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Vizient Office of Public Policy and Government Relations

CY 2024 Policy and Technical Changes to the Medicare Advantage and Part D (CMS-0057-P)

December 22, 2022

Summary

On December 14, 2022, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule (hereinafter "Proposed Rule") that would revise the Medicare Advantage (MA), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Elderly Care (PACE) regulations. Among other changes, the Proposed Rule modifies regulations related to utilization management (including prior authorization), medication therapy management, marketing and communications, health equity, provider directories, network adequacy and formulary changes. This summary focuses on proposed changes to utilization management requirements, particularly prior authorization.

Comments on the Proposed Rule are due by **February 13, 2023, at 5:00pm** and the final rule will be released in spring 2023. Vizient looks forward to working with members to help inform our letter to the agency.

Utilization Management Requirements: Clarifications of Coverage Criteria for Basic Benefits and Use of Prior Authorization, Additional Continuity of Care Requirements, and a Mandated Annual Review of Utilization Management Tools

In the Proposed Rule, CMS notes that utilization management tools, including prior authorization, are designed to help MA plans determine the medical necessity of services, which helps contain costs and protects beneficiaries from receiving unnecessary care. However, CMS has also received stakeholder feedback that utilization management in MA, especially prior authorization, can sometimes create a barrier to patients accessing medically necessary care. As a result, CMS proposes several requirements and "guardrails" to help ensure that utilization management tools are used appropriately and associated coverage decisions are made in ways that ensure timely and appropriate access to medically necessary care for beneficiaries enrolled in MA plans.

Basic Benefits Coverage

In current subregulatory guidance, MA plans are to make medical necessity determinations based on internal policies, which include coverage criteria that are no more restrictive than traditional Medicare's national and local coverage determination policies and are approved by a plan's medical director. However, the Office of the Inspector General (OIG) has recommended that CMS issue new guidance on the appropriate use of MA organization clinical criteria in medical necessity reviews. As a result, CMS proposes to codify standards for coverage criteria to ensure that basic benefits coverage for MA enrollees is no more restrictive than traditional Medicare.

While CMS clarifies that MA organizations would still be permitted to cover items and services more broadly than traditional Medicare by using supplemental benefits, the agency also proposes to codify a policy for when an MA organization is making a coverage determination on a Medicare covered item or service. More specifically, CMS proposes to codify that the MA organization cannot deny coverage of the item or service based on internal, proprietary, or external clinical criteria not found in traditional Medicare coverage policies. Notably, CMS indicates that certain utilization management processes, such as clinical treatment guidelines that require another item or service to be furnished prior to receiving the requested item or service, would violate the proposed requirements (unless specified within an applicable National Coverage Determination (NCD) or Local Coverage Determination (LCD)). The agency further clarifies that it is not proposing to revise

regulations which authorize MA plans to use step therapy policies for Part B drugs. **CMS seeks comment about the specificity of the coverage conditions in traditional Medicare regulations and whether CMS should consider, and under what circumstances, allowing MA organizations to have internal coverage criteria in addition to requirements in current regulations.**

In addition, CMS proposes that when coverage criteria are not fully established in an applicable Medicare statute, regulation, NCD or LCD, an MA plan may create internal coverage criteria. The MA plan's internal coverage criteria must be based on current evidence in widely used treatment guidelines or clinical literature that is made publicly available. In creating these policies, CMS proposes that MA organizations must follow similar rules that CMS and MACs must follow when creating NCDs or LCDs (e.g., providing publicly available information regarding the factors the MA organization considered in making coverage criteria for medical necessity determinations).

Medical Necessity Determinations

CMS regulations require that MA plans have policies and procedures that allow for individual medical necessity determinations. In the Proposed Rule, CMS seeks to codify and expand on current guidance. Specifically, CMS proposes to codify that MA organizations must make medical necessity determinations based on coverage and benefit criteria and may not deny coverage for basic benefits based on coverage criteria not found in those sources. In addition, MA plans must consider whether the item or service is reasonable and necessary and consider the enrollee's medical history (e.g., diagnoses, conditions, functional status), physician recommendations, and clinical notes. Lastly, CMS proposes that MA organizations' medical directors be involved in ensuring the clinical accuracy of medical necessity determinations where appropriate.

CMS notes that it is unable to quantify the impact of the Proposed Rule's policies because many MA organizations may already be interpreting the agency's rules in a way that aligns with the proposed policies.

Appropriate Use of Prior Authorization

With limited exceptions, all services covered by MA coordinated care plans may be subject to prior authorization. CMS proposes that prior authorization should only be used to confirm the presence of diagnosis or other medical criteria and to ensure that the furnishing of a service or benefit is medically necessary (or clinically appropriate for supplemental benefits) and should not function to delay or discourage care.

Continuity of Care

CMS proposes additional continuity of care requirements to help ensure coordinated care plans provide access to all medically necessary and Medicare covered benefits. More specifically, CMS proposes that MA coordinated care plans must have, as part of their arrangements with contracted providers, policies for using prior authorization for basic benefits. CMS clarifies these prior authorization policies must be valid for the duration of the entire approved, prescribed or ordered course of treatment or service. **CMS seeks comment this policy.**[1] CMS also proposes a 90-day transition period when an enrollee currently undergoing treatment switches to a new MA plan.

[1] CMS proposes criteria in the Proposed Rule which would impact §422.101(b) and (c); §422.101 address requirements relating to basic benefits.

Annual Review of Utilization Management (UM) Policies by a UM Committee

CMS has received feedback that enrollees are facing unreasonable barriers to needed care. In response, CMS proposes to require MA organizations to establish a UM committee to operate similar Pharmacy and Therapeutics (P&T) committees. Among other policies, CMS proposes that an MA plan may not use any UM policies for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed by the UM committee. CMS proposes a range of responsibilities for a UM committee, including review of the policies and procedures for all utilization management used by the MA plans. Also, CMS proposes that the committee approve only utilization management policies and procedures that meet certain criteria.[2] **CMS seeks comment on whether it should require the UM committee to ensure that UM policies and procedures are developed in consultation with contracted providers; and whether the UM committee should ensure that MA organizations communicate information about practice guidelines and policies to providers, and when appropriate, to enrollees. CMS also seeks comment on whether the UM committee should have an ongoing or active oversight role in ensuring that decisions made by an MA plan throughout the year are consistent with the final, approved practice guidelines and UM policies.** CMS also notes that it expects MA organizations to update their UM policies after the UM committee approves or revises them.

CMS is also considering expanding the duties of the UM committee (e.g., all internal coverage policies of an MA plan or all coordinated care plans). **CMS seeks comment on the UM committee duties and committee membership (e.g., majority practicing physicians; other health care professionals that should be included; additional members for specific items or services). CMS also seeks comment on whether an MA plan should be permitted to utilize the proposed UM committee to also meet P&T committee requirements, provided that all applicable regulatory requirements are met.**

CMS also proposes that the UM committee must document in writing the reason for its decisions regarding the development of UM policies and make this documentation available to CMS upon request.

Termination of Services in Post-Acute Care

CMS indicates it has received complaints about potential quality of care issues regarding early termination of services in post-acute care settings by MA organizations (e.g., before the beneficiary is healthy enough to return home). CMS notes that it is proposing to revoke the current policy that when a health care service is covered by Medicare and delivered in more than one way, or by more than one type of practitioner, an MA plan can no longer choose how the covered services will be provided. **CMS indicates this change may help address issues regarding early termination of services, however, the agency seeks feedback regarding this issue to gain more insight to this situation. CMS also seeks comment on potential changes it could make to better manage incentives between MA organizations and post-acute care providers to deliver the best possible care for Medicare beneficiaries.**

[2]CMS proposes that the committee approve only utilization management policies and procedures that: use of impose coverage criteria that comply with the requirements and standards at §422.101(b) (requirements related to basic benefits); comply with the requirements and standards at §422.138(a)-(c) (newly proposed); comply with the requirements and standards at §422.202(b)(1) (participation procedures); and apply and rely on medical necessity criteria that comply with §422.101(c)(1).

Gold-Carding Programs

CMS reiterates that it believes the use of gold-carding programs could help alleviate the burden associated with prior authorization and that such programs could facilitate more efficient and timely delivery of health care services to enrollees.

Addressing Vulnerabilities that can lead to Manual Review Errors and System Errors

CMS notes that a recent report indicates that some denials were the result of MA plan errors. Currently, all MA organizations must have administrative and management arrangements that include an effective compliance program which must include measures that prevent, detect, and correct fraud, waste, and abuse. **CMS seeks comment on whether current requirements could be adjusted to better account for these medical review and system errors.**

What's Next?

Vizient's Office of Public Policy and Government Relations looks forward to hearing continued member feedback on this Proposed Rule. This feedback will help inform our comments to the agency. Stakeholder input plays a major role in shaping future changes to policy. We encourage you to reach out to our office if you have any questions or regarding any aspects of this proposed regulation – both positive reactions and provisions that cause you concern. Please direct your feedback to Jenna Stern, AVP Regulatory Affairs and Public Policy in the Washington, D.C. office.
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