Feb 13, 2023

Centers for Medicare & Medicaid Services, Department of Health and Human Services
Attention: CMS–4201–P
P.O. Box 8013
Baltimore, MD 21244

Submitted Electronically via www.regulations.gov

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications. (CMS–4201–P, RIN 0938–AU96)

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We are pleased to submit this comment letter on behalf of OneOncology in response to the formal request for comments regarding the proposed rule "Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS–4201–P, RIN 0938–AU96)."

OneOncology was founded by community oncologists, for community oncologists, with the mission of improving the lives of everyone living with cancer. Our goal is to enable community oncology practices to remain independent and to improve patient access to care in their communities, all at a lower cost than in the hospital setting. OneOncology supports our platform of community oncology practices through group purchasing, operational optimization, practice growth, and clinical innovation. Our 750 cancer care providers care for 478,000 patients at 546 sites of care nationwide, including approximately 238,000 Medicare beneficiaries per year (inclusive of Medicare Advantage) and approximately 129,000 traditional Medicare beneficiaries per year.

OneOncology acknowledges the importance CMS's ongoing efforts to improve payment policies for cancer care services that better achieve the Quadruple AIM: (1) Access to high quality cancer care for

Medicare beneficiaries; (2) Enhancing the patient experience; (3) Minimizing the cost of cancer care for patients and the Medicare Trust Funds; (4) Workforce health among care teams dedicated to the treatment of cancer and blood disorders and whom OneOncology serves.

OneOncology appreciates the efforts of CMS to reform the current state of utilization management (UM) and step therapy (ST) among Medicare Advantage Organizations (MAOs) and Medicare Part D Plans (MPDPs), and we appreciate the clarification of the existing policies in this area that are addressed in this Proposed Rule and that have been aggressively taken advantage of by MAOs and MPDPs in ways that are contrary to their original policy intent. Such MAO and MPDP actions have been detrimental to the health of patients living with cancer and blood disorders and contrary CMS's stated goals for improving health equity.

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Executive Summary of OneOncology's Comments:

1. **Coverage Criteria for Basic Benefits [87 FR p.79499]**

   Recommendation:

   - OneOncology appreciates that CMS has proposed to further emphasize and clarify that Medicare Advantage Organizations (MAOs) are prohibited from implementing Step Therapy (ST) and Utilization Management tactics (UM) that have the effect of "restrict[ing] access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD." If CMS enforces this policy, this should enhance access for Medicare enrollees to cancer and hematology related medications that are critical to enhancing and maintaining their health. CMS should also add equal emphasis and clarity in this Proposed Rule and/or through additional rulemaking that would prohibit Medicare Part D Plans (MPDPs) from implementing similar ST and UM tactics to those that are prohibited for MAOs under this section of the Proposed Rule.

2. **Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee [87 FR p.79505]**

   Recommendations:

   - We support CMS policy proposals within this section of the Proposed Rule which stipulate that UM Committees for MAOs should be required to ensure that UM and ST processes and actions taken by the MAOs are consistent with current evidence-based nationally-recognized clinical guidelines. These requirements should include:
     - Quarterly review of MAO's clinical policies and practice guidelines to ensure consistency with evidence-based nationally-recognized clinical guidelines

- Removal of prior MAO UM and ST policies and related processes that that should no longer require UM in light of up-to-date evidence-based clinical guidelines;
- Review of UM decisions made throughout the prior quarter to ensure UM processes and actions taken by (or on behalf of) the MAOs are compliant with clinical policies established by the committee and the requirements of this Proposed Rule.

- The responsibilities of UM Committees noted above should be expanded to include all internal coverage policies of MAOs, and any other processes implemented by the plan that would have the effect of (or could be reasonably perceived by Medicare beneficiaries or contracted providers to have the effect) limiting enrollee access to plan-covered services.
- UM Committees that establish clinical policies for the treatment of cancer and blood disorders should be required to include at least two physicians who are board certified in the medical specialty of oncology or hematology (for cancer and blood disorders respectively).
- MPDPs should be required to comply with the same provisions of this proposed rule as they apply to MAOs.

3. **Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629) [87 FR p.79509]**

Recommendations:

- In the interest of maintaining the improving the health of Medicare enrollees, we support CMS's clarifications to the definition of the appropriate medical expertise of a physician reviewer who renders any adverse medical necessity decision on behalf of an MAO.
- We urge CMS to further clarify that any physician reviewer who is authorized to make an adverse medical necessity determination on behalf of an MAO, when such decisions involve the treatment of patients with cancer and blood disorders, the definition of appropriate medical expertise should be explicitly limited to board certification in oncology or hematology (respectively), in addition to the requirement that the reviewer be licensed to practice medicine in the state, commonwealth or territory in which the beneficiary is seeking care.

4. **Gold Carding [87 FR p.79507]**

Recommendation:

We appreciate that CMS has encouraged MAOs to implement Gold Carding programs. In finalizing this proposed rule, we urge CMS to more strongly mandate that MAOS adopt gold-carding programs, and apply such mandates to MPD plans to the same degree that they would apply to MAOs.

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1. Coverage Criteria for Basic Benefits [87 FR p.79499].

Recommendations:

- OneOncology appreciates that CMS has proposed to further emphasize and clarify that Medicare Advantage Organizations (MAOs) are prohibited from implementing Step Therapy (ST) and Utilization Management techniques (UM) that have the effect of "restrict[ing] access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD." If CMS adequately enforces this policy, this should enhance Medicare enrollees' access to cancer and hematology related medications that are critical to enhancing and maintaining their health.
- CMS should also add equal emphasis and clarity in this Proposed Rule and/or through additional rulemaking that would prohibit Medicare Part D Plans (MPDPs) from implementing similar ST and UM tactics to those that are prohibited for MAOs under this section of the Proposed Rule.

Background:

We appreciate that CMS has clearly articulated its policy objectives in this proposed rule in stating that:

- *"Our proposal is designed to prohibit MA organizations from limiting or denying coverage when the item or service would be covered under Traditional Medicare and continue the existing policies that permit MA organizations to cover items and services more broadly than original Medicare by using supplemental benefits." [p.79499]*
- *"This means that when an MA organization is making a coverage determination on a Medicare covered item or service, 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. It is our interpretation that certain utilization management processes, such as clinical treatment guidelines*

that require another item or service be furnished prior to receiving the requested item or service, would violate the proposed requirements at § 422.101(b) and (c), and thus, would be prohibited under this proposal unless it is specified within the applicable NCD or LCD or Medicare statute or regulation." [p.79500]

- *"Clinical criteria that restrict access to a Medicare covered item or service unless another item or service is furnished first, when not specifically required in NCD or LCD, would be considered additional internal coverage criteria that are prohibited under this proposal." [p.79500]*

The experience of clinicians throughout our national network (specifically with regard to ST and UM in tactics employed by MAOs) has been consistent with the Office of the Inspector General Report findings that CMS has cited in its rationale for these policy clarifications within this Proposed Rule, specifically:

- *"The OIG found that some prior authorization requests were denied by MA plans, even though the requested services met Medicare coverage guidelines. In other cases, the OIG found that prior authorization requests were inappropriately denied due to errors that were likely preventable through process or system changes by MA organizations."[p.79498]*
- *"CMS guidance is not sufficiently detailed to determine whether MA organizations may deny authorization based on internal MA organization clinical criteria that go beyond Medicare coverage rules." [p.79503]*

Therefore we agree with CMS's determination that these clarifications in this section of the Proposed Rule are necessary to protect Medicare enrollees' access to cancer and hematology related medications that are critical to improving and maintaining the health of vulnerable populations of Medicare enrollees. Furthermore, for reasons that we will describe in more detail in Section 2 of these comments related to UM Committee responsibilities, the policy clarifications contained in this section of the Proposed Rule should substantially contribute to improving health equity, as the current state of MAO and MPDP clinical policies — which are frequently more restrictive than those of Traditional Medicare — impose disproportionate harm on Medicare enrollees with complex health related social needs.

We have the following concerns regarding the limitations of this proposed rule in accomplishing CMS's stated objectives above, and therefore we urge CMS to add additional clarity to this section of the Proposed Rule to ensure that the Proposed Rule sufficiently accomplishes these objectives.

- CMS notes that this Proposed Rule does not constitute any revision to existing regulations related to ST and UM that are already in effect [p.79500]. However, the experience of OneOncology's national network of clinicians, and the findings of the OIG report, reflects that ST and UM policies (that are currently publicly available on the websites of many MAOs) are inconsistent with this Proposed Rule and the existing regulations that CMS has cited in this section. Therefore we advocate that CMS take

additional action to streamline the avenues through which providers can report violations of this policy and CMS should enhance its investigatory and enforcement infrastructure to address ongoing violations of its existing and proposed ST and UM policies.

- In finalizing this proposed rule, CMS should remove references to "other clinical literature" throughout this section. The published compendia guidelines for the treatment of patients with cancer and blood disorders, such as those published by the National Comprehensive Cancer Network, American Society of Clinical Oncology, American Society of Hematology, and American Society of Radiation Oncology (which we will refer to throughout the remainder of this simply as "nationally-recognized evidence-based clinical guidelines"), are sufficiently comprehensive to serve as a basis for the clinical policies of MAOs and MPDPs in the absence of published NCDs and LCDs. Based on the experience of clinicians throughout our national network, CMS's references to "other clinical literature" could provide an unintended loophole for MAOs and MPDPs to exploit for purposes of creating internally-derived interpretations of clinical literature that could restrict access to high quality care beyond applicable policies for Traditional Medicare, which would be contrary to the objectives of this Proposed Rule.
- CMS should also add equal emphasis and clarity, in this Proposed Rule and/or through additional rulemaking, that would prohibit MPDPs from implementing similar ST and UM tactics similar to those that would be prohibited for MA plans under this section of the Proposed Rule.

2. Mandate Annual Review of Utilization Management (UM) Policies by a UM Committee [87 FR p.79505]

Recommendations:

- We support CMS policy proposals within this section of the Proposed Rule which stipulate that UM Committees for MAOs should ensure that UM and ST processes implemented by MAOs are consistent with current nationally-recognized evidence-based clinical guidelines. These requirements should include:
  - Quarterly review of the MA plan's clinical policies and practice guidelines to ensure consistency with nationally-recognized evidence-based clinical guidelines
  - Removal of prior UM and ST policies and related processes that should no longer require UM tactics in light of up-to-date nationally-recognized evidence-based clinical guidelines;
  - Review of UM decisions made throughout the prior quarter to ensure UM processes and actions taken by the on behalf of the MA plans are compliant with clinical policies established by the committee and the requirements of this Proposed Rule.
  - UM policies related to specialist and subspecialist services should be developed in consultation with contracted providers in the given specialties and subspecialties.

- The responsibilities of UM Committees noted above should also apply to all internal coverage policies of MAOs, and any other policies or processes implemented by the MAO that would have the effect (or could be reasonably perceived by Medicare enrollees or contracted providers to have the effect) of restricting Medicare enrollee access to plan-covered services.
- UM Committees that establish clinical policies for the treatment of cancer and blood disorders should be required to include at least two physicians who are board certified in the medical specialty of oncology or hematology (for cancer and blood disorders respectively).
- CMS should clearly prohibit multiple MAOs from sharing the same UM Committee or the UM Committee of a parent organization when such MAOs are not party to a distinct provider contract. MAOs that contract as separate entities with their provider networks should be required to have their own distinct UM committees that comply with the provisions of this section of the proposed rule and the recommendations above.
- MPD plans should be required to comply with the same provisions of this proposed rule as they apply to MAOs.

Background:

With the rapidly increasing complexity of cancer diagnostics and treatment strategies, notably molecular and genomic testing and targeted therapies, the science of treating cancer and blood disorders has evolved well-beyond the extent at which a physician without formal oncology or hematology training can reasonably be assumed to have the requisite expertise to establish MAO or MPDP clinical policies related to this complex diagnostic and treatment landscape.

These standards that we have recommended above (pertaining to requisite expertise for MAO and MPDP healthcare professionals who serve on UM Committees that establish MAO or MPDP clinical policies) would help ensure that Medicare enrollees are not unduly harmed by clinical policies that inappropriately restrict access to medications that are critical to the treatment of cancers and blood disorders.

Furthermore, CMS should put forth policies that mandate that UM committees formally attest to having considered the health equity implications of their clinical policies for patient populations that face challenging health-related social needs (HRSN). CMS should also mandate that UM committees include members with specialized expertise in the health equity implications of clinical policies.

The current landscape of MAO and MPDP UM and ST policies frequently restrict access for Medicare enrollees to medications that can serve to alleviate HRSN and improve health equity for patients undergoing treatment for cancer and blood disorders (and such restrictions extend beyond the NCDs and LCDs that apply to Traditional Medicare).

As an example, for patients with blood disorders characterized by iron deficiency anemia, many MAOs currently have ST requirements in place that limit patient access to long-acting IV iron agents that require fewer in-office infusions than the "comparable" agents that required through ST policies.[1] For both urban and rural patient populations for who face logistically and financially challenging transportation barriers to more frequent infusions, the longer-acting IV iron agents that require less frequent infusions have a remarkable impact on their quality of life. However, when clinicians throughout our national network have discussed these concerns with UM reviewers of MAOs, the UM reviewers often trivialize such concerns by referring to them as "patient convenience" factors that they are not compelled to consider in their clinical policies. This lack of empathy for patients that face severe HRSN challenges is highly prevalent among MAOs. Without more stringent regulation from CMS that requires that the UM Committees of MAOs be held accountable for the health equity implications that their clinical policies impose for patients with challenging HRSNs, vulnerable patient populations of Medicare enrollees will continue to face unnecessary hardship.

3. **Review of Medical Necessity Decisions by a Physician or Other Health Care Professional With Expertise in the Field of Medicine Appropriate to the Requested Service and Technical Correction to Effectuation Requirements for Standard Payment Reconsiderations (§§ 422.566, 422.590, and 422.629) [87 FR p.79509]**

Recommendations:

- In the interest of maintaining the improving the health of Medicare enrollees, we support CMS's attempt to add emphasis and clarity to the definition of the appropriate medical expertise of a physician reviewer who renders any adverse medical necessity decision on behalf of an MAO.
- We urge CMS to further clarify that for any physician reviewer who is authorized to make an adverse medical necessity determination on behalf of an MAO, when such determinations involve the treatment of patients with cancer or blood disorders, the definition of appropriate medical expertise should be explicitly limited to board certification in oncology or hematology (respectively for cancers and blood disorders), in addition to requirement that the reviewer be licensed to practice medicine in the state, commonwealth or territory in which the beneficiary is seeking care.
- MPDPs should be required to comply with the same provisions of this proposed rule as they apply to MAOs.

[1] David Eagle MD, Rahul Seth MD, "Doctors Push to Protech Patients with Iron Deficiency Anemia." *Empire Report.* June 7, 2022. https://empirereportnewyork.com/doctors-push-to-protect-patients-with-iron-deficiency-anemia/.

Background:

In seeking comments on these proposed policies related to the qualifications of healthcare professionals who are authorized to make adverse medical necessity determinations on behalf of MAOs, CMS notes its policy intention to modify existing regulations with a more explicit requirement "linking the requisite expertise of the reviewer to the specific service that is the subject of the organization determination request."

With the rapidly increasing complexity of cancer diagnostics and treatment strategies, notably molecular and genomic testing and targeted therapies, the science of treating cancer and blood disorders has evolved well-beyond the extent at which a physician without formal oncology or hematology training can reasonably be assumed to have the requisite expertise to safely render medical necessity determinations regarding the recommended treatments of an oncologist or hematologist caring the Medicare enrollees

However within this section CMS also states its consideration of the administrative burden on MAOs in implementing UM policies as we've recommended above, suggesting that "the burden will be negligible and that this proposal will not require changes to AIPs and other MA organizations overall staffing."

The recommendations above reflect our view that CMS's paramount consideration should be maintaining and enhancing the health Medicare enrollees, which should include protecting Medicare enrollees from being unduly harmed by UM and ST determinations made by health care professionals that do not meet these standards that we have recommended for the required expertise in the treatment of cancer and blood disorders; and the burdens to MAOs in implementing these policies should be subordinate considerations regardless of whether that burden is "negligible."

4. **Gold Carding [87 FR p.79507]**

Recommendation:

We appreciate that CMS has encouraged MAOs to implement Gold Carding programs. In finalizing this proposed rule, we urge CMS to more strongly mandate that MAOS adopt gold-carding programs, and apply such mandates to MPD plans to the same degree that they would apply to MAOs.

Background:

Within this section of the proposed rule, CMS acknowledges that gold carding programs — defined as MAO programs that relax or reduce prior authorization requirements for contracted providers that have demonstrated a consistent pattern of compliance with plan policies and procedures — could potentially contribute substantially to CMS's policy objectives that are noted in the following excerpt:

> *"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. We encourage MA plans to adopt gold-carding programs that would allow providers to be exempt from prior authorization and provide more streamlined medical necessity review processes for providers who have demonstrated compliance with plan requirements."[79507]*

CMS's encouragement of Gold-carding in this Proposed is consistent with the perspective of clinicians throughout our national network, mainly that Gold-carding programs could potentially facilitate and enhance access to medically necessary care for Medicare enrollees.

Furthermore, we appreciate the opportunity for stakeholder comment on Gold-carding that CMS is requesting in the December 2022 Proposed Rule regarding "Advancing Interoperability and Improving Prior Authorization Processes" [87 FR 76307, CMS-0057-P, RIN 0938-AU87) pertaining to the details of how such programs should be developed and implemented, and we intend to submit comments on that Dec. 2022 Prior Authorization Proposed Rule regarding such details. More detailed rule-making regarding how MA plans implement gold-carding will be necessary to ensure that the potential advantages of these programs are realized by Medicare enrollees and the clinicians that who provide care to Medicare enrollees.

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We appreciate this opportunity to submit comments on the provisions of this Proposed Rule relating to utilization management and step therapy as these proposed policies relate to our common goals of achieving the Quadruple Aim in cancer care.

You may contact David Eagle, MD (deagle@nycancer.com), Chair of the OneOncology Advocacy Committee, at any time with any questions regarding these comments.

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