<u>Prior Authorization Demonstration for Certain Ambulatory Surgical Center</u> <u>Services</u>

Prior Authorization (General)

1. Q: What is the Prior Authorization Demonstration for Certain Ambulatory Surgical Center Services?

A: CMS is implementing a five-year demonstration project for the prior authorization of certain services provided in Ambulatory Surgical Centers (ASC) located in a limited number of demonstration states which include California, Florida, Texas, Arizona, Ohio, Tennessee, Pennsylvania, Maryland, Georgia, and New York. This demonstration will test a program under which ASCs submit a prior authorization request and obtain a provisional affirmation before providing a service or be subject to prepayment review and potentially be denied payment if services are deemed ineligible. This demonstration will start January 19, 2026 for California, Florida, Tennessee, Pennsylvania, Maryland, Georgia, and New York. The demonstration will start February 16, 2026 for Texas, Arizona, and Ohio.

2. Q: Why is CMS conducting this demonstration?

A: The Calendar Year 2020 Outpatient Prospective Payment System/Ambulatory Surgical Center Final Rule (CMS -1717-FC) established a nationwide prior authorization process and requirements for certain hospital outpatient department (OPD) services, which are blepharoplasty, botulinum toxin injections, rhinoplasty, panniculectomy, and vein ablation. These targeted services can potentially be provided as cosmetic procedures, rather than medically necessary procedures, resulting in unnecessary increases in the volume of covered OPD services. Data analysis¹ from 2019 to 2021 shows these services have also experienced significant increases in utilization in the ASC setting. These increases are likely related to OPD services shifting to the ASC, as the OPD prior authorization program continues. Additionally, there have been several recent law enforcement actions for each of the selected services. These cases demonstrate the need for greater oversight to help prevent fraudulent behavior. Implementing prior authorization in the ASC setting would help improve methods for the investigation and prosecution of fraud and may prevent that shift in unnecessary utilization.

3. Q: How do you define an ambulatory surgical center?

¹The Integrated Data Repository (IDR) is a high-volume data warehouse integrating Medicare Parts A, B, C, and D, and DME claims, beneficiary and provider data sources, along with ancillary data such as contract information and risk scores. Additional information is available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/IDR/index.html.

² https://www.justice.gov/usao-mdfl/pr/clermont-eye-doctors-agree-pay-over-157000-settle-false-claims-act-liability-improperly

³ https://www.justice.gov/usao-cdca/pr/sherman-oaks-woman-pleads-guilty-charges-multimillion-dollar-scheme-defraud-health

A: The ambulatory surgical center setting is defined as visits and/or services/procedures that are submitted with a place of service 24. As part of this demonstration, ASC facilities will be subject to prior authorization or prepayment review further defined by type of service F or provider specialty code 49.

4. Q: Why did CMS pick these 10 states?

A: We considered the overall improper payment rates specific to each state selected, as fraudulent activity may be more likely in those states. The states were not selected solely based on the state's overall improper payment rate or improper payment rate on the services included in the demonstration, but also upon which states will likely maximize the benefits of the demonstration based on claim volumes and the number of Medicare Administrative Contractor jurisdictions that will be involved.

5. Q: Which services will be subject to prior authorization?

A: The service categories targeted by the demonstration are blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation procedures. These are the same service categories targeted by the prior authorization process for certain OPD services. Other OPD services that require prior authorization (cervical fusion with disc removal, implanted spinal neurostimulators, and facet joint interventions) are not included in this demonstration at this time.

6. Q: What will the Prior Authorization Demonstration for Certain Services in Ambulatory Surgical Centers do?

A: CMS believes this demonstration will help improve methods for the investigation and prosecution of fraud. We will review the documentation submitted by providers to ensure the requested service meets Medicare requirements prior to providers submitting claims for payment, thereby helping to prevent improper payments, including payments representing potential fraud, waste, or abuse. We also see the demonstration as another step in our overall approach to enhancing our ability to separate problematic providers from those providers proactively working to comply with our coverage and documentation requirements, thus helping prevent fraud, waste, and abuse.

7. Q: What provider types are subject to prior authorization for these services?

A: This demonstration will establish a process for eligible ASC facilities in the selected states to submit a prior authorization request and obtain a provisional affirmation before providing a service or be subject to prepayment review and potentially be denied payment if services are deemed ineligible.

8. Q: How does prior authorization help patients with Medicare?

A: Patients with Medicare are able to receive the items and services they need quickly and efficiently. They also appreciate the reduced stress of knowing that the appropriate

items and services should be covered by Medicare.

9. Q: Does this prior authorization process protect beneficiary access to care?

A: CMS believes that this prior authorization demonstration will both help protect the Medicare Trust Funds from improper payments and make sure beneficiaries are not hindered from accessing necessary services when they need them. Prior authorization helps CMS to make sure services frequently subject to unnecessary utilization are provided in compliance with applicable Medicare coverage, coding, and payment rules before they are provided, and it allows the beneficiary to be notified if the service would be covered by Medicare or if Medicare will likely deny payment earlier in the payment process. Access is preserved by having set timeframes for contractors to complete any prior authorization request decisions, and an expedited process in cases where delays jeopardize the life or health of beneficiaries.

10. Q: How does prior authorization help Medicare suppliers, physicians, and other practitioners?

A: Suppliers, physicians, and other Medicare practitioners can be confident that the items and services that their patients need will likely be covered and paid for without time delays, subsequent paperwork, or the need to file an appeal for a claim that was later deemed not payable. In addition, paid claims for which there is an associated affirmed prior authorization decision will be afforded some protection from future audits.

Prior Authorization Request Process

11. Q: What form should be used to submit a prior authorization request, and is it available on the website?

A: There is no specific form to request prior authorization. Your Medicare Administrative Contractor (MAC) may make a cover sheet or other templates available for voluntary use.

12. Q: How can providers submit prior authorization requests/what methods can be used?

A: Providers can submit prior authorization requests to their respective MAC by all of the following methods: fax, mail, Electronic Submission of Medical Documentation (esMD), and MAC electronic portals. For more information about esMD, see http://www.cms.gov/esMD or contact your MAC.

13. Q: What should be included in the Prior Authorization Request (PAR)?

A: The PAR must include evidence that the service complies with all applicable Medicare coverage, coding, and payment rules. The PAR must include necessary documentation from the medical record to support the medical necessity of the services

and any other relevant documents as deemed necessary by the MAC. This information can be found through your local MAC website in the relevant local and national coverage determinations.

14. Q: How long will it take for the MAC to make a prior authorization decision?

A: Decisions will be sent within 7-days of the request for standard review and 2- business days for expedited review.

15. Q: In what instances would CMS expect an ASC to submit a request for expedited review? How will the MAC's review those requests?

A: The requester can submit an expedited review of the PAR if it is determined that a delay could seriously jeopardize the beneficiary's life, health, or ability to regain maximum function. The requester will be notified regarding the acceptance of the PAR for expedited review or if the request will be converted to the standard PA review process. The affirmative or non-affirmative decision will be rendered within the CMS-prescribed expedited review timeframe of 2 business days for requests that are deemed valid for expedited review and provide the decision to the provider via telephone, fax, electronic portal, or other "real-time" communication within the requisite timeframe.

To prevent the claim from being stopped for prepayment review, the provider should hold their claim and not submit it until the UTN is provided and can be appended to the claim. The MAC will follow the normal process to obtain a UTN from CMS shared systems.

A provider may resubmit a request for expedited review.

Prior Authorization Request Process-Medical Review

16. Q: Does this demonstration create new documentation requirements?

A: This demonstration does not change Medicare benefit or coverage requirements, nor does it create new documentation requirements. Instead, regularly required documentation must be submitted earlier in the process.

17. Q: What are the different decisions that can result from a PAR and how will this decision be communicated?

A: The MACs can render a provisional affirmation, non-affirmation decision, or partial affirmation decision.

- A provisional affirmation decision is a preliminary finding that a future claim submitted to Medicare for the service likely meets Medicare's coverage, coding, and payment requirements.
- A non-affirmation decision is a preliminary finding that if a future claim is submitted for the service, it does not meet Medicare's coverage, coding, and payment requirements.

• A provisional partial affirmation decision means that one or more service(s) on the request received a provisional affirmation decision, and one or more service(s) received a non-affirmation decision.

MACs will send the requester of the PAR (i.e., the entity who will submit the claim for payment) a letter providing the PA decision (i.e., affirmation, non-affirmation, or partial affirmation), and if applicable, giving the detailed reasons for the non-affirmation. The MAC will also share such information with beneficiaries upon request.

MACs will send decision letters with a unique tracking number (UTN) to the requester using the method the prior authorization request was received.

18. Q: What steps should be taken upon receiving a non-affirmation decision?

A: The MAC will provide a detailed reason for a non-affirmation decision. Providers should review the information provided and consider if there is additional documentation that could address the non-affirmation decision upon resubmission of the prior authorization request. Providers may also request additional information or clarification from their MAC.

19. Q: How will the MACs know the claim has undergone prior authorization?

A: After the MAC reviews the PAR, they will assign a UTN. Each UTN is specific to a PAR and provisional affirmation, non-affirmation, or partial affirmation decision.

20. Q: How will the MACs process claims that did not go through prior authorization for non-exempt providers?

A: If a non-exempt ASC provider submits a claim without going through prior authorization, the claim will be stopped for prepayment medical review. This means that prior to paying the claim, the MAC will send the provider an Additional Documentation Request (ADR) letter through the US Postal Service and/or electronically. The provider will have 45 days to respond to the ADR with all requested documentation to support the services that are billed. The MAC will have 30 days to review the documentation and render a claim determination.

21. Q: What should a provider do if they disagree with a prior authorization decision?

A: Providers may resubmit the prior authorization request to their MAC an unlimited number of times. Non-affirmation decisions are not considered initial determinations and cannot be appealed; however, if a claim is submitted with a non-affirmation decision and is subsequently denied, that is considered an initial determination and is appealable. MACs will review all issues raised by the appellant on appeal and all relevant documentation to determine whether the service is covered and payable.

22. Q: Will education be provided on the reasons for the non-affirmation prior authorization decision?

A: Yes. When the prior authorization request results in a non-affirmation decision, the MAC will provide the requester with detailed information about missing or non-compliant documentation that resulted in the non-affirmation decision.

23. Q: Will these claims still be subject to additional postpayment reviews?

A: Generally, claims that have a provisional affirmation decision will not be subject to additional review; however, CMS contractors, including Unified Program Integrity Contractors or MACs, may conduct targeted pre-and postpayment reviews if the provider shows evidence of potential fraud or gaming. In addition, the Comprehensive Error Rate Testing contractor must review a random sample of claims for postpayment review for purposes of estimating the Medicare improper payment rate.

Prior Authorization Request Process- UTN

24. Q: Will there be a tracking number for each prior authorization decision?

A: Yes. MACs will list the prior authorization UTN on the decision letter. The UTN must be submitted on the claim in order to receive payment and prevent prepayment review.

- a. When submitting an electronic 837 professional claim for a prior authorized service, the UTN must be submitted in the 2300 Claim Information loop in the Prior Authorization reference (REF) segment where REF01 = "G1" qualifier and REF02 = UTN. A UTN submitted in this loop applies to the entire claim unless it is overridden in the REF segment in the 2400 Service Line loop. This is in accordance with the requirements of the ASC X12 837 Technical Report 3 (TR3).
- b. When submitting a paper CMS 1500 Claim form for a prior authorized service, the UTN must populate the first 14 positions in item 23. All other data submitted in item 23 must begin in position 15.

25. Q: How far in advance are we able to submit a prior authorization request from the anticipated date of service?

A: A provisional affirmation is valid for 120 days from the date the decision was made. If the date of service is not within 120 days of the decision date, the provider will need to submit a new prior authorization request.

26. Q: How long is the UTN valid?

A: Each UTN is valid for 120 days. The decision date is counted as the first day of the 120 days. For example: if the prior authorization request affirmation decision is documented on January 1, 2026, the prior authorization will be valid for dates of service through April 30, 2026. After that, the provider will need to submit a new request.

27. Q: Botulinum toxins can be injected for certain indications every 12 weeks. If an affirmation UTN is valid for 120 days, can a provider bill for two separate dates of services under one prior authorization request/UTN, or does each separate procedure need a new prior authorization request/UTN regardless if the next injection falls within 120 days?

A: Each procedure needs a new prior authorization request regardless of whether the next service falls within 120 days. Each UTN for botulinum toxin injection is valid for one claim.

28. Q: Regarding vein ablations, these procedures may be staged. If all procedures occur within 120 days, do providers need to submit a separate prior authorization request for each procedure?

A: Each procedure needs a new prior authorization request regardless of whether the next service falls within 120 days. Each UTN for vein ablation is valid for one claim.

29. Q: If multiple procedures on the prior authorization list are to be performed on the same day, should the prior authorization request include all procedures?

A: The requestor should include all applicable procedures on the prior authorization request. Each prior authorization request will receive a single UTN, regardless of the number of procedures being requested.

30. Q: If one procedure is affirmed and one is non-affirmed, will each procedure receive a different UTN?

A: No. In the event of a partial affirmation, where one or more procedures receive an affirmation decision and one or more receives a non-affirmation decision, there will be only one UTN for the prior authorization request. The UTN will be encoded to match the affirmation/non-affirmation decisions to the respective procedure and must be included on the ASC claim submitted for payment. Each service and decision will be tracked and coded in the UTN. Claims submitted with non-affirmed procedures will be denied.

Exemption

31. Q: Can providers be exempt from prior authorization?

A: CMS plans to implement an exemption process for those providers who continually show compliance with meeting coverage requirements, and those providers will not need to request prior authorization for all or most of the selected services. CMS will provide more information regarding the exemption process.

Claims Submission and Processing

32. Q: What types of associated services will be denied when a service subject to prior authorization is denied?

A: Associated/related (professional) services will be denied when there was a non-affirmation prior authorization request decision for the ASC service(s), or when the ASC facility claim was denied after prepayment review. These associated services include but are not limited to services such as anesthesiology services and/or physician services.

33. Q: Should physicians and other associated providers submit the UTN on their claims?

A: No. As part of this demonstration, ASC facility providers should include the UTN on their claim, as this prior authorization demonstration is only applicable to ASC facility services, or they will be subject to prepayment review. Other billing practitioners should submit their claims as usual; however, claims related to/associated with services in this prior authorization demonstration will not be paid if the service subject to prior authorization or pre-payment review is not eligible for payment.

34. Q: Are associated/related services payable if the procedure subject to prior authorization is not payable?

A: No. Associated/related services performed in ASCs, will not be paid if the service subject to prior authorization is not eligible for payment.

35. Q: Does this prior authorization process apply to patients with Medicare Advantage plans?

A: No. This prior authorization process is only applicable to claims submitted to Medicare Fee-for-Service.

36. Q: Will patients who have Fee-for-Service Medicare secondary to other insurance coverage be subject to prior authorization for these services?

A: If the provider is seeking payment from Medicare as a secondary payer for an applicable ASC service, prior authorization should be obtained. The provider or beneficiary must include the UTN on the claim submitted to Medicare for payment or the claim will be stopped for prepayment review.

37. Q: If an ASC provider submits a claim for a non-affirmed procedure and the claim is denied, as well as claims for related physician services, must the physician appeal separately, or can the ASC provider appeal the associated physician claim as well?

A: The appeal process has not changed. Each provider who determines that appealing a denial decision is appropriate must file their own appeal.

38. Q: What will happen to related physician or other practitioner claims if the ASC provider has not yet submitted its claim for the service subject to prior authorization?

A: For services that are part of this prior authorization demonstration, related service claims may be held, and/or records may be requested for review to determine what action should be taken on the claim.

39. Q: Can prior authorizations be submitted retroactively – meaning that the service was already provided, but the claim has not yet been billed?

A: No. A prior authorization request must be submitted before the service is provided to a beneficiary.

40. Q: If the ASC provider performed an applicable procedure but received a non-affirmed prior authorization decision based on determination that service was not medically reasonable and necessary, would this scenario qualify for issuance of an Advance Beneficiary Notice of Non-coverage (ABN) to bill the service to the patient?

A: An ABN must be issued in advance of performing the procedure if it is expected that payment for a service will be denied by Medicare because the service is not medically reasonable and necessary. (See Claims Processing Manual, Pub. 100-04, Chapter 30 for additional information on ABNs.) The provider must submit the claim with a GA modifier, and the MAC will review it to determine if the ABN was issued appropriately.

41. Q: What will Medicare pay if the prior authorization request is non-affirmed as the service is determined to be not medically reasonable and necessary, and the patient signs an ABN?

A: Medicare will make no payment for claims submitted with a non-affirmation UTN and/or with the GA modifier if an ABN has been properly executed. (See Claims Processing Manual, Pub. 100-04, Chapter 30 for additional information on ABNs.)

42. Q: If the physician determines that an applicable procedure is purely cosmetic but the patient requests the ASC provider bill Medicare for the procedure, should the ASC provider give an ABN in order to bill the patient for the services?

A: An ABN may be issued if the provider advises the beneficiary in advance that they expect payment for a service to be denied by Medicare under the statutory exclusion for cosmetic services. The provider should submit the claim with a GX modifier. The ABN is voluntary and is not required to bill the patient for the service if it is denied under the cosmetic services exclusion. However, we encourage providers to issue an ABN in this situation to inform the beneficiary of the likelihood of financial liability.

43. Q: If the ASC provider performs an applicable procedure that is ordinarily considered cosmetic but could be determined medically reasonable and necessary

for the patient's specific condition, and the provider believes that Medicare will deny the procedure as not medically reasonable and necessary, should the beneficiary be given an ABN in order to be billed for the services?

A: Yes. An ABN must be issued if the provider advises the beneficiary in advance that they expect payment for a service to be denied by Medicare as not medically reasonable and necessary. The provider should submit the claim with a GA modifier, and the MAC will review it to determine if the ABN was issued appropriately.