

Supporting Statement – Part A
Prior Authorization Process for Certain Durable Medical
Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items
(CMS-10524; OMB-0938-1293)

General Instructions

A. Background

The CMS has had longstanding concerns about the improper payments related to DMEPOS items. The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2024 Medicare FFS program improper payment rate for the DMEPOS was 21.41%, accounting for over \$1.92 billion in projected improper payments¹. As a result of these longstanding concerns, CMS has implemented several initiatives to help combat fraud, waste, and abuse within the benefit, including prior authorization.

CMS is continuing the use of prior authorization in fee for service Medicare. Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before an item is rendered to a Medicare patient and before a claim is submitted for payment. Prior authorization helps ensure that applicable Medicare coverage, payment, and coding rules are met before item(s) are rendered. Prior to furnishing the item to the beneficiary and prior to submitting the claim for processing, a requester must submit a prior authorization request that includes evidence that the item complies with all applicable Medicare coverage, coding, and payment rules. Consistent with § 414.234(d), such evidence must include the order, relevant information from the beneficiary's medical record, and relevant supplier-produced documentation. After receipt of all applicable required Medicare documentation, CMS or one of its review contractors will conduct a medical review and communicate a decision that provisionally affirms or non-affirms the request. A provisional affirmative decision is a preliminary finding that a future claim submitted to Medicare for the DMEPOS item likely meets Medicare's coverage, coding, and payment requirements. Suppliers who receive a non-affirmative decision have unlimited resubmission opportunities.

The prior authorization demonstration for power mobility devices (PMDs) began in 2012 in 7 states with high incidences of fraudulent claims and improper payments. Because of significant cost savings, in 2014, the demonstration was expanded to 12

¹ <https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/comprehensive-error-rate-testing-cert>

additional states. The demonstration was initially scheduled to end on August 31, 2015, but was extended to August 31, 2018, for all 19 states.

There were significant cost savings based on claims processed as of August 31, 2018, monthly expenditures for the power mobility device codes included in the PMD demonstration decreased from:

- \$11.5 million in September 2012 to \$2.3 million by August 31, 2018 in the original 7 demonstration states,
- \$10.4 million in September 2012 to \$2.2 million by August 31, 2018 in the 12 additional expansion states,
- \$9.7 million in September 2012 to \$2.4 million by August 31, 2018 in the non-demonstration states.

On December 30, 2015, CMS promulgated a final rule (80 FR 81674) titled, "Medicare Program; Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, that established a national prior authorization process as a condition of payment for certain durable medical equipment, prosthetics, orthotics, and supplies and created a "Master List" CMS created a "Master List" of items that are potentially subject to prior authorization. Under this authority, in 2017, CMS added two types of PMDs not already subject to the prior authorization under the demonstration to the Required Prior Authorization List.

On September 1, 2018, after the conclusion of the demonstration, CMS added the 31 Healthcare Common Procedure Coding System (HCPCS) codes items that were part of the demonstration to the Required Prior Authorization List nationwide.

On July 22, 2019, five HCPCS for Pressure Reducing Support Surfaces (PRSS) were added to required prior authorization for states of California, Indiana, New Jersey, and North Carolina. The prior authorization requirement for PRSS expanded nationwide on October 21, 2019. Additionally on July 22, 2019, seven more PMD HCPCS codes were added nationwide.

On January 1st, 2020 CMS promulgated rule (84 FR 60648) Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Fee Schedule Amounts, DMEPOS Competitive Bidding Program (CBP) Amendments, Standard Elements for a DMEPOS Order, and Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements. This rule streamlines the requirements for ordering DMEPOS items and develops a new list of DMEPOS items potentially subject to a face-to-face encounter, written orders prior to delivery and/or prior authorization requirements. This rule allows CMS to

capture more items on the Master List that represent Medicare vulnerabilities. This rule also finalized policy allowing suppliers to submit prior authorization requests for certain DMEPOS accessories on a voluntary basis, when associated with an item on the Required Prior Authorization List.

On September 1, 2020, six Lower Limb Prosthetics (LLPs) were added to required prior authorization in California, Michigan, Pennsylvania, and Texas. The requirement expanded nationwide on December 1, 2020.

On April 13, 2022, six additional PMDs were added to required prior authorization nationwide. CMS also announced the addition of orthoses as a policy group and added five codes subject to required prior authorization implemented through three incremental phases.

On February 24, 2023, CMS selected 53 PMD accessory items that are eligible for voluntary prior authorization.

On August 12, 2024, an additional six Orthoses codes were added and one code (L1833) as removed from required prior authorization.

B. Justification

1. Need and Legal Basis

Section 1834(a)(15) of the Social Security Act (the Act) authorizes the Secretary to develop and periodically update a list of DMEPOS that the Secretary determines, on the basis of prior payment experience, are frequently subject to unnecessary utilization and to develop a prior authorization process for these items. Pursuant to this authority, CMS published final rules CMS-6050-F and CMS-1713-F.

The Secretary's authority to request information supporting the prior authorization request was created by Section 1833(e) which states, in part, "no payment shall be made to any provider... unless there has been furnished such information as may be necessary in order to determine the amounts due such provider."

The Department of Health and Human Services' Office of the Inspector General and the U.S. Government Accountability Office have published multiple reports indicating questionable billing practices by suppliers, inappropriate Medicare payments, and questionable utilization of DMEPOS items. The fiscal year (FY) 2024 Medicare FFS program improper payment rate for the DMEPOS was 21.41%, accounting for over \$1.92 billion in projected improper payments.

Payment made when the item does not meet Medicare policy is an improper payment. It is important to keep in mind that all fraud is considered to be improper payment, but not all improper payments are fraud. Prior authorization is a tool utilized by private sector health care payers to prevent unnecessary utilization. CMS's prior authorization efforts have shown that prior authorization effectively prevents unnecessary utilization for Medicare as well. Consequently, we believe

prior authorization for items on the Required Prior Authorization List, a subset of the Master List, prevents and reduces improper payments for those items as well.

2. Information Users

The information required under this collection is used to determine proper payment and coverage for DMEPOS items. The information requested includes all documents and information that demonstrate the DMEPOS item requested is reasonable and necessary for the beneficiary and meets applicable Medicare requirements. The documentation will be reviewed by trained registered nurses, therapists, or physician reviewers to determine if item(s) or service requested meets all applicable Medicare coverage, coding and payment rules.

3. Use of Information Technology

Some of this collection of information could involve the use of electronic data or other forms of information technology at the discretion of the submitter. Where available, providers may submit their prior authorization requests and/or other documentation through electronic means. CMS offers electronic submission of medical documentation (esMD)² and the Medicare Administrative Contractors (MACs) provide an electronic portal for providers to submit their documentation. Other electronic means may include standards based application programming interfaces (APIs) such as Fast Healthcare Interoperability Resources (FHIR), or other interoperable technologies.

4. Duplication and Similar Information

CMS published final rules CMS-6050-F and CMS-1713- F that requires prior authorization under the Medicare fee-for- service program for the list of items on the Required Prior Authorization List, a subset of the Master List. Prior authorization does not require any new or duplicative documentation than what the provider or supplier are already required to maintain for purposes of Medicare payment. CMS as a whole does not collect all of the information in any existing format.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those small businesses order and bill Medicare for DMEPOS items on the Required Prior Authorization List. The retention and submission of required information by suppliers and physicians are routine business practices. We do not have the number of small businesses that will be impacted. This collection will only impact small business and all respondents in that they must work with providers to obtain the necessary medical documentation to support their claims.

6. Less Frequent Collection

² www.cms.gov/esMD

Since this information is only collected when potential program vulnerability exists, less frequent collections of this information would be imprudent. CMS and its agents continue to refine their tools for identifying improper billing practices.

7. Special Circumstances

There are no special circumstances.

8. Federal Register/Outside Consultation

The 60-day Federal Notice was published in the Federal Register on 06/11/2025 (FR 24630)

The 30-day Federal Notice was published in the Federal Register on 09/02/2025 (FR 42411)

No additional outside consultation was sought.

The 60-day notice (90 FR 24630) and the 30-day notice (90 FR 42411) were published as extensions of the currently approved collection. However, due to an administrative oversight, we were not able to submit the information collection request to OMB before the August 31, 2025, expiration date. For that reason, the information collection request is being submitted as a reinstatement without change of the previously approved collection.

9. Payment/Gifts to Respondents

No payments or gifts will be given to respondents to encourage their response to any request for information under this control number.

10. Confidentiality

Medicare contractors have procedures in place to ensure the protection of the health information provided. The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule allows for the disclosure of health records for payment purposes.

The Medicare contractors will safeguard all protected health information collected in accordance with HIPAA and the Privacy Act of 1974 standards as applicable.

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

The burden associated with this program is the time and effort necessary for the submitter to locate and obtain the supporting documentation for the prior authorization request and to forward the materials to the MAC for review. CMS

expects that this information will generally be maintained by providers as a normal course of business and that this information will be readily available. The documentation submitted must support medical necessity for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, Medicare benefit eligibility, and meet all other applicable Medicare statutory and regulatory requirements.

Wage Estimates:

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' ([May 2023 Occupational Employment Statistics report](#)). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage. Based on Bureau of Labor Statistics report (Healthcare Support Occupations), we estimate an average hourly rate of \$18.37 with a loaded rate of \$36.74.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Overhead (\$/hr)	Adjusted Hourly Wage (\$/hr)
Healthcare Support Occupations	31-0000	\$18.37	\$18.37	\$36.74

The process of submitting a prior authorization request for an expedited review is the same as for a standard review. The unit cost for CMS performing an expedited review is the same as for a standard review. If the volume of expedited claims increases steeply, a larger workforce may be required to ensure that those claims are processed within established timeframes. Items on the Master List are rarely used in emergent situations, consequently, we expect the request for expedited reviews to be few.

In addition to mail, providers have a number of methods to submit documentation quickly including fax, electronic portals, and esMD, so provider burden should not be affected by the method of submission. CMS anticipates clerical staff will collect the information from the medical record and prepare it to be submitted for review. CMS estimates that the average time for office clerical activities associated with this task to be 30 minutes. Average labor costs (including 100 percent fringe benefits) used to estimate the costs are calculated using data available from the Bureau of Labor Statistics.

We based the estimated number of responses for Year One on the number of prior authorization requests for the DMEPOS items currently on the Required Prior

Authorization List for Calendar Year 2024. There were 132,414 initial requests and 15,050 resubmissions for a total of 132,414 requests. We estimate around 48,000 prior authorization requests for DMEPOS items that could potentially be added to the Required Prior Authorization List in the future.

For items potentially added to the list in the future we estimate only 80% of suppliers will submit an initial prior authorization request, resulting in 38,400 additional initial requests, for a total of 155,764 initial requests in Year One.

We assume that 20% of this subset (31,153) will receive a non-affirmative decision and will resubmit their request. An additional 10% of this subset (3,115) will receive a non-affirmative decision and resubmit their request a second time, and another 10% of this subset (312) will receive a non-affirmative decision again and resubmit their request a third time. In sum, we estimate the total number of submissions for year one is 155,764 initial requests plus 34,580 resubmissions (as described above) for a total of 190,344 submissions.

Suppliers may use electronic submission of medical documentation (esMD) as an alternative to mail or fax for sending in medical documents. Additional information on esMD can be found [here](#). Additionally, the MACs offer electronic portals for suppliers to submit documentation. In recent years, the rate of electronic submissions using esMD, portals, and fax was 99.6% and the mail submission rate was 0.4%. We estimate the cost of mailing medical records to be \$5 per prior authorization request, with the total mailing cost for year one estimated to be \$3,807. The total estimated burden for year one is \$3,500,419, which includes the time associated with submitting prior authorization requests multiplied by the loaded rate of \$36.74 an hour, plus the cost of mailing records and documents.

Prior Authorization Process for Certain DMEPOS Items – Year One

Activity	Responses Per Year (number of prior authorization requests submitted)	Time Per Response (hours) or Dollar Cost	Total Burden Per Year (hours)	Total Burden Costs Per Year Using Loaded Rate
Fax and Electronic Submitted Requests: Initial Submissions	155,764	0.5	77,570	\$2,849,939

Fax and Electronic Submitted Requests: Resubmissions	34,580	0.5	17,221	\$632,686
Mail Submitted Requests: Initials	623	0.5	312	\$11,446
Mail Submitted Requests: Resubmissions	138	0.5	69	\$2,541
Mail Cost	761	\$5	N/A	\$3,807
Total	190,344	N/A	95,172	\$3,500,419

We assume the same rates of submission for initial prior authorization requests and resubmissions to calculate the annual burden for Year Two and Year Three. We expect an annual growth rate of 3 percent for the number of requests based on more people aging into the program and qualifying for coverage. Accordingly, in Year Two we estimate that there will be 196,054 initial prior authorization requests from year one plus and an additional 30,000 initial requests from codes that will potentially be added to the Required Prior Authorization List in year two for a total of 226,054 initial requests. Using the same rates of resubmissions described in year one, we estimate 50,184 resubmission requests for the total number of submissions in year two of 276,238. Of those, we expect 275,133 electronic submissions and 1,105 mail submissions. Accordingly, we estimate a total burden of \$5,080,015 for Year Two.

In Year Three, we assume that there will be 232,836 initial prior authorization requests based on codes subject to prior authorization requirements (based on a 3 percent increase from year two) and an additional 30,000 initial requests from codes that will potentially be added to the required prior authorization list in Year Three, for a total of 262,836 initial requests. Using the same rates of resubmissions described in year one, we estimate that there will be 58,349 resubmissions for a total of 321,185 submissions in Year Three. We expect electronic submissions will be 319,900 and mail submissions will be 1,285. Using the assumptions above, we estimate a total burden of \$5,906,593 for Year Three.

Total Annual Burden

Year One	Year Two	Year Three	Average Annual Burden
\$3,500,419	\$5,080,015	\$5,906,593	\$4,829,009

The annual burden for Year One is \$3,500,419, the annual burden for Year Two is \$5,080,015, and the annual burden for Year Three is \$5,906,593 for an average annual burden of \$4,829,009.

13. Capital Costs

There are no capital costs associated with this collection. Providers and suppliers maintain these medical records and routinely submit them to various healthcare entities.

14. Cost to Federal Government

Consistent with Sections 1833(e), 1842(a)(2)(B), and 1862(a)(1) of the Social Security Act, CMS is required to protect the Medicare Trust Fund against inappropriate payments and take corrective actions.. Medical review is the collection of information and clinical review of medical records by Medicare Contractors to ensure that payment is made only for services that meet all Medicare coverage, coding, and medical necessity requirements. MACs also review the prior authorization requests when making prior authorization determinations.

The cost for the DME MACs to review the number of prior authorization requests as described above is \$12,372,335 for Year One, \$17,955,463 for Year Two, and \$20,877,026 for Year Three. CMS estimates that the costs associated with this package would be \$51,204,824 over the 3-year period under the current program.

15. Changes to Burden

This is a renewed collection. The overall average burden has decreased because we underestimated the effectiveness of the prior authorization program during our prior collection. In the years since the last collection the program saw a reduction in requests for certain items as potentially fraudulent actors moved to other targets. In our previous collection, the average burden estimate was 445,921 cases per year in years one through three with a projected annual average burden cost of \$7,857,090.

The previous burden estimate was based on the broadened potential number of prior authorization requests from the Master List as finalized in CMS 1713-F. Since then we added prior authorization requirements for certain orthoses items which saw

large drops in utilization upon implementation which reduced both the cost and burden of the program relative to initial estimates. While we do not intend to require prior authorization for every item on the Master List, we do anticipate adding additional items to the Required Prior Authorization List.

The updated average burden estimate is 262,589 cases per year in years one through three with a projected annual average burden cost of \$4,829,009.

This is based on the number of prior authorization requests for items on the Required Prior Authorization List in Calendar Year 2024, as well as additional items that could be added to the Required Prior Authorization List over the next 3 years.

16. Publication/Tabulation Dates

There are no plans to publish or tabulate the information collected due to this information being confidential. However, CMS will periodically publish summary level information on the program (such as the number of request submitted, number of request affirmed, number of request non-affirmed, etc) on the prior authorization website³.

17. Expiration Date

There is no collection data instrument used in the collection of this information. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date.

18. Certification Statement

There are no exceptions to the certification statements.

³ <https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/prior-authorization-and-pre-claim-review-initiatives/prior-authorization-process-certain-durable-medical-equipment-prosthetics-orthotics-and-supplies>