THE ORTHOTIC AND PROSTHETIC ALLIANCE

1501 M Street, NW, 7th Floor
Washington, DC 20005
Phone: 202-466-6550
Fax: 202-785-1756

New Rules to Help O&P Providers Challenge Medicare Advantage Denials

Are you experiencing Medicare Advantage ("MA") plan denials for O&P patient care? Help is in sight. New regulations have been issued by the Centers for Medicare and Medicaid Services ("CMS") ("Final Rule") that create a new regulatory framework for MA coverage decisions that will positively impact O&P providers and patients for years to come. The new regulations:

- Require MA plans to abide by fee-for-service Medicare coverage rules,
- Limit the use of internal MA or proprietary coverage guidelines,
- Establish guardrails around the use of prior authorization ("PA"),
- Strengthen medical necessity determinations, and
- Create new standards for MA reviewers who deny claims.

These new requirements will help reduce the incidence of O&P care denials and delays as a result of misuse of PA by MA plans as a utilization management technique. The MA program now covers over half of all Medicare beneficiaries. Given this extensive growth of the program, these new standards are critical to maintaining access to O&P care in the future.

The final regulations went into effect on June 5, 2023, although the policies will be fully implemented in MA plan documents in the new contract year starting on January 1, 2024. Until then, O&P practitioners and patients can use the following rules to help address O&P coverage denials from MA plans. The five members of the O&P Alliance (AAOP, ABC, AOPA, BOC, and NAAOP) supported these proposed regulations and submitted comments during the regulatory process.

- ***Application of Traditional Medicare Coverage Criteria***: The Final Rule requires MA plans to make medical necessity determinations based on Traditional fee-for-service Medicare coverage and benefit criteria such as Medicare statutes, regulations, national coverage determinations ("NCDs"), and local coverage determinations ("LCDs") (unless superseded by laws applicable to MA plans). These directives include, but are not limited to, the LCD on Knee Orthoses (L33318), Spinal Orthoses (L33790), Ankle-Foot/Knee-Ankle-Foot Orthosis (L33686), and Lower Limb Prostheses (L33787).

- ***Use of Internal, Proprietary, or External Coverage Criteria:*** Under the Final Rule, when an MA plan is rendering a coverage determination on an item or service with fully established Medicare coverage criteria, the MA plan cannot deny coverage on the basis of internal, proprietary, or external clinical criteria that are not found in Traditional Medicare coverage policies. However, MA plans are permitted to utilize internal, proprietary, or external coverage criteria when "coverage criteria are *not fully established*

in applicable Medicare statutes, regulations, NCDs or LCDs."[1] When coverage criteria are not "fully established," the MA plan is required to "explain how 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."[2] In addition, MA plans must follow certain procedures to develop and publish internal coverage policies.

- ***Medical Necessity Determination:*** MA plans must make medical necessity determinations based on the circumstances of the specific individual, as opposed to using an algorithm or software that does not account for a patient's circumstances. MA plans must make medical necessity determinations based, in part, on the patient's medical history (e.g., diagnoses, conditions, functional status), physician recommendations, and clinical notes. Although the final regulations do not address O&P clinical notes specifically, we encourage practitioners to make this argument.

- ***MA Coordinated Care Plan's Prior Authorization:*** The Final Rule establishes safeguards regarding prior approval of health care services to limit an MA coordinated care plan's ability to partially approve what a provider ordered, to avoid disruptions in care, and to minimize repetitive prior authorization. Under the Final Rule, approval of a PA request for a course of treatment must be valid for as long as medically necessary to avoid disruptions in care, in accordance with applicable coverage criteria, the individual patient's medical history, and the treating provider' recommendation. In addition, the Final Rule establishes that when a patient switches to a new MA coordinated care plan, or switches from Traditional Medicare to an MA coordinated care plan, the MA coordinated care plan may not disrupt or require reauthorization for an active course of treatment for new plan enrollees for at least 90 days. Once an MA coordinated care plan approves a PA request, it is barred from denying coverage later on the basis of lack of medical necessity unless there is good cause or evidence of fraud.

- ***Utilization Management Tools:*** MA plans must be more transparent by establishing a utilization management ("UM") committee that is led by a plan's medical director. An MA plan is prohibited from using any UM policies and procedures, including PA policies, on or after January 1, 2024, unless the UM committee reviews and approves them. These policies and procedures must be reviewed annually by the UM committee.

- ***Qualifications of MA Claims Reviewers:*** Under the Final Rule, all MA benefit denials must be reviewed and approved by "a physician or other appropriate health care professional with expertise in the field of medicine or health care that is appropriate for the services at issue, including knowledge of Medicare coverage criteria."[3] However, the Final Rule does not go as far as the O&P Alliance advocated. The rule does not require the reviewing physician or health care professional to be of the same specialty or subspecialty as the treating practitioner or require the reviewer to have a minimum

[1] 42 C.F.R. § 422.101(b)(6) (emphasis added).
[2] 88. Fed. Reg. at 22,197.
[3] 42 C.F.R. § 422.566(d).

number of years of specialized training in the field of medicine related to the service at issue. Overall, however, this is a major advance to ensure that benefit denials are reviewed by qualified professionals.