Supporting Statement Part A
Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services
CMS-10711

BACKGROUND

In the Calendar Year (CY) 2020 Outpatient Prospective Payment System/Ambulatory Surgical Center (OPPS/ASC) Final rule (CMS-1717-FC), we established a prior authorization process for certain hospital OPD services using our authority under section 1833(t)(2)(F) of the Social Security Act (the Act), which allows the Secretary to develop "a method for controlling unnecessary increases in the volume of covered OPD services.[1]" The regulations governing the prior authorization process are located in Subpart I of 42 CFR Part 419, specifically at §§ 419.80 – 419.89. In finalizing the process, we initially identified five service categories for which prior authorization was required: (i) blepharoplasty, (ii) botulinum toxin injections, (iii) panniculectomy, (iv) rhinoplasty, and (iv) vein ablation. As part of the CY 2021 OPPS/ASC Final Rule (CMS -1736-FC), we added two more service categories to the prior authorization process: (i) cervical fusion with disc removal and (ii) implanted spinal neurostimulators.

The final rules stated that, as a condition of Medicare payment, a provider must submit a prior authorization request for services on the list of hospital OPD services requiring prior authorization to CMS or its contractor. The prior authorization request must be submitted before the service is rendered to the beneficiary and before the claim is submitted. The request should include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Claims submitted for services that require prior authorization that have not received a provisional affirmation will be denied unless the provider is exempt. The rules also stated that, even when a provisional affirmation has been received, a claim for services may be denied based upon either technical requirements that can only be evaluated after the claim has been submitted for formal processing or information was not available at the time the prior authorization request is received.

While most prior authorization reviews will be decided within 10 days, providers have an opportunity to submit prior authorization requests for expedited review when a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function.

If the request meets the applicable Medicare coverage, coding, and payment rules, CMS or its contractor will issue a provisional affirmation to the requesting provider. If the request does not meet the applicable Medicare coverage, coding, and payment rules, CMS or its contractor will issue a non-affirmation decision to the requesting provider. OPD prior authorization requests that are non-affirmed will not be considered an initial determination and, therefore, will not be appealable; however, the provider may resubmit a prior authorization request with any applicable additional relevant documentation provided the claim has not yet been submitted and denied. This includes the resubmission of requests for expedited reviews.

[1] See 84 FR 61142 issued November 12, 2019 and Correction Notice 85 FR 224 issued January 3, 2020.

If a claim is submitted for the selected services without a provisional affirmation, it will be denied. CMS intends to deny claims associated with or related to a selected service that requires PA as a condition of payment when a provider either did not submit a prior authorization request, received non-affirmation decisions, and/or has denied claims.

Also, CMS may elect to exempt a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules, and that this exemption would remain in effect until CMS elects to withdraw the exemption. CMS may elect to exempt providers that achieve a prior authorization provisional affirmation threshold of at least 90 percent during an annual assessment. In addition, CMS may withdraw an exemption if evidence becomes available based on a review of claims that such claims do not meet Medicare's billing, coding, or payment guidelines. Moreover, CMS may suspend the outpatient department services prior authorization process requirements generally or for a particular service(s) at any time by issuing notification on CMS' website.

As part of the CY 2022 OPPS/ASC final rule, CMS is proposing to add a new service category to the list of OPD services requiring prior authorization at § 419.83(a): Facet Joint Interventions, beginning for dates of service on or after March 1, 2023. Data analysis for these services showed a claim volume increase greater than expected based on the growth rate for OPD services overall. The process associated with prior authorization for this new covered outpatient department service category will be the same as the first seven service categories.

JUSTIFICATION

1. Need and Legal Basis

Section 1833(t)(2)(F) of the Act authorizes CMS to develop a method for controlling unnecessary increases in the volume of covered OPD services. CMS believes the increases in volume associated with certain covered OPD services described above are unnecessary because the data show that the volume of utilization of the first seven service categories far exceeds what would be expected in light of the average rate-of-increase in the number of Medicare beneficiaries. Therefore, CMS is using the authority under section 1833(t)(2)(F) of the Act to require prior authorization for certain covered OPD services as a condition of Medicare payment. Furthermore, CMS is using the authority under paragraph (b) of 42 CFR 419.83, proposing to add additional services. The reviews conducted under the program will help to reduce unnecessary utilization and payments for these services.

2. Information Users and Use

The information required for the prior authorization request includes all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules. Trained clinical reviewers at the Medicare Administrative Contractors (MACs) will receive and review the information required for this collection. Review of that documentation will be used to determine if the requested services are medically necessary and meet Medicare requirements in order to help reduce unnecessary increases for these services.

3. Improved Information Techniques

Some of this collection of information could involve the use of electronic or other forms of information technology at the discretion of the requester. Where available, requesters may submit their requests and/or other documentation through electronic means. CMS offers electronic submission of medical documentation (esMD)[2] and the MACs provide electronic portals for providers to submit their documentation.

4. Duplication and Similar Information

The CMS as a whole does not collect the information in any existing format. With the exception of basic identifying information such as beneficiary name, address, etc., there is no standard form or location where this information can be gathered.

5. Small Businesses

This collection will impact small businesses or other entities to the extent that those hospital outpatient departments that qualify as small businesses bill Medicare for the services that require prior authorization. Providers regardless of size must maintain and submit the necessary documentation to support their claims.

6. Less Frequent Collections

Under prior authorization, a request is submitted for a service prior to the service being rendered and the claim being submitted. As the reviews under this program help reduce unnecessary increases in utilization for these services, less frequent collection of information would be imprudent and undermine that goal. However, CMS has a process for less frequent collections for those providers who demonstrate compliance with Medicare rules after an initial assessment period. CMS may elect to exempt a provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules by achieving a prior authorization provisional affirmation threshold of at least 90 percent during an annual assessment. An exemption may be withdrawn if a provider's rate of non-payable claims submitted becomes higher than 10 percent during an annual assessment.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice

The 60-day notice published as part of a proposed rule on July 26, 2022 (87 FR 44502). No additional outside consultation was sought.

[2] http://www.cms.gov/esMD

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

11. Sensitive Questions

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

12. Burden Estimate

The information collection requirements associated with prior authorization requests for these covered outpatient department services is the required documentation submitted by providers. The prior authorization request must include all relevant documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules and that the request be submitted before the service is provided to the beneficiary and before the claim is submitted for processing. The burden associated with this process is the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation.

CMS expects that this information will generally be maintained by providers within the normal course of business and that this information will be readily available. CMS estimates that the average time for office clerical activities associated with this task is 30 minutes, which is equivalent to normal prepayment or postpayment medical review. CMS anticipates that most prior authorization requests would be sent by means other than mail. However, CMS estimates a cost of $5 per request for mailing medical records.

Current Seven Service Categories (Blepharoplasty, Botulinum Toxin Injections, Panniculectomy, Rhinoplasty, Vein Ablation, Cervical Fusion with Disk Removal, and Implanted Spinal Neurostimulators):

Due to a July start date, the first year of the prior authorization program for current services included only six (6) months. Based on calendar year 2018 data, CMS estimated that for those first six months at a minimum there would be 21,999 initial requests mailed during a year. In addition, CMS estimated there would be 7,221 resubmissions of a request mailed following a non-affirmed

decision. Therefore; the total mailing cost was estimated to be $146,100 (29,220 mailed requests x

$5 per request). Based on calendar year 2018 data, CMS estimated that annually at a minimum there would be 43,996 initial requests mailed during a year. In addition, CMS estimated there would be 14,439 resubmissions of a request mailed following a non-affirmed decision. Therefore; the total mailing cost was estimated to be $292,175 (58,435 mailed requests x $5 per request). CMS also estimated that an additional 3 hours would be required for attending educational meetings, training staff on what services require prior authorization, and reviewing training documents. While there may be an associated burden on beneficiaries while they wait for the prior authorization decision, CMS was unable to quantify that burden.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using data available from the Bureau of Labor Statistics (BLS). Based on the BLS 2018 rate for Miscellaneous Healthcare Support Occupations at the time of the estimate, CMS estimated an average hourly rate of $16.63 with a loaded rate of $33.26.[3] The prior authorization program does not create any new documents or administrative requirements. Instead, it just requires the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate used the clerical rate as CMS does not feel that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the demonstration. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. CMS estimated that the total number of submissions for the first year (6 months) would be 97,400 (68,180 submissions through fax or electronic means + 29,220 mailed submissions). Therefore, CMS estimated that the total burden for the first year (six months), allotted across all providers, would be 75,646 hours (.5 hours x 97,400 submissions plus 3 hours x 8,982 providers for education). The burden cost for the first year (6 months) was $2,662,086 (75,646 hours x $33.26 plus $146,100 for mailing costs). In addition, CMS estimated that the total number of annual submissions would be 194,785 (136,350 submissions through fax or electronic means + 58,435 mailed submissions). The total annual burden hours, allotted across all providers, would be 124,339 hours (.5 hours x 194,785 submissions plus 3 hours x 8,982 providers for education). The annual burden cost would be $4,427,674 (124,339 hours x $33.26 plus $292,175 for mailing costs). For the total burden and associated costs, we estimated the annualized burden to be 108,108 hours and $3,839,144 million. The annualized burden was based on an average of 3 years, that is, 1 year at the 6-month burden and 2 years at the 12-month burden.

Year 1 (6 Month) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services- Current Seven Service Categories

Activity	Responses Per Year (i.e. number of reviewed claims)	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	51,330	0.5	25,665	$853,618

[3] https://www.bls.gov/oes/tables.htm

Fax and Electronic Submitted Requests- Resubmissions	16,850	0.5	8,425	$280,216
Mailed in Requests- Initial Submissions	21,999	0.5	11,000	$365,843
Mailed in Requests- Resubmissions	7,221	0.5	3,611	$120,085
Mailing Costs	29,220	$5		$146,100
Provider Demonstration- Education	8,982	3	26,946	$896,224
Total			75,646	$2,662,086

Annual (12 Month) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services- Current Seven Service Categories

Activity	Responses Per Year (i.e. number of reviewed claims)	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	102,658	0.5	51,329	$1,707,203
Fax and Electronic Submitted Requests- Resubmissions	33,692	0.5	16,846	$560,298
Mailed in Requests- Initial Submissions	43,996	0.5	21,998	$731,653
Mailed in Requests- Resubmissions	14,439	0.5	7,220	$240,121
Mailing Costs	58,435	$5		$292,175
Provider Demonstration- Education	8,982	3	26,946	$896,224
Total			124,339	$4,427,674

One New Service Category (Facet Joint Interventions):

As with the current seven service categories, the burden associated with the prior authorization

process for the new category, Facet Joint Interventions, would be the time and effort necessary for the submitter to locate and obtain the relevant supporting documentation to show that the service meets applicable coverage, coding, and payment rules, and to forward the information to CMS or its contractor (MAC) for review and determination of a provisional affirmation. As stated above, we expect that this information would generally be maintained by providers and that the average time for office clerical activities associated with this task would be 30 minutes, which is equivalent to that for normal prepayment or post payment medical review. We again anticipate that most prior authorization requests would be sent by means other than mail. However, we estimate a cost of $5 per request for mailing medical records. Due to the March 1, 2023 start date, the first year of the prior authorization for the new service category would only include 10 months. Based on CY 2019 data, we estimate that for those first 10 months at a minimum there would be 69,501 initial requests mailed during the year. In addition, we estimate there would be 22,805 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $461,532 (92,306 mailed requests x $5). Based on CY 2019 data for the new service category, we estimate that annually at a minimum there would be 83,401 initial requests mailed during a year. In addition, we estimate there would be 27,366 resubmissions of a request mailed following a non-affirmed decision. Therefore, the total mailing cost is estimated to be $553,838 (110,768 mailed requests x $5). We also estimate that an additional 3 hours would be required for attending educational meetings and reviewing training documents.

The average labor costs (including 100 percent fringe benefits) used to estimate the costs were calculated using the 2019 (BLS rate for Miscellaneous Healthcare Support Occupations[4]. Based on the BLS information (we estimate an average clerical hourly rate of $17.13 with a loaded rate of $34.26. The prior authorization program for this new service category would also not create any new documentation or administrative requirements. Instead, it would just require the currently needed documents to be submitted earlier in the claim process. Therefore, the estimate continues to use the clerical rate since we do not believe that clinical staff would need to spend more time on completing the documentation than would be needed in the absence of the prior authorization policy. The hourly rate reflects the time needed for the additional clerical work of submitting the prior authorization request itself. We estimate that the total number of submissions for the first year (10 months) would be 307,688 (215,382 submissions through fax or electronic means + 92,306 mailed submissions). Therefore, we estimate that the total burden for the first year (10 months) for the new service category, allotted across all providers, would be 161,305 hours (.5 hours x 307,688 submissions plus 3 hours x 2,487 providers for education). The burden cost for the first year (10 months) is $5,987,841 (161,305 hours x $34.26 plus $461,532 for mailing costs). In addition, we estimate that the total annual number of submissions would be 369,225 (258,458 submissions through fax or electronic means + 110,768 mailed submissions). The annual burden hours for the new service category, allotted across all providers, would be 192,074 hours (.5 hours x 369,225 submissions plus 3 hours x 2,487 providers for education). The annual burden cost would be $7,134,276 (192,074 hours x $34.26 plus $553,838 for mailing costs). For the total burden and associated costs for the new service category, we estimate the annualized burden to be 181,818 hours and $6,752,131 million. The annualized burden is based on an average of 3 years, that is, 1 year at the 10-month burden and 2 years at the 12-month burden. The ICR approved under OMB control number 0938-1368 will be revised and submitted to OMB for approval.

4 https://www.bls.gov/oes/2019/may/oes_nat.htm#31-0000

Year 1 (10 Months) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services- New Service Category

Activity	Responses Per Year (i.e. number of reviewed claims)	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	162,169	0.5	81,085	$2,777,955
Fax and Electronic Submitted Requests- Resubmissions	53,213	0.5	26,606	$911,532
Mailed in Requests- Initial Submissions	69,501	0.5	34,751	$1,190,552
Mailed in Requests- Resubmissions	22,805	0.5	11,403	$390,657
Mailing Costs	92,306	$5		$461,532
Provider Education	2,487	3	7,461	$255,614
Total			161,305	$5,987,841

Annual (12 Month) Estimated Burden and Cost Table for the Prior Authorization Process and Requirements for Certain Hospital Outpatient Department (OPD) Services- New Service Category

Activity	Responses Per Year (i.e. number of reviewed claims)	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	194,603	0.5	97,301	$3,333,546
Fax and Electronic Submitted Requests- Resubmissions	63,855	0.5	31,927	$1,093,831
Mailed in Requests- Initial Submissions	83,401	0.5	41,701	$1,428,663

Mailed in Requests-Resubmissions	27,366	0.5	13,683	$468,785
Mailing Costs	110,768	$5		$553,838
Provider Education	2,487	3	7,461	$255,614
Total			192,074	$7,134,276

13. Capital Costs

There are no capital costs associated with this collection.

14. Costs to Federal Government

The average annual cost associated with performing reviews for the current seven service categories is $9.3 million. The estimate for the costs associated with performing reviews for the new service category would be approximately $16 million for the first year, which includes ten months, and $19.2 million for a full year, for an average annual cost of $18 million. The average annual cost for the existing seven service categories and the new category would be $27.3 million.

15. Changes in Burden

The annualized burden hours and costs have increased due to the addition of the new service category. The annualized burden hours have increased from 108,108 hours stated in the CY 2021 OPPS/ASC final rule for the current services to 289,926 with the addition of the new service category. The annualized burden cost has increased from $3.8 million for the current seven service categories to $10.6 million with the inclusion of the new service category.

2023 Proposed List of Additional Outpatient Department Services That Require Prior Authorization

	Beginning for service dates on or after March 1, 2023
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level

64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint
64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

16. Publication or Tabulation

There are no plans to publish or tabulate the information collected.

17. Expiration Date

There are no instruments for this PRA package. The expiration date can be found on the OMB website here.