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) 2020 Medicare FFS program improper payment rate for the DMEPOS was 31.8 %, accounting for over $2.8 billion in projected improper payments. 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 additional states. The demonstration was initially scheduled to end on August 31st, 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, 2020, Pressure Reducing Support Surfaces (PRSS) and certain additional PMDs were also added. Additionally, prior authorization was required for certain Lower Limb Prosthetics (L5856, L5857, L5858, L5973, L5980, and L5987), with dates of service on or after September 1, 2020 in California, Michigan, Pennsylvania, and Texas. On December 1, 2020, prior authorization for these codes were required in all of the remaining states and territories.

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. Pursuant to this rule we plan to add certain orthoses and power operated vehicles on April 13, 2022.[1] On January 13, 2022, CMS published a Federal Register Notice which adds certain orthoses and power operated vehicles to the Required Prior Authorization List, beginning April 13, 2022.[2]

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) 2020

[1] https://www.federalregister.gov/documents/2022/01/13/2022-00572/medicare-program-updates-to-lists-related-to-durable-medical-equipment-prosthetics-orthotics-and

[2] https://www.federalregister.gov/documents/2022/01/13/2022-00572/medicare-program-updates-to-lists-related-to-durable-medical-equipment-prosthetics-orthotics-and

Medicare FFS program improper payment rate for the DMEPOS was 31.8%, accounting for over $2.7 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. CMSs' 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)[3] 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.

[3] www.cms.gov/esMD

4. Duplication and Similar Information

CMS published final rules CMS-6050-F and CMS-1717- 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 business 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

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

More often than quarterly - This information is collected on an as-needed basis. That is, information is requested only when an entity submits a request for prior authorization for an eligible item, as required in CMS Final Rule 1717-FC. Improper Medicare payments caused by overutilization may increase if not mitigated by the requirement for prior authorization.

More than original and two copies - There is no requirement to submit more than 1 copy of the requested documentation.

Retain records more than three years - This estimate does not impose any new or additional record retention requirements beyond those requirements currently in place. Providers and suppliers are reminded that Medicare claims can be reopened for review at any time where fraud or improper payment is suspected, or within 4 years of an initial determination for good cause or within 1 year for any reason.

Conjunction with a statistical survey - This information collection is not associated with a statistical survey.

Use of statistical data classification - This collection does not require a statistical data classification.

Pledge of confidentiality - This collection does not require a pledge of confidentiality.

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

8. Federal Register/Outside Consultation

The 60-day Federal Notice was published in the Federal Register (86 FR 71502) on 12/16/2022.
No comments were received.

The 30-day Federal Notice was published in the Federal Register (87 FR 12456) on 03/04/2022.

No additional outside consultation was sought.

9. Payments/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 will safeguard all protected health information collected in accordance with HIPAA and Privacy Act standards as applicable. 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.

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 demonstration is the time and effort necessary for the submitter to locate and obtain the supporting documentation for 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 2020 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 (Miscellaneous Health care support occupations), we estimate an average hourly rate of $17.60 with a loaded rate of $35.20.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Healthcare Support Occupations	31-0000	$17.60	$17.60	$35.20

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 beneficiaries who were billed for one of the DMEPOS items currently on the Required Prior Authorization List for Calendar Year 2020 (85,994) and estimated an additional 177,449 for the number of beneficiaries that may bill for a DMEPOS item that could potentially be added to the Required Prior Authorization List in the future, for a total of 263,443 beneficiaries.

For items already on our Required Prior Authorization List (85,994) where suppliers are accustomed to prior authorization submissions, we assume that 95% of suppliers will submit an initial prior authorization request for these items (81,694). For items potentially added to the list in the future we assume that fewer suppliers will initially submit requests, as they will potentially be less accustomed to our prior authorization process. Thus, we estimate only 80% of suppliers will submit an initial prior authorization request, resulting in 141,959 additional requests, for a total of 223,653 initial requests in Year One.

We assume that 20% of this subset (44,731) will receive a non-affirmative decision and will resubmit their request. An additional 10% of this subset (4,473) will receive a non-affirmative decision and resubmit their request a second time, and another 10% of this subset (447) 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 223,653 initial submissions plus 49,651 resubmissions (as described above) for a total of 273,305 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. For the last two 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 $5,878. The total estimated burden for year one is $4,816,039, which includes the time associated with submitting prior authorization requests multiplied by the loaded rate of $35.20 an hour, plus the cost of mailing records and documents.

Prior Authorization Process for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (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
DMEPOS - Fax and Electronic Submitted Requests	Initial Submissions 222,691	0.5	111, 346	$3,919,369
	Resubmissions - 49,437	0.5	24,719	$870,100
DMEPOS - Mail Requests	Initial Submissions - 962	0.5	481	$16,933
	Resubmissions -214	0.5	107	$3,759
Mail Costs	Total Submissions – 1,176	$5	n/a	$5,878
DMEPOS Total	273,305	n/a	136,652	$4,816,039

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. Accordingly, in Year Two we estimate that there will be 250,271 initial prior authorization requests from year one plus and an additional 141,959 initial requests from codes that will potentially be added to the Required Prior Authorization List in year two for a total of 392,230 initial requests. We estimate an additional 87,075 resubmission requests for the total number of submissions in Year Two of 479,305.

Of those, we expect 477,243 electronic submissions and 2,062 mail submissions. Accordingly, we estimate a total burden of $8,446,079 for Year Two.

In Year Three, we assume that there will be 418,847 initial prior authorization requests based on codes subject to prior authorization requirements (based on year two) and an additional 60,000 initial requests from codes that will potentially be added to the required prior authorization list in Year Three, for a total of 478,847 initial requests. Using the same rates of resubmissions described in year one, we estimate that there will be 106,304 resubmissions for a total of 585,152 submissions in Year Three. We expect electronic submissions will be 582,634 and mail submissions will be 2,517. Using the assumptions above, we estimate a total burden of $10,311,253 for Year Three.

Total Annual Burden

Year One	Year Two	Year Three	Average Annual Burden
$4,816,039	$8,446,079	$10,311,253	$7,857,790

The annual burden for Year One is $4,816,039, the annual burden for Year Two is $8,446,079, and the annual burden for Year Three is $10,311,253 for an average annual burden of 7,857,790.

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, the Centers for Medicare & Medicaid Services (CMS) is required to protect the Medicare Trust Fund against inappropriate payments and take corrective actions. To meet this requirement CMS contracts with Part A and Part B Medicare Administrative Contractors (A/B MACs), Durable Medical Equipment Medicare Administrative Contractors (DME MACs) and others to perform analysis of fee-for-service (FFS) claim data to identify atypical billing patterns and perform medical review. These entities are referred to Medicare Contractors. 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, as well as CMS program oversight is $13,665,229 for Year One, $23,965,256 for Year Two, and $29,757,756 for Year Three. CMS estimates that the costs associated with this package would be $67,388,241 over the 3-year period.

15. Changes to Burden

This is a revised collection. The overall average burden has increased because we estimate more prior authorization requests submitted over the next three years. In our previous collection, the average burden estimate was 330,210 cases per year in years one through three with a projected annual average burden cost of $5,300,000.

The previous burden estimate was based on the potential number of prior authorization requests from the Master List as finalized in CMS 6050-F. Since then we have broadened the criteria for the Master List through CMS 1713-F, which significantly increases the number of items on the Master List from which we can choose for required prior authorization. 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 445,920 cases per year in years one through three with a projected annual average burden cost of $7,860,000.
This is based on the number of beneficiaries who were billed for items on the Required Prior Authorization List in Calendar Year 2020, 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.

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.