Module 7: Medical Necessity and Non-Coverage

I. Overview of Medicare Coverage

A. In order to be covered by Medicare, items and services must:

1. Fall into a Medicare benefit category;
2. Not be statutorily excluded;
3. Be reasonable and necessary; and
4. Meet other Medicare program requirements for payment. <*Medicare Program Integrity Manual*, Chapter 3 § 3.6.2.1>

B. Coverage guidance:

1. The Social Security Act defines Medicare benefit categories and exclusions, supplemented by regulatory guidance (e.g., 42 *C.F.R.* §§ 409, 410) and sub-regulatory guidance (e.g., the *Medicare Benefit Policy Manual*) published by CMS.
2. In some cases, CMS publishes National Coverage Determinations (NCDs), discussed later in this module, specifying the circumstances under which an item or service is reasonable and necessary. <*Medicare Program Integrity Manual*, Chapter 3 § 3.6.2.2>
3. If there is no NCD, MACs may publish Local Coverage Determinations (LCDs), discussed later in this module, specifying the circumstances under which an item or service is reasonable and necessary. <*Medicare Program Integrity Manual*, Chapter 3 § 3.6.2.2>
4. If there is no NCD or LCD applicable to an item or service, contractors determine if it is reasonable and necessary based on the following criteria:
   a. It is safe and effective;
   b. It is not experimental or investigational;
   c. It is appropriate, including duration and frequency;

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d. It is furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the beneficiary's condition or to improve the function of a malformed body member;

e. It is furnished in a setting appropriate to the beneficiary's medical needs and condition;

f. It is ordered and furnished by qualified personnel; and

g. It meets, but does not exceed, the beneficiary's medical need. <*Medicare Program Integrity Manual*, Chapter 3 § 3.6.2.2>

II. National and Local Coverage Policies

A. Medicare Coverage Database

1. CMS hosts a comprehensive coverage website entitled the Medicare Coverage Database where they publish National and Local Coverage Determinations and related documents. CMS publishes a helpful guide entitled "How to Use the Medicare Coverage Database".

Link: Coverage Database (NCDs, NCAs, LCDs) under Medicare-Related Sites – General

2. Types of Documents on the Medicare Coverage Database

a. National Coverage Determinations (NCDs)

i. NCDs describe national Medicare coverage policy and generally provide the conditions under which an item or service is considered to be covered. <*Medicare Program Integrity Manual,* Chapter 13 § 13.1.1>

ii. NCDs are binding on all Medicare contractors and in most cases on ALJs in the appeals process. <42 *C.F.R.* 405.1060; *Medicare Program Integrity Manual*, Chapter 13 § 13.1.1>

b. National Coverage Analyses (NCAs) and Decision Memoranda

CMS publishes NCAs and Decision Memoranda describing CMS coverage decisions and providing the **clinical basis and rationale** of the decisions, including **clinical evidence and studies**.

i. NCAs and Coverage Decision Memoranda are not binding on Medicare Contractors or ALJs, but CMS directs contractors to consider them in

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their medical review activities. <*Medicare Program Integrity Manual,* Chapter 12 § 13.1.1>

c. Coding Analyses for Labs (CALs), Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) Meeting minutes, Technology Assessments (TAs) and Medicare Coverage Documents (MCDs)

   i. CALs, MEDCAC meeting minutes, TAs, and MCDs provide additional guidance on national Medicare coverage policies and decisions.

d. Local Coverage Determination (LCDs)

   i. MACs publish LCDs to describe local coverage policy and as educational tools to assist and furnish guidance to providers within their jurisdiction. <*Medicare Program Integrity Manual,* Chapter 13 § 13.1.3>

   ii. LCDs are not binding on Medicare contractors or ALJs, beyond the contractor that established them. Regulations require contractors and ALJs give substantial deference to LCDs applicable to a case and if they do not follow an LCD, explain why in their decision letter. <42 *C.F.R.* 405.1062>

e. Local Coverage Articles

   i. MACs publish coverage articles addressing local coverage, coding, billing, medical review, and claims considerations. The articles may include newly developed educational materials, coding instructions, or clarification of existing billing or claims policy.

B. Coverage with Evidence Development (CED)

1. CED policies cover items or services on the condition they are furnished in the context of approved clinical studies or with the collection of additional clinical data. <*Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document*, Issued on November 20, 2014>

> Link: Coverage with Evidence Development (CED) under Medicare-Related Sites – General
>
> Use links on the left navigation to access an information page for each item or service covered under CED.

2. The routine costs of items and services, associated with services covered under CED, are also covered if the items or services are generally covered for Medicare beneficiaries. <*Guidance for the Public, Industry, and CMS Staff; Coverage with Evidence Development Document,* Issued on November 20, 2014>

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3. Clinical Trial Reporting for CEDs

   a. The following should be reported on claims for services covered under CED. <*Medicare Claims Processing Manual,* Chapter 32 §§ 69.5, 69.6>

      i. Condition code 30 ("Qualifying Clinical Trials"); and

      ii. Value code D4 with the eight-digit clinical trial number of the study the service is covered under, as specified on the CED website or on clinicaltrials.gov; and

      iii. ICD-10 code Z00.6 ("Encounter for examination for normal comparison and control in clinical research program"); and

      iv. For outpatient claims, as appropriate:

         a) Modifier -Q0 ("Investigational clinical service provided in a clinical research study that is an approved clinical research study")

         b) Modifier -Q1 ("Routine clinical service provided in a clinical research study that is an approved clinical research study")

C. Laboratory NCD Manual

1. CMS publishes laboratory NCDs, along with additional coding and coverage information in a "*Lab NCD Manual*" entitled *Medicare National Coverage Determination (NCD) Coding Policy Manual and Change Report, Clinical Diagnostic Laboratory Services*.

   Link: Clinical Diagnostic Laboratory NCD Manual under Medicare -Related Sites - General

2. The *Lab NCD Manual* contains a list of "Non-covered ICD-10-CM Codes for All Lab NCD Edits" that are never covered by Medicare for a diagnostic laboratory service. It is not clear whether the list applies to other NCDs or to laboratory tests not covered by an NCD. <*Lab NCD Manual*>

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III. Prior Authorization

A. For specified services, CMS requires a prior authorization as a condition of payment. The provider must submit a request for and receive a provisional affirmation of coverage for the specified service to be covered and paid. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61447, 85 *Fed. Reg.* 86236-248>

> Although CMS refers to this process as the "prior authorization" process in regulations and other guidance, they refer to the actual approval as a "provisional affirmation".

1. CMS has published a "Prior Authorization (PA) Program for Certain Hospital Outpatient Department (OPD) Services Operational Guide", referred to in this section as the Operational Guide, available on the CMS website.

> Link: Prior Authorization for Certain Hospital Outpatient Department Services – HCPCS Codes under Medicare -Related Sites - General

B. The prior authorization process only applies to services paid through Medicare Fee-for-Service and provided in hospital outpatient departments. <84 *Fed. Reg.* 61453>

C. The prior authorization process does not apply to:

1. Services provided outside a hospital outpatient department (e.g., ASC or physician office) <84 *Fed. Reg.* 61453>;

2. Services paid through a Medicare Advantage plan or Medicare Advantage IME only claims <84 *Fed. Reg.* 61453; Operational Guide, Section 9.2>;

3. Critical Access Hospital (CAH) outpatient departments <Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services, Frequently Asked Questions, Q12>;

4. Part A/B rebilling claims (presumably 12X with CCW2)<Operational Guide, Section 9.2>;

5. Emergency department claims with modifier ET or revenue code 45X <Operational Guide, Section 9.2>;

6. Part A and Part B Demonstration claims <Operational Guide, Section 9.2>; and

7. Veterans Affairs and Indian Health Services <Operational Guide, Section 9.5>.

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D. The list of CPT/HCPCS codes requiring prior authorization can be found in Appendix A of the Operational Guide and Table 103 of the CY2023 OPPS Final Rule, included in the materials behind the outline. <See Operational Guide, Appendix A, 87 *Fed. Reg.* 72230-233>

1. CMS finalized five categories of services requiring prior authorization, effective July 1, 2020:

   a. Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair;

      i. Effective January 7, 2022, CMS removed 67911 (Correction of lid retraction) from the list of applicable blepharoplasty codes.

   b. Rhinoplasty;

   c. Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy);

   d. Botulinum Toxin Injections;

      i. Prior authorization is only required when one of the listed Botulinum Toxin codes is billed with one of the listed injection codes. Botulinum Toxin billed with other procedure codes will not require prior authorization. <Operational Guide, Section 6.2.2>

   e. Vein ablation. <84 *Fed. Reg.* 61448, 42 *C.F.R.* 419.83(a)(1)>

2. CMS finalized two additional categories of services requiring prior authorization, effective July 1, 2021:

   a. Cervical Fusion with Disc Removal; and

   b. Implanted Spinal Neurostimulators. <85 *Fed. Reg.* 86246-248, 42 *C.F.R.* 419.83(a)(2)>

      i. In May 2021, CMS announced that two codes (63688 and 63685), which were finalized as requiring prior authorization July 1, 2021, were temporarily removed from the list, presumably because they can be used to code revision, removal, or replacement procedures. <Operational Guide, Appendix A>

      ii. If a trial and permanent implantation are performed, a PAR should be request for the trial and the Unique Tracking Number (UTN) for the trial should be reported for both the trial and permanent implantation. <Operational Guide, Section 6.3.2.2>

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3. CMS finalized one additional category of services requiring prior authorization, effective July 1, 2023:

    a. Facet Joint Interventions <87 *Fed. Reg.* 72230, 42 *C.F.R.* 419.83(a)(3)>

    b. The following were removed from the HOPD Prior Authorization List on August 16, 2024:

        i. CPT code 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)); and

        ii. CPT 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))

E. Prior Authorization Process

1. Responsibility for Obtaining Prior Authorization

    a. CMS has determined that the hospital is ultimately responsible for obtaining prior authorization as a condition of payment, although they allow for either physicians or hospitals to obtain the prior authorization. <84 *Fed. Reg.* 61453>

2. The provider must submit a prior authorization request (PAR) to the MAC before the service is provided to the beneficiary, including all documentation necessary to show the service meets all applicable Medicare coverage, coding and payment rules. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61454; Operational Guide, Section 3>

    a. The prior authorization Operational Guide provides general documentation requirements for each service requiring prior authorization and refers providers to their MAC's LCDs and LCAs for more detailed requirements. <Operational Guide, Section 6.2>

    b. For services requiring prior authorization that do not have specific NCDs or LCDs, contractors may make individual claim determinations to assess whether or not the services are reasonable and necessary. <84 *Fed. Reg.* 61459>

3. The MAC reviews the PAR, assigns a UTN and makes a provisional affirmation or non-affirmation decision and issues a decision to the provider within 7 calendar days . <Operational Guide, Section 4>

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a. Note: This was changed from 10 to 7 days for requests submitted on or after January 1, 2025.

4. A provider may request an expedited review, with a decision in 2 business days, if a delay in the service may jeopardize the beneficiary's life, health, or ability to regain maximum function. <See 42 *C.F.R.* 419.82; 84 *Fed. Reg.* 61454; Operational Guide, Section 4.2>

5. If the MAC makes a provisional affirmation decision, the MAC will issue a decision letter to the provider and the beneficiary. <Operational Guide, Section 4.3>

   a. A provisional affirmation is valid for 120 days from the date of the decision. <Operational Guide, Section 7.1>

   b. Claims receiving a provisional affirmation may later be denied based on technical requirements that can only be evaluated after the claim has been submitted or information not available at the time of the PAR. <84 Fed. Reg. 61447; Operational Guide, Section 8.1>

6. If the MAC makes a provisional non-affirmation decision, the MAC will provide detailed information about all missing or non-compliant information. <Operational Guide, Section 4; 84 Fed. Reg. 61461>

   a. The provider may resubmit the PAR with additional or updated documentation any number of times until a provisional affirmation is received. <Operational Guide, Section 4.1.2>

   b. A provisional non-affirmation is not an initial claim determination and cannot be appealed. <Operational Guide, Section 11>

   c. If the provider receives a non-affirmation and believes the service is not medically necessary, the provider should issue an Advanced Beneficiary Notice (ABN) to transfer liability to the patient for the non-covered service. <Operational Guide, 9.1>

      i. CMS also "encourages" providers to issue an ABN to the patient if the provider believes the service will be denied under the statutory exclusion for purely cosmetic services. <Operational Guide, 9.1>

F. Claims Submission

1. To be paid, the provider must submit a Unique Tracking Number (UTN) corresponding to a provisional affirmation on any claim submitted for a service requiring prior authorization. <84 *Fed. Reg.* 61453>

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a. For electronic claims, the UTN is submitted in positions 1-18 of the Treatment Authorization field and moved to positions 19-32 by the FISS for processing. For other claims, the provider tabs to the second field (positions 19-32) to enter the UTN. <Operational Guide, Section 8.1>

2. Claims for services requiring prior authorization submitted without a UTN or a UTN corresponding to a provisional non-affirmation will be automatically denied. <84 *Fed. Reg.* 61447; Operational Guide, Section 8.3>

   a. When a service that requires prior authorization is denied, CMS "intends" to deny claims for codes associated with or related to the service (e.g., anesthesiologist's or surgeon's services). <84 *Fed. Reg.* 61453, Operational Guide, Section 8.4.1>

      i. CMS published a list of codes associated with the services requiring prior authorization in Appendix B of the Operational Guide.

   b. The denial of a claim for lack of prior authorization (i.e., submitted without a UTN corresponding to a provisional affirmation) is considered an initial claim determination and may be appealed by the provider. <Operational Guide, Section 11>

      i. CMS has instructed MACs to review appealed claims to determine if a prior authorization request was submitted and deny payment if no prior authorization request was made due to the failure to comply with a mandatory condition of payment, even if the item or service is otherwise covered. <Prior Authorization Process for Certain Hospital Outpatient Department (OPD) Services, Frequently Asked Questions, Q28>

   c. If the provider issued an ABN to transfer liability to the patient, the claim should be submitted with modifier -GA if the provider believes the denial is based on medical necessity or modifier -GX if the provider believes the denial is based on the statutory exclusion for purely cosmetic services. <Operational Guide, Section 9.1>

      i. Claims for services requiring prior authorization reported with an ABN modifier will be stopped by the MAC for an additional documentation request and review of the validity of the ABN. <Operational Guide, Section 9.1>

   d. If the beneficiary has secondary insurance, including Medicaid, this process can be used to obtain a denial from Medicare for submission to secondary insurance. For more information see the Operational Guide, Section 10.1.

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G. Exemption from Prior Authorization

1. CMS may exempt a provider from the prior authorization process when a provider demonstrates compliance by achieving a 90% provisional affirmation rate with at least 10 submitted claims. <42 *C.F.R.* 419.83(c); 84 *Fed. Reg.* 61448; *Medicare Program Integrity Manual*, Chapter 3 § 3.10.2, Operational Guide, Section 5>

    a. The exemption applies for the full calendar year and applies to all services requiring prior authorization, regardless of whether they were part of the sample used to determine compliance and grant the exemption. <Operational Guide, Section 5.1>

    b. PARs submitted by exempt providers will be rejected. <Operational Guide, Section 5.1>

    c. Providers will receive a notification of continued exemption or withdrawal of exemption 60 days prior to the effective date, generally by November 1. <Operational Guide, Section 5.1; 42 *C.F.R.* 419.83(c)(2)>

        i. Providers may opt out of the exemption by submitting a request to their MAC no later than November 30. <Operational Guide, Section 5.1>

    d. Retaining exemption from the prior year:

        i. A provider with an exemption must have 10 claims submitted by June 30. The MAC will sample 10 claims beginning August 1. Providers must demonstrate a 90% claim approval rate on the 10-claim review to retain their exemption. <Operational Guide, Section 5.1>

        ii. Gaining exemption if not exempt in prior year: The MAC will calculate the affirmation rate of initial PARs beginning in January and notify providers in October if they have achieved the required 90% affirmation rate to qualify for an exemption for the following year. <Operational Guide, Section 5.1>

        iii. See the Operational Guide, Section 5.1 for details on timeframes and the process for exemption for calendar year 2024.

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Case Study 1

Facts: A Medicare patient is scheduled for a first diagnostic joint injection procedure described by HCPCS code 64635 (Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint) at a pain clinic that is an outpatient department of a PPS hospital.

The following documentation is in the pain clinic electronic record for the patient:

1. Pain clinic nursing assessment showing pain level 6/10.
2. Bilateral hip, sacroiliac (SI) joint, and lower back x-rays.
3. H&P signed by the pain clinic physician detailing the intended procedure, referencing x-rays, and referencing the nursing pain assessment.

Turn to the *LCD – Facet Joint Interventions for Pai Management L34892)* and *Article – Billing and Coding: Facet Joint Interventions for Pain Management (A56670)* in the materials behind the outline and review the requirements for coverage of the procedure. What additional documentation is needed to demonstrate coverage?

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IV. Medicare's Financial Liability Protections

A. The Limitation on Liability ("LOL") statute is a Medicare law designed to protect beneficiaries from unexpected personal liability for a non-covered service if they are unaware the service is not covered by Medicare. <*Medicare Claims Processing Manual*, Chapter 30 § 10>

The beneficiary may not be charged for a non-covered service if:

- The service is denied for a reason specified in the "LOL" statute; AND
- The beneficiary did not have advance notice Medicare would not pay for it.

B. Circumstances When Limitations on Liability Applies (and Advance Notice is Mandatory to Charge the Patient)

1. The item or service is not reasonable and necessary. <*Medicare Claims Processing Manual*, Chapter 30 §§ 20, 20.1>

   a. The item or service is not considered by Medicare to be medically necessary under the circumstances.

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b. The service is a preventative service that is usually covered but will not be covered in this instance because frequency limitations have been exceeded.

2. The service is custodial care. <*Medicare Claims Processing Manual*, Chapter 30 § 20.1>

3. The item or service is experimental (e.g., research use only or experimental use only laboratory tests). <*Medicare Claims Processing Manual*, Chapter 30 §§ 20.1 and 40.2.2>

C. Circumstances When Limitations on Liability Does Not Apply (and Advance Notice is Voluntary, Beneficiary May be Charged Without Notice)

1. Although ABNs are not required for services that are statutorily excluded from coverage or that fail to meet a technical benefit requirement, CMS "strongly encourages" providers to issue ABNs in these circumstances. <*Medicare Claims Processing Manual,* Chapter 30 § 50.2.1>

2. The LOL provisions do not apply to items or services that fail to meet a technical benefit requirement. <*Medicare Claims Processing Manual,* Chapter 30 § 20.2>

   a. "Technical denials" occur if coverage requirements for an item or service are not met or there is a failure to meet a condition of payment required by regulation. <*Medicare Claims Processing Manual*, Chapter 30 § 20.2>

   Example: Denial of a drug or biological because it is usually self-administered by the patient is considered a technical denial.

3. The LOL provisions do not apply to items or services that do not fit into a Medicare benefit (i.e., are statutorily excluded). <*Medicare Claims Processing Manual,* Chapter 30 § 20.2>

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4. "Categorical denials" occur when the denial is based on other statutory provisions not referenced in the LOL statute. <M*edicare Claims Processing Manual*, Chapter 30 §§ 20.1 and 20.2>

Items or services excluded from Medicare coverage include:

- Routine physicals and most screening tests, except the Initial Preventative Physical Exam and Annual Wellness Visit
- Most vaccinations, except flu, pneumococcal, hepatitis B, COVID 19
- Routine eye care, examinations and most eyeglasses
- Hearing aids and hearing examinations
- Dental care and dentures
- Routine foot care and flat foot care
- Orthopedic shoes and orthotic foot supports
- Cosmetic surgery and surgery performed for cosmetic purposes

V. Advance Beneficiary Notice (ABN)

A. General Rule

1. A properly prepared and delivered ABN form satisfies the Limitations on Liability notice requirement for outpatient services that are not considered reasonable and necessary or are custodial. <*Medicare Claims Processing Manual*, Chapter 30 §§ 20, 30, and 50>

B. The ABN Form

1. The Advance Beneficiary Notice (CMS-R-131 (Exp. 01/31/2026)), available in English, Spanish, and large print, is the required form for providing notice of non-coverage for outpatient services. Handout 6 is the ABN Form.

2. The ABN may not be modified except as specifically allowed in the completion instructions. <*Medicare Claims Processing Manual*, Chapter 30 § 50.5, C>

Link: Beneficiary Notice Initiative under Medicare-Related Sites – General
Use the links on the left navigation to go to the FFS ABN page.

C. Delivery of the ABN

1. The ABN should be delivered in person to the beneficiary, or their representative and the provider must answer all inquiries of the beneficiary, including the basis for the determination that the service is not covered. <*Medicare Claims Processing Manual*, Chapter 30 § 50.8, 50.8.1>

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a. If delivery in person is not possible, delivery may be by telephone, mail, secure fax, or email. <*Medicare Claims Processing Manual*, Chapter 30 § 50.8.1>

i. If notice is by telephone, a copy should be mailed, faxed or emailed to the beneficiary for them to sign and return to the provider. In order to be effective, the beneficiary must not dispute the contact. <*Medicare Claims Processing Manual*, Chapter 30 § 50.8.1>

2. Beneficiary Comprehension

a. An ABN will not be considered effective unless the beneficiary, or their authorized representative, comprehends the notice. <*Medicare Claims Processing Manual*, Chapter 30 § 50.8>

b. The only printed versions of the form allowed are the OMB approved English and Spanish versions, and insertions should be made in the language of the printed form. <*Medicare Claims Processing Manual,* Chapter 30 § 50.5, A>

c. Oral assistance should be provided for languages other than English and Spanish and documented in the "Additional Information" section. <*Medicare Claims Processing Manual*, Chapter 30 § 50.5, A>

3. Beneficiary Representative

a. If the patient is unable to comprehend the notice, notice must be provided to a known legal representative if the patient has one. < *Medicare Claims Processing Manual,* Chapter 30 § 50.3>

i. An authorized representative is an individual authorized under State or other applicable law to act on behalf of a beneficiary when the beneficiary is temporarily or permanently unable to act for themselves (e.g., a legally appointed representative or legal guardian). <*Medicare Claims Processing Manual,* Chapter 30 § 500>

ii. If the beneficiary does not have a representative, one may be appointed following CMS guidelines and as permitted by State and Local laws. <*Medicare Claims Processing Manual,* Chapter 30 § 50.3>

b. In states with health care consent statutes providing for health care decision making by surrogates for individuals who lack advance directives or guardians, it is permissible to rely on individuals designated under those statutes to act as authorized representatives. <*Medicare Claims Processing Manual,* Chapter 30 § 500>

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c. If a representative signs on behalf of the beneficiary, the name of the representative should be printed on the form and the signature should be annotated with “rep” or “representative”. <*Medicare Claims Processing Manual,* Chapter 30 § 50.3>

4. Timing of Delivery

a. The ABN must be provided far enough in advance of delivery of potentially non-covered items or services to allow the beneficiary time to consider all available options and make an informed decision without undue pressure. <*Medicare Claims Processing Manual*, Chapter 30 §§ 40.2.1, 50.8>

i. The ABN is not effective if it is provided during an emergency, the beneficiary is under great duress, or the beneficiary is coerced or misled by the notifier, the notice, or the manner of delivery. <*Medicare Claims Processing Manual,* Chapter 30 § 40.2>

b. A valid ABN remains effective as long as there has been no change in:

i. The care described on the original ABN;

ii. The beneficiary’s health status which would require a change in the treatment for the condition; and/or

iii. The Medicare coverage guidelines for the non-covered item or service (i.e., updates or changes to the coverage policy of the item or service). <*Medicare Claims Processing Manual,* Chapter 30 § 50.8, A>

c. For items or services that are repetitive or continuous, a new ABN may be issued after one year, however, it is not required unless a change has occurred making the ABN no longer effective. <*Medicare Claims Processing Manual,* Chapter 30 § 50.8, A>

Caution: *Medicare Claims Processing Manual,* Chapter 30 § 40.2 continues to state that notice is not effective if delivered more than a year before the item or service is provided. This section was published in 2019 and is presumably superseded by the above guidance published in 2021.

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5. Completion of the Form

   a. "Notifier(s)"

      i. If the notifier in the header is an entity other than the billing entity, the notifier should annotate the Additional Information section of the ABN with information for contacting the billing entity for questions. <*Medicare Claims Processing Manual*, Chapter 30 § 50.3>

Unless noted otherwise, information in this section is from the "Form Instructions, Advance Beneficiary Notice of Non-coverage (ABN), OMB Approval Number: 0938-0566" available on the FFS ABN webpage and included in the materials behind the outline.

      ii. If multiple entities are involved in rendering or billing for the care (e.g., one entity provides the technical component and another entity provides the professional component), separate ABNs are not necessary. <*Medicare Claims Processing Manual,* Chapter 30 § 50.3>

   b. "Blank D"

      i. The "Blank D" field is filled in with one of the following general categories as applicable: Item, Service, Laboratory Test, Test, Procedure, Care, Equipment. All "Blank D" fields must be filled in for the ABN to valid.

      ii. In the column under "Blank D", describe the specific item or service that is non-covered, including the frequency or duration of repetitive or continuous services. Items can be grouped, e.g., "wound care supplies" or "observation services" rather than listed individually.

   c. "Reason Medicare May Not Pay:"

      i. Explain the reason the item may not be covered by Medicare.

      ii. Simply stating "medically unnecessary" or the equivalent is not acceptable. <*Medicare Claims Processing Manual*, Chapter 30 § 40.2.1, C>

Tip: Be specific about the reason for denial, for example:
- "Medicare does not pay for custodial care, except for some hospice services"
- "Medicare does not pay for this test for your condition".

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d. "Estimated Cost"

i. Provide a good faith estimate of the cost of the non-covered services to the patient. The cost to the patient is the provider's usual and customary charge and is not limited by the Medicare allowable or payment amount.

> **Caution:** The final amount billed to the patient may be affected by state laws requiring providers to give uninsured patients a discount, including discounts based on financial need or equal to the discount given to their largest payer.

a) An estimate will be considered to be made in good faith if the estimate is within the greater of $100 or 25% of the cost of the service to the patient (i.e., amount billed to the patient) and may be given as a range or may exceed the final amount billed.

> Examples of good faith cost estimates for a service with a $1000 charge:
> - Any estimate greater than $750
> - Between $750 - $1100
> - No more than $1200

ii. Multiple services may be grouped together into a single cost estimate.

iii. An average daily cost estimate may be provided for complex projections (i.e., observation services).

iv. Unknown costs

a) The physician may not have a policy of routinely or frequently failing to provide a cost estimate, however, the patient may sign an ABN without a cost estimate in limited circumstances.

1) If additional services may be required (i.e. reflexive testing), the cost of the initial services should be given, along with a notation that additional services may be provided.

2) If the costs cannot be determined, make a notation in the cost estimate area that no cost estimate is available.

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e. "Options"

i. The beneficiary or their representative must check one of the options or have the provider check the option if they are unable to do so.

a) The provider should make a note on the ABN if they checked the option at the request of the beneficiary.

ii. If the beneficiary refuses to choose an option, the ABN should be annotated with the refusal and the annotation should be witnessed. <*Medicare Claims Processing Manual,* Chapter 30 § 40.2.2, B and 50.6, A.2.>

iii. Special Instructions for Dually Eligible Beneficiary

a) Dually eligible beneficiaries have both Medicare and Medicaid, including patients enrolled in a Qualified Medicare Beneficiary (QMB) Program.

b) For dually eligible beneficiaries, Option 1 must be modified by lining through certain language as designated in the "Form Instructions", included in the materials behind the outline. This is an exception to the general prohibition on modifying the ABN form.

c) Dually eligible beneficiaries should be instructed to choose Option 1 in order for the claim to be submitted for Medicare adjudication and, if denied, submitted to Medicaid for a determination.

1) If both Medicare and Medicaid deny coverage, refer to the "Form Instructions" or MLN Booklet *Dually Eligible Beneficiaries under Medicare and Medicaid*, available on the CMS website, for more information on potential beneficiary liability.

iv. If there are multiple items on the ABN and the beneficiary wants to select different options for each of the items, more than one ABN should be used to accommodate the beneficiary's choices.

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f. "Additional Information"

i. May be used for witness signatures or to make annotations, such as advising the beneficiary to notify their provider of tests or services that were ordered but not received. If items are added after the date of the ABN, they must be dated.

g. "Signature"

i. The beneficiary or their representative should sign and date the notice.

ii. If the beneficiary refuses to sign but still desires to receive the item or service, the ABN should be annotated with the refusal and the annotation should be witnessed. <*Medicare Claims Processing Manual,* Chapter 30 § 40.2.2, B and 50.6, A.2.>

6. Copy of the ABN

a. The physician practice should retain the original ABN and give a copy to the beneficiary. <*Medicare Claims Processing Manual*, Chapter 30 §§ 40.2.1 B and 50.5 C>

i. The ABN should be retained for 5 years, or longer as required by state law. <*Medicare Claims Processing Manual*, Chapter 30 § 50.7>

> **Caution:** The ABN should be retained even if the beneficiary refuses the service or refuses to sign or choose an option.

b. Carbon copies, fax copies, electronically scanned copies, and photocopies are all acceptable. <*Medicare Claims Processing Manual*, Chapter 30 §§ 40.2.1 B and 50.5 C>

VI. ABN Modifiers

A. Billing for Services For Which an ABN Was Given

1. The GA modifier should be reported in Item 24D of the claim for all services for which an ABN was properly given to the beneficiary. <Medicare Claims Processing Manual, Chapter 23 §20.9.1.1(E)(2)>

a. Effective January 1, 2011, the GA modifier definition was slightly revised to "Waiver of Liability Issued as Required by Payer Policy, individual case".

2. Effective April 1, 2010, modifier GX may be reported to identify those items or services for which a voluntary ABN was given. <MLN Matters MM6563>

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a. Modifier GX is defined "Notice of Liability Issued, Voluntary Under Payer Policy". <MLN Matters MM6563>

i. Modifier –GX may be reported with other liability modifiers, including modifier –GY. <Medicare Claims Processing Manual, Transmittal 1921>

B. Billing For Non-Covered Services (Other Than Services for Which an ABN was Given)

1. In certain circumstances, practitioners may find they need to submit a claim for services that are not covered by Medicare.

a. Examples of such circumstances include:

i. When a claim must be submitted to Medicare in order to obtain a Medicare Explanation of Benefits for submission to a supplemental insurer.

ii. Circumstances where the beneficiary specifically requests submission of a claim to Medicare.

2. The Compliance Issue

a. Whenever a physician/practitioner bills Medicare for services that the physician/practitioner believes to be non-covered, the physician/practitioner should make sure that the claim clearly indicates that the physician/practitioner is aware that the services are non-covered.

i. Otherwise, the government could take the position that the claim was a "false claim."

3. Indicating Non-Covered Services on a Claim

a. CMS developed two HCPCS Level II modifiers that may be used to indicate on a claim that a physician/practitioner believes a service is not covered by Medicare. <Medicare Claims Processing Manual, Chapter 23 §20.9.1.1(E)>

i. The GY Modifier

a) The GY modifier is defined as "Item or service statutorily excluded, does not meet the definition of any Medicare benefit."

b) By definition, the GY modifier is intended for use when non-coverage is due to a categorical denial. Although not clear, presumably, the GY modifier would also be appropriate when billing for non-covered services where non-coverage is due to a technical denial.

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1) CMS permits Contractors to auto-deny services billed with the GY modifier. <Medicare Claims Processing Manual, Chapter 23 §20.9.1.1(E)(5)>

c) While not entirely clear, the difference between the GY and the GX modifiers reporting on services that do not meet a Medicare benefit is whether the beneficiary was provided with a voluntary ABN.

ii. The GZ Modifier

a) The GZ modifier is defined as "Item or service expected to be denied as not reasonable and necessary."

b) The GZ modifier is intended to be used to indicate that a service is expected to be non-covered for lack of medical necessity, but for which no ABN was given. <Medicare Claims Processing Manual, Chapter 23 §20.9.1.1(E)(2)>

c) CMS will allow its contractors to generate an automatic denial for claims reporting the GZ modifier. <MLN Matters MM 7228>

C. Other Considerations for an Effective ABN

1. Interplay between the ABN and EMTALA requirements

a. EMTALA Requirements Take Priority over ABN Requirements

i. Under the Emergency Medical Treatment and Active Labor Act (EMTALA) hospitals have an obligation to complete a medical screening examination (MSE) and stabilize a patient presenting to its emergency department, or in certain circumstance, presenting to other areas of the hospital. <*Medicare Claims Processing Manual*, Chapter 30 § 40.4>

a) CMS and the OIG take the position that where EMTALA applies, it is improper to present an ABN to a patient before completing the MSE and stabilizing the patient. <*Medicare Claims Processing Manual*, Chapter 30 § 40.4>

b. Contractor's Medical Necessity Determinations for EMTALA required care

i. The MAC is required to make medical necessity determinations of EMTALA screening/stabilization services based on the "information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished". <Social Security Act § 1862 (d)>

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ii. The Intermediary should not apply frequency edits to EMTALA screening/stabilization services. <Social Security Act § 1862 (d)>

2. Medicare Advantage Plan Beneficiaries

   a. The ABN form may not be used for services provided under Medicare Advantage Plans. <*Medicare Claims Processes Manual*, Chapter 30 § 50.1>

3. Prohibition on Routine, Blanket, and Generic ABNs

   a. In general, "generic" ABNs (i.e., merely stating denial is possible"), "routine," ABNs (i.e., no specific reason Medicare will not pay), and "blanket" ABNs (i.e., given for all claims) will not be considered to be effective. <*Medicare Claims Processing Manual*, Chapter 30 § 40.2.2 C>

   Routine ABNs may be given for frequency limited service (e.g., screening mammography) if the ABN states the frequency limitation (e.g., "Medicare does not pay for this service more often than _____.")

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES

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Editor's note: This LCD was abbreviated for these materials. The full LCD with applicable jurisdictions and full Summary of Evidence is available in the Medicare Coverage Database.

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CMS National Coverage Policy

This LCD supplements but does not replace, modify or supersede existing Medicare applicable National Coverage Determinations (NCDs) or payment policy rules and regulations for FACET JOINT interventions for pain management. Federal statute and subsequent Medicare regulations regarding provision and payment for medical services are lengthy. They are not repeated in this LCD. Neither Medicare payment policy rules nor this LCD replace, modify or

supersede applicable state statutes regarding medical practice or other health practice professions acts, definitions and/or scopes of practice. All providers who report services for Medicare payment must fully understand and follow all existing laws, regulations and rules for Medicare payment for FACET JOINT interventions for pain management and must properly submit only valid claims for them. Please review and understand them and apply the medical necessity provisions in the policy within the context of the manual rules. Relevant CMS manual instructions and policies may be found in the following Internet-Only Manuals (IOMs) published on the CMS Web site:

IOM Citations:

- CMS IOM Publication 100-02, *Medicare Benefit Policy Manual*,
  - Chapter 15, Section 50 Drugs and Biologicals
- CMS IOM Publication 100-03, *Medicare National Coverage Determinations (NCD) Manual*, Chapter 1,
  - Part 1, Section 30.3 for Acupuncture
  - Part 2, Section 150.7 for Prolotherapy, Joint Sclerotherapy, and Ligamentous Injections with Sclerosing Agents
  - Part 4, Section 220.1 for Computed Tomography (CT)
- CMS IOM Publication 100-08, *Medicare Program Integrity Manual*,
  - Chapter 13, Section 13.5.4 Reasonable and Necessary Provision in an LCD

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1861(s)(2)(K), medical or surgical services provided by a physician, certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist;
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no Medicare payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1862(a)[14], which are other than physicians' services described by section 1861(s)(2)(K)
- Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations.

Code of Federal Regulations (CFR) References:

- CFR, Title 42, Volume 2, Chapter IV, Part 410.74 Physician assistants' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.75 Nurse practitioners' services.
- CFR, Title 42, Volume 2, Chapter IV, Part 410.76 Clinical nurse specialists' services.
- CFR, Title 42, Volume 3, Chapter IV, Part 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.
- FR, Volume 65, Number 68, Page 18543. April 7, 2000, non-physician providers services, as defined

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

The spine is the most common source of chronic pain. Chronic axial spinal pain is one of the major causes of

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disability and accounts for a substantial U.S. health burden. Chronic spine pain poses a peculiar diagnostic and therapeutic challenge due to multiple pain sources, overlapping clinical features, and nonspecific radiological findings.

The FACET JOINTs can cause axial spinal pain and referred pain in the extremities. The pathology of the pain source is due to FACET JOINTs being richly innervated by the nerve fibers from the medial branch of the dorsal ramus of spinal nerves. Each facet has a dual nerve supply. One exception is at the C2–C3 zygapophysial joint, which has a singular nerve supply from the third occipital nerve (the superficial medial branch of C3 dorsal ramus).[1]

FACET JOINT interventions may be used in pain management for chronic cervical/thoracic and back pain arising from the paravertebral FACET JOINTs. The facet block procedure is an injection of a local anesthetic, with or without a steroid medication, either into the FACET JOINT (intra-articular) or outside the joint space around the nerve supply to the joint (the medial branch nerve) known as medial branch block (MBB). Imaging guidance (fluoroscopy or CT per code descriptor) is used to assure accurate placement of the needle for the injection. Paravertebral FACET JOINT denervation is a therapeutic intervention used to provide both long-term pain relief and reduce the likelihood of recurrence of chronic cervical/thoracic or back pain confirmed as originating in the FACET JOINT's medial branch nerve.[1]

There are various methods that may be used in performing FACET JOINT denervation. Percutaneous radiofrequency ablation (RFA) is a minimally invasive procedure done with imaging guidance (fluoroscopy or CT per code descriptor) and involves using energy in the radiofrequency range to cause necrosis of specific nerves (medial branches of the dorsal rami), preventing the neural transmission of pain. Conventional radiofrequency ablation (non-pulsed or continuous) applies thermal energy of typically 80 to 85 degrees Celsius. The terms RFA and radiofrequency neurotomy are used interchangeably. Both terms refer to a procedure that destroys the functionality of the nerve using radiofrequency energy. Non-thermal methods of denervation include chemical (chemodenervation), low-grade thermal energy (less than 80 degrees Celsius), pulsed RFA, laser neurolysis, and cryoablation.[1]

Throughout this document, societal recommendations with the grading of evidence are referenced. There are multiple systems to grade or rank the quality of medical evidence and develop evidence-based recommendations. Not all grading systems are equivalent, so while there are typically similarities in the grades or recommendations from various grading systems, they must be considered independent of the other. The references in this document refer to the following grading systems.

1. GRADE Guidelines used in some systematic reviews, the basis for NASS recommendations align with GRADE.
2. A Modified approach to the grading of evidence[2] and development of interventional pain management specific instrument[3] used in American Society of Interventional Pain Physicians (ASIPP) Guidelines and some systematic reviews.
3. The U.S. Preventive Services Task Force grading of evidence guidelines used by 2020 Consensus Guidelines by Cohen et al[4].
4. Levels of Evidence for Primary Research Question and Grades of Recommendation for Summaries or Review of Studies adopted by North American Spine Society (NASS).[5]

A Multi-MAC Subject Matter Expert (SME) Panel on FACET JOINT and Medial Nerve Branch Procedures meeting was held on 5/28/2020.

Covered Indications

A. **FACET JOINT Interventions:**

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FACET JOINT Interventions generally consist of four types of procedures: Intraarticular (IA) FACET JOINT Injections, Medial Branch Blocks (MBB), Radiofrequency Ablations (RFA) and Facet cyst rupture/aspiration.

FACET JOINT Interventions are considered medically reasonable and necessary for the diagnosis and treatment of chronic pain in patients who meet **ALL** of the following criteria:

1. Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale[11]; **AND***
2. Pain that has been present for a minimum of 3 months with documented failure to respond to noninvasive conservative care management (as tolerated)[4,12]; **AND**
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by FACET JOINT synovial cyst)[4,7]; **AND**
4. There is no non-facet pathology per clinical assessment or radiology studies that could explain the source of the patient's pain, including but not limited to fracture, tumor, infection, or significant deformity.[11]

*Pain assessment must be performed and documented at baseline, after each diagnostic procedure using the same pain scale for each assessment. A disability scale must also be obtained at baseline to be used for functional assessment (if patient qualifies for treatment).

B. **Diagnostic FACET JOINT Injection Procedures (IA or MBB):**

The primary indication of a diagnostic FACET JOINT procedure is to diagnose whether the patient has facet syndrome.[1,4,7,12,16] Intraarticular (IA) facet block(s) are considered medically reasonable and necessary as a diagnostic test only if MBB cannot be performed due to specific documented anatomic restrictions or there is an indication to proceed with therapeutic intraarticular injections. These restrictions must be clearly documented in the medical record and made available upon request.

Diagnostic procedures should be performed with the intent that if successful, a RFA procedure would be considered the primary treatment goal at the diagnosed level(s).[11]

A second diagnostic facet procedure is considered medically reasonable and necessary to confirm validity of the initial diagnostic facet procedure when administered at the same level. The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure.[7]

1. An initial diagnostic FACET JOINT procedure will be considered medically reasonable and necessary when the patient meets the criteria outlined under the indications for FACET JOINT interventions.
2. A second confirmatory diagnostic FACET JOINT procedure is considered medically reasonable and necessary in patients who meet **BOTH** of the following criteria:
   - The patient meets the criteria for the first diagnostic procedure; **AND**
   - After the first diagnostic FACET JOINT procedure, there must be a consistent positive response of at least 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used).[11]

<u>Frequency limitation</u>: For each covered spinal region no more than four (4) diagnostic joint sessions will be considered medically reasonable and necessary per rolling 12 months, in recognition that the pain generator cannot always be identified with the initial and confirmatory diagnostic procedure.

C. **Therapeutic FACET JOINT Injection Procedures (IA):**

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Therapeutic FACET JOINT procedures are considered medically reasonable and necessary for patients who meet **ALL** of the following criteria:

1. The patient has had two (2) medically reasonable and necessary diagnostic FACET JOINT procedures with each one providing a consistent minimum of 80% relief of primary (index) pain (with the duration of relief being consistent with the agent used); **AND**
2. Subsequent therapeutic FACET JOINT procedures at the same anatomic site result in at least consistent 50% pain relief for at least three (3) months from the prior therapeutic procedure or at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale[11]; **AND**
3. Documentation of why the patient is not a candidate for radiofrequency ablation (such as established spinal pseudarthrosis, implanted electrical device) is in the medical record.[5,42,43,44]

Frequency limitation: For each covered spinal region no more than four (4) therapeutic FACET JOINT injection (IA) sessions will be reimbursed per rolling 12 months.

D. **FACET JOINT Denervation:**

An initial thermal RFA of cervical, thoracic, or lumbar paravertebral FACET JOINT (medial branch) nerves is considered medically reasonable and necessary for patients who have had at least two (2) medically reasonable and necessary diagnostic MBBs, with each one providing a consistent minimum of 80% sustained relief of primary (index) pain (with the duration of relief being consistent with the agent used).

Repeat thermal[11] FACET JOINT RFA at the same anatomic site is considered medically reasonable and necessary provided the patient had a minimum of consistent 50% improvement in pain for at least six (6) months **or** at least 50% consistent improvement in the ability to perform previously painful movements and ADLs as compared to baseline measurement using the same scale.

Frequency limitation: For each covered spinal region no more than two (2) radiofrequency sessions will be reimbursed per rolling 12 months.

E. **Facet Cyst Aspiration/Rupture**

Intra-articular FACET JOINT injection performed with synovial cyst aspiration is considered medically reasonable and necessary when **BOTH** of the following criteria are met:

1. Advanced diagnostic imaging study (e.g., MRI/CT/myelogram) confirm compression or displacement of the corresponding nerve root by a FACET JOINT synovial cyst; **AND**
2. Clinical and physical symptoms related to synovial facet cyst are documented in the medical record.

Frequency limitation: Cyst aspiration/rupture may be repeated once and only if there is 50% or more consistent improvement in pain for at least three (3) months.[11]

Limitations

1. FACET JOINT interventions done without CT or fluoroscopic guidance are considered not medically reasonable and necessary. This includes FACET JOINT interventions done without any guidance,

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performed under ultrasound guidance,[4,11] or with Magnetic Resonance Imaging (MRI).[4]

2. General anesthesia is considered not medically reasonable and necessary for FACET JOINT interventions. Neither conscious sedation nor Monitored Anesthesia Care (MAC) is routinely necessary for intraarticular FACET JOINT injections or medial branch blocks and are not routinely considered medically reasonable and necessary. Individual consideration may be given on redetermination (appeal) for payment in rare, unique circumstances if the medical necessity of sedation is unequivocal and clearly documented in the medical record. Frequent reporting of these services together may trigger focused medical review.[4]
3. It is not expected that patients will present with pain in both cervical/thoracic and lumbar spinal regions. Therefore, FACET JOINT interventions (both diagnostic and therapeutic) are limited to one spinal region per session.
4. It is not routinely necessary for multiple blocks (e.g., epidural injections, sympathetic blocks, trigger point injections, etc.) to be provided to a patient on the same day as FACET JOINT procedures. Multiple blocks on the same day could lead to improper or lack of diagnosis. If performed, the medical necessity of each injection (at the same or a different level[s]) must be clearly documented in the medical record. For example, the performance of both paravertebral FACET JOINT procedures and a transforaminal epidural steroid injection (TFESI) at the same or close spinal level at the same encounter would not be expected unless a synovial cyst is compressing the nerve root. In this situation, TFESI may provide relief for the radicular pain, while the facet cyst rupture allows nerve root decompression. Frequent reporting of multiple blocks on the same day may trigger a focused medical review.
5. FACET JOINT intraarticular injections and medial branch blocks may involve the use of anesthetic, corticosteroids, anti-inflammatories and/or contrast agents and do not include injections of biologicals or other substances not FDA designated for this use.
6. One to two levels, either unilateral or bilateral, are allowed per session per spine region. The need for a three or four-level procedure bilaterally may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. A session is a time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) that are performed during the same day.
7. If there is an extended period of time, two years or more, since the last RFA and/or there is a question as to the source of the recurrent pain then diagnostic procedures must be repeated.
8. Therapeutic intraarticular facet injections are not considered medically reasonable and necessary unless there is documentation explaining why RFA cannot be performed.[5,42,43,44]
9. FACET JOINT procedures in patients for the indication of generalized pain conditions (such as fibromyalgia) or chronic centralized pain syndromes are considered not medically reasonable and necessary. Individual consideration may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.[56]
10. In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

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The following are considered not medically reasonable and necessary:

1. Intraarticular and extraarticular FACET JOINT prolotherapy [5,42,43,44]
2. Non-thermal modalities for FACET JOINT denervation including chemical, low-grade thermal energy (less than 80 degrees Celsius), laser neurolysis, and cryoablation
3. Intra-facet implants[58]
4. FACET JOINT procedure performed after anterior lumbar interbody fusion (ALIF)
5. Definitive clinical and/or imaging findings pointing to a specific diagnosis other than FACET JOINT syndrome
6. Diagnostic injections or MBB at the same level as the previously successful RFA procedure

Notice: Services performed for any given diagnosis must meet all the indications and limitations stated in this LCD, the general requirements for medical necessity as stated in CMS payment policy manuals, any and all existing CMS

national coverage determinations, and all Medicare payment rules.

Provider Qualifications

Patient safety and quality of care mandate that healthcare professionals who perform facet injections/procedures are appropriately trained and/or credentialed by a formal residency/fellowship program and/or are certified by either an accredited and nationally recognized organization or by a post-graduate training course accredited by an established national accrediting body or accredited professional training program. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and kinetics as well as proficiency in diagnosis and management of disease, the technical performance of the procedure, and utilization of the required associated imaging modalities.

In addition to the above requirements, non-physician providers, such as certified nurse anesthetist, with certain exceptions, may certify, order and establish the plan of care as authorized by State law. (See Sections 1861[s][2] and 1862[a][14] of Title XVIII of the Social Security Act; 42 CFR, Sections 410.74, 410.75, 410.76 and 419.22; FR Vol. 65, No. 68 page18543, April 7, 2000). Each practitioner must provide only those services within the scope of practice for each state.

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Definitions

Acute Pain: The temporal definition of pain persisting for up to 4 weeks after the onset of the pain.

Axial: Relating to or situated in the central part of the body, in the head and trunk as distinguished from the limbs, e.g., axial skeleton.

Biopsychosocial Model: Interdisciplinary model that looks at the interconnection between biology, pathology and socioenvironmental factors.

Central Neuropathic Pain: Pain, which is causally related to a lesion or disease of the central somatosensory nerves.

Centralized Pain: A neurological chronic pain syndrome of the central nervous system (brain, brainstem, and spinal cord) which commonly presents with widespread generalized allodynia which is causally related to the increased responsiveness of nociceptive nerves in the central nervous system to the normal threshold or subthreshold simulation from the afferent nerves. The condition has also been called “central sensitization,” “central amplification,” and “central pain syndrome.” Fibromyalgia is considered one of the most common centralized pain syndromes.

Cervical Facet Pain: Pain located in the cervical spine, which may be characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Chronic Pain: The temporal definition of pain persisting for greater than or equal to 12 weeks after the onset of the pain.

Dual Diagnostic Blocks: The diagnostic technique of injecting the same spinal nerve on two separate occasions to be used as an efficacy comparison to increase diagnostic accuracy.

Epidural Steroid Injection: The administration via injection of steroid medicine into the potential epidural space in the spinal column to deliver steroids to the spinal nerves.

FACET JOINT Intraarticular Injections, Diagnostic: The placement of local anesthetic and possibly a corticosteroid into the FACET JOINT to diagnose FACET JOINT pain.

FACET JOINT Intraarticular Injections, Therapeutic: The placement of local anesthetic and possibly a corticosteroid into the FACET JOINT to produce the beneficial effect of pain reduction.

FACET JOINT: A diarthrodial joint in the spinal column (also called the zygapophysial joint or z-joint), producing the articulation of the posterior elements of one vertebra with its neighboring vertebra. There are bilateral superior and inferior articular surfaces at each spinal level. The terminology or nomenclature of the FACET JOINT is classified by the specific vertebrae level that forms it (e.g., C4-5 or L2-3). There are two (2) FACET JOINTs, right and left, at each spinal level.

Facet Injection: (also called facet block) A general term used to describe the injection of local anesthetic and possibly a corticosteroid in the FACET JOINT capsule or along the medial branch nerves supplying the FACET JOINTs.

FACET JOINT Denervation or Radiofrequency Ablation (RFA): A general term used to describe the minimally invasive procedure that uses thermal energy generated by the radiofrequency current to deprive the FACET JOINT of its nerve supply. The procedure is also known as a Medial Branch Radiofrequency Neurotomy (Ablation) because it is used to thermally remove the medial branch nerve by using electrical current to create thermal energy to coagulate the adjacent tissues around the targeted medial branch nerve.

FACET JOINT Syndrome: A set of concurrent signs or symptoms to describe FACET JOINT pain as the pain generator. The typical clinical signs or symptoms of a facet syndrome may include local paraspinal tenderness; pain that is brought about or increased on hyperextension, rotation, and lateral bending; low back stiffness; absence of neurologic deficit; absence of root tension signs (non-radiating below the knee, absence of paresthesia). Cervical facet pain is often characterized by chronic headaches, restricted motion, and axial neck pain, which may radiate sub-occipitally to the shoulders or mid-back.

Facet Level: Refers to the zygapophyseal joint or the two medial branch (MB) nerves that innervate that zygapophyseal joint. Each level has a pair of FACET JOINTs: one on the right side and one of the left side of the spine.

Intra-Articular Injection (IA): The injection of local anesthetic and possibly a corticosteroid into the FACET JOINT capsule.

Medial Branch: The dorsal ramus is the dorsal branch of a spinal nerve that forms from the dorsal root of the nerve after it emerges from the spinal cord.

Medial Branch Block (MBB): The placement of local anesthetic and possibly a corticosteroid near the medial branch nerve which supplies the sensory innervation to a specific FACET JOINT.

Neuropathic Pain: The pain which is caused by a lesion or disease of the somatosensory nerves.

Neurogenic Claudication: Intermittent leg pain from impingement of the nerves emanating from the spinal cord

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(also called pseuduoclaudication).

New Onset of Spinal Pain: The new onset of the spinal pain must be materially and significantly different in location, type, duration and character from the previously treated spine pain.

Noninvasive Conservative Management: The use of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, physical therapy, acupuncture (applies to only chronic low back pain), or spinal manipulation. This management should include the application of a biopsychosocial treatment technique.

Non-Radicular Back Pain: The radiating non-neuropathic pain which is not causally related to a spinal nerve root irritation and does not produce reproducible neuropathic symptoms in an objective dermatomal pattern.

Peripheral Neuropathic Pain: Pain, which is causally related to a lesion or disease of the peripheral somatosensory nerves.

Radicular Back Pain: The radiating neuropathic pain causally related to the spinal nerve root irritation which extends into the distal distribution, typically the lower extremity, producing neuropathic pain in a dermatomal pattern.

Radiculopathy: Radiating neuropathic pain causally related to the spinal nerve root irritation, which extends distal producing neuropathic pain in a dermatomal pattern.

Region: The segments of the back involved will be defined in this policy as two regions:

1. Cervical/Thoracic region = C1-C7/T1-T12
2. Lumbar/Sacral region = L1-L5/S1-S5

Session: A time period, which includes all procedures (i.e., MBB, IA, facet cyst ruptures, and RFA ablations) performed during one day.

Subacute Pain: The temporal definition of pain occurring during the 4-12-week time period.

Transforaminal Epidural Steroid Injection (TFESI): An epidural injection performed via a paramedian approach to enter the epidural space by placing the needle in the posterior-superior quadrant of the intervertebral foramen (neuroforamen) to inject near the dorsal root ganglion and exiting spinal nerve root (previously known as a selective nerve root block).

Summary of Evidence

<u>Diagnostic FACET JOINT Injections</u>

Due to the lack of reliable history, physical exam, or imaging to predict response, providers must rely on facet interventions diagnostic injections given for diagnostic purposes to determine if the FACET JOINT is the source of suspected spinal pain. There is controversy over optimal patient selection for diagnostic injections, which measures successful response and type and number of diagnostic injections performed.

Numerous investigations have been undertaken to correlate symptoms and physical exam findings with facet pathology and have concluded conventional clinical findings are unreliable in identifying FACET JOINT success.

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES

Article Information

General Information

Article ID
A56670

Article Title
Billing and Coding: FACET JOINT Interventions for Pain Management

Article Type
Billing and Coding

Original Effective Date
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04/25/2021

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N/A

Editor's Note:This LCA was abbreviated for these materials. The full LCA with applicable jurisdictions and full revision history is available in the Medicare Coverage Database.

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CMS National Coverage Policy

Internet-Only Manuals (IOMs)

- CMS IOM Publication 100-04, *Medicare Claims Processing Manual*,

- Chapter 12, Section 40.7 Claims for Bilateral Surgeries
- Chapter 13, Section 10.1 Billing Part B Radiology Services and Other Diagnostic Procedures, Section 20 Payment Conditions for Radiology Services, and Section 30 Computerized Axial Tomography (CT) Procedures

Social Security Act (Title XVIII) Standard References:

- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

Article Guidance

Article Text

This Billing and Coding Article provides billing and coding guidance for Local Coverage Determination (LCD) L34892, FACET JOINT Interventions for Pain Management. Please refer to the LCD for reasonable and necessary requirements.

Coding Guidance

Notice: It is not appropriate to bill Medicare for services that are not covered (as described by the entire LCD) as if they are covered. When billing for non-covered services, use the appropriate modifier.

Diagnostic and Therapeutic Procedures:

Each paravertebral facet level refers to either the FACET JOINT, also called the zygapophyseal joint **OR** the two medial branch nerves that innervate each zygapophyseal joint.

Each facet level has a pair of FACET JOINTs (one on the right side and one on the left side of the spine). Unilateral or bilateral facet interventions may be performed during the FACET JOINT procedure (a diagnostic nerve block, a therapeutic FACET JOINT [intraarticular] injection, or a medial branch block injection, in one session. A bilateral facet nerve intervention is still considered a single level intervention.

For paravertebral spinal nerves and branch injections, image guidance (fluoroscopy or CT) is required for the performance of CPT codes 64490, 64491, 64493, and 64494 with any injection contrast, which is an included component of the code.

As defined by the Current Procedural Terminology (CPT) Professional edition code book, there are two distinct anatomic spinal regions for paravertebral facet injections: cervical /thoracic (codes 64490, 64491) and lumbar/sacral (codes 64493, 64494).

For each initial, single level injection, diagnostic or therapeutic, performed with image guidance (fluoroscopy or CT), use code 64490 (cervical or thoracic) or code 64493 (lumbar or sacral).

For any additional diagnostic or therapeutic procedures on the same day, use add-on codes 64491 (cervical/thoracic) or 64494 (lumbar/sacral) to report second level injections performed with image guidance (fluoroscopy or CT) in addition to the primary procedure codes 64490 or 64493.

Note: Each unilateral or bilateral intervention at any level should be reported as one unit of service (UOS).

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If an initial (64490 or 64493) or second level add-on (64491 or 64494) paravertebral facet injection procedure is performed bilaterally, report the procedure with modifier -50 as a single line item using one UOS. Do not use modifier RT or LT when performing these procedures bilaterally (modifier -50).

For services performed in the Ambulatory Surgical Center (ASC), do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.

When an intraarticular FACET JOINT injection is used for facet cyst aspiration/rupture, it should be reported with CPT code 64999. Providers are required to indicate in block 19 of the 1500 claim form or the EMC Equivalent the date of the initial injection procedure and if the injection procedure is being repeated.

For CPT codes 64492 and 64495, the need for a three-level procedure may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal.

KX modifier requirements:

The KX modifier should be appended to the line for all diagnostic injections. In most cases the KX modifier will only be used for the two initial diagnostic injections. If the initial diagnostic injections do not produce a positive response as defined by the LCD and are not indicative of identification of the pain generator, and it is necessary to perform additional diagnostic injections, at a different level, append the KX modifier to the line. Aberrant use of the KX modifier may trigger focused medical review.

Neurolytic Destruction Procedures (Radiofrequency Ablation):

For destruction of paravertebral FACET JOINT medial branch nerves, image guidance and localization (fluoroscopy or CT) are required and inclusive in codes 64633, 64634, 64635, and 64636.

Per the current CPT Professional edition code book, codes 64633, 64634, 64635, and 64636 are reported per joint, not per nerve. Although two nerves innervate each FACET JOINT, only one unit per code may be reported for each joint denervated, regardless of the number of nerves treated. There are two distinct anatomic spinal regions for paravertebral facet destruction: cervical/thoracic (codes 64633, 64634) and lumbar/sacral (codes 64635, 64636). For each initial, single level thermal radiofrequency destruction performed with image guidance (fluoroscopy or CT), use code 64633 (cervical or thoracic) or code 64635 (lumbar or sacral).

For any additional thermal radiofrequency destruction performed on the same day, use add-on codes 64634 (cervical/thoracic) or 64636 (lumbar/sacral) in addition to the primary procedure codes 64633 or 64635.

Note: Each unilateral or bilateral intervention at any level should be reported as one UOS.

If initial (64633 or 64635) or each additional add-on (64634 or 64636) paravertebral neurolytic destruction procedure is performed bilaterally, report the procedure with modifier -50 as a single line item using one UOS. Do not use modifier RT or LT when performing these services bilaterally (modifier -50).

For services performed in the Ambulatory Surgical Center (ASC), do not use modifier 50. Report the applicable procedure code on two separate lines, with one unit each and append the -RT and -LT modifiers to each line.

Non-thermal FACET JOINT denervation (including chemical, low grade thermal energy [<80 degrees Celsius] or any other form of pulsed radiofrequency) should not be reported with CPT codes 64633, 64634, 64635 or 64636. These services should be reported with CPT code 64999.

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Note: Report CPT code 64999 when facet cyst aspiration/rupture is performed.

Note: CPT code 64999 is non covered when used to report non thermal FACET JOINT denervation including chemical, low grade thermal energy (less than 80 degrees Celsius) or any form of pulsed radiofrequency.

Note: When reporting CPT code 64999 ensure that the description of the service is included on the claim.

If FACET JOINTs are injected with biologicals or other substances not designated for this use the entire claim may deny per CMS IOM *Medicare Benefit Policy Manual*, Chapter 16, Section 180-Services Related to and Required as a Result of Services Which Are Not Covered Under Medicare.

Utilization Parameters

Note: A session is defined as all procedures (i.e., MBB, IA, facet cyst ruptures, and destruction by a neurolytic agent (e.g., RFA) performed on the same date of service.

CPT codes 64490 through 64494 will be limited to no more than four (4) sessions, per region, per rolling 12 months.

CPT code 64490 through 64494 with the KX modifier will be limited to no more than four (4) sessions, per region, per rolling 12 months.

CPT codes 64633 through 64636 will be limited to no more than two (2) sessions, per region, per rolling 12 months.

Consistent with the LCD, CPT code 64999 may only be reported twice for an intraarticular FACET JOINT injection for a facet cyst aspiration/rupture.

Documentation Requirements

1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.
2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.
3. The submitted medical record must support the use of the selected ICD-10-CM code(s). The submitted CPT/HCPCS code must describe the service performed.
4. The medical record must include the assessment of the patient by the performing provider as it relates to the complaint of the patient for that visit, relevant medical history, and the results of any pertinent tests/procedures.
5. Documentation of why the patient is not a candidate for radiofrequency ablation (RFA) must be submitted for therapeutic injection procedures.
6. The scales used to assess the measurement of pain and/or disability must be documented in the medical record. Acceptable scales include but are not limited to: verbal rating scales, Numerical Rating Scale (NRS), Visual Analog Scale (VAS) for pain assessment, Pain Disability Assessment Scale (PDAS), Oswestry Disability Index (ODI), Oswestry Low Back Pain Disability Questionnaire (OLBPDQ), Quebec Back Pain Disability Score (QBPDS), Roland Morris Pain Scale, Back Pain Functional Scale (BPFS), and the Patient-Reported Outcomes Measurement Information System (PROMIS) profile domains to assess function.

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Coding Information

CPT/HCPCS Codes

Group 1 Paragraph:

Providers are reminded to refer to the long descriptors of the CPT codes in their CPT book.

Note: Report CPT code **64999** when facet cyst aspiration/rupture is performed.

The following CPT codes need to be listed separately in addition to a code for the primary procedure: **64491, 64494, 64634,** and **64636**.

Group 1 Codes: (9 Codes)

CODE	DESCRIPTION
64490	Inj paravert f jnt c/t 1 lev
64491	Inj paravert f jnt c/t 2 lev
64493	Inj paravert f jnt l/s 1 lev
64494	Inj paravert f jnt l/s 2 lev
64633	Destroy cerv/thor facet jnt
64634	Destroy c/th facet jnt addl
64635	Destroy lumb/sac facet jnt
64636	Destroy l/s facet jnt addl
64999	Nervous system surgery

Group 2 Paragraph:

Note: CPT code **64999** is non-covered when used to report non-thermal facet joint denervation including chemical, low grade thermal energy (less than 80 degrees Celsius), or any form of pulsed radiofrequency.

The following CPT/HCPCS codes do not support medical necessity and will not be covered by Medicare.

Group 2 Codes: (13 Codes)

CODE	DESCRIPTION
64492	Inj paravert f jnt c/t 3 lev
64495	Inj paravert f jnt l/s 3 lev
64999	Nervous system surgery
0213T	Njx paravert w/us cer/thor
0214T	Njx paravert w/us cer/thor
0215T	Njx paravert w/us cer/thor
0216T	Njx paravert w/us lumb/sac
0217T	Njx paravert w/us lumb/sac

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CODE	DESCRIPTION
0218T	Njx paravert w/us lumb/sac
0219T	Plmt post facet implt cerv
0220T	Plmt post facet implt thor
0221T	Plmt post facet implt lumb
0222T	Plmt post facet implt addl

CPT/HCPCS Modifiers

Group 1 Paragraph:

N/A

Group 1 Codes: (4 Codes)

CODE	DESCRIPTION
50	BILATERAL PROCEDURE: UNLESS OTHERWISE IDENTIFIED IN THE LISTINGS, BILATERAL PROCEDURES THAT ARE PERFORMED AT THE SAME OPERATIVE SESSION SHOULD BE IDENTIFIED BY ADDING THE MODIFIER -50 TO THE APPROPRIATE FIVE DIGIT CODE OR BY USE OF THE SEPARATE FIVE DIGIT MODIFIER CODE 09950
KX	REQUIREMENTS SPECIFIED IN THE MEDICAL POLICY HAVE BEEN MET
LT	LEFT SIDE (USED TO IDENTIFY PROCEDURES PERFORMED ON THE LEFT SIDE OF THE BODY)
RT	RIGHT SIDE (USED TO IDENTIFY PROCEDURES PERFORMED ON THE RIGHT SIDE OF THE BODY)

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ICD-10-CM Codes that Support Medical Necessity

Group 1 Paragraph:

It is the provider's responsibility to select codes carried out to the highest level of specificity and selected from the ICD-10-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

The following ICD-10-CM codes support medical necessity and provide coverage for CPT codes: **64490, 64491, 64493, 64494, 64633, 64634, 64635, 64636,** and **64999** (facet cyst aspiration/rupture).

Note: ICD-10 Codes **M71.30** or **M71.38** is allowed for facet cyst rupture procedures only.

Group 1 Codes: (20 Codes)

CODE	DESCRIPTION
M47.812	Spondylosis without myelopathy or radiculopathy, cervical region

CODE	DESCRIPTION
M47.813	Spondylosis without myelopathy or radiculopathy, cervicothoracic region
M47.814	Spondylosis without myelopathy or radiculopathy, thoracic region
M47.815	Spondylosis without myelopathy or radiculopathy, thoracolumbar region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.892	Other spondylosis, cervical region
M47.893	Other spondylosis, cervicothoracic region
M47.894	Other spondylosis, thoracic region
M47.895	Other spondylosis, thoracolumbar region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M48.12	Ankylosing hyperostosis [Forestier], cervical region
M48.13	Ankylosing hyperostosis [Forestier], cervicothoracic region
M48.14	Ankylosing hyperostosis [Forestier], thoracic region
M48.15	Ankylosing hyperostosis [Forestier], thoracolumbar region
M48.16	Ankylosing hyperostosis [Forestier], lumbar region
M48.17	Ankylosing hyperostosis [Forestier], lumbosacral region
M71.30	Other bursal cyst, unspecified site
M71.38	Other bursal cyst, other site

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ICD-10-CM Codes that DO NOT Support Medical Necessity

Group 1 Paragraph:

All those not listed under the "ICD-10 Codes that Support Medical Necessity" section of this article.

Group 1 Codes: (1 Code)

CODE	DESCRIPTION
XX000	Not Applicable

ICD-10-PCS Codes

N/A

Additional ICD-10 Information

N/A

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Bill Type Codes

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article should be assumed to apply equally to all claims.

CODE	DESCRIPTION
999x	Not Applicable

Revenue Codes

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the article, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the article should be assumed to apply equally to all Revenue Codes.

CODE	DESCRIPTION
99999	Not Applicable

Other Coding Information

N/A

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Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/25/2021	R4	Article revised and published on 05/27/2021 effective for dates of service on and after 04/25/2021. The "Diagnostic and Therapeutic Procedures:" and Neurolytic Destruction Procedures (Radiofrequency Ablation):" sections of the article were revised to clarify coding guidance for the add-on CPT codes 64491/64494 (second level) and 64634/ 64636 (each additional) when billing bilaterally. Also, the "Internet-Only Manuals" section of the article was updated to include Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 12, Section 40.7 Claims for Bilateral Surgeries.
04/25/2021	R3	Article revised and published on 04/22/2021 effective for dates of service on and after 04/25/2021. This revision was to add clarifying language to the paragraph under the "KX modifier requirements:" section of the Article. Also, minor formatting change made

the efficiency of our prior authorization processes, increase provider willingness to submit requests electronically, reduce provider burden, decrease delays in patient care, and promote high-quality, affordable health care.

In sum, we continue to believe prior authorization is an effective mechanism to ensure Medicare beneficiaries receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in volume by virtue of improper payments without adding onerous new documentation requirements. A broad program integrity strategy must use a variety of tools to best account for potential fraud, waste, and abuse, including unnecessary increases in volume. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in the volume of these services and expect that it will reduce the instances in which Medicare pays for services that are determined not to be medically necessary.

After consideration of the public comments we received, we are finalizing our proposal to add the Facet joint interventions service category to the list of hospital outpatient department services requiring prior authorization with modification. In particular, we are finalizing an implementation date for prior authorization for the Facet joint interventions service category of July 1, 2023, rather than the March 1, 2023 implementation date we proposed and making this change in the proposed regulation text at § 419.83(a)(3). Other than this change in the implementation date, we are finalizing the proposed regulation text changes as proposed.

BILLING CODE 4120–01–P

TABLE 103: FINAL LIST OF OUTPATIENT DEPARTMENT SERVICES THAT REQUIRE PRIOR AUTHORIZATION

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[330]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit

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Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk
Code	(iv) Rhinoplasty, and related services[331]
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites

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36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites
Beginning for service dates on or after July 1, 2021	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators[332]
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 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

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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

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XXI. Overall Hospital Quality Star Rating

A. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information based on publicly available quality measure results reported through CMS programs in a way that is simple and easy for patients to understand, by assigning hospitals between one and five stars (85 FR 86193). The Overall Hospital Quality Star Rating was first introduced and reported on our Hospital Compare website in July 2016 [333] (now reported on its successor website at *https://www.medicare.gov/care-compare* and referred to as Care Compare) and has been refreshed multiple times, with the most current refresh planned for 2022.[334] [335] [336] [337] [338] [339] [340] In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86182), we finalized a methodology to calculate the Overall Hospital Quality Star Rating. We refer readers to section XVI (Overall Hospital Quality Star Rating Methodology for Public Release in CY 2021 and Subsequent Years) of the CY 2021 OPPS/ASC final rule with comment period and 42 CFR 412.190 for details.

In the CY 2023 OPPS/ASC proposed rule (87 FR 44807–44809), we: (1) provided information on the previously finalized policy for inclusion of quality measure data from Veterans Health Administration (VHA) hospitals; (2) proposed to amend the language of § 412.190(c) to state that we would use publicly available measure results on Hospital Compare or its successor websites from a quarter within the prior twelve months; and (3) conveyed that although CMS intends to publish Overall Hospital Quality Star Ratings in 2023, we may apply the suppression policy if applicable.

B. Veterans Health Administration Hospitals

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86197 and 86198), we finalized a policy to include Veterans Health Administration hospitals' (VHA hospitals) quality measure data for the purpose of calculating the Overall Hospital Quality Star Ratings beginning with the 2023 refresh. In that final rule, we also stated that we intended to provide more information about the statistical impact of adding VHA hospitals to the Overall Star Rating and discuss procedural aspects in a future rule (85 FR 48999). Since the publication of the CY 2021 OPPS/ASC final rule, we conducted an internal analysis from February 28, 2022, through March 30, 2022, with measure data from all VHA hospitals in the calculation of the Overall Hospital Quality Star Ratings methodology. The internal analysis included a period of confidential reporting and feedback during which VHA hospitals reviewed their Overall Hospital Quality Star Ratings internal analysis results, and in addition, further familiarized themselves with the Overall Hospital Quality Star Ratings methodology and had the opportunity to ask questions. All VHA hospitals were made aware of the internal analysis and were provided the opportunity to participate. For the internal analysis, the Overall Hospital Quality Star Ratings were calculated using VHA hospital measure data along with subsection (d) hospitals and CAHs. The internal analysis included the same measures used for the April 2021 refresh of Overall Hospital Quality Star Ratings on our public reporting website, Care Compare. At the time of the 2022 VHA internal analysis, VHA hospitals in each peer group reported a similar number of measures when compared to non-VHA hospitals for most measure groups. VHA hospitals in the five-measure group peer group reported a lower median number of Safety and Readmission measures. VHA hospitals in all three peer groups reported fewer measures in the Timely and Effective Care measure group. The measurement periods for VHA and non-VHA hospitals were the same, except for the HAI–1, HAI–2, PSI 04, PSI 90, and OP–22 measures. The specific performance periods for these measures were provided to VHA hospitals during the internal analysis. The reasons for the differing measure reporting periods are:

- The HAI–1 and HAI–2 measures were first publicly reported for VHA hospitals in July 2021, but only included one quarter of measure data. Therefore, we chose to use the next public reporting, April 2022, which included four quarters of these measures' data.
- For the PSI 04 and PSI 90 measures, we used measure data that were publicly reported in July 2021. VHA hospitals first publicly reported these measures in October 2020; however, a different software was used for the measure calculations than the software used to calculate subsection (d) hospitals and CAHs measure data. We

[330] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

[331] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

[332] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule comment period.

[333] Centers for Medicare & Medicaid Services. (2016, July 27). First Release of the Overall Hospital Quality Star Rating on Hospital Compare. Retrieved from *CMS.gov* newsroom at: *https://www.cms.gov//newsroom//fact-sheets//first-release-overall-hospital-quality-star-rating-hospital-compare.*

[334] Centers for Medicare & Medicaid Services. (2016, May). Overall Hospital Quality Star Rating on Hospital Compare: July 2016 Updates and Specifications Report.

[335] Centers for Medicare & Medicaid Services. (2016, October). Overall Hospital Quality Star Rating on Hospital Compare: December 2016 Updates and Specifications Report.

[336] Centers for Medicare & Medicaid Services. (2017, October). Overall Hospital Quality Star Rating on Hospital Compare: July 2017 Updates and Specifications Report.

[337] Centers for Medicare & Medicaid Services. (2019, November 4). Overall Hospital Quality Star Rating on Hospital Compare: January 2020 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[338] Centers for Medicare & Medicaid Services. (2018, November 30). Overall Hospital Quality Star Rating on Hospital Compare: February 2019 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

[339] Centers for Medicare & Medicaid Services. (2017, November). Star Methodology Enhancement for December 2017 Public Release. Retrieved from *www.qualitynet.org*: *https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources.*

[340] Centers for Medicare & Medicaid Services. (2022, May 17). Overall Hospital Quality Star Rating on Hospital Compare: July 2022 Updates and Specifications Report. Retrieved from *qualitynet.org: https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2.*

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2. Whether the beneficiary and/or the healthcare provider or supplier knew or could reasonably have been expected to know that the item or service was not covered.

Knowledge of the Non-covered Item/Service	Liability	Payment Responsibility
If the beneficiary knew, or should have known (e.g. a valid liability notice such as an ABN, Form CMS-R-131 was issued and the beneficiary consented to receiving the item or service).	Rests with the beneficiary	The beneficiary is responsible for making payment for the usual and customary charges to the healthcare provider or supplier for the denied item and/or service.
If the beneficiary did not know (and should not have known), and the healthcare provider or supplier knew, or should have known.	Rests with the healthcare provider or supplier	The beneficiary may not be charged for any costs related to the denied item and/or service, including copayments and deductibles.
If neither the beneficiary nor the healthcare provider or supplier knew, and could not reasonably be expected to have known.	Neither the beneficiary or the healthcare provider or supplier	The Medicare program makes payment for the assigned claim.

20.1 - LOL Coverage Denials (Rev. 1, 10-01-03)

(Rev.:4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

A. Statutory Basis

The following table provides examples of denials based on §1862(a)(1), §1862(a)(9), §1879(e), or §1879(g) of the Act:

Statutory Provision (section of the Act)	Description
§1862(a)(1)(A)	Items and services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.
§1862(a)(1)(B) & §1861(s)(10)	Pneumococcal vaccine and its administration, influenza vaccine and its administration, and hepatitis B vaccine and its administration furnished to an individual at high or intermediate risk of contracting hepatitis B, that are not reasonable and necessary for the prevention of illness.
§1862(a)(1)(C)	In the case of hospice care, items and services that are not reasonable and necessary for the palliation or management of terminal illness.

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Statutory Provision (section of the Act)	Description
§1862(a)(1)(E)	Items and services that, in the case of research conducted pursuant to §1142 of the Act, are not reasonable and necessary to carry out the purposes of that section (which concerns research on outcomes of health care services and procedures).
§1862(a)(1)(F)	Screening mammography that is performed more frequently than is covered under §1834(c)(2) of the Act or that is not conducted by a facility described in §1834(c)(1)(B) of the Act and screening pap smears and screening pelvic exams performed more frequently than is provided for under §1861(nn) of the Act.
§1862(a)(1)(F)	Screening for glaucoma, which is performed more frequently than is provided under §1861(uu) of the Act.
§1862(a)(1)(G)	Prostate cancer screening tests (as defined in §1861(oo) of the Act), which are performed more frequently than is covered under such section.
§1862(a)(1)(H)	Colorectal cancer screening tests, which are performed more frequently than is covered under §1834(d) of the Act.
§1862(a)(1)(I)	The frequency and duration of home health services which are in excess of normative guidelines that the Secretary shall establish by regulation.
§1862(a)(1)(J)	Drugs or biologicals specified in §1847A(c)(6)(C) of the Act, for which payment is made under part B, furnished in a competitive area under §1847B of the Act, but not furnished by an entity under a contract under §1847(B) of the Act.
§1862(a)(1)(K)	An initial preventive physical examination, which is performed more than 1 year after the date the individual's first coverage period begins under Medicare Part B.
§1862(a)(1)(L)	Cardiovascular screening blood tests (as defined in §1861(xx)(1) of the Act), which are performed more frequently than is covered under §1861(xx)(2).
§1862(a)(1)(M)	A diabetes screening test (as defined in §1861(yy)(1) of the Act), which is performed more frequently than is covered under §1861(yy)(3) of the Act.
§1862(a)(1)(N)	An ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under §1861(s)(2)(AA) of the Act.
§1862(a)(1)(O)	Kidney disease education services (as defined in §1861(ggg)(1) of the Act) which are furnished in excess of the number of sessions covered under §1861(ggg)(4) of the Act.
§1861(dd)(3)(A)	Hospice care determined to be non-covered because the beneficiary was not "terminally ill," as referenced by §1879(g)(2) of the Act since the Balanced Budget Act of 1997.
§1862(a)(1)(O)	Personalized prevention plan services (as defined in § 1861 (hhh)(1) of the Act), which are performed more frequently than is covered under such section.

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Statutory Provision (section of the Act)	Description
§1814(a)(2)(C) & §1835(a)(2)(A) on or after July 1, 1987 §1879(g)(1) before December 31, 1995	Home health services determined to be non-covered because the beneficiary was not "homebound" or did not require "intermittent" skilled nursing care.
§1879(e)	Inpatient hospital services or extended care services if payment is denied solely because of an unintentional, inadvertent, or erroneous action that resulted in the beneficiary's transfer from a certified bed (one that does not meet the requirements of §1861(e) or (j) of the Act) in a skilled nursing facility (SNF) or hospital.
§1862(a)(9)	Custodial care, unless otherwise permitted under paragraph §1862(a)(1)(C) of the Act.

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20.2 - Denials When the LOL Provision Does Not Apply

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Type of Denial	Description	Example(s)
Categorical	Categorical Denials are circumstances in which the LOL provision does not apply because the Medicare payment denial is based on a statutory provision not referenced in §1879 of the Act. Refer to §1862(a) of the Act for a complete listing.	• Personal comfort items (§1862(a)(6) of the Act). • Routine physicals and most screening tests (§1862(a)(7) of the Act). • Most immunizations (vaccinations) (§1862(a)(7) of the Act). • Routine eye care, most eyeglasses and examinations (§1862(a)(7) of the Act). • Hearing aids and hearing aid examinations (§1862(a)(7) of the Act). • Cosmetic surgery (§1862(a)(10) of the Act). • Orthopedic shoes and foot supports (orthotics) (§1862(a)(8) of the Act).

Type of Denial	Description	Example(s)
		NOTE: §22.1 of this chapter provides a more expansive list of examples.
Technical	When coverage requirements are not met for a particular item or service, it is not a Medicare benefit; therefore, Medicare denies payment or when payment for a medically unreasonable or unnecessary item or service that is also barred because of failure to meet a condition of payment required by regulations.	• Payment for the additional cost of a private room in a hospital or SNF is denied when the private accommodations are not required for medical reasons (§1861(v)(2) of the Act). • Payment for a dressing is denied because it does not meet the definition for "surgical dressings" (§1861(s)(5) of the Act). • Payment for SNF stays not preceded by the required 3-day hospital stay or Payment for SNF stay because the beneficiary did not meet the requirement for transfer to a SNF and for receiving covered services within 30 days after discharge from the hospital and because the special requirements for extension of the 30 days were not met (§1861(i) of the Act). • Drugs and biologicals which are usually self-administered by the patient. • Ambulance services denied because transportation by other means is not contraindicated or because regulatory criteria specified in 42 CFR 410.40, such as those relating to destination or nearest appropriate facility, are not met. (See the Medicare Benefit Policy Manual, Chapter 10) • Other items or services that must be denied under 42 CFR 410.12 through 410.105 of the Medicare regulations.

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20.2.1 - Categorical Denials

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

Below is a more expansive list of examples of categorical denials:

Statutory Provision (section of the Act)	Description
§1862(a)(12)	Dental care and dentures (in most cases).
§1862(a)(13)	Routine foot care and flat foot care.
§1862(a)(19)	Services under a physician's private contract.
§1862(a)(3)	Services paid for by a governmental entity that is not Medicare.
§1862(a)(4)	Health care received outside of the U. S. not covered by Medicare.
§1862(a)(11)	Services by immediate relatives.
§1862(a)(5)	Services required as a result of war.
§1862(a)(2)	Services for which there is no legal obligation to pay.
§1862(a)(21)	Home health services furnished under a plan of care, if the agency does not submit the claim.
§1862(a)(16)	Items and services excluded under the Assisted Suicide Funding Restriction Act of 1997.
§1862(a)(17)	Items or services furnished in a competitive acquisition area by any entity that does not have a contract with the Department of Health and Human Services (except in a case of urgent need).
§1862(a)(14)	Physicians' services performed by a physician assistant, midwife, psychologist, or nurse anesthetist, when furnished to an inpatient, unless they are furnished under arrangement with the hospital.
§1862(a)(18)	Items and services furnished to an individual who is a resident of a skilled nursing facility or of a part of a facility that includes a skilled nursing facility, unless they are furnished under arrangements by the skilled nursing facility.
§1862(a)(15)	Services of an assistant at surgery without prior approval from the peer review organization.
§1862(a)(20)	Outpatient occupational and physical therapy services furnished incident to a physician's services.
§1862(a)(22)	Claims submitted other than in an electronic form specified by the Secretary, subject to the exceptions set forth in §1862(h) of the Act.

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Statutory Provision (section of the Act)	Description
§1862(a)(23)	Claims for the technical component of advanced diagnostic imaging services described in §1834(e)(1)(B) of the Act for which payment is made under the fee schedule established under §1848(b) of the Act and that are furnished by a supplier (as defined in §1861(d) of the Act), if such supplier is not accredited by an accreditation organization designated by the Secretary under §1834(e)(2)(B) of the Act.
§1862(a)(24)	Claims for renal dialysis services (as defined in §1881(b)(14)(B) of the Act) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services.

30 - Determining Liability for Disallowed Claims Under §1879

(Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

When a Medicare contractor determines that a review under the LOL provisions is appropriate under §20 of this chapter, the Medicare contractor must next determine who is liable, based on who knew, or should have known that Medicare was going to deny payment on the item or service. In order to make this determination, the contractor must take the following steps:

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Form Instructions
Advance Beneficiary Notice of Non-coverage (ABN)
OMB Approval Number: 0938-0566

Overview

The ABN is a notice given to beneficiaries in Original Medicare to convey that Medicare is not likely to provide coverage in a specific case. "Notifiers" include:

- Physicians, providers (including institutional providers like outpatient hospitals), practitioners and suppliers paid under Part B (including independent laboratories);
- Hospice providers and religious non-medical health care institutions (RNHCIs) paid exclusively under Part A; and
- Home health agencies (HHAs) providing care under Part A or Part B.

All of the aforementioned healthcare providers and suppliers must complete the ABN as described below in order to transfer potential financial liability to the beneficiary, and deliver the notice prior to providing the items or services that are the subject of the notice.

Medicare inpatient hospitals and skilled nursing facilities (SNFs) use other approved notices for Part A items and services when notice is required in order to shift potential financial liability to the beneficiary; however, these facilities must use the ABN for Part B items and services.

The ABN must be reviewed with the beneficiary or his/her representative and any questions raised during that review must be answered before it is signed. The ABN must be delivered far enough in advance that the beneficiary or representative has time to consider the options and make an informed choice. Employees or subcontractors of the notifier may deliver the ABN. ABNs are never required in emergency or urgent care situations. Once all blanks are completed and the form is signed, a copy is given to the beneficiary or representative. In all cases, the notifier must retain a copy of the ABN delivered to the beneficiary on file.

The ABN may also be used to provide notification of financial liability for items or services that Medicare never covers. When the ABN is used in this way, it is not necessary for the beneficiary to choose an option box or sign the notice.

ABN Changes

The ABN is a formal information collection subject to approval by the Executive Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA). As part of this process, the notice is subject to public comment and re-approval every 3 years. With the latest PRA submission, a change has been made to the ABN. In accordance with Title 18 of the Social Security Act, guidelines for Dual Eligible beneficiaries have been added to the ABN form instructions.

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Completing the Notice

ABNs may be downloaded from the CMS website at: http://www.cms.gov/Medicare/Medicare-General-Information/BNI/ABN.html . Instructions for completion of the form are set forth below:

ABNs must be reproduced on a single page. The page may be either letter or legal-size, with additional space allowed for each blank needing completion when a legal-size page is used.

There are 10 blanks for completion in this notice, labeled from (A) through (J). We recommend that notifiers remove the lettering labels from the blanks before issuing the ABN to beneficiaries. Blanks (A)-(F) and blank (H) may be completed prior to delivering the notice, as appropriate. Entries in the blanks may be typed or hand-written, but should be large enough (i.e., approximately 12-point font) to allow ease in reading. (Note that 10 point font can be used in blanks when detailed information must be given and is otherwise difficult to fit in the allowed space.) The notifier must also insert the blank (D) header information into all of the blanks labeled (D) within the Option Box section, Blank (G). One of the check boxes in the Option Box section, Blank (G), must be selected by the beneficiary or his/her representative. Blank (I) should be a cursive signature, with printed annotation if needed in order to be understood.

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Header:

Blanks A-C, the header of the notice, must be completed by the notifier prior to delivering the ABN.

1. **Blank (A) Notifier(s):** Notifiers must place their name, address, and telephone number (including TTY number when needed) at the top of the notice. This information may be incorporated into a notifier's logo at the top of the notice by typing, hand-writing, pre- printing, using a label or other means.

   If the billing and notifying entities are not the same, the name of more than one entity may be given in the Header as long as it is specified in the Additional Information (H) section who should be contacted for billing questions.

2. **Blank (B) Patient Name:** Notifiers must enter the first and last name of the beneficiary receiving the notice, and a middle initial should also be used if there is one on the beneficiary's Medicare card. The ABN will not be invalidated by a misspelling or missing initial, as long as the beneficiary or representative recognizes the name listed on the notice as that of the beneficiary.

3. **Blank (C) Identification Number:** Use of this field is optional. Notifiers may enter an identification number for the beneficiary that helps to link the notice with a related claim. The absence of an identification number does not invalidate the ABN. An internal filing number created by the notifier, such as a medical record number, may

be used. Medicare numbers (HICNs), Medicare beneficiary identifiers (MBIs), or Social Security numbers should not appear on the notice.

Body:

4. **Blank (D): The following descriptors may be used in the Blank (D) fields:**

   Item
   Service
   Laboratory test
   Test
   Procedure
   Care
   Equipment

   - The notifier must list the specific names of the items or services believed to be non-covered in the column directly under the header of Blank (D).
   - In the case of partial denials, notifiers must list in the column under Blank (D) the excess component(s) of the item or service for which denial is expected.
   - For repetitive or continuous non-covered care, notifiers must specify the frequency and/or duration of the item or service.
   - General descriptions of specifically grouped supplies are permitted in this column. For example, "wound care supplies" would be a sufficient description of a group of items used to provide this care. An itemized list of each supply is generally not required.
   - When a reduction in service occurs**,** notifiers must provide enough additional information so that the beneficiary understands the nature of the reduction. For example, entering "wound care supplies decreased from weekly to monthly" would be appropriate to describe a decrease in frequency for this category of supplies; just writing "wound care supplies decreased" is insufficient.
   - Please note that there are a total of 7 Blank (D) fields that the notifier must complete on the ABN. Notifiers are encouraged to populate all of the Blank (D) fields in advance when a general descriptor such as "Item(s)/Service(s)" is used. All Blank (D) fields must be completed on the ABN in order for the notice to be considered valid.

5. **Blank (E) Reason Medicare May Not Pay:** In the column under this header, notifiers must explain, in beneficiary friendly language, why they believe the items or services listed in the column under Blank (D) may not be covered by Medicare. Three commonly used reasons for non-coverage are:

   "Medicare does not pay for this test for your condition."
   "Medicare does not pay for this test as often as this (denied as too frequent)."
   "Medicare does not pay for experimental or research use tests."

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To be a valid ABN, there must be at least one reason applicable to each item or service listed in the column under Blank (D). The same reason for non-coverage may be applied to multiple items in Blank (D) when appropriate.

6. **Blank (F) Estimated Cost:** Notifiers must complete the column under Blank (F) to ensure the beneficiary has all available information to make an informed decision about whether or not to obtain potentially non-covered services.

   Notifiers must make a good faith effort to insert a reasonable estimate for all of the items or services listed under Blank (D). In general, we would expect that the estimate should be within $100 or 25% of the actual costs, whichever is greater; however, an estimate that exceeds the actual cost substantially would generally still be acceptable, since the beneficiary would not be harmed if the actual costs were less than predicted.

   Multiple items or services that are routinely grouped can be bundled into a single cost estimate. For example, a single cost estimate can be given for a group of laboratory tests, such as a basic metabolic panel (BMP). An average daily cost estimate is also permissible for long term or complex projections. As noted above, providers may also pre-print a menu of items or services in the column under Blank (D) and include a cost estimate alongside each item or service. If a situation involves the possibility of additional tests or procedures (such as in laboratory reflex testing), and the costs associated with such tests cannot be reasonably estimated by the notifier at the time of ABN delivery, the notifier may enter the initial cost estimate and indicate the possibility of further testing. Finally, if for some reason the notifier is unable to provide a good faith estimate of projected costs at the time of ABN delivery, the notifier may indicate in the cost estimate area that no cost estimate is available. We would not expect either of these last two scenarios to be routine or frequent practices, but the beneficiary would have the option of signing the ABN and accepting liability in these situations.

7. **Blank (G) Options:** Blank (G) contains the following three options:

- **OPTION 1.** I want the (D)_____listed above. You may ask to be paid now, but I also want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). I understand that if Medicare doesn't pay, I am responsible for payment, but I can appeal to Medicare by following the directions on the MSN. If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

This option allows the beneficiary to receive the items and/or services at issue and requires the notifier to submit a claim to Medicare. This will result in a payment decision that can be appealed.

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Suppliers and providers who don't accept Medicare assignment may make modifications to Option 1 only as specified below under "**H. Additional Information**."

*** Special guidance for people who are dually enrolled in both Medicare and Medicaid, also known as dually eligible individuals (has a Qualified Medicare Beneficiary (QMB) Program and/or Medicaid coverage) ONLY:**

Dually Eligible beneficiaries must be instructed to check **Option Box 1** on the ABN in order for a claim to be submitted for Medicare adjudication.

Strike through **Option Box 1** as provided below:

☐ **OPTION 1.** I want the (D)_____listed above. ~~You may ask to be paid now, but~~ I ~~also~~ want Medicare billed for an official decision on payment, which is sent to me on a Medicare Summary Notice (MSN). ~~I understand that if Medicare doesn't pay, I am responsible for payment, but **I can appeal to Medicare** by following the directions on the MSN.~~

These edits are required because the provider cannot bill the dual eligible beneficiary when the ABN is furnished. Providers must refrain from billing the beneficiary pending adjudication by both Medicare and Medicaid in light of federal law affecting coverage and billing of dual eligible beneficiaries. If Medicare denies a claim where an ABN was needed in order to transfer financial liability to the beneficiary, the claim may be crossed over to Medicaid or submitted by the provider for adjudication based on State Medicaid coverage and payment policy. Medicaid will issue a Remittance Advice based on this determination.

Once the claim is adjudicated by both Medicare and Medicaid, providers may only charge the patient in the following circumstances:

- If the beneficiary has QMB coverage without full Medicaid coverage, the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy.

- If the beneficiary has full Medicaid coverage and Medicaid denies the claim (or will not pay because the provider does not participate in Medicaid), the ABN could allow the provider to shift financial liability to the beneficiary per Medicare policy, subject to any state laws that limit beneficiary liability.

Note: These instructions should only be used when the ABN is used to transfer potential financial liability to the beneficiary and not in voluntary instances. More information on dual eligible beneficiaries may be found at: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf

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- **OPTION 2.** I want the (D)_____listed above, but do not bill Medicare. You may ask to be paid now as I am responsible for payment. **I cannot appeal if Medicare is not billed.**

  This option allows the beneficiary to receive the non-covered items and/or services and pay for them out of pocket. No claim will be filed and Medicare will not be billed. Thus, there are no appeal rights associated with this option.

- **OPTION 3**. I don't want the (D)_____listed above. I understand with this choice I am not responsible for payment, and I cannot appeal to see if Medicare would pay.

  This option means the beneficiary does not want the care in question. By checking this box, the beneficiary understands that no additional care will be provided; thus, there are no appeal rights associated with this option.

The beneficiary or his or her representative must choose only one of the three options listed in Blank (G). Unless otherwise instructed to do so according to the specific guidance provided in these instructions, the notifier must not decide for the beneficiary which of the 3 checkboxes to select. Pre-selection of an option by the notifier invalidates the notice. However, at the beneficiary's request, notifiers may enter the beneficiary's selection if he or she is physically unable to do so. In such cases, notifiers must annotate the notice accordingly.

If there are multiple items or services listed in Blank (D) and the beneficiary wants to receive some, but not all of the items or services, the notifier can accommodate this request by using more than one ABN. The notifier can furnish an additional ABN listing the items/services the beneficiary wishes to receive with the corresponding option.

If the beneficiary cannot or will not make a choice, the notice should be annotated, for example: "beneficiary refused to choose an option."

8. **Blank (H) Additional Information:** Notifiers may use this space to provide additional clarification that they believe will be of use to beneficiaries. For example, notifiers may use this space to include:

   - A statement advising the beneficiary to notify his or her provider about certain tests that were ordered, but not received;
   - Information on other insurance coverage for beneficiaries, such as a Medigap policy, if applicable;
   - An additional dated witness signature; or
   - Other necessary annotations.

   Annotations will be assumed to have been made on the same date as that appearing in Blank J, accompanying the signature. If annotations are made on different dates, those dates should be part of the annotations.

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***Special guidance for non-participating suppliers and providers (those who don't accept Medicare assignment) ONLY:**

Strike the last sentence in the Option 1 paragraph with a single line so that it appears like this: ~~If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.~~

This single line strike can be included on ABNs printed specifically for issuance when unassigned items and services are furnished. Alternatively, the line can be hand-penned on an already printed ABN. The sentence must be stricken and can't be entirely concealed or deleted. There is no CMS requirement for suppliers or the beneficiary to place initials next to the stricken sentence or date the annotations when the notifier makes the changes to the ABN before issuing the notice to the beneficiary.

When this sentence is stricken, the supplier should include the following CMS-approved unassigned claim statement in the (H) Additional Information section:

> "This supplier doesn't accept payment from Medicare for the item(s) listed in the table above. If I checked Option 1 above, I am responsible for paying the supplier's charge for the item(s) directly to the supplier. If Medicare does pay, Medicare will pay me the Medicare-approved amount for the item(s), and this payment to me may be less than the supplier's charge."

This statement can be included on ABNs printed for unassigned items and services, or it can be handwritten in a legible 10 point or larger font.

An ABN with the Option 1 sentence stricken must contain the CMS-approved unassigned claim statement as written above to be considered valid notice. Similarly, when the unassigned claim statement is included in the "Additional Information" section, the last sentence in Option 1 should be stricken.

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Signature Box:

Once the beneficiary reviews and understands the information contained in the ABN, the Signature Box is to be completed by the beneficiary (or representative). This box cannot be completed in advance of the rest of the notice.

9. **Blank (I) Signature:** The beneficiary (or representative) must sign the notice to indicate that he or she has received the notice and understands its contents. If a representative signs on behalf of a beneficiary, he or she should write out "representative" in parentheses after his or her signature. The representative's name should be clearly legible or noted in print.

10. **Blank (J) Date:** The beneficiary (or representative) must write the date he or she signed the ABN. If the beneficiary has physical difficulty with writing and requests assistance in completing this blank, the date may be inserted by the notifier.

Disclosure Statement: The disclosure statements in the footer of the notice are required to be included on the document.

CMS will work with its contractors to ensure consistency when determining validity of the ABN in general. In addition, contractors will provide ongoing education to notifiers as needed to ensure proper notice delivery. Notifiers should contact the appropriate CMS regional office if they believe that a contractor inappropriately invalidated an ABN.

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Final List of Outpatient Department Services That Require Prior Authorization

Beginning for service dates on or after July 1, 2020	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair[1]
15820	Blepharoplasty, lower eyelid
15821	Blepharoplasty, lower eyelid; with extensive herniated fat pad
15822	Blepharoplasty, upper eyelid
15823	Blepharoplasty, upper eyelid; with excessive skin weighting down lid
67900	Repair of brow ptosis (supraciliary, mid-forehead or coronal approach)
67901	Repair of blepharoptosis; frontalis muscle technique with suture or other material (eg, banked fascia)
67902	Repair of blepharoptosis; frontalis muscle technique with autologous fascial sling (includes obtaining fascia)
67903	Repair of blepharoptosis; (tarso) levator resection or advancement, internal approach
67904	Repair of blepharoptosis; (tarso) levator resection or advancement, external approach
67906	Repair of blepharoptosis; superior rectus technique with fascial sling (includes obtaining fascia)
67908	Repair of blepharoptosis; conjunctivo-tarso-Muller's muscle-levator resection (eg, Fasanella-Servat type)
Code	(ii) Botulinum Toxin Injection
64612	Chemodenervation of muscle(s); muscle(s) innervated by facial nerve, unilateral (eg, for blepharospasm, hemifacial spasm)
64615	Chemodenervation of muscle(s); muscle(s) innervated by facial, trigeminal, cervical spinal and accessory nerves, bilateral (eg, for chronic migraine)
J0585	Injection, onabotulinumtoxina, 1 unit
J0586	Injection, abobotulinumtoxina, 5 units
J0587	Injection, rimabotulinumtoxinb, 100 units
J0588	Injection, incobotulinumtoxin a, 1 unit
Code	(iii) Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services
15830	Excision, excessive skin and subcutaneous tissue (includes lipectomy); abdomen, infraumbilical panniculectomy
15847	Excision, excessive skin and subcutaneous tissue (includes lipectomy), abdomen (eg, abdominoplasty) (includes umbilical transposition and fascial plication)
15877	Suction assisted lipectomy; trunk

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[1] CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

Code	(iv) Rhinoplasty, and related services[2]
20912	Cartilage graft; nasal septum
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)
30400	Rhinoplasty, primary; lateral and alar cartilages and/or elevation of nasal tip
30410	Rhinoplasty, primary; complete, external parts including bony pyramid, lateral and alar cartilages, and/or elevation of nasal tip
30420	Rhinoplasty, primary; including major septal repair
30430	Rhinoplasty, secondary; minor revision (small amount of nasal tip work)
30435	Rhinoplasty, secondary; intermediate revision (bony work with osteotomies)
30450	Rhinoplasty, secondary; major revision (nasal tip work and osteotomies)
30460	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip only
30462	Rhinoplasty for nasal deformity secondary to congenital cleft lip and/or palate, including columellar lengthening; tip, septum, osteotomies
30465	Repair of nasal vestibular stenosis (eg, spreader grafting, lateral nasal wall reconstruction)
30520	Septoplasty or submucous resection, with or without cartilage scoring, contouring or replacement with graft
Code	(v) Vein Ablation, and related services
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; subsequent vein(s) treated in a single extremity, each through separate access sites
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; subsequent vein(s) treated in a single extremity, each through separate access sites
36482	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; first vein treated
36483	Endovenous ablation therapy of incompetent vein, extremity, by transcatheter delivery of a chemical adhesive (eg, cyanoacrylate) remote from the access site, inclusive of all imaging guidance and monitoring, percutaneous; subsequent vein(s) treated in a single extremity, each through separate access sites

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[2] CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020

Beginning for service dates on or after July 1, 2021	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators [3]
63650	Percutaneous implantation of neurostimulator electrode array, epidural
Beginning for service dates on or after July 1, 2023	
Code	Facet Joint Interventions[4]
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
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
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

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[3] CPT codes 63685 (Insertion or replacement of spinal neurostimulator pulse generator or receiver) and 63688 (Revision or removal of implanted spinal neurostimulator pulse generator or receiver) were temporarily removed from the list of OPD services that require prior authorization, as finalized in the CY 2021 OPPS/ASC final rule with comment period.

[4] CPT codes 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)) and 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)) will be removed on August 16, 2024.

64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

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