American Society for
Gastrointestinal Endoscopy

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January 27, 2025

Mr. Jeff Wu
Acting Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted via regulations.gov

Dear Acting Administrator Wu:

The American Society for Gastrointestinal Endoscopy (ASGE) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services ’(CMS’) proposed rule, Medicare and Medicaid Programs; Contract Year 2026 Policy and Technical Changes to the Medicare Advantage (MA) Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly [CMS-4208-P].

Specifically, ASGE offers comment on the following sections of the rule:

- Improving Access – Enhancing Rules on Internal Coverage Criteria
- Ensuring Equitable Access – Enhancing Health Equity Analyses: Annual Health Equity Analysis of Utilization Management Policies and Procedures
- Part D Coverage of Anti-Obesity Medications and Application to the Medicaid Program
- Formulary Inclusion and Placement of Generics and Biosimilars

IMPROVING ACCESS – ENHANCING RULES ON INTERNAL COVERAGE CRITERIA

Prior authorization continues to be a significant contributor to physician burnout. With more than half (54%) the Medicare eligible population enrolled in a MA plan,[1] regulatory actions are urgently needed to reduce the burden of prior authorization on physician practices, as well as to improve patient outcomes by preventing delays in care and minimizing the number of patients who forego treatment altogether when it is denied or subjected to a lengthy appeal.

Prior authorization processes used by MA and other private insurance plans are cumbersome, and gastroenterologists are not given rules or indications of how these authorizations will be adjudicated.

With authorizations for prescribed therapeutics, such as biologics to treat gastrointestinal conditions, physicians must frequently prove a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved.

Prior authorization and step therapy protocols unnecessarily delay patient care and shift costs onto providers who are uncompensated for the administrative time and staff required for authorization and appeals.

[1] Meredith Freed et al., Medicare Advantage in 2024: Enrollment Update and Key Trends, KFF (Aug. 8, 2024).

ASGE applauds CMS for its recent regulatory actions related to prior authorization and the criteria MA organizations may use in approving or denying requests, including that MA organizations may only use internal coverage criteria when traditional Medicare criteria are not fully established. We appreciate CMS' recognition there is a need to build upon and enhance the regulations from its April 2023 final rule,[2] specifically those related to the use of internal coverage criteria by:

- defining the phrase "internal coverage criteria;"
- establishing policy guardrails to preserve access to basic benefits; and
- adding more specific rules about publicly posting internal coverage criteria content on MA organization websites.

ASGE supports strengthening regulations related to the use of internal coverage criteria and encourages CMS to finalize these proposals.

ASGE offers the following feedback on specific aspects of the proposed revisions:

Using Internal Coverage Criteria to Interpret or Supplement General Provisions

ASGE supports CMS' proposal to replace the term "general provisions" with "the plain language of applicable Medicare coverage and benefit criteria" to make it explicitly evident that internal coverage cannot be used to add new, unrelated coverage criteria for an item or service that already has existing, but not fully established, coverage policies.

CMS states it has found that an assessment about whether the internal criteria used by MA organizations provide clinical benefits that are highly likely to outweigh any clinical harms is difficult to definitively prove through evidence and, consequently, enforce. Therefore, CMS is proposing to remove the existing requirement that an MA organization must demonstrate 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. CMS proposes to replace this language with the requirement that an MA organization must "demonstrate through evidence that the additional criteria explicitly support patient safety."

We ask CMS to consider whether this language should be modified or whether the Agency should create clarity around the requirements and methods for MA organizations to show the clinical benefits of internal criteria are highly likely to outweigh any clinical harms.

Alternatively, ASGE suggests that CMS replace the existing requirement with the following: "An MA organization must demonstrate through evidence the additional criteria provide clinical benefit and explicitly support patient safety." While patient safety is important, clinical benefit cannot be discounted. Evidence should refer back to "widely-used clinical guidelines and clinical literature" as defined in the April 2023 final rule.[3]

If regulations are changed to require additional criteria support patient safety, CMS asks how it could define patient safety in a way that MA organizations understand how to comply with the rule. In this regard, ASGE recommends that patient safety should be defined, at least in part, as avoidance of harm from medical care that could have been prevented or lessened with earlier, appropriate care or management.

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[2] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

[3] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly

Definition of Internal Coverage Criteria

ASGE strongly supports additional rules to define and clarify what CMS considers "internal coverage criteria." Specifically, we support the proposed definition of internal coverage criteria as "any policies, measures, tools, or guidelines, whether developed by an MA organization or a third party, that are not expressly stated in applicable statutes, regulations, NCDs, LCDs, or CMS manuals and are adopted or relied upon by an MA organization for purposes of making a medical necessity determination. This includes any coverage criteria that restrict access to, or payment for, medically necessary Part A or Part B items or services based on the duration or frequency, setting or level of care, or clinical effectiveness of the care."

It has been reported that EviCore by Evernorth, a medical benefits management company owned by Cigna, manages prior authorization requests for more than 100 million insured lives across the United States,[4] — about 1 in 3 insured people. Therefore, it is critically important that when MA organizations outsource medical reviews, they be held accountable for understanding whether the proprietary third-party criteria contain any standards or requirements that go beyond what is found in existing Medicare coverage criteria.

We concur with CMS that an MA organization maintains ultimate responsibility for adhering to and complying with all regulations and terms and conditions of its contract with CMS, including when criteria are built into an algorithm or software tool that generates a decision.

Prohibitions

CMS proposes two requirements that prohibit the use of all internal coverage criteria:

- internal coverage criterion is prohibited when it does not have any clinical benefit, and therefore, exists to reduce utilization of the item or service; and

- internal coverage criterion is prohibited when the criterion is used to automatically deny coverage of basic benefits without the MA organization making an individual medical necessity determination.

ASGE strongly supports these proposed prohibited uses of internal coverage criteria which, if finalized, will help to ensure timely Medicare beneficiary access to medically necessary care.

Recently published stories,[5,6,7,8,9] shine a bright light on the extent to which insurance

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[4] Evicore by Evernorth

[5]" I wrote about high-priced drugs for years. Then my toddler needed one." Washington Post, Jan. 30, 2023. https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies/

[6]" UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings." ProPublica, Feb. 2, 2023. https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis

[7] Insurance requirements for prior authorization may prompt 'devastating' delays. Lauren Sausser, Kaiser Health News, March 10, 2023. https://www.cnn.com/2023/03/10/health/prior-authorization-khn-partner/index.html

[8] How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them; Patrick Rucker, Maya Miller and David Armstrong. March 25, 2023. https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims?utm_medium=social&utm_source=twitter&utm_campaign=TwitterThread

[9] "'Not Medically Necessary': Inside the Company Helping America's Biggest Health Insurers Deny Coverage for Care." ProPublica, Oct. 23, 2024. https://www.propublica.org/article/evicore-health-insurance-denials-cigna-unitedhealthcare-aetna-prior-authorizations

companies are making health care decisions over the recommendations of treating clinicians and medical society guidelines to the significant detriment of patient health and outcomes. One investigative story[10] reported how insurance company reviewers would sign off on denials for authorization in batches without meaningfully reviewing each claim.

The April 2023 rule[11] finalized that when MA plans are permitted to adopt internal criteria, it must be based on current evidence in widely used treatment guidelines or clinical literature and made publicly available. 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.[12] 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.[13]

In this proposed rule, CMS solicits comment on whether it should consider other prohibitions on internal coverage criteria that support and promote access to medically necessary care in the MA program. Current regulations are written that internal criteria must be based on current evidence in widely-used treatment guidelines *or* clinical literature. ASGE recommends that internal coverage criterion be expressly prohibited when it conflicts with medical guidelines. Further, widely-used treatment guidelines should correlate with their respective subspecialty. For example, gastroenterology care should be governed by consensus guidelines developed by the gastrointestinal medical societies. As an example for why this prohibition is needed, some insurance companies require a patient be treated with lower efficacy biologics instead of vedolizumab as first-line treatment for ulcerative colitis even though it conflicts with GI society guidelines.

Regarding enforcement of the proposed prohibitions, CMS states in this proposed rule it will continue to conduct routine monitoring and auditing of MA organizations, and if it discovers internal coverage criteria do not comply with rules or the anti-discrimination rules, it will utilize current compliance and enforcement processes to determine if any action should be taken. ASGE requests that clear direction be given to health care providers and Medicare beneficiaries to file complaints with CMS when MA plans are in violation of the proposed prohibitions.

Public Availability

ASGE supports adding more structure and detail to the public accessibility requirements to ensure MA organizations are making information regarding internal coverage criteria available in a manner that is routinized and easy to follow. Such information will allow medical societies, health care professionals, as well as CMS, to determine whether an MA plan applies internal coverage criteria to a particular Medicare item or service and whether those criteria are in compliance with Medicare regulations. ASGE urges CMS to finalize the following proposals:

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[10] How Cigna Saves Millions by Having Its Doctors Reject Claims Without Reading Them; Patrick Rucker, Maya Miller and David Armstrong. March 25, 2023. https://www.propublica.org/article/cigna-pxdx-medical-health-insurance-rejection-claims?utm_medium=social&utm_source=twitter&utm_campaign=TwitterThread

[11] Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (page 22329)

[12] Ibid

[13] Ibid.

- Require MA organizations examine and identify each internal coverage criterion being used and mark or label it as such within their policy documents for readers to understand that the specific internal criterion noted is being applied and may be specific to the MA plan.

- Update the word "criteria" to "criterion" to make it clear that each single coverage criterion used be listed and identified and require the evidence be connected to the internal coverage criterion with a corresponding footnote.

- Require that by January 1, 2026, MA organizations must publicly display on the MA organization's website a list of all items and services for which there are benefits available under Part A or Part B where the MA organization uses internal coverage criteria when making medical necessity decisions.

ENSURING EQUITABLE ACCESS – ENHANCING HEALTH EQUITY ANALYSES: ANNUAL HEALTH EQUITY ANALYSIS OF UTILIZATION MANAGEMENT POLICIES AND PROCEDURES

ASGE strongly supports proposals contained in this rule that build upon the April 2024 final rule[14] with regard to the disclosure by MA organizations of prior authorization data. Specifically, ASGE supports the disclosure of the following as proposed:

- The percentage of standard prior authorization requests that were approved, reported by each covered item and service.

- The percentage of standard prior authorization requests that were denied, reported by each covered item and service.

- The percentage of standard prior authorization requests that were approved after appeal, reported by each covered item and service.

- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, reported by each covered item and service.

- The percentage of expedited prior authorization requests that were approved, reported by each covered item and service.

- The percentage of expedited prior authorization requests that were denied, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, reported by each covered item and service.

- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, reported by each covered item and service.

When data regarding the use of prior authorization by MA organizations is aggregated, it is difficult to determine whether certain kinds of care are being singled out for denials. Requiring the disclosure of data by "each covered item and service" will facilitate targeted CMS audits. For example, if MA organization

[14] Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2024-Remaining Provisions and Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (PACE) (April 23, 2024)

data show a significant increase in denial rates for a particular service category, this should prompt additional CMS scrutiny.

An October 2024 report, U.S. Senate Permanent Subcommittee on Investigations[15], found the largest MA organizations increased the use of prior authorization for post-acute services and denial rates grew at the same time the MA organizations were expanding their use of automation and predictive technologies for reviewing medical authorization requests. As the Senate subcommittee report highlighted, MA organizations can calibrate their use of prior authorization to target certain costly services, yet the overall organization determination data reported to CMS will show little change. If CMS had access to MA prior authorization data by service level, rather than at an aggregated level, it would have been obvious that MA organizations were singling out post-acute care for prior authorization and that denial rates were increasing.

More transparency of prior authorization practices by MA organizations is desperately needed and is why disclosure of prior authorization data by service level should be required and is why ASGE urges CMS to make finalizing these enhanced disclosure requirements a priority.

Use of Artificial Intelligence for Prior Authorization

In Spring of 2023, ASGE learned that UnitedHealthcare (UHC) was going to implement a prior authorization program for 62 endoscopy codes (nearly half of all endoscopy codes), including endoscopy services that are considered low volume. Despite multiple requests from ASGE and other gastrointestinal medical societies, UHC refused to share data from its own system that showed overuse or geographic variation of the endoscopy services that were going to be subjected to prior authorization. UHC's proposal to move a large volume of endoscopy services through prior authorization, including low-volume codes, underscores the extent to which automated and predictive technologies (or AI) have made it economically feasible for payers to require prior authorization for more services, including lower-costs tests and services for which prior authorization was not previously cost-effective. Ultimately, UHC did not implement its proposal and instead put in place a "voluntary," although no less onerous, prior notification program for these endoscopy codes.

ASGE is concerned the use of AI by MA plans to review requests for medical care may make it easier for MA organizations to deny requests for care without making an individual medical necessity determination. In fact, the Senate Permanent Subcommittee on Investigations report[16] found evidence of MA organizations pressuring human reviewers to follow the recommendations of predictive technologies.

As stated above, ASGE supports proposed changes to ensure that MA organizations are responsible for ensuring that use of AI tools comply with internal coverage criteria rules. ASGE also supports the recommendations of the Senate subcommittee to expand its regulations by:

- requiring MA companies disclose how predictive technologies are used in their prior authorization process; and

- requiring utilization management committees to develop rules to ensure that predictive technologies are not influencing decisions by human reviewers.

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[15] Refusal of Recovery: How Insurers Have Denied Patients Access to Post-Acute Care. Oct. 17, 2024. U.S. Senate Permanent Subcommittee on Investigations. https://www.hsgac.senate.gov/wp-content/uploads/2024.10.17-PSI-Majority-Staff-Report-on-Medicare-Advantage.pdf

[16] Ibid.

FORMULARY INCLUSION AND PLACEMENT OF GENERICS AND BIOSIMILARS

In this proposed rule, CMS clarifies that plan formularies must provide beneficiaries with broad access to generics, biosimilars, and other lower-cost drugs to be compliant with the requirement that a Part D plan have in place a" cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate, such as through the use of multiple source drugs." ASGE supports this goal. The reality is, however, that rebating schemes between pharmacy benefit managers (PBMs) and drug manufacturers have hampered the uptake of biosimilars among Medicare beneficiaries. Rebates are often in exchange for preferred formulary placement, including "fail-first" status.

These rebates are reflected in manufacturers 'quarterly average sales price (ASP) reporting to CMS, and, consequently, ASP has been artificially lowered to the point that many providers 'acquisition costs for office-administered biosimilars substantially exceed Medicare and other private health plan payments.

When the ASP for a biosimilar falls short of a provider's acquisition cost — a situation referred to as being "underwater" — the provider is unlikely to administer the drug at a financial loss. Instead, the patient will most likely be transferred to a more costly site of care (e.g., a hospital), or, the provider may be forced to switch the patient's therapy when they are stable on current therapy. Oftentimes even switching a patient to another biologic is complicated by "step therapy" requirements imposed by payers, including MA organizations. These options are not good for patients, Medicare or the health care system.

ASGE asks CMS to work with congressional lawmakers to resolve the problem of underwater biosimilars in an effort to broaden Medicare beneficiary access to potentially lower-cost therapies.

PART D COVERAGE OF ANTI-OBESITY MEDICATIONS AND APPLICATION TO THE MEDICAID PROGRAM

Obesity stands as a formidable public health challenge with far-reaching implications, necessitating urgent attention and comprehensive action. As a leading authority in gastrointestinal health, the ASGE recognizes the profound impact of obesity on both individual well-being and the health care system.

Obesity not only contributes to a spectrum of gastrointestinal disorders, but it also exacerbates the burden of chronic diseases, including diabetes, cardiovascular disease, and certain cancers. The prevalence of multiple gastrointestinal and hepatic diseases escalates significantly with obesity including but not limited to metabolic dysfunction-associated steatotic liver disease, gastroesophageal reflux disease, gallstone disease, gastrointestinal cancers, pancreatitis and Barrett's esophagus. This underscores the interconnectedness between obesity treatment management and optimal gastrointestinal health.

The ASGE supports a multi-pronged approach to combat obesity. This entails implementing evidence-based interventions spanning prevention, diagnosis, and treatment. It is important to integrate all available obesity treatment options for optimal patient care. The ASGE supports a full range of treatments and interventions to treat obesity, which include lifestyle modification, anti-obesity medications (AOMs), endoscopic metabolic and bariatric therapy, and bariatric surgery. It is also critical that health care professionals are educated and trained in the proper use of these interventions to provide patients with the best possible care.

Consistent with ASGE's position that coverage and payment policies should support a comprehensive approach to obesity treatment and management, we support reinterpretation of the statutory exclusion of agents when used for weight loss to *allow* Medicare and Medicaid to cover AOMs when used to treat obesity by reducing excess body weight or maintaining weight reduction long-term for individuals with

obesity who do not have another condition for which the prescribed use is an medically accepted indication that is covered under the current Part D policy. ASGE also supports requiring Medicaid programs to cover AOMs for the treatment of obesity.

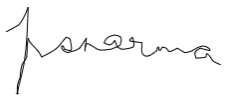
This new interpretation rightly recognizes obesity as a chronic disease more than a decade after the American Medical Association recognized obesity as a disease state with multiple pathophysiological aspects requiring a range of interventions for treatment and prevention.

ASGE also wishes to use this opportunity to voice its support for the use of endoscopic bariatric and metabolic therapies (EBMT) in clinical practice — therapies not well known to patients or physicians that include minimally invasive procedures such as intragastric devices and gastric remodeling procedures, and small bowel therapies. These procedures aid in weight loss and have a weight-loss dependent effect on improving obesity-related diseases. Therapies targeting the small bowel may improve glycemic control and obesity-related metabolic disease independent of weight loss but are not yet approved for use in the United States. EBMTs are an integral component across the spectrum of obesity treatments and provide patients a treatment option that does not require lifelong medication use or surgery.

CONCLUSION

ASGE appreciates the Agency's consideration of its comments. We reiterate our request that CMS act expeditiously to finalize proposals that will further safeguard beneficiaries from MA organization utilization management practices that restrict or delay patient access to otherwise medically necessary care. Should you have questions or require additional information, contact Lakitia Mayo, ASGE Chief Policy and Member Engagement Officer, at (630) 570-5641 or lmayo@asge.org.

Sincerely,



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ASGE President