



Submitted Electronically - www.regulations.gov

March 10, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave., S.W.
Washington, DC 20201

Re: Comments on CMS-0057-P, “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children’s Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program,” (87 Fed. Reg. 76238, December 13, 2022)

Dear Administrator Brooks-LaSure,

Introduction

The American Association for Homecare (AAHomecare) is the national association representing durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures beneficiaries and other patients receive cost-effective, safe, and reliable home care products and services. Our members supply home oxygen therapy, positive airway pressure devices (PAP), ventilator services, complex rehabilitation technology (CRT), urological, ostomy, wound care supplies and many other medically necessary home medical equipment items and services.

AAHomecare and our durable medical equipment prosthetic, orthotic and supplies (DMEPOS) supplier members share Medicare’s goal of providing quality and timely equipment and services to Medicare beneficiaries and improving patient outcomes while lowering overall health care expenses. DME suppliers contain health care costs by serving patients in the home (the least expensive site of care). This, in turn, allows patients to be discharged from hospitals, nursing homes, and other health care facilities (the most expensive sites of care) to continue their care in the home setting. DMEPOS is a critical component of the health care continuum, requiring investment

and a sound financial footing to preserve continued access to high quality, cost-effective DMEPOS.

Twenty years after its inception, the Medicare Advantage (MA) program now has over 28 million participants, representing almost half of all Medicare beneficiaries. It is an appropriate time for CMS to closely examine the MA program and require policies “to reduce payer, provider, and patient burden by improving prior authorization processes and helping patients remain at the center of their own care.”¹

Over the last several decades, home care technology has made tremendous strides, enabling an increasing number of patients to receive safe, efficacious, and costs-effective health care at home - the site patients prefer to be. Our country’s experience with the ongoing COVID-19 public health emergency has demonstrated that DMEPOS suppliers can take care of many patients at home, thereby alleviating hospital overcrowding and containing overall healthcare costs.

AAHomecare is pleased to submit comments on this proposed rule. Given our membership perspectives, our comments focus on the prior authorization proposals as they would impact DMEPOS suppliers.

Federal Oversight Agencies Have Called for CMS to Protect Beneficiaries and Providers from Inappropriate Denials, and CMS has Agreed with Specific Recommendations

The Department of Health and Human Services Office of the Inspector General (OIG) released a report in 2018 that detailed “widespread and persistent problems related to denials of care and payment in Medicare Advantage plans.”² A second OIG report in 2022 found persistent problems with MA plans issuing inappropriate denials of service and payment, including denials of prior authorization requests that met Medicare coverage rules.³ A recent Kaiser Family Foundation report found that in 2021, MA plans received over 35 million prior authorization requests.⁴ More than 2 million of these requests were fully or partially denied and yet, when appealed, the vast majority (more than 80%) of appeals were fully or partially overturned. Unfortunately, only 11% of initial denials were appealed, demonstrating not only the burden of appealing prior authorization denials but also indicating that many beneficiaries are likely seeing their care being inappropriately denied. These OIG and Kaiser Family Foundation reports suggest many health plans utilize prior authorization processes to delay or deny approval for items and services that meet Medicare coverage rules and/or are, in the end, routinely approved.⁵ These findings

¹ 87. *Fed. Reg.* at 76240.

² U.S. Department of Health and Human Services, Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denial; Report (OEI-09-16-00410) (Sept. 2018).

³ U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

⁴ Biniek, Jeannie Fuglesten and Sroczynski, Nolan. Kaiser Family Foundation (KFF) (Feb. 2023).

<https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021>.

⁵ U.S. Department of Health and Human Services, Office of Inspector General. Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care; Report (OEI-09-18-00260) (Apr. 2022).

echo previous figures reported by OIG, including the finding that when beneficiaries and providers appealed initial denials, MA plans overturned their own denials 75% of the time.⁶

These reports of MA plan prior authorization and payment denials underscore the need for (1) significantly more CMS oversight of plan PA processes and (2) CMS enforcement of the requirement that MA plans adhere to Medicare coverage rules. These reports make strong recommendations that CMS take action to ensure that MA beneficiaries have timely access to all necessary health care services and that providers are paid appropriately.

A central concern about capitated payment models, including MA and many State Medicaid plans, is the potential incentive for insurers to deny access to services for enrollees and deny payments to providers to increase profits. Inappropriate PA denials can result in many negative impacts, including not receiving necessary health care, delays in receiving care, and beneficiaries paying out of pocket. The denials can also delay or prevent providers from receiving payment for services that have already been provided to beneficiaries.

AAHomecare agrees with the OIG recommendations on ways CMS can better protect beneficiaries and providers from inappropriate denials.

Prior Authorization Proposals

We support the Centers for Medicare and Medicaid Services' (CMS') policy objective of prior authorization (PA) requirements; that they are designed to help control costs and ensure payment accuracy by verifying that an item or service is medically necessary, meets coverage criteria, and is consistent with the standards of care before the item or service is provided. Overall, we agree with the CMS proposals designed to improve the PA process for payers, providers, and patients. CMS proposes to require payers to implement and maintain an Application Programming Interface (API) to support and streamline the PA process; respond to PA requests within certain timeframes; provide a clear reason for PA denials; and publicly report on PA approvals, denials and appeals. Transparency, consistency and timeliness in the PA system are paramount to ensure patients maintain access to appropriate care. One component of the PA process that is critical, but is not expressly addressed in the proposals, is the need for an impartial and expeditious appeal process for PA requests that are denied. We explain further in our comments below.

In the proposed rule, CMS explains that while this proposed rule does not directly affect Medicare fee-for-service, if these rules are finalized, the Medicare FFS program would modify its PA programs to align with these rules. AAHomecare would support those modifications to the fee-for-service PA process for DME items if CMS adopts the additional improvements that we recommend.

Comments on CMS PA Proposals

PA Proposals for the Medicare Advantage Program:

- *Proposed 42 C.F.R. §422.122 and 42 C.F.R. §422.568, PA Requirements and Standard Timeframes and Notice Requirement for organization determinations.* CMS proposes that, starting January 1, 2026, MA

⁶ U.S. Department of Health and Human Services, Office of Inspector General. Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denial; Report (OEI-09-16-00410) (Sept. 2018).

organizations provide specific information about PA requests to the provider/supplier, including a specific reason if there is a denial, has an electronic process for the PA documentation and decision, and publicly report PA metrics. CMS also proposes specific timeframes for these processes.

- **Comment:** AAHomecare generally supports these proposals, particularly the specific reason of a denial, but is concerned about the lack of an objective/impartial and expeditious appeal process for negative PA determinations. We strongly recommend that CMS require MA plans to establish a timely, objective appeal process that is available to providers/suppliers and enrollees, to quickly appeal a negative PA determination. The deficiencies of current appeal processes are primarily lack of timeliness and a lack of impartiality/objectivity. For MA plans, we recommend that CMS establish a Part C medical director office within CMS to provide HME/DME providers the opportunity for an appeal process with more objectivity than currently exists.

PA Proposals for State Medicaid Plans:

- Proposed 42 C.F.R. §431.80 and 42 C.F.R. 431.220(a)(1)(vi) PA Requirements and When a Hearing is Required CMS is proposing that, starting January 1, 2026, states must communicate PA statuses to provider/suppliers and implement electronic processes to implement these PA processes and decisions. CMS is also proposing to require the state agency to grant an opportunity for a hearing regarding a PA decision.

Comment: AAHomecare fully supports these proposals but recommends that CMS mandate more details on the hearing process to ensure that a hearing can be conducted in an expeditious and objective manner.

- PA Proposals for Medicaid Managed Care Plans and State Medicaid Programs, and PA Proposals for State Plans for Child Health Insurance Programs (CHIP) and Medicaid Expansion Programs (Proposed 42 C.F.R. §438.210 Coverage and Authorization of Services; Proposed 42 C.F.R. §440.230 Sufficiency of amount duration and scope, Proposed 42 C.F.R. §457.732 PA Requirements; Proposed 42 C.F.R. §156.223 PA Requirements) CMS is proposing that, for certain Medicaid managed care plans, the state’s contract with those plans (MCOs, PIHPs and PAHPs), as well as QHP issuers on a Federally-facilitated Exchange, establishes requirements related to authorization of services, including a requirement that if a provider or the plan “determines that the standard timeframe could seriously jeopardize the enrollee’s life or health or ability to attain, maintain, or regain maximum function, the plan must make an expedited authorization decision and provide notice as expeditiously as the enrollee’s health condition requires, no later than 72 hours after receipt of the request for service” unless the state has established a shorter time frame.

Comment: For many DMEPOS items, PA needs to be processed on an expedited timeframe, faster than even 72 hours, to enable the enrollee to be timely discharged from a hospital or nursing facility. For these reasons, **we recommend that PA be limited to only certain high-cost complex rehab technology and non-invasive ventilators (NIVs). For items such as NIV, an expedited PA decision must be turned around within 24 hours to facilitate patient discharge.**

- CMS is also proposing that state Medicaid programs, their managed care and CHIP plans must publicly report PA metrics, aggregated for all items and services, including:
 - a list of all items and services that require PA;

- the percentage of standard PA requests that were approved;
- the percentage of standard PA requests that were denied;
- the percentage of standard PA requests that were approved after appeal;
- the percentage of PA request for which the timeframe for review was extended, and the request was approved;
- the percentage of expedited PA requests that were approved;
- The percentage of expedited PA requests that were denied; and
- The average and median time that elapsed between the submission of a request and a decision by the plan.

Comment: While we agree with CMS' proposal to require state Medicaid programs and their managed care and CHIP plans to publicly report all these PA metrics, we recommend that CMS also require the plans to report these metrics by item/service. For example, it is important for each type of provider/supplier to understand the impact of the PA process on their particular items/services. With respect to DME, we recommend the states be required to publicly report these metrics separately for different types of DME, including complex rehab technology, respiratory and other DME items.

Additional Comments on PA for DME Items and Services

The OIG and GAO reports and statements cited above underscore the need for PA to be applied judiciously, fairly and expeditiously, and that payers be required to provide a fair/objective and timely appeal process for negative PA determinations.

With respect to DME items and services, PA should only be applied to high-cost items such as complex rehab technology (CRT) and non-invasive ventilators (NIVs), For life-sustaining equipment that a patient needs post-discharge, the PA decision must be made within 24 hours to allow for timely discharge. We have the following detailed recommendations for PA when applied to DME items and services provided to enrollees under any of the state Medicaid fee for service, managed care, CHIP and other health plans covered by this proposal rule.

- a. Health plans should limit the application of PA to only those DMEPOS items and services above certain dollar thresholds. Many DMEPOS items are low cost and immediately necessary to facilitate hospital or nursing facility discharge, and the coverage requirements are fairly straightforward, and their expense is relatively small. Therefore, PA should not be required for most DME items.
- b. If PA is required for life-sustaining items or items, or is an item that the patient requires immediately post-discharge, then the PA needs to be completed within 24 hours to allow for timely hospital discharge.
- c. We recommend that the following DME items be subject to PA, with the caveat that coverage criteria be objective and consistently applied:

1. Complex Rehab Technology (CRT): CRT includes individually configured manual and power wheelchairs, seating and positioning systems, and other adaptive equipment such as standing devices and gait trainers. The provision of this specialized equipment requires evaluation, configuration, fitting, adjustment, and programming along with long-term maintenance and repair services.
 2. Non-Invasive Ventilators (NIVs): Our members experience with PA for NIVs is that payers' lack of objective coverage criteria leads to subjective coverage and/or inconsistent application of coverage criteria, oftentimes resulting in denials that should have been approved. In order for the PA process to be workable, coverage criteria must be clear and objective.
- d. Health plans should eliminate PA processes for complex rehab technology service repair claims because these PA processes result in unreasonable delays when the consumer has a need to obtain repair services. Importantly, the consumer has already met the coverage/medical need requirements upon initial issue of that complex rehab technology.
- e. When a health plan utilizes PAs for DMEPOS items, the health plan should have electronic and "real time" processes to ensure timely access. This is often critical to facilitate timely discharge from a hospital or nursing facility.
- f. CMS should require MAPs to have an electronic "real time" PA system for DMEPOS items. The PA system should meet the following criteria:
- 1) PA decisions should be completed and communicated to the DMEPOS supplier, the ordering physician, and the beneficiary within 24 hours or sooner.
 - 2) A PA request for equipment needed on an emergency basis, as determined by the ordering physician, should be "fast tracked" and decided within two or fewer hours.
 - 3) ***An affirmative PA for a DMEPOS item should be conclusive with respect to the medical necessity and payment of that item.*** An affirmative PA claim can only be audited subsequently for technical issues such as proof of delivery but cannot be audited for medical necessity since that is the entire objective of prior authorization.) Based upon our members' experiences, many plans who issue affirmative PA decisions reversed those decisions in subsequent audits, which seems wholly at odds with the objective of a PA process. We therefore strongly recommend that affirmative PA determinations be upheld on medical need grounds in the event of any later audits. In the case of CRT items, if a subsequent audit reverses an initial PA determination, the patient has typically had use of the customized wheelchair for several years. If the DME provider must recoup the funds, the provider is financially responsible and cannot at that time recover the equipment from the patient.
 - 4) An affirmative PA for a DMEPOS item should be conclusive with respect to the medical necessity for all of the options, supplies, and accessories (submitted at the same time as the underlying item) that will be used with the item. (Although, claims could be audited subsequently for technical issues such as proof of delivery and suspected fraud, waste, and abuse.)

5) An affirmative PA for a DMEPOS item should be conclusive with respect to the medical necessity for (i) resupply items (e.g., for any product category that has an ongoing resupply of medical supplies, for example CPAP devices) and (ii) repairs to the DMEPOS item. (Although, claims could be audited subsequently for technical issues such as proof of delivery and suspected fraud, waste, and abuse).

6) CMS should require MA plans to issue PR denials when there is a negative PA determination. While Medicare FFS allows and recognizes the GA modifier to provide providers a “patient responsibility” or PR denial, MA plans do not issue PR denials or recognize the GA modifier. PR denials are necessary to communicate with secondary payors about the primary insurer’s non-coverage decision and allow the secondary insurer to make a coverage and payment decision. Without a PR denial, DME suppliers are unable to collect from a secondary insurance plan and are often forced to write off significant sums of money.

7) Advance Beneficiary Notice (ABN) – Unlike Medicare FFS, MA plans do not have an ABN process in place. As a result, there is no process/mechanism to confirm patient financial responsibility in the event of a non-coverage decision. CMS should specifically allow/authorize MA plans to utilize the same ABN process to ensure that patients understand their potential financial responsibility in the event of a non-coverage decision.

8) The PA length should be consistent with the length of need ordered by the physician. A length of need of 99 should be considered a lifetime need.

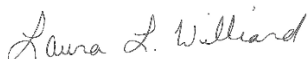
Medicare Advantage PA Recommendation

AAHomecare recommends that CMS create a Medicare Part C Medical Director position at the national level who can provide a more objective and timely appeal role for negative MA PA determinations. The current MA appeal processes take considerable time, denying beneficiaries access to medically necessary DME/CRT items and services. While current appeals process often utilize physicians to conduct peer reviews for appeals, we recommend a more objective PA appeal process be required. In addition, we recommend that physicians who are part of the peer review process have substantive experience in the same medical field for which they are providing peer review services.

Conclusion

Thank you for the opportunity to comment. If you have any questions, please contact me at lauraw@aahomecare.org.

Sincerely,



Laura Williard
Vice President, Payer Relations
American Association for Homecare