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Centers for Medicare & Medicaid Services
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DATE: February 6, 2024

TO: All Medicare Advantage Organizations and Medicare-Medicaid Plans

SUBJECT: Frequently Asked Questions related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

On April 5, 2023, CMS issued the "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" final rule which included requirements and clarifications relating to Medicare Advantage (MA) coverage criteria for basic benefits, use of prior authorization, and the annual review of utilization management tools. The new regulatory provisions are applicable to coverage beginning January 1, 2024. Since the issuance of this rule, CMS has received questions about the application of these rules once they are effective. In this memo, we provide clarification about how we expect MA plans to comply with these new rules.

1. **Question: When are MA organizations able to use internal coverage criteria when making medical necessity determinations for basic Medicare benefits?**

   Answer: For Medicare basic benefits, MA organizations must make medical necessity determinations in accordance with all medical necessity determination requirements, outlined at § 422.101(c)[1]; based on the circumstances of each specific individual, including the patient's medical history, physician recommendations, and clinical notes; and in line with all fully established Traditional Medicare coverage criteria. This includes established criteria in applicable Medicare statutes, regulations, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When Medicare coverage criteria are not fully established, MA organizations may create publicly accessible internal coverage criteria that are based on current evidence in widely used treatment guidelines or clinical literature, as permitted in § 422.101(b)(6).

[1] MA organizations must make medical necessity determinations based on all of the following:
(A) Coverage and benefit criteria as specified at § 422.101(b) and (c) and may not deny coverage for basic benefits based on coverage criteria not specified in § 422.101(b) or (c).
(B) Whether the provision of items or services is reasonable and necessary under section 1862(a)(1) of the Act.
(C) The enrollee's medical history (for example, diagnoses, conditions, functional status), physician recommendations, and clinical notes.
(D) Where appropriate, involvement of the organization's medical director as required at § 422.562(a)(4).

2. **Question: Do the new rules on clinical coverage criteria for basic Medicare benefits mean that MA organizations cannot use algorithms or artificial intelligence to make coverage decisions?**

   Answer: There are many overlapping terms used in the context of rapidly developing software tools. Algorithms can imply a decisional flow chart of a series of if-then statements (i.e., if the patient has a certain diagnosis, they should be able to receive a test), as well as predictive algorithms (predicting the likelihood of a future admission, for example). Artificial intelligence has been defined as a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments[2]. Artificial intelligence systems use machine- and human-based inputs to perceive real and virtual environments; abstract such perceptions into models through analysis in an automated manner; and use model inference to formulate options for information or action[3].

   An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made. For example, compliance is required with all of the rules at § 422.101(c) for making a determination of medical necessity, including that the MA organization base the decision on the individual patient's circumstances, so an algorithm that determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes would not be compliant with § 422.101(c). In an example involving a decision to terminate post-acute care services, an algorithm or software tool can be used to assist providers or MA plans in predicting a potential length of stay, but that prediction alone cannot be used as the basis to terminate post-acute care services. For those services to be terminated in accordance with § 422.101(c), the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services. Additionally, for inpatient admissions, algorithms or artificial intelligence alone cannot be used as the basis to deny admission or downgrade to an observation stay; the patient's individual circumstances must be considered against the permissible applicable coverage criteria under § 422.101(c).

   MA organizations may only deny coverage for basic benefits based on coverage criteria that are specified in § 422.101(b) or (c) or for other expressly permissible bases, such as network limitations or failure to comply with prior authorization requirements. Therefore, the algorithm or software tool should only be used to ensure fidelity with the posted

[2] 15 U.S.C. 9401(3)

[3] *Id. See also* Executive Order (E.O.) 14110 on Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (88 FR 75191 (11/1/2023), https://www.federalregister.gov/documents/2023/11/01/2023-24283/safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence;

internal coverage criteria which has been made public under § 422.101(b)(6)(ii). Because publicly posted coverage criteria are static and unchanging, artificial intelligence cannot be used to shift the coverage criteria over time. And, predictive algorithms or software tools cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard in § 422.101(b)(6).

Furthermore, we are concerned that algorithms and many new artificial intelligence technologies can exacerbate discrimination and bias. We remind MA organizations of the nondiscrimination requirements of Section 1557 of the Affordable Care Act, which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. MA organizations should, prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases.

3. **Question: For purposes of § 422.101(b)(6)(ii), which states that MA organizations must provide internal coverage criteria in a publicly accessible way, what does "publicly accessible" mean?**

   Answer: In the 2024 MA and Part D final rule, CMS did not specify how compliant MA plan internal coverage criteria and related information must be made publicly available. We recommended that MA organizations refer to the coverage criteria and summary of evidence presented by Medicare Administrative Contractors (MACs) as a guide and best practice for how to present this information publicly. However, in response to additional questions about what would meet the standard to be "publicly accessible," we are further elaborating here that the internal coverage criteria used by plans must be accessible via a website and cannot be behind a paywall or require a subscription for access. The information must be available to all in the public (not just enrollees and/or contracted providers of the MA plan) and may be hosted on the MA plan's website or a delegated vendor's website that is accessible from the MA plan's website. MA organizations are required to have a website under § 422.111(h)(2); therefore, use of that website is appropriate. At this time, we do not believe that requiring one or two pieces of basic information to gain access to the internal coverage criteria information required by § 422.101(b)(6)(ii) *necessarily* undermines public access. However, we have concerns that in cases where plans contract with multiple utilization management vendors and place a link to each vendor's website on the plan website to comply with this provision, the burden of accessing and reviewing the collective internal coverage criteria used by the plan could compromise the public accessibility required by § 422.101(b)(6)(ii).. We will continue to monitor access and transparency limitations and may revisit this issue if we see overly burdensome information collection in order to gain access to and analyze internal coverage criteria that should be accessible and transparent to all in the public. The final rule clearly explained that the information required by § 422.101(b)(6) must be publicly accessible, which means generally accessible to CMS, enrollees, providers, researchers, and other stakeholders and that CMS believes that this transparency provides

a measure of protection for enrollees and assurances that the coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature.

4. **Question: What does the internal coverage criteria standard "based on current evidence in widely used treatment guidelines or clinical literature" mean as used in § 422.101(b)(6)?**

   Answer: In circumstances when Medicare Part A and B coverage criteria are not fully established and MA plan internal coverage criteria are permitted, CMS elaborated on the meaning of current, widely used treatment guidelines and clinical literature in the preamble of the final rule on pages 22189, 22196, and 22197. Current, 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. 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. MA organizations may not add coverage criteria that are not supported in such guidelines or literature, or change the substantive recommendations contained in such guidelines or literature to support coverage criteria. If the internal coverage criteria cannot be supported by current evidence in widely used treatment guidelines or clinical literature, publicly and in a way that meets the evidentiary standard in the final rule, plans should not develop internal coverage criteria even if the Traditional Medicare coverage criteria are not fully established. Referencing information, such as a book, website, or third-party criteria, without directly describing and referencing the requisite source citations from primary literature that are widely used treatment guidelines or clinical literature, would not comply with § 422.101(b)(6)(ii). These transparency measures will protect beneficiaries by ensuring that coverage criteria are rational and supportable by current, widely used treatment guidelines and clinical literature. This requirement provides further transparency into MA organizations' medical necessity decision making and is consistent with CMS's expectation that MA organizations develop and use coverage criteria in a way that aligns with Traditional Medicare.

5. **Question: What does it mean for internal coverage criteria to have clinical benefits that are highly likely to outweigh any clinical harms?**

   Answer: Section 422.101(b)(6)(i)(A) requires that when additional, unspecified criteria are needed to interpret or supplement general provisions, the MA organization must demonstrate in a publicly accessible way how the additional criteria provide clinical benefits that are highly likely to outweigh any clinical harms, including (but not limited to) from delayed or decreased access to services. CMS expects that, in order to demonstrate in its public explanation of the rationale support for establishing the internal coverage criteria, the MA organization would compare the clinical benefits of the policy

to the harms that patients may experience as a result of the coverage criteria. For example, take the hypothetical example of an MA organization that establishes internal coverage criteria for Magnetic Resonance Imaging (MRIs) with contrast for patients with a history of established hypersensitivity to Gadolinium-based contrast media (a type of contrast often used in MRIs). NCD 220.2 Magnetic Resonance Imaging states that physicians elect to use a specific Magnetic Resonance Angiography or Contrast-enhanced technique *based upon clinical information from each patient*. Here, the MA organization may adopt an internal policy to not allow contrast-enhanced MRIs with Gadolinium-based contrast media when the patient has a history of hypersensitivity to Gadolinium unless the patient receives appropriate pretreatment. In its rationale, the clinical benefit of avoiding MRIs in patients with established hypersensitivity to Gadolinium-based contrast media may be avoidance of hypersensitivity reaction, which for some patients can be life threatening and cause significant morbidity and mortality. However, omitting contrast when it is indicated can lead to diagnostic and treatment errors, or repeated tests and delayed diagnoses. Additionally, the coverage criteria in and of itself could cause a dangerous delay in an important diagnosis. In order to compare the relative clinical harm and benefit, factors such as prevalence of expected clinical benefits and harms, relative morbidity and mortality, and frequency of delayed diagnoses for specific conditions that result from delayed or decreased access to MRIs, and relative outcomes, including through pretreatment, could be weighed in the public rationale.

Demonstrating that the additional coverage criterion (or criteria) meets the regulatory standard in § 422.101(b)(6)(i)(A) would involve a discussion of the relative clinical benefits and harms to the patient population. The clinical coverage criteria should be narrowly tailored to the patient population that stands to benefit in the public rationale and justification (i.e. the internal coverage criteria could be created for patients with a history of gadolinium hypersensitivity who have been ordered an MRI with Gadolinium contrast in this example—not all patients who have been ordered an MRI). Because the MA organization must demonstrate the comparative benefit of the additional coverage criteria, a public explanation that *assumes* that clinical coverage criteria *in general offers clinical benefits* to patients that are highly likely to outweigh clinical costs is not sufficient. The public explanation should systematically explain the harms and benefits and use appropriate clinical evidence and citation of current, widely used treatment guideline or clinical literature. (See also § 422.101(b)(6)(ii)(C).)

Further, if the standards in § 422.101(b)(6) and 422.101(b)(6)(i)(A) cannot be met because there are no widely used treatment guidelines or high-quality clinical literature to suggest that the clinical benefit of the internal coverage criteria is highly likely to outweigh the clinical harm, the MA organization is not permitted to adopt that internal coverage criteria even if the Traditional Medicare coverage criteria are not fully established. Stated succinctly, we believe that all internal coverage criteria should clearly and explicitly support patient safety before the criteria are used by an MA plan, even

where other minimum requirements in the regulation (that is, where Traditional Medicare coverage policies are not fully established) are met.

We will continue to monitor the rationales made public under § 422.101(b)(6) to ensure compliance. We may issue additional guidance as needed to ensure that internal coverage criteria are being developed only in those situations where clinical benefit is highly likely to outweigh clinical harm, including from delayed or decreased access to items or services.

6. **Question: Can MA organizations apply coverage criteria from a Traditional Medicare Local Coverage Determination (LCD) that is not applicable to the service area where the MA plan is available?**

   Answer: If the LCD is not from the applicable service area, use of the LCD is use of internal coverage criteria and all associated requirements would still apply; an MA organization is not exempted from the requirements of § 422.101(b)(6) by using an LCD adopted in a geographic area that is not the MA plan's service area. MA organizations must follow all Traditional Medicare NCDs, LCDs applicable to the MA plan's service area, and general coverage and benefit conditions included in Traditional Medicare per 42 CFR § 422.101. In situations where Traditional Medicare coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs (applicable to the applicable service area), MA organizations may create internal coverage criteria as long as they comply with rules at § 422.101(b)(6). An MA plan's internal coverage criteria may be similar or the same as criteria found in LCDs that are applicable outside of the MA plan's service area, but the MA organization must still ensure that the criteria are based on current evidence in widely used treatment guidelines or clinical literature and is made publicly available, as required by § 422.101(b)(6).

7. **Question: Can an MA organization deny admission of a patient to a post-acute care facility from an acute care hospital if it's ordered by their physician and the patient meets the coverage criteria for admission into that facility?**

   Answer: No, if a patient is being discharged from an acute care hospital to a post-acute care facility that would be covered under Traditional Medicare and the patient's attending physician orders post-acute care in the specific type of facility (i.e., Skilled Nursing Facility (SNF), Long Term Care Hospital (LTCH)) and the patient meets all applicable Medicare coverage criteria for admission into that facility type, the MA organization cannot deny admission to that post-acute setting and/or redirect the care to a different setting. In the context of post-acute care services furnished in a particular setting, MA organizations may only deny a request for Medicare covered post-acute care services if the MA organization determines that the Traditional Medicare coverage criteria (e.g., for SNF care in §§ 409.30-409.36) or internal coverage criteria when applicable and

authorized by § 422.101(b) for the services cannot be satisfied in that particular setting. We explained this clearly as part of the proposal that we adopted in the final rule. 88 FR 22189. We reiterate here that MA organizations may only deny a request for Medicare covered post-acute care services in a particular setting if the MA organization determines that the Traditional Medicare coverage criteria or internal coverage criteria (when applicable and authorized by § 422.101(b)) for the services cannot be satisfied in that particular setting. However, MA plans are permitted to offer coverage of alternatives to Medicare covered post-acute care services in a particular setting and an enrollee is permitted to elect different treatment. The requirement for MA plans to cover all basic benefits consistent with Traditional Medicare coverage criteria does not prohibit discussions with the enrollee of other treatment options that are covered by the MA plan. However, the flexibility for MA plans to cover and deliver care in cost-effective approaches does not replace the obligation for MA plans to cover all basic benefits consistent with the established coverage criteria for Traditional Medicare.

MA organizations may only terminate coverage for post-acute care services based on coverage criteria that are specified in § 422.101(b) or (c), which include medical necessity. An algorithm or software tool may be used to assist MA plans in predicting a length of stay, but that prediction alone must not be used as the basis to terminate post-acute care services; the patient must no longer meet the level of care requirements needed for the post-acute care at the time the services are being terminated, which can only be determined by re-assessing the individual patient's condition prior to issuing the notice of termination of services. An MA organization's decision to terminate post-acute care services and discharge a patient from a home health agency (HHA), skilled nursing facility (SNF), or comprehensive outpatient rehabilitation facilities (CORF) is an organization determination and is appealable in accordance with rules in §§ 422.624 and 422.626.[4] The specific expedited appeal process applicable to such terminations of provider services provides that the burden of proof rests with the MA organization to demonstrate that termination of coverage is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies, and that the MA organization must supply a specific and detailed explanation why services are either no longer reasonable and necessary or are no longer covered, including a description of the applicable coverage criteria and rules. 42 CFR § 422.626(c) and (e).

8. **Question: Does the CY 2024 final rule mean that MA organizations must follow the Medicare "two-midnight rule"?**

[4] Discharge from an inpatient hospital is appealable in accordance with §§ 422.620 and 422.622. In these expedited reviews by the QIO, the MA organization also bears the burden of proof that the discharge "is the correct decision, either on the basis of medical necessity, or based on other Medicare coverage policies." § 422.622(c).

Answer: The term 'two-midnight rule' is sometimes used to describe different things: either the "two-midnight presumption" or the "two-midnight benchmark" admission criteria. As explained further below, MA plans do not have to follow the "two-midnight presumption," which relates to medical review instructions for contractors in Traditional Medicare. However, another colloquial use of the term "two-midnight rule" is to describe the inpatient admission criteria in 42 C.F.R. § 412.3, which include a "two-midnight benchmark;" MA plans are required to follow these inpatient admission criteria.

In regard to the two-midnight presumption, we explained in the preamble of the CY 2024 final rule that the "two-midnight presumption" (the presumption that all inpatient claims that cross two midnights following the inpatient admission order are "presumed" appropriate for payment under Medicare Part A and are not the focus of medical review absent other evidence) does not apply to MA plans' decision about when and how to engage in review of a particular inpatient stay. The two-midnight presumption is a medical review instruction given to Medicare post-payment audit and compliance contractors (for example, Recovery Audit Contractors, or Quality Improvement Organizations) to help them in the selection of claims for post-payment medical necessity reviews in Traditional Medicare, which are conducted to ensure that claims have been appropriately paid under Medicare rules. Any sub-regulatory guidance issued by these contractors does not directly apply to MA plans but likely contain useful explanations and interpretations of Traditional Medicare policies. As clarified in the CY 2024 final rule,[5] MA organizations are not required to use the two midnight presumption to decide which claims to review, but may instead decide which claims are subject to review in accordance with procedures for making determinations as provided by Section 1852(g)(1)(A) of the Act. MA plans may still use prior authorization or concurrent case management review of inpatient admissions to determine whether the complex medical factors documented in the medical record support medical necessity of the inpatient admission under 42 C.F.R. 412.3. MA medical necessity reviews may be conducted before the service is provided (i.e., prior authorization), during (i.e., concurrent case review), or after the service is provided (i.e., claim review). In all of these circumstances, MA organizations must comply with § 422.101(c).

The two-midnight benchmark is part of the inpatient admission criteria outlined in 42 C.F.R. § 412.3. MA plans must follow these criteria, in line with the requirement that they must follow general coverage and benefit conditions included in Traditional Medicare when making a decision about coverage of an inpatient stay. In the CY 2024 final rule, CMS updated and clarified requirements affecting MA plan coverage guidelines and the relation of such guidelines to Traditional Medicare coverage policies. The updated regulations explain that MA plans must follow all NCDs, LCDs applicable to the plan's service area, and general coverage and benefit conditions included in Traditional Medicare laws. We directly cited the inpatient admission criteria at 42 CFR §

[5] 88 FR 22191-22192.

412.3 as an example of Traditional Medicare rules that apply in MA (42 CFR § 422.101(b)(2)) to establish coverage. More specifically, under 42 CFR § 412.3, MA plans must provide coverage, by furnishing, arranging for, or paying for an inpatient admission when, based on consideration of complex medical factors documented in the medical record:

- the admitting physician expects the patient to require hospital care that crosses two-midnights (§ 412.3(d)(1) (the "two midnight benchmark");
- when the admitting physician does not expect the patient to require care that crosses two-midnights, but determines, based on complex medical factors documented in the medical record that inpatient hospital care is nonetheless necessary (§ 412.3(d)(3), (the "case-by-case exception"); or
- when inpatient admission is for a surgical procedure specified by Medicare as inpatient only (§ 412.3(d)(2)).

We note that inpatient admission criteria at § 412.3(d)(1) and (3) are both based on the *expectation of the admitting physician* at the time of admission, as supported by the medical record. Whether the admission actually crossed two midnights is not a factor in the inpatient admission criteria at § 412.3. An MA organization may evaluate whether the admitting physician's expectation that the patient would require hospital care that crosses two-midnights was reasonable based on complex medical factors documented in the medical record. Consistent with § 412.3, that evaluation should defer to the judgment of the physician as long as that judgment was reasonable based upon the complex medical factors documented in the medical record.

CMS will continue to monitor inpatient coverage criteria, in addition to all other clinical areas, to evaluate areas where there may need to be more well-established criteria implemented to best support beneficiary access to the timely care they need.

9. Question: Are plans able to do post-claim audits and deny payment and still be compliant with the effect of a prior authorization or pre-service approval rule at 422.138(c)?

Answer: Plans can conduct post-claim reviews, but it must be compliant with reopening rules and only revised within specific parameters. Subject to the limitation in § 422.138(c), discussed below, a plan is permitted to conduct post-payment review on a selected claim, consistent with the reopening rules in § 422.616 and other applicable rules in Part 422, Subpart M.

If an organization determination is reopened and revised, the plan must notify the parties of its revised determination. If the revised determination is adverse, the notice to the parties must state the rationale and basis for the reopening and revision and any applicable right to appeal. However, the final rule codified at § 422.138(c) states that if an

MA organization approved the furnishing of a covered item or service through a prior authorization or pre-service determination of coverage or payment, it may not deny coverage later on the basis of lack of medical necessity and may not reopen such a decision for any reason except for good cause (as provided at 42 CFR § 405.986) or if there is reliable evidence of fraud or similar fault per the reopening provisions at § 422.616. This means that if the MA organization pre-authorized the inpatient admission, it would be a violation of § 422.138(c) to later deny payment based on a determination that the level of care was not medically necessary.

We have heard frequently that MA organizations utilize post-claim review audits and examinations that routinely result in the denial of payment for the inpatient care that was provided to the enrollee. Further, we have heard that MA organizations characterize these reviews as "payment" reviews and that these reviews are "not organization determinations" or "level of care or medical necessity reviews." We disagree with those characterizations of decisions that are denials of coverage or otherwise a refusal to provide or pay for services, in whole or in part, including the type or level of services, that the enrollee believes should be furnished or arranged for by the MA organization. We reiterate here that the refusal to provide or pay for services, in whole or in part, including the type or level of services (e.g., inpatient services versus outpatient services) is an organization determination by the MA plan under § 422.566(b)(3). Therefore, if the MA organization expects to issue a partially or fully adverse decision about whether the services are or were medically necessary, that decision – meaning that organization determination - must be reviewed 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, before the MA organization issues the organization determination decision. See 42 CFR § 422.566(d).

10. Question: Does the Medicare "Interrupted Stay" policy apply in MA?

Answer: Traditional Medicare pays SNFs using the SNF Prospective Payment System (PPS). The SNF PPS includes an "interrupted stay" policy that if a patient in a covered Part A SNF stay is discharged from the SNF but returns to the same SNF no more than three consecutive calendar days after having been discharged, then this would be considered a continuation of the same SNF stay (see 83 FR 39162, 39243). In such cases, no new patient assessments are required and the variable per diem adjustment is not reset. This policy of not resetting the variable per diem adjustment is not applicable in MA when MA organizations provide benefits through their contracted network of providers. The contract between MA organizations and their contracted providers governs the rates and payment policies for the delivery of services.

However, in the final rule, we strengthened policies related to prior authorization at § 422.112(b)(8)(i)(A), by requiring that approval of a prior authorization 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's recommendation. This requirement applies in the context of an interrupted stay in a SNF: a new prior authorization for admission is not required when the patient returns no more than three consecutive calendar days after having been discharged. Therefore, if the MA plan uses prior authorization for a stay in a SNF, an interruption in the stay within the scope of the SNF PPS interrupted stay policy does not change or alter the scope of that prior authorization approval. Under § 422.112(b)(8)(i)(A), MA organizations that offer coordinated care plans must not require another prior authorization when a patient returns no more than three consecutive calendar days after having been discharged and the patient is still undergoing the same course of treatment that was previously approved. This policy is meant to avoid disruptions in care for the patient and does not impact or change payment or rates set between the MA organization and the provider.

When an MA plan covers out of network services (that is, services furnished by a non-contracted provider), the MA plan must pay the provider the amount that the provider would have received as payment in the Traditional Medicare program. See section 1852 of the Act and 42 CFR § 422.100(b)(2) and 422.214. Therefore, MA organizations must follow payment rates in the SNF PPS for services delivered by non-contracted SNF providers.

11. Question: Can MA plans still use prior authorization and how does the CY 2024 final rule impact the use of prior authorization?

Answer: Yes, use of prior authorization (also called pre-certification) to ensure the patient meets the applicable guidelines is still allowed ***except for*** emergency, urgently needed, and stabilization services (§ 422.113(a)), and out-of-network services covered by MA PPO plans. In addition, MA Private Fee For Service and MA Medical Savings Account plans are not permitted to use prior authorization policies or "prior notification" policies that reduce cost sharing for enrollees based on whether the enrollee or provider notifies the plan in advance that services will be furnished.

That said, the CY 2024 final rule adopted several provisions applicable beginning January 1, 2024, on the use of prior authorization:

- Prior authorization may only be used by MA coordinated care plans to confirm the presence of diagnoses or other medical criteria, to ensure that the furnishing of a service or benefit is medically necessary or, for supplemental benefits, clinically

appropriate (§ 422.138(b)). Therefore, prior authorization should not function to delay or discourage care.

- For MA coordinated care plans, approval of a prior authorization request for a course of treatment must be valid for as long as medically reasonable and necessary to avoid disruptions in care in accordance with applicable coverage criteria, the patient's medical history, and the treating provider's recommendation. Further, MA coordinated care plans must provide a minimum 90-day transition period for new enrollees, during which the new MA plan may not require prior authorization for any active course of treatment, even if the course of treatment was for a service that commenced with an out-of-network provider (§ 422.112(b)(8)).
- To ensure prior authorization is being used appropriately, all MA plans must establish a Utilization Management Committee to annually review utilization management policies and ensure consistency with Traditional Medicare's national and local coverage decisions and guidelines (§ 422.137).

In addition, prior authorization decisions must be made as expeditiously as the enrollee's health condition requires, but no later than the deadlines established in §§ 422.568 (for non-expedited requests) and 422.572 (for expedited requests).

12. Question: Can MA organizations that share a common parent organization use personnel that serve on multiple Utilization Management (UM) committees?

Answer: CMS required that an MA organization that uses utilization management (UM) policies and procedures, including prior authorization (PA), must establish a UM committee that is led by a plan's medical director (described in § 422.562(a)(4)). The final rule provides that MA organizations may elect to establish UM committees at the MA organization or plan level, but does not permit the UM committee to be established at the parent organization level for all MA plans offered under that parent organization and its subsidiaries. In some cases, it may be appropriate for parent organizations that operate multiple MA organizations to establish UM committees with substantially the same membership. If all regulatory requirements, including UM committee membership, scope of work, and documentation requirements, are satisfied, then it may be appropriate for the same group of members to serve on the UM committees for multiple MA organizations. Since there are no requirements regarding how many individuals may serve on the UM committee, MA organizations and parent organizations have sufficient flexibility to establish UM committees, while also complying with all regulatory requirements. For example, a parent organization may choose to have one core group of UM committee members that serve across multiple committees under the subsidiary MA organizations, while also supplementing those committees with additional personnel based on which UM policies or procedures the UM committee must review, the geographic area served by the particular MA organization, or other factors relevant to the development, review and use of UM policies. Further, as outlined in the CY2024 final

rule, MA organizations are permitted to leverage existing committees to satisfy the new regulatory requirement. MA organizations may adapt or alter existing committees, including committees required by accrediting bodies and existing P&T committees, to conform with the regulatory requirements of § 422.137.

For additional information on this topic, please see the HPMS memo titled "Additional Operational Instruction on the Utilization Management Committee Structure," issued on November 15, 2023. Also, please see the proposed rule Medicare Program; 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; Health Information Technology Standards and Implementation Specifications (88 FR 78476), in which CMS proposed additional changes to the UM committee: https://www.federalregister.gov/documents/2023/11/15/2023-24118/medicare-program-contract-year-2025-policy-and-technical-changes-to-the-medicare-advantage-program.

13. **Question: How do the new CY 2024 utilization management requirements apply to MA supplemental benefits?**

Answer: As stated in the CY 2024 final rule, MA organizations may use prior authorization to ensure that the furnishing of supplemental benefits is clinically appropriate. The regulation text uses the term "clinically appropriate" as opposed to "medically necessary." While supplemental benefits must be medically necessary based on long standing guidance, certain supplemental benefits (that is, SSBCI) may be non-primarily health related and must have a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Thus, a standard based on medical necessity may not always be appropriate and using the term "clinically appropriate" is more inclusive of SSBCI. In line with these standards, prior authorization for supplemental benefits may only be used to ensure the furnishing of a service or benefit is clinically appropriate. As it relates to coverage criteria, Medicare does not have coverage criteria for supplemental benefits because, by their nature, they are not Medicare Part A or Part B benefits.

14. **Question: How will CMS enforce the CY 2024 changes in coverage criteria and utilization management requirements?**

Answer: As we first announced on October 24, 2023, in the HPMS memo titled, "2024 Oversight Activities" and subsequently on December 19, 2023, in the HPMS memo titled, "2024 Program Audit Updates" CMS will conduct both routine and focused program audits of organizations in 2024 to assess compliance with the coverage and UM requirements finalized in the CY 2024 final rule. For MA organizations that have routine program audits scheduled for 2024, these audits will follow our standard process similar to prior years, covering all applicable program areas, but will target the new UM

requirements during the Part C Organization Determinations, Appeals, and Grievances (ODAG) review, as well as the Compliance Program Effectiveness (CPE) review. In addition, CMS is also adding new focused audits for plans that don't have routine scheduled audits, which are limited to ODAG and CPE, and are designed specifically to target compliance with the coverage and UM policies in the CY 2024 final rule. Through this combination of routine and focused audits in 2024, CMS expects to evaluate the UM-related performance of plans serving approximately 88% of people with MA. This expansion of our audit activity will help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled. During both the routine and focused program audits, CMS will utilize physician reviewers to review denied requests to assess whether MAOs are meeting new clinical coverage requirements, such as following coverage and benefit conditions included in Medicare laws, NCDs, or LCDs, , and when permissible, applying internal coverage criteria only when coverage criteria are not fully established in statute, regulation, National Coverage Decisions, and Local Coverage Decisions. CMS program audits will also ensure that internal coverage criteria are publicly available and otherwise meet regulatory requirements, MAOs are only using physicians (or other appropriate health care professionals) with appropriate expertise in the field of medicine for the service at issue when issuing adverse medical necessity decisions, and MAOs have established UM committees in accordance with regulatory requirements, including who the members of the committee are and the responsibilities they are required to complete.

CMS has increased its scheduled program audit activities to help make sure that MA beneficiaries get the care they need without excessive burden or delays and have access to the benefits and services to which they are entitled.

We will be monitoring closely whether MA plans are utilizing and applying internal coverage criteria that are not found in Medicare laws, NCDs, or LCDs, and whether the internal coverage criteria are publicly accessible and coverage policies meet the regulatory requirements.

CMS has a number of tools it can use to address non-compliance with the new requirements, including issuing compliance and enforcement actions.

- Compliance actions include Notices of Non-Compliance, Warning Letters, and Requiring Corrective Action Plans.
- Enforcement actions include civil money penalties and enrollment and/or marketing sanctions.

If you have any questions, please submit an inquiry to the Part C Policy portal at: dpap.lmi.org