized by health care providers practicing in the relevant clinical specialties;
- (v) recommended by federal agencies;
- (vi) approved by the federal Food and Drug Administration as part of drug labeling;
- (vii) taking into account the needs of atypical patient populations and diagnoses, including the unique needs of children and adolescents;
- (viii) sufficiently flexible to allow deviations from norms when justified on a case-by-case basis, including the need to use an off-label prescription drug;
- (ix) ensuring quality of care of health care services;
- (x) reviewed, evaluated, and updated at least annually and as necessary to reflect any changes; and
- (xi) in compliance with any other criteria and standards required for coverage under this title, including compliance with § 15-802(d) of this title for the treatment of substance use disorders.