May 13, 2021

Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services
Frequently Asked Questions (FAQs)

Prior Authorization (General)

1. **Q: What is prior authorization?**

   A: Prior authorization is a process through which a request for provisional affirmation of coverage is submitted for review before the service is rendered to a beneficiary and before a claim is submitted for payment. The prior authorization program for certain hospital OPD services ensures that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered services and improper payments. The prior authorization process does not alter existing medical necessity documentation requirements. Prior authorization helps to make sure that applicable coverage, payment, and coding requirements are met before services are rendered while ensuring access to and quality of care.

2. **Q: When did the Prior Authorization Process for Hospital Outpatient Department (OPD) Services begin?**

   A: Prior Authorization for the initial five services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation) started on June 17, 2020 for dates of service on or after July 1, 2020. Two new additional hospital OPD services (cervical fusion with disc removal and implanted spinal neurostimulators) will require prior authorization for dates of service on or after July 1, 2021.

3. **Q: What services require prior authorization under this process**?

   A: As part of the Calendar Year 2020 OPPS/ASC Final Rule (CMS-1717-FC), CMS required prior authorization for the following services: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. As part of the Calendar Year 2021 OPPS/ASC Final Rule (CMS-1736-FC), CMS will require prior authorization for two additional services: cervical fusion with disc removal and implanted spinal neurostimulators. The Final List of Outpatient Services that Require Prior Authorization is located here.

4. **Q: What codes require prior authorization for implanted spinal neurostimulators?**

   A: CMS will only require prior authorization for CPT code 63650 (Implantation of spinal neurostimulator electrodes, accessed through the skin) at this time. CMS is temporarily removing CPT codes 63685 and 63688 from the list of OPD services that require prior authorization.

5. **Q: Why is CMS temporarily removing CPT codes 63685 and 63688 from**

the list of OPD services that require prior authorization?

A: CMS is temporarily removing CPTs 63685 and 63688 to streamline requirements for the intial implementation of prior authorization for implanted spinal neurostimulators. CMS will monitor prior authorization for CPT 63650 to determine if it is effective in reducing the volume of unnecessary implanted spinal neurostimulator services.

6. **Q: When will CMS announce any changes with respect to these two codes and whether they require prior authorization?**

   A: CMS will monitor prior authorization for CPT 63650 and will provide public notice if there are any changes to the prior authorization requirements for CPTs 63685 and 63688.

7. **Q: Is prior authorization required for both the trial and the permanent implantation procedures for CPT 63650?**

   A**:** No**.** Providers who plan to perform **both** the trial and permanent implantation procedures using CPT 63650 in the hospital OPD will **only** require prior authorization for the trial procedure. To avoid a claim denial, providers must place the Unique Tracking Number (UTN) received for the trial procedure on the claim submitted for the permanent implantation procedure. When the trial is rendered in a setting other than hospital OPD, providers will need to request prior authorization for CPT 63650 as part of the permanent implantation procedure in the hospital OPD.

8. **Q: Why is Medicare implementing prior authorization for these OPD Services?**

   A: The CMS has observed significant increases in the utilization volume of some covered OPD services. During our analysis of the five original services, we targeted services that represent procedures that are likely to be cosmetic surgical procedures and/or are directly related to cosmetic surgical procedures that are not covered by Medicare but may be combined with or masquerading as therapeutic services. As part of our responsibility to protect the Medicare Trust Funds, we continually analyze data to determine if there are additional covered OPD services that are exhibiting unnecessary increases in volume for which prior authorization would be appropriate. We believe prior authorization for these two new services (cervical fusion with disc removal and implanted spinal neurostimulators) will be an effective method for controlling unnecessary increases in volume and will reduce instances in which Medicare pays for services that do not meet Medicare requirements.

9. **Q: How does prior authorization help Medicare suppliers, providers, and other practitioners?**

   A: Suppliers, providers, and other Medicare practitioners can be confident that the items and services that their patients need will be covered 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 provisional affirmation decision will be afforded some protection from future audits.

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

A: Yes. The CMS believes this prior authorization program 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 allows CMS to make sure items and services frequently subject to unnecessary utilization are furnished or provided in compliance with applicable Medicare coverage, coding, and payment rules before they are furnished or provided. It also allows the beneficiary to be notified if the item or service would be covered by Medicare and any potential financial implications 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 is available in cases where delays may jeopardize the life or health of beneficiaries.

11. Q: Who will be required to submit prior authorization requests?

A: Hospital OPDs must submit a prior authorization request and receive a provisional affirmation decision as a condition of payment. Physicians and other third parties may submit the request on behalf of the hospital OPD, but hospital OPDs are responsible for ensuring that this condition of payment is met. Claims for these services submitted without a provisional affirmation decision will be denied.

12. Q: What provider types require prior authorization for these services?

A: Only hospital OPD services require prior authorization as part of this program. Other facility/provider types such as physician's offices, critical access hospitals, or ambulatory surgery centers that submit claims other than type of bill 13X are not required to submit prior authorization requests.

13. Q: Are emergency department services subject to prior authorization?

A: No. CMS excludes the Emergency Department services from prior authorization requirements when an outpatient service is submitted with an ET modifier or 045x revenue code. These claims are not excluded from future pre-payment or postpayment medical review.

14. Q: Does the prior authorization requirement apply to Maryland waiver hospitals?

A: Yes. The Maryland hospital waiver does not affect their OPD requirement to participate in this program. Maryland OPDs are required to submit prior authorization requests for the services listed in this program.

15. Q: How will CMS exempt certain providers from the prior authorization process? How can I obtain an exemption?

A: The CMS may elect to exempt a Part A provider from the PA 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. Starting February 1, 2021, your MAC will calculate the affirmation rate of initial prior authorization requests for all five original service categories combined and hospital OPD providers will be notified if their affirmation rate is 90% or greater. Providers who met the above compliance rate threshold should have received a written Notice of Exemption through the US mail or MAC provider portal no later than the first business day on or after March 1, 2021. Those hospital OPDs will be exempt from submitting prior authorization requests for dates of service beginning May 1, 2021. Exempt providers should not submit prior authorization requests after this date. More detailed information about the exemption process and subsequent exemption cycles is available in the Operational Guide.

16. Q: Where can I find the regulations implementing the new Hospital OPD Prior Authorization process?

A: The regulations are located at 42 CFR §§419.80-419.83.

17. Q: Where can I find additional operational details related to prior authorization?

A: An operational guide with additional details is available within the download section on the OPD Prior Authorization website.

Prior Authorization Request Process

18. Q: What form do I use 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.

19. 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.

20. Q: How many days will it take to receive a prior authorization decision?

A: The standard review timeframe is up to ten (10) business days from the date the prior authorization request is received, excluding federal holidays.

21. Q: What if I need a decision on my prior authorization request sooner than 10 days?

A: You can request an expedited review timeframe of up to two (2) business days if the standard timeframe for making a decision could seriously jeopardize the life or health of the beneficiary. The expedited request must include justification showing that the standard timeframe would not be appropriate. If the MAC determines that the request does not substantiate the need for an expedited review, they will provide notification and communicate a decision within the regular timeframe.

Prior Authorization Request Process-Medical Review

22. Q: Does the Prior Authorization process require new coverage or documentation requirements?

A: No. Prior authorization does not create new coverage or documentation requirements. Instead, regularly required documentation must be submitted earlier in the process. Separate from the prior authorization process, MACs may develop Local Coverage Decisions (LCD) specific to their jurisdiction. Providers should follow National Coverage Determinations and their jurisdiction's LCDs /Local Coverage Articles, when applicable.

23. Q: What are the different decisions that a prior authorization request can obtain and how will this decision be communicated?

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

- A provisional affirmation decision is a preliminary finding that a future claim submitted to Medicare for the item or service 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 item or 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.

- The MAC will send the hospital OPD provider a written decision (i.e., provisional affirmation, provisional partial affirmation, or non-affirmation), and if applicable, provide the detailed reasons for the non-affirmation decision. The

MAC will also share such information with beneficiaries.

24. Q: I received a non-affirmation decision. What should I do?

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.

25. Q: Will physicians and other related service practitioners receive a copy of the prior authorization decision letter?

A: The requester (hospital OPD) and beneficiary will receive a prior authorization decision letter. Physicians and other practitioners who do not submit the prior authorization request on behalf of the hospital OPD may obtain a copy of the decision letter from the hospital OPD. Physicians/practitioners who submit the prior authorization request on behalf of the OPD should include their contact information on the PA request cover sheet, in addition to the hospital OPD's contact information.

26. Q: What is a resubmitted request?

A: A resubmitted request is a subsequent prior authorization review request submitted after the initial review request was submitted, reviewed, and a non- affirmation decision was made. A request that is resubmitted with no additional documentation or information will likely receive a non-affirmation decision.

27. Q: Can non-affirmation decisions be appealed?

A: Provided the claim has not been submitted for payment, the provider 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.

28. Q: Will we be provided education 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 detailed information about missing or non-compliant documentation that resulted in the non-affirmation decision.

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

A: Generally, the 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-Unique Tracking Number (UTN)

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

A: Yes. MACs will list the prior authorization unique tracking number (UTN) on the decision notice. The UTN must be submitted on the claim in order to receive payment.

a. The submission of the prior authorized claim is to have the 14 byte UTN that is located on the decision letter. For submission of electronic claims, the UTN must be in positions 1 through 18. When the claim enters the Fiscal Intermediary Shared System (FISS), the UTN will move it to positions 19 through 32 and zeros will autofill the first field. For providers submitting electronic claims, the Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at the loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.

b. For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN.

31. 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.

32. Q: For how long is the Unique Tracking Number (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, 2021, the prior authorization will be valid for dates of service through April 30, 2021. After that, the provider will need to submit a new request.

33. 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 require a new prior authorization request/UTN regardless if the next injection falls within 120 days?**

A: Each procedure requires 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.

34. 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 requires 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.

35. Q: Can the same UTN be used for both trial and permanent spinal neurostimulator implantation procedures?

A: Yes. The UTN received for the trial should be used on both trial and permanent implantation claims when billing for CPT 63650 in hospital OPD setting. Please refer to Question #7 for spinal neurostimulators' prior authorization request submissions.

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

A: A hospital OPD 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.

37. 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 be 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 hospital OPD 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.

Claims Submission and Processing

38. Q: Do the botulinum toxin J-codes listed in this program require prior authorization when they are used for injection procedures other than 64612 and 64615?

A: No. Prior authorization is only required when one of the required Botulinum Toxin codes (J0585, J0586, J0587, or J0588) is used in conjunction with one of the required CPT injection codes (64612, injection of chemical for destruction of nerve muscles on one side of face, or 64615, injection of chemical for destruction of facial and neck nerve

muscles on both sides of face). Use of these Botulinum Toxin codes in conjunction/paired with procedure codes other than 64612 or 64615 will not require prior authorization under this program.

39. **Q: The Rule states that any claims associated with or related to a service that requires prior authorization for which a claim denial is issued would also be denied. What types of associated services will be denied**?

    A: Associated/related (professional) services will be denied when there was a non-affirmation prior authorization request decision for the hospital OPD service(s), or there was no prior authorization request on file, and the hospital OPD claim was denied. These associated services include but are not limited to, services such as anesthesiology services, physician services, and/or facility services. The full list of associated codes is available in Appendix B of the the Operational Guide.

40. **Q: Are physicians and other associated providers required to submit the unique tracking number (UTN) on their claims?**

    A: No. Only the hospital OPD is required to include the UTN on their claim, as the prior authorization process is only applicable to hospital OPD services. The physician and other billing practitioners should submit their claims as usual; however, claims related to/associated with services that require prior authorization as a condition of payment will not be paid if the service requiring prior authorization is not eligible for payment.

41. **Q: Are associated/related services, such as a physician service billed under the Physician Fee Schedule, payable if the procedure requiring prior authorization is not payable?**

    A: No. Associated/related services, such as physician services performed in hospital OPDs, will not be paid for services that require prior authorization as a condition of payment for hospital OPD claims if the service requiring prior authorization is not eligible for payment. Claims from other places of service are not affected.

42. **Q: In some situations, a surgeon may change a procedure intraoperatively from the planned procedure to one that was not prior authorized. What can providers do to avoid receiving claim denials for these services and having to file an appeal?**

    A: If a service requiring prior authorization as a condition of payment is billed without an associated affirmation decision, it will be denied. Providers may submit prior authorization requests for multiple potential procedures if they believe that this could be a possibility. It may be best to submit a prior authorization request with several potential service codes; however, providers should be aware that this may result in a partial affirmation decision if the documentation does not support the need for all of the services requested.

43. **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.

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

A: If the provider is seeking payment from Medicare as a secondary payer for an applicable hospital OPD service, prior authorization is required. The provider or beneficiary must include the UTN on the claim submitted to Medicare for payment.

45. Q: If a hospital OPD 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 hospital OPD 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.

46. Q: What will happen to related physician or other practitioner claims if the hospital OPD has not yet submitted its claim for the service requiring prior authorization?

A: For services requiring prior authorization in this program, related service claims may be held, and/or records may be requested for review to determine what action should be taken on the claim.

47. Q: Can we submit prior authorizations 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.

48. Q: If the hospital OPD 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 to determine if the ABN was issued appropriately.

49. 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.)

50. Q: If a hospital OPD does not request prior authorization for an applicable procedure that they believe may be covered under Medicare, can the hospital issue an ABN to the beneficiary?

A: No. An ABN would not be appropriate in a situation where a hospital bypasses the prior authorization process. Medicare will deny the claim and the hospital may not charge the beneficiary.

51. Q: If the physician determines that an applicable procedure is purely cosmetic but the patient requests the hospital bill Medicare for the procedure, should the hospital 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.

52. Q: If the hospital 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 physician or hospital 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 to determine if the ABN was issued appropriately.

53. Q: How do you define a hospital outpatient department and/or hospital outpatient department services?

A: The hospital outpatient department setting is defined as visits and/or services/procedures paid for under the Medicare Outpatient Prospective Payment System that are submitted with a type of bill 13x.

54. Q: **Is prior authorization required for CPT 21235 (obtaining ear cartilage for grafting)?**

A: No. CPT 21235 was originally in the list of hospital OPD services that require prior authorization; however, in response to stakeholder feedback, we are removing this code from the list, as it is commonly used in other procedures not related to rhinoplasty that are not likely to be cosmetic in nature. This code will not require prior authorization as a condition of payment.