

**Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics,
Orthotics, and Supplies Items
Final Rule**

Frequently Asked Questions

1. Q. What does the final rule do?

A: The final rule establishes a prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items through a two-step process. First, the rule establishes a Master List of DMEPOS items that are frequently subject to unnecessary utilization and potentially subject to prior authorization based on certain criteria. Second, it creates a “Required Prior Authorization List,” a subset of items on the Master List that are subject to prior authorization. CMS will inform the public of those items on the Required Prior Authorization List by publishing a notice in the Federal Register with 60-days’ notice before implementation.

2. Q: To whom does this final rule apply?

A: This rule applies to any entity seeking payment for an item listed on the “Require Prior Authorization List.”

3. Q. What is prior authorization?

A: Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before a DMEPOS item is furnished to a beneficiary and before a claim is submitted for payment. Prior authorization helps ensure that applicable coverage, payment, and coding rules are met before supplies are delivered.

4. Q. Does the final rule create new documentation requirements?

A: The final rule does not create new documentation requirements. The final rule simply requires the submission of all required documentation earlier in the claims payment process.

5. Q. How does a DMEPOS item get included on the master list?

A: Any DMEPOS item included on the Master List was identified as:

- Having potentially unnecessary utilization in at least one report from the Department of Health and Human Services’ (HHS) Office of the Inspector General (OIG) since 2007; the Government Accountability Office (GAO) reports published since 2007; or the Annual Medicare Fee-for-Service Improper Payment Report Durable Medical Equipment (DME and/or) Report’s DMEPOS Service Specific Reports in 2011 or later;
And
- Having an average purchase fee of \$1,000 or greater or an average rental fee schedule of \$100 or greater (adjusted annually for inflation) on the DMEPOS Fee Schedule List.

6. Q. How many DMEPOS items are on the Master List?

A. Under the final rule, the Master List contains 135 DMEPOS items. The master list can be seen at Table 5 in the final rule or by clicking this link: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html>.

7. Q. How long do the DMEPOS items stay on the Master List?

A: Under the final rule, items will remain on the Master List for 10 years from the date the item was added. An item would be removed from the list sooner than 10 years if the purchase amount drops below the payment threshold (an average purchase fee of \$1,000 or greater or an average monthly rental fee schedule of \$100 or greater, adjusted annually for inflation). DMEPOS items aging off the Master List because they have been on the list for 10 years can remain on or be added back to the Master List if a subsequent GAO, OIG, or CERT Appendix report identifies the item to be frequently subject to unnecessary utilization and it remains above the payment threshold.

8. Q. Will new items be included in the Master List in the future?

A: Yes. Under the final rule, any item on the DMEPOS Fee Schedule meeting the inclusion criteria would be added to the Master List annually. Notice will be provided in the Federal Register and on the CMS Prior Authorization website.

9. Q. Will prior authorization be required for every item on the Master List?

A: Not at this time. Under the final rule, CMS will limit the number of items requiring prior authorization to those items included on the Required Prior Authorization List. Thus, presence on the Master List will not automatically require prior authorization of the item.

10. Q. How will we know which item on the Master List requires prior authorization?

A: Under the final rule, CMS will publish a notification of the items on the Required Prior Authorization List in the Federal Register 60 days before implementation. In addition, CMS will conduct education for beneficiaries and industry before implementation.

11. Q. Does this final regulation specify the first item(s) that will require prior authorization?

A: No. Under the final rule, notification of the first items on the Required Prior Authorization List that require prior authorization will appear in the Federal Register after the publication date of the final rule, but 60 days before implementation of prior authorization for those items.

12. Q. How does the final rule affect the Prior Authorization of Power Mobility Device Demonstration?

A: The final rule does not affect the Prior Authorization of Power Mobility Device (PMDs) Demonstration. Because the Master List under the final rule contains PMDs (currently included in the CMS Prior Authorization of PMDs Demonstration), CMS will not require prior authorization for them under this final rule at this time. These items may be included on the Required Prior Authorization List once the demonstration is complete.

13. Q. What states will this final rule impact?

A: Requirements established under the final rule could be implemented locally or nationally. For example, if data shows that a particular DMEPOS item is frequently subject to unnecessary utilization in one or several states, but not nationally, then CMS may implement the prior authorization requirement in those states only. Once the Required Prior Authorization List is published in the Federal Register, CMS will release additional guidance regarding what areas of the country are affected by the prior authorization process for specific DMEPOS items.

14. Q. Where can I find a list of items on the Master List?

Currently, the Master List can be found in Table 5 of the final rule. This link will take you to the final rule and the Master List: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Prior-Authorization-Initiatives/Prior-Authorization-Process-for-Certain-Durable-Medical-Equipment-Prosthetic-Orthotics-Supplies-Items.html>.

15. Q: Will there be more information on the prior authorization process available?

A: Yes. Guidance related to the DMEPOS item(s) on the Required Prior Authorization List will be posted at this site: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/index.html>. We will include a link to the Federal Register notice of the Required Prior Authorization List as well as a link to the final rule.

16. Q: What are some changes in the final rule from the proposed?

A: We did not finalize the proposed timelines required for receiving a prior authorization decision after the contractor has received all of the required documentation. In the final rule, we stated we will create a prior authorization process in subregulatory guidance that is customized for the DMEPOS item subject to prior authorization. We may develop prior authorization timelines for certain items that permits fewer days than the proposed maximum 10 business days (for initial prior authorization request) or 20 business days (for resubmitted prior authorization requests). In the final rule, we noted that the prior authorization timeframe(s) detailed in subregulatory guidance will not exceed the timeframes described in the proposed rule. In addition, we added that we will make an annual inflation adjustment to the payment threshold. This adjustment will be the same percentage as the DMEPOS fee schedule annual adjustments. The other change from the proposed rule is that we added oxygen concentrator (Healthcare Common Procedure Coding System (HCPCS) code E1390) to the Master List since it meets the criteria and should have been included on the proposed Master List. Finally, we removed five proposed items from the list that did not meet the criteria of \$1,000 or greater average purchase fee schedule or an average rental fee schedule of \$100 or greater. These items include the following:

- HCPCS L5705: Custom shaped protective cover, above knee.
- HCPCS L5706: Custom shaped protective cover, knee disarticulation.
- HCPCS L5718: Addition, exoskeletal knee shin system, polycentric, friction swing and stance phase control.
- HCPCS L5722: Addition, exoskeletal knee shin system, single axis, pneumatic swing, friction stance phase control
- HCPCS L5816: Addition, endoskeletal knee shin system, polycentric, mechanical stance phase lock.

17. Q: Will there be exceptions to those timelines when delay in receiving DMEPOS products and supplies may adversely affect the health and safety of the beneficiary?

A: Yes, beneficiaries' full access to the covered care they need is preserved in this rule by having both specified timeframes for review and approval of requests, and an expedited process in cases where delays jeopardize the health of beneficiaries.

18. Q: Oxygen was not on the Master List in the proposed rule but it is included in the final? Why was it included in the final?

A: Oxygen concentrator (Healthcare Common Procedure Coding System (HCPCS) code E1390) meets the Master List inclusion criteria. It was mistakenly left off the proposed Master List but included in the final Master List.

19. Q: When does CMS anticipate announcing the DMEPOS items included on the Required Prior Authorization List?

A: We do not have an announcement date scheduled. The notice in the Federal Register will be published 60 days before the start of prior authorization for a particular item. CMS will be communicating to the community in a variety of ways before posting the 60 day notice. For example, we may conduct Open Door Forum calls or the Medicare contractors may host informational webinars. We believe that through education and community interaction before the 60 day notice, suppliers will be well informed of the upcoming prior authorization program requirements and can be ready 60 days after the official posting of the public notice.

20. Q: How will CMS determine what DMEPOS items are included on the Required Prior Authorization List?

A: CMS may consider factors such as geographic location, item utilization or cost, system capabilities, administrative burden, emerging trends, vulnerabilities identified in official agency reports, or other data analysis. Such exemplary factors are not being provided to create a definitive list or set of pre-determined considerations, nor to indicate whether such factors could be reviewed in singular or aggregate, nor to indicate the level of priority to be applied to a specific item(s). Rather, they are cited for the limited purpose of notifying stakeholders of the types of factors CMS may take into consideration to create the Required Prior Authorization List.

21. Q: Won't the two lists – the Master List and the Required Prior Authorization List – be confusing to providers, suppliers, and beneficiaries?

A: We believe having two lists is necessary. The Required Prior Authorization List is selected from the Master List of Items Frequently Subject to Unnecessary Utilization. The Required Prior Authorization List is defined as a subset of Master List items subject to prior authorization.

Having the two lists minimizes burdens associated with implementation of prior authorization. For example, CMS may elect to implement prior authorization for a limited number of items. Having only one list would require us to implement prior authorization on all items on the list. In addition, implementing prior authorization for the entire list would create undue burden for

suppliers, physicians, and beneficiaries. Implementing prior authorization on a subset of the items on the Master List allows us to closely monitor the prior authorization program for each selected item and make changes, if needed.

In order to allow flexibility in updating the Required Prior Authorization List, we have not included the frequency of the updates in the final rule. We do not anticipate frequent updates as to not burden the community, but could envision a scenario where there was a need to update the Required Prior Authorization List once or twice a year.

22. Q: Will CMS monitor to ensure Medicare Administrative Contractors (MACs) are meeting their maximum review timelines?

A: We conduct quality checks of the prior authorization decisions through a sample of random claims. We also perform annual performance evaluations of MACs to ensure that they are meeting all requirements of their contract. We may require action plans for standards that are not met and also consider documented past performance for future MAC contract awards.

In addition, we conduct day to day contractor oversight by, among other things, frequent communication with the contractor medical review components. In these communications, we receive status updates about the different types of medical review decisions. For example, we monitor contractors' pre- and post-pay medical review strategies. Upon implementation, we will also monitor contractors' prior authorization processes, including the decisions they render and the timeframes in which the decisions are rendered.

23. Q: How much is this prior authorization process expected to save the Medicare program and beneficiaries?

A: We expect to see savings in the form of reduced unnecessary utilization, fraud, waste, and abuse, including a reduction in improper Medicare FFS payments (note that not all improper payments are fraudulent). The dollar amount of the anticipated savings is difficult to quantify and would depend ultimately on the actual utilization numbers. We provide a range of estimated savings that are dependent on the number of prior authorization requests submitted. Based on the mid-range projection, Medicare could save \$10 million in the first year, \$200 million in 5 years and \$580 million in 10 years.

24. Q: How will access to care be protected?

A: This final rule creates a prior authorization program that supports our goals and makes sure beneficiaries are not hindered from accessing necessary DMEPOS items and services when they need them. We believe using a prior authorization process would help to make sure items frequently subject to unnecessary utilization are furnished in compliance with applicable Medicare coverage, coding, and payment rules before they are delivered. Access is preserved in this rule by having both specified maximum timeframes for review and approval of requests, and an expedited process in cases where delays jeopardize the health of beneficiaries.