ASRA Guide to Medicare Prior Authorization for Implanted Spinal Neurostimulator Procedures Performed in Outpatient Hospital Settings

Effective for services starting July 1, 2021, the Centers for Medicare and Medicaid Services (CMS) is requiring certain implanted spinal neurostimulators implanted in hospital outpatient departments (OPDs) to receive prior authorization as a condition of payment.[1] This guide provides additional information on these new prior authorization requirements.

What is Prior Authorization?

According to CMS, prior authorization is a process through which a request for "provisional affirmation of coverage" is submitted for review before a service is furnished to a Medicare patient and before a claim is submitted for payment. The prior authorization process will be conducted by Medicare Administrative Contractors (MACs).

A provisional affirmation decision is a preliminary finding that a future claim submitted to Medicare for hospital OPD services likely meets Medicare's coverage, coding, and payment requirements.

Notably, Medicare coverage policies and documentation requirements are unchanged.

Which Implanted Spinal Neurostimulators Require Prior Authorization?

At present, CMS is only requiring prior authorization for CPT code 63650, *Implantation of spinal neurostimulator electrodes, accessed through the skin*[2], for services performed in the hospital OPD under Medicare fee-for-service.

CMS will monitor prior authorization of this code to determine if it is effective in reducing the volume of unnecessary implanted spinal neurostimulator services. CMS may, at a future date, require prior authorization of the additional spinal neurostimulator codes (see footnote 2).

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[1] Additional services also require prior authorization in the hospital OPD setting. The full list of codes requiring prior authorization in the hospital OPD setting can be found on the CMS website at https://www.cms.gov/files/document/opd-services-require-prior-authorization.pdf.

[2] In the Calendar Year 2021 Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) Final Rule, released for Public Inspection on December 4, 2020, CMS finalized that the following three spinal neurostimulator codes would be subject to prior authorization:

- CPT 63650 – Implantation of spinal neurostimulator electrodes, accessed through the skin
- CPT 63685 – Insertion or replacement of spinal neurostimulator pulse generator or receiver
- CPT 63688 – Revision or removal of implanted spinal neurostimulator pulse generator or receiver

On May 13, 2021, CMS announced that it was temporarily removing CPT codes 63685 and 63688 from the list of OPD services that require prior authorization. CMS stated that it will monitor prior authorization for CPT 63650 and will provide public notice if there are any changes to the prior authorization requirements for CPT codes 63685 and 63688.

Is Separate Prior Authorization Required for both Trial and Permanent Implantation Procedures for CPT 63650?

No. However, prior authorization requirements will depend on where the trial procedure is performed:

- **If the trial procedure is performed in the hospital OPD**, CMS will only require prior authorization for the trial procedure, and the permanent implantation in the hospital OPD will not require separate prior authorization. As further detailed below, the Medicare Administrative Contractor (MAC) will provide a Unique Tracking Number (UTN) upon approval of the initial prior authorization request for the trial procedure. To avoid a claim denial on the permanent procedure, hospital OPD providers must place the UTN on the claim submitted for the permanent implantation procedure.

- **If the trial procedure is performed in a setting other than a hospital OPD** (e.g. an ambulatory surgical center), then prior authorization will be required for a permanent implantation performed in the hospital OPD. No prior authorization is required for the trial procedure performed in a non-hospital OPD setting.

When do the Prior Authorization Requirements Take Effect for Implanted Spinal Neurostimulators?

Prior authorization requirements have applied for certain services in the hospital OPD since July 1, 2020. For implanted spinal neurostimulators, the prior authorization requirement for hospital OPD services applies to services performed on or after July 1, 2021. MACs will begin accepting prior authorization requests for implanted spinal neurostimulators on June 17, 2021, for services rendered on or after July 1, 2021.

What Provider Types Require Prior Authorization for These Services?

These prior authorization requirements technically only apply to hospital OPD services that are paid for under the Medicare Outpatient Prospective Payment System and submitted with a type of bill 13x. Other facility/provider types such as physician's offices, critical access hospitals, or ambulatory surgical centers that submit claims other than type of bill 13X are not required to submit prior authorization requests.

However, claims for services furnished by other types of providers or suppliers related to or 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.

Do I Have to Submit Prior Authorization Requests for Implanted Spinal Neurostimulators?

In general, a prior authorization request must be submitted for CPT code 63650 if it is to be performed in the hospital OPD. This request must generally be submitted by the hospital OPD, which must receive

a provisional affirmation decision prior to the service being performed 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. Physicians and hospital OPDs should coordinate on submitting and managing prior authorization requests.

In some cases, CMS may elect to exempt a provider from the PA process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules. CMS or its contractors would exempt providers that submitted at least 10 requests and achieved a PA provisional affirmation threshold of at least 90 percent during a semiannual assessment. Providers exempted under this process should receive a written Notice of Exemption.

- The exemption will remain in effect until CMS elects to withdraw the exemption.
- Notice of exemption or withdraw of an exemption will be provided at least 60 days prior to the effective date.

What is the Process for Submitting a Prior Authorization Request?

Providers must submit prior authorization requests to their respective MAC prior to furnishing the service and prior to submitting a claim.

Prior authorization requests must generally identify:

- The beneficiary's name, Medicare Beneficiary Identifier (MBI), and date of birth
- Name of facility, PTAN/CCN, address, and National Provider Identifier (NPI)
- Physician/Practitioner's name, NPI, PTAN, and address
- The requester's name, telephone number, and email address
- HCPCS code(s), diagnosis code(s), type of bill, and units of service

However, MACs may request additional, optional elements for submission of the request.

For resubmitted requests, the Unique Tracking Number (UTN) associated with the previous submission must also be included, along with an exact match of the beneficiary's first name, last name, and date of birth as the previous submission.

Requests must also indicate if the request is an initial or resubmission review, and if the request is expedited (and if so, provide a reason expedited review is needed). Requests must also include documentation from the medical record that fully supports the medical necessity of the service.

Requests can be:

- Mailed
- Faxed
- Submitted through the Electronic Submission of Medical Documentation (esMD), content type 8.5
- Submitted through the MAC's portal

However, CMS encourages providers to use fax, esMD, or the MAC portals to avoid delays with mail.

What are General Documentation Requirements for Trial or Permanent Implanted Spinal Neurostimulators?

According to the CMS Operational Guide, general documentation requirements for trial or permanent implanted spinal neurostimulators include the following:

- Information indicating if the request is for a trial or permanent placement
- Physician office notes including:
    - Conditions requiring the procedure
    - Physical examination
    - Treatments tried and failed including but are not limited to:
        - Spine surgery
        - Physical therapy
        - Medications
        - Injections
        - Psychological therapy
- Documentation of appropriate psychological evaluation[3]
- For permanent placement, documentation of pain relief with the temporary implanted electrode(s)
    - A successful trial should be associated with at least 50% reduction of target pain or 50% reduction of analgesic medications.

Additionally, services associated with devices approved under an Investigational Device Exemption (IDE) study must undergo prior authorization and meet the coverage requirements in NCD 160.7.

Does the Prior Authorization Process Require New Coverage or Documentation Requirements?

No. The documentation required to be included with a prior authorization request is information that hospital OPDs are regularly required to maintain for Medicare payments.

However, under the prior authorization process, regularly required documentation must be submitted earlier in the process. Providers and health professionals should follow National Coverage Determinations and their jurisdiction's local coverage policies (e.g., Local Coverage Determinations and Local Coverage Articles), when applicable, as well as all other applicable Medicare statutory and regulatory requirements.

[3] See Medicare Learning Network (MLN1986542) booklet and Publication# 100-2, Chapter 15 for more information on psychological evaluations.

What are the Potential Responses to a Prior Authorization Request?

MACs may make one of the following three decisions in response to a prior authorization request:

- **Provisional affirmation.** This is a preliminary finding that a future claim submitted to Medicare for the requested service meets Medicare's coverage, coding, and payment requirements. This provisional affirmation is valid for 120 days from the date of the decision.
- **Partial affirmation.** This is a preliminary finding that one or more service(s) on the prior authorization request received a provisional affirmation decision, and one or more service(s) received a non-affirmation decision.
- **Non-affirmation.** This is a preliminary finding that, if a future claim is submitted to Medicare for the requested item or service, it would not meet Medicare's coverage, coding, and payment requirements.

For each prior authorization request, MACs will provide a prior authorization Unique Tracking Number (UTN) on the decision notice. Even in the event of a partial affirmation, there will only be one UTN for the prior authorization request.

MACs will send decision letters providing one of the above decisions to the requester (the hospital OPD) via the same method the request was submitted. (However, CMS notes in the Operational Guide that decision letters sent via esMD are not available at this time.) MACs will also have the option to send a copy of the decision to the requester via fax if a valid fax number was provided with the request, even if the submission was sent via mail. MACs will also send a copy of the decision letter to the beneficiary.

For services that are non-affirmed, the decision letter will provide a detailed explanation for the decision.

Will Physicians Receive Information from the MAC about a Prior Authorization Decision?

Physicians and other 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. 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.

How Do Providers Get Paid for a Service that Received Provisional Affirmation?

In general, claims for services with a provisional affirmation decision (including those services with provisional affirmation on a prior authorization request that received partial affirmation) will be paid in full (see the next question for exceptions). To receive payment, hospital OPD claims submitted for services that require prior authorization and that have received provisional affirmation must include the associated UTN to receive payment.

Physicians and other billing providers are not required to submit the UTN on their claims, and claims should be submitted as usual.

Could Services that Received Provisional Affirmation Be Denied Payment?

Yes, it is possible that a service with provisional affirmation could be denied.

Any hospital OPD claim for CPT code 63650, or for any other code on the CMS' hospital OPD prior authorization list, that is submitted without a UTN will be denied, unless the provider is exempt.

CMS or a MAC may also deny a claim that has received provisional affirmation based on either of the following:

- Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or
- Information not available at the time of a prior authorization request.

What Steps Can Be Taken for Services that Receive a Non-Affirmation Decision?

If a hospital OPD receives a non-affirmation decision and the reason for non-affirmation can be resolved, the prior authorization request can be resubmitted for another review. The MAC will provide a detailed reason for a non-affirmation decision. Providers should review the information and consider if there is additional information or documentation that could address the non-affirmation decision upon resubmission. Providers may also request additional information or clarification from their MACs.

Alternatively, providers can decide to furnish the hospital OPD service and submit the claim for payment (see next question).

- While the claim will be denied, the denial would be considered an initial payment determination and could be appealed through standard appeals processes.
- Note that an Advance Beneficiary Notice of Non-coverage (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. In such cases, a claim must be submitted with a GA modifier, and the MAC will review to determine if the ABN was issued properly. Additionally, Medicare will not make payment for claims submitted with the GA modifier.

No appeals processes are available for prior authorization decisions, but unlimited resubmissions of prior authorization requests are allowed, provided the claim has not yet been submitted and denied.

What Will Happen to a Claim for a Service that Has Not Received Provisional Affirmation?

Any hospital OPD claim for CPT code 63650, or any other code on the CMS' hospital OPD prior authorization list, that is submitted without provisional affirmation will be denied, unless the provider is exempt. The denial may be appealed through standard appeals processes.

CMS or a MAC may also deny claims for services *related to* services on the CMS hospital OPD prior authorization list for which a provider has received a denial. Associated services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services.

Depending on the timing of claim submission for any related service, claims may be automatically denied or denied on a postpayment basis. A full list of associated codes is available in Appendix B of the CMS Operational Guide.

Claims denials for services that have not received provisional affirmation may be appealed through standard appeals processes. Notably, if there is no provisional affirmation for a service that requires prior authorization, and claims for *related services* are also denied, CMS notes that "each provider who determines that appealing a denial decision is appropriate must file their own appeal."

How Long Will CMS or a MAC Take to Make a Decision on A Prior Authorization Request?

For both initial and resubmitted requests, the MAC will ensure the determination is postmarked, faxed, or delivered electronically within 10 business days following receipt of the request, excluding federal holidays.

In certain circumstances, if it is determined that delays in receipt of a prior authorization decision could jeopardize the life, health, or ability to regain maximum function of the beneficiary, then the MAC will process the Prior Authorization request under an "expedited" timeframe, upon request. The request must include justification showing that the standard timeframe would not be appropriate. In these cases, the MAC will make reasonable efforts to communicate a determination within 2 business days of the expedited request. However, if the MAC determines that the request does not require expedited review, the MAC will provide notification and communicate a decision within the regular 10-business-day timeframe.

Is Prior Authorization Required for Patients with Medicare Advantage Plans?

Prior authorization is not required for patients who are enrolled in Medicare Advantage plans. The hospital OPD prior authorization requirements only apply to Medicare fee-for-service.

Will Patients Who Have Fee-for-Service Medicare Secondary to Other Insurance Coverage Require Prior Authorization?

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.

What Will Happen to a Related Claim if the Hospital OPD Has Not Yet Submitted its Claim for the Service Requiring Prior Authorization?

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.

Who Should I Contact If I Have Additional Questions?

Providers who have questions about the prior authorization review process should contact their local MAC jurisdiction.

References

The following sources were used in the preparation of this guide. All materials were accessed June 8, 2021.

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