



February 1, 2023

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

Submitted online via www.regulations.gov

Re: File Code CMS-4201-P Medicare Program: Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program Proposed Rule

Dear Sir/Madam:

The American Association of Oral and Maxillofacial Surgeons (AAOMS) represents more than 9,000 oral and maxillofacial surgeons (OMSs) in the United States. AAOMS appreciates Agency efforts to increase transparency in the prior authorization process under the Medicare Advantage program. On behalf of our members, AAOMS is pleased to offer comment on the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program Proposed Rule.

According to the Kaiser Family Foundation, in 2022 more than 28 million people, nearly half of all eligible Medicare beneficiaries were enrolled in a Medicare Advantage plan¹. With projections to surpass the 50 percent threshold potentially as soon as this year, Agency efforts to clarify Medicare Advantage coverage policies and better align decision-making processes with that of traditional Medicare are imperative both to ensure access to medically necessary healthcare services and mitigate administrative burden on providers.

OMSs understand the important role oral health can have on a patient's overall health. As the integration of medicine and dentistry evolves, it is vital for CMS to implement policies that encourage multidisciplinary engagement in healthcare, from the provision of services to the practices that define and shape medical necessity determinations.

The development of internal coverage criteria should allow for draft policy review and public comment

When creating internal policies to guide medical necessity determinations, in the absence of fully established Medicare coverage criteria, Medicare Advantage (MA) plans must make publicly available

¹ Henry J. Kaiser Family Foundation. Medicare Advantage in 2022: Enrollment Update and Key Trends. <https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/> Aug. 25, 2022. Accessed Jan. 1, 2023.

the evidence, clinical data and rationale used in the development process. This is a fundamental step towards increasing the transparency of coverage determinations, as well as providing much needed consumer protection. However, CMS is not proposing to require that such internal coverage policies be subject to a draft policy review or public comment period, unlike both national and local coverage determinations.

The opportunity for interested parties and industry stakeholders to engage with CMS and/or Medicare Administrative Contractors (MACs) has become an integral part of the Medicare program, helping to facilitate the development of evidence-based policies that reflect current clinical practice. This process allows specialty organizations to weigh in on key issues that may impact their membership and the patient populations their members serve. It is also a mechanism for physicians and other specialists to offer clinical and/or professional expertise on a particular procedure or condition, an opportunity they may not have unless involved directly in the clinical research or development of treatment guidelines.

The OMS scope of practice straddles the line between medicine and dentistry. For example, medication-related osteonecrosis of the jaw (MRONJ) is a rare and complex condition that affects both the soft and hard tissues of the jaw and often requires a multimodal treatment approach, ranging from conservative therapies to invasive surgical intervention. Certain services related to the treatment of MRONJ are historically considered for payment under Medicare, when deemed medically appropriate and necessary. However, there is an overall lack of fully established Medicare coverage policies and guidelines, in terms of both National and Local Coverage Determinations related to MRONJ. As OMSs play an integral role in both the differential diagnosis and management of the condition, it is foreseeable the development of internal coverage criteria related to this condition would be impactful to the specialty of oral and maxillofacial surgery.

According to CMS, widely used treatment guidelines and high-quality clinical literature (e.g., randomized controlled trials or cohort studies or all-or-none 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 published in a peer-reviewed journal with clear and consistent results) must be used to develop internal coverage policies under the Medicare Advantage program, if finalized. AAOMS believes this to be an appropriate definition of “clinical literature”; however, we wish to acknowledge that a lack of “big data” on certain conditions, such as MRONJ may pose challenges in meeting this threshold. For instance, the published peer-reviewed clinical data on MRONJ, including cohort studies and retrospective literature reviews typically consist of small sample sizes which can increase the margin of error or prevent the findings from being extrapolated, in certain circumstances. Despite ongoing specialty society research efforts, there is an absence of standardized, widely accepted treatment protocols for MRONJ. These factors may impact how data from MRONJ research is translated into clinical policy and practice. Therefore, a draft policy review and comment period would allow specialty societies and practitioners with expertise in treating certain conditions to provide insight and context to the existing data, which may be used to inform the development of meaningful and appropriate medical necessity criteria.

As such, AAOMS encourages CMS to extend the requirement for draft policy review and public comment period to any internal coverage criteria developed by Medicare Advantage organizations in the absence of fully established Medicare coverage guidelines.

Medical necessity determinations should be performed by a provider of the same or similar specialty relevant to the service(s) under review

AAOMS appreciates Agency efforts to apply the standard of “expertise appropriate for the specific service at issue” to utilization management and policies and practices for Medicare Advantage organizations. A provider's attestation that a service is medically necessary is an important consideration in the prior authorization process. Likewise, the party responsible for issuing a determination of medical necessity is integral to ensuring the right care is provided in the right place at the right time. An adverse benefit determination can limit beneficiary access to important and clinically appropriate healthcare services, particularly when the decision is issued by a physician or other qualified healthcare professional unfamiliar with or lacking expertise in the type of service(s) under medical necessity review.

Medicare defines medically necessary as "healthcare services or supplies needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." Given this, it stands to reason that a reviewer responsible for issuing a determination of medical necessity must possess expert clinical knowledge of a diagnosis or condition, as well as knowledge of current standards of care in the treatment of the condition to render an appropriate decision on patient care.

For example, an OMS submits a prior authorization request for the segmental resection of the mandible for a Medicare Advantage enrollee with a differential diagnosis of stage 3² MRONJ of the lower jaw. In this scenario, it is imperative for the reviewer to understand the nuances of the complex condition as well as clinical best practices for disease management, including but not limited to the refractory nature of MRONJ and the necessity of timely intervention. A provider specializing in conditions of the head, neck, mouth, face and jaws – such as an oral and maxillofacial surgeon – would be best suited to issue a medical necessity determination regarding such treatment. AAOMS believes the inclusion of OMSs within utilization management processes for Medicare Advantage organizations is crucial to ensuring access to clinically appropriate, medically necessary oral surgical services for all MA plan enrollees. Therefore, **AAOMS supports CMS's proposal to require medical necessity and coverage decisions to be issued by physicians or other qualified healthcare professionals of the same or similar specialty relevant to the service(s) under review.**

Health IT limitations should not prevent providers from capitalizing on prior authorization process improvements

AAOMS also appreciates Agency efforts to streamline utilization management processes including prior authorization and to reduce the administrative burden placed on providers. Many of the proposed changes encompass updated standards and processes for all interested parties, including providers.

Although an integral part of hospital systems and trauma teams, many OMSs are part of small practices and therefore face unique challenges with respect to health IT and economies of scale. Outside of our those practicing in academic or institutional settings, many utilize dental/surgical practice management software systems that lack certified electronic health record (EHR) technology capabilities, limiting OMSs, as well as other dental specialists, from meaningful participation in electronic transactions and data interchange process and quality payment programs. As this space evolves, OMSs and their staff

² American Association of Oral and Maxillofacial Surgeons. Medication-Related Osteonecrosis of the Jaw – 2022 Update. https://www.aaoms.org/docs/govt_affairs/advocacy_white_papers/mronj_position_paper.pdf. 2022.

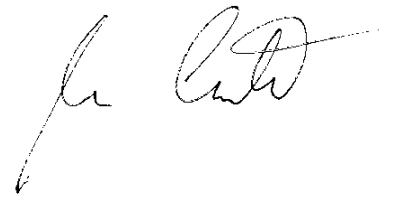
must continue to utilize manual processes for healthcare transactions, such as prior authorization requests. Given the current barriers to implementing certified EHR technology including cost and dental software limitations with interoperability and prior authorization transactions, AAOMS would encourage CMS to engage with industry stakeholders to improve current mechanisms involving the use of proprietary payer portals for prior authorization transactions. Although the use of individualized portals presents its own set of challenges, working to streamline the process may still help to mitigate some of the administrative burden placed on providers who lack more advanced, technology-based solutions. To this end, **we encourage CMS to offer providers the flexibility to benefit from the proposed utilization management process changes, such as prior authorization decision time frames and medical necessity thresholds regardless of the mechanism used for the prior authorization request (e.g., manual process versus electronic transaction).**

Thank you for your consideration of these comments. Please contact Patricia Serpico, Director, Health Policy, Quality & Reimbursement with any questions at 800-822-6637, ext. 4394 or pserpico@aaoms.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Paul J. Schwartz, DMD". The signature is fluid and cursive, with the letters "P", "J", and "S" being particularly prominent.

Paul J. Schwartz, DMD
AAOMS President

A handwritten signature in black ink, appearing to read "Joshua E. Everts". The signature is fluid and cursive, with the letters "J", "E", and "E" being particularly prominent.

Joshua E. Everts, DDS, MD, FACS
Chair, AAOMS Committee on Healthcare Policy, Coding & Reimbursement