Health Care Compliance Association
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What's Next for Prior Authorization in Medicare & Medicaid Managed Care

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Program Overview

I. DHHS OIG Spotlights Access to Care in Medicare & Medicaid Managed Care

II. Congress Focuses on Access to Care in Medicare & Medicaid Managed Care

III. CMS Responds with Prior Authorization Reform to Protect Access to Care in Medicare & Medicaid Managed Care

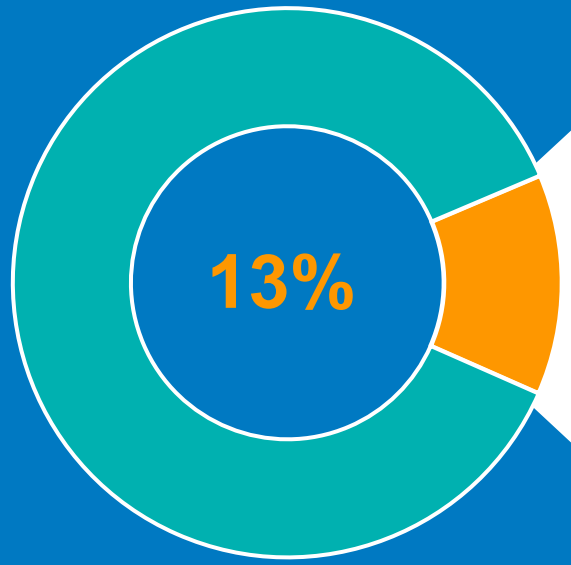
IV. CMS Audits to Ensure Access to Care in Medicare Managed Care

V. Plaintiffs Sue over Access to Care in Medicare Managed Care

I. DHHS OIG Spotlights Access to Care in Medicare & Medicaid Managed Care

OIG 4/22 MA PA Report Findings

- OIG examined whether prior authorization denials in Medicare Advantage capitated environment diminish access to medically necessary care
- OIG found 13% of 12,273 denied prior authorization requests met Medicare coverage rules
  - Likely would have been approved under Original Medicare



Two common causes of erroneous prior authorization denials:

1) MAOs used clinical criteria not present in Medicare coverage rules
2) MAOs denied prior authorizations for insufficient information OIG reviewers found in case file

OIG 4/22 MA PA Report Findings

OIG highlighted 3 coverage areas illustrating erroneous prior authorization denials:

- Imaging tests (*e.g.*, MRI)
- Post-acute facility stays (*e.g.*, rehabilitation facilities)
- Pain management injections

OIG found CMS's guidance lacked sufficient detail for MAOs to apply own clinical criteria:

- In manner not contradictory to Medicare coverage rules
- In absence of Medicare coverage rules

OIG 4/22 MA PA Report Recommendations

OIG recommended CMS:

- **Issue additional guidance for MAOs making prior authorization decisions**
- **Update Program Audit Protocols to pinpoint issues with MAO clinical criteria use and with case examples and service types in OIG's MA Report**

CMS concurred:

- **Plans to issue clarifying guidance on use of clinical criteria for medical necessity determinations**
- **Will update Program Audit Protocols to align with clarifying guidance**

OIG 7/23 MMC PA Report Findings

OIG examined Medicaid MCOs' prior authorization denials and State oversight of denials

OIG found Medicaid MCOs denied 1 in 8 prior authorization requests

Wide variation in denial rates across States, parent companies, and plans

OIG noted most States have limited oversight of prior authorization denials

OIG 7/23 MMC PA Report Recommendations

OIG recommended CMS:

- Require States to review regularly appropriateness of prior authorization denials
- Require States to collect data on Medicaid MCO prior authorization decisions
- Issue guidance to States on use of prior authorization data for oversight
- Require States to effect automatic external medical reviews of upheld Medicaid MCO prior authorization denial

CMS concurred only with OIG recommendation to work with States on actions to identify and address Medicaid MCOs issuing inappropriate prior authorization denials

II. Congress Focuses on Access to Care in Medicare & Medicaid Managed Care

Congressional Action on MA & MMC PA

4/5/19—U.S. Senate Special Committee on Aging Ranking Member Letter to DHHS OIG requesting investigation of access to care in Medicaid managed care

6/28/22—U.S. House Energy & Commerce Committee, Subcommittee on Oversight and Investigations Hearing, "Protecting America's Seniors: Oversight of Private Sector Medicare Advantage Plans"

9/14/22—U.S. House unanimous voice vote for H.R. 3173, "Improving Seniors Timely Access to Care Act"

Congressional Action on MA & MMC PA

5/17/23—U.S. Senate Homeland Security & Governmental Affairs Committee, Subcommittee on Investigations Hearing, "Examining Health Care Denials and Delays in Medicare Advantage"

Followed by investigation of largest MAOs' prior authorization practices

9/28/23—U.S. Senate Finance Committee Chair and U.S. House Committee on Energy & Commerce Ranking Member investigation of largest Medicaid MCOs' prior authorization practices

Congressional Action on MA & MMC PA

9/29/23—U.S. House Ways & Means Committee reported amended H.R. 4822, "Health Care Price Transparency Act," with MAO prior authorization use requirements

11/3/23—30+ U.S. House of Representatives' Letter to CMS regarding CMS oversight of MAO use of AI for prior authorization

12/7/23—4 Senators' Letter to CMS regarding MAO data collection and reporting to CMS for prior authorization oversight

III. CMS Responds with Prior Authorization Reform to Protect Access to Care in Medicare & Medicaid Managed Care

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23))

- Final Rule effective 1/1/24

- Answered question—when MAOs may use Prior Authorization:

For specific Part C covered item or service:

To confirm presence of diagnoses or other medical criteria bases for coverage determination for that item or service

For Part C Basic Benefits:

To ensure item or service covered is medically necessary based on Final Rule medical necessity determination standards

For Part C Supplemental Benefits:

To ensure item or service covered is clinically appropriate

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

- **Answered question—how long are Prior Authorization approvals valid:**

For Part C Basic Benefits, as long as medically necessary to avoid care disruptions, consistent with:

- Applicable coverage criteria
- Patient's medical history
- Treating provider's recommendation

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

Added Transition Period for Continuity of Care:

- MAOs must grant minimum 90-day transition period for active course of treatment
  - For beneficiary newly enrolling into MA plan after starting course of treatment
  - No changed or new prior authorization permitted

"Active course of treatment" = enrollee actively seeing provider and following course of treatment

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

Coverage Criteria

CMS Coverage Criteria Fully Established	When CMS Criteria Not Fully Established
• General coverage and benefit conditions in Medicare statute and regulations	• No applicable Medicare statutes, regulations, NCDs or LCDs
• National Coverage Determinations (NCDs)	• Additional unspecified criteria needed to interpret or supplement general provisions to consistently determine medical necessity*
• Local Coverage Determinations (LCDs)	• NCD or LCD explicitly allows coverage beyond listed indications

*Note: Additional internal coverage criteria benefits must outweigh potential clinical harms

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

When setting internal coverage criteria, MAOs and/or their delegates must use:

- Current evidence in widely used clinical guidelines or literature
- These criteria must be made publicly available

MAOs' adverse medical necessity determinations must be reviewed by physician or other appropriate health care professional with expertise in field of medicine or health care appropriate for Part C-covered item or service at issue

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

Use of Artificial Intelligence ("AI")

- Final Rule does not expressly prohibit use of AI or algorithmic tools in prior authorization
- MAOs must not use AI to change coverage or payment criteria available in Original Medicare
- When making medical necessity determinations, must take into consideration case's individual facts and circumstances

CMS CY2024 Medicare Advantage Policy/Technical Changes Final Rule (88 Fed. Reg. 22120 (4/12/23)) (Cont'd)

- **MAOs must establish Utilization Management Committee:**
  - Led by Plan's Medical Director
  - With at least one physician who is conflict free
  - That reviews and approves annually Policies and Procedures ("P&Ps") for all utilization management, including prior authorization
  - That ensures approved utilization management P&Ps are consistent with Original Medicare coverage requirements
  - That documents and retains decision-making records for utilization management P&Ps

Note: If UM Committee flexibility per HPMS Memorandum 11/15/23 is used, documentation or rationale should be clear

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24))

- **Effective 2026—MAOs and Medicaid MCOs must, for standard prior authorization requests for covered items and services (not drugs):**

Notify provider and enrollee of prior authorization decision:

- As expeditiously as enrollee's health condition requires
- But no later than 7 days after request receipt
- Unless applicable State law requires faster response time

Furnish provider specific reason for request denial, regardless of response method

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2026—MAOs and Medicaid MCOs must, for expedited prior authorization requests for covered items and services (not drugs):**

Notify provider and enrollee of prior authorization decision:

- As expeditiously as enrollee's health condition requires
- But no later than 72 hours after request receipt

Furnish provider specific reason for request denial, regardless of response method

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2026—for prior authorization requests for covered items and services (not drugs):**

Annually by 3/31

MAOs must at contract-level and Medicaid MCOs must at plan-level post to website on aggregated basis:

- All covered items and services requiring PA
- For standard PA requests
  - % approved
  - % denied
  - % approved after appeal
  - Average and median elapsed time between request and response
- For expedited PA requests
  - % approved
  - % denied
  - Average and median elapsed time between request and response
- For PA requests
  - % approved after review time extended

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must make accessible to enrollee following PA request and decision information through Patient Access API

- PA status
- PA request approval or denial date
- For approved PA request, end date or circumstance and approved items and services
- For denied PA request, specific reason
- Provider-submitted structured clinical or administrative documentation

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must make accessible to enrollee PA request and decision information through Patient Access API

- Within 1 business day after PA request receipt
- Within 1 business day after PA status change update
- For period approved PA active
- For at least 1 year after PA's last status change

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must implement and maintain Provider Access API

- **Fast Healthcare Interoperability Resources ("FHIR"®)-based**
- **Enables network providers to request access to PA request and decision information for enrollees with which have treatment relationship**
- **Same PA request and decision information and same time frames as for Patient Access API**

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must, for Provider Access API:

- Establish and maintain attribution process for determining provider-enrollee treatment relationship
- Establish and maintain opt-out process for enrollees to opt out of data exchange through Provider Access API
- Make available "plain-language" educational resources to enrollees and network providers

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must make PA request and decision information they maintain accessible to network providers through Provider Access API within 1 business day after receipt of provider's request when:

- Provider's identity authenticated
- Provider-enrollee treatment relationship confirmed
- No enrollee opt out of Provider Access API data exchange
- Data disclosure not prohibited by other law

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must implement and maintain Payer-to-Payer API

- FHIR-based
- Enables concurrent and successor payer(s) to request access to PA request and decision information for enrollees

- PA request and decision information includes:
  - PA Status
  - PA request approval date
  - Approved PA request end date or circumstance
  - Approved items and services
  - Provider-submitted structured and unstructured clinical or administrative documentation

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items & services (not drugs):**

MAOs and Medicaid MCOs must, for Payer-to-Payer API:

- Establish and maintain identification process for determining enrollees' prior and concurrent payer(s)
- Establish and maintain opt-in process for obtaining enrollees' permission for data exchange through Payer-to-Payer API
- Make available "plain-language" educational resources to enrollees

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items & services (not drugs):**

MAOs and Medicaid MCOs must, for Payer-to-Payer API:

- Request enrollee's PA request and decision information through enrollee's prior payer(s) API within 1 week after obtaining sufficient prior payer identifying information and enrollee opt-in and, thereafter, upon enrollee request
- Request enrollee's PA request and decision information through enrollee's concurrent payer(s) API within 1 week after obtaining sufficient prior payer identifying information and enrollee opt-in and, thereafter, quarterly and upon enrollee request
- Incorporate received information into enrollee's record

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items & services (not drugs):**

MAOs and Medicaid MCOs must make PA request and decision information they maintain accessible to enrollee's concurrent or successor payer(s) through Payer-to-Payer API within 1 business day after receipt of payer request when:

- Payer's identity authenticated
- Payer furnished attestation of enrollee's enrollment with payer and opt-in to Payer-to-Payer data exchange
- Data disclosure not prohibited by other law

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items and services (not drugs):**

MAOs and Medicaid MCOs must make enrollee's PA request and decision information accessible to enrollee's concurrent or successor payer(s) through Payer-to-Payer API

- For period approved PA active
- For at least 1 year after PA's last status change

CMS Interoperability & Prior Authorization Final Rule (unofficial form (1/17/24)) (Cont'd)

- **Effective 2027—for prior authorization requests for covered items & services (not drugs):**

MAOs and Medicaid MCOs must implement and maintain Prior Authorization API

- FHIR-based
- Enables providers to:
  - Determine PA-required covered items and services and documentation
  - Create and send HIPAA-compliant PA request
- Enables MCO or Medicaid MCO to create and send HIPAA-compliant PA response

DHHS expected to issue enforcement discretion for HIPAA Transaction Rule X12 278 PA transaction standard to permit FHIR-only Prior Authorization API implementation

IV. CMS Audits to Ensure Access to Care in Medicare Managed Care

CMS HPMS Memorandum 2024 Oversight Activities
(10/24/23)

- **CMS guidance states that, in January 2024, routine and focused audits will assess compliance with Final Rule's Utilization Management ("UM") requirements**

Routine Audits:

  - Will be conducted using the audit protocols currently in place

Focused Audits:

  - Will be limited in scope and duration to Compliance Program Effectiveness and Organization Determinations, Appeals & Grievances

Audit Preparation Tips

Re-Focus on FDRs

- Many MAOs delegate UM
- Final Rule necessitates close look at relationship
- More transparency may be needed

Know Your PA Data

- PA data often use notes fields to document cases
- Understand all case statuses
- Pay careful attention to AI or algorithms and understand underlying questions and workflow

Review Hierarchy & UM P&Ps

- Closely review clinical hierarchy to ensure alignment with Final Rule
- Review UM Committee structure and function
- Review UM P&Ps to align with Final Rule

Select & Review Targeted Samples

- Select and review targeted samples
- Review Inter-Rater Reliability results
- Leverage available data resources (IRE)

V. Plaintiffs Sue over Access to Care in Medicare Managed Care

Lokken v. UHG Class Action Complaint

(D. Minn., filed 11/14/23)

- **Allegations re UHG's AI use for MA plans:**
  - **"nH Predict" AI Model illegally deployed in place of "real medical professionals" to deny "elderly" care coverage obligations of UHG MA plans**
  - **"nH Predict" AI Model "systematically" denies post-acute care coverage with "90% error rate"**
  - **"nH Predict" AI Model not held accountable for "aggressively" denying post-acute care coverage because less than 0.2% of denials appealed**

Barrows v. Humana Class Action Complaint

(W.D. Ky., filed 12/12/23)

- **Allegations re Humana's AI use for MA plans:**
  - **"nH Predict" AI Model illegally deployed in place of "real doctors" to deny "elderly" care coverage obligations of Humana MA plans**
  - **"nH Predict" AI Model "systematically" denies claims without accountability because less than 0.2% of denied claims appealed**
  - **"nH Predict" AI Model "affords" Humana "clear financial windfall" by collecting premiums "without having to pay for promised care"**

Lokken & Barrows Causes of Action

- **Causes of action**
  - **Violations of various state laws—insurance claim settlement practices; insurance bad faith; competition laws**
  - **Breach of contract; breach of implied covenant of good faith and fair dealing**
  - **Unjust enrichment**
- **Claimed violations pertain to existing law; not to any new AI-specific law**

Resources

- ✓ **OIG Managed Care webpage:** https://oig.hhs.gov/reports-and-publications/featured-topics/managed-care/
- ✓ **CMS Medicare Advantage Rule 42 CFR Part 422:** https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-422
- ✓ **CMS Medicaid Managed Care Rule 42 CFR Part 438:** https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-C/part-438
- ✓ **CMS Medicare Advantage Program Audit webpage:** https://www.cms.gov/medicare/audits-compliance/part-c-d/program-audits
- ✓ **CMS Medicare Advantage 2024 Oversight Activities HPMS Memorandum (10/24/23)**
- ✓ **CMS Medicare Advantage Additional Operational Instruction on the Utilization Management Committee Structure HPMS Memorandum (11/15/23)**
- ✓ **CMS Interoperability and Prior Authorization Final Rule webpage:** https://www.cms.gov/priorities/key-initiatives/burden-reduction/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

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Thanks for attending!

Questions?

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