



## Federally Qualified Health Center Version

### KEY CONCEPTS OUTLINE

#### Module 2: Medicare Coverage Guidance and the Advance Beneficiary Notice

##### I. Web-Based Resources

- A. There are two main websites with Medicare source authority (i.e., Medicare “rules”):
1. The U.S. Government Printing Office (GPO) Federal Digital System (FDsys) website hosts statutes and regulations. The FDsys generally has prior versions of statutes and regulations going back several years.
  2. The CMS website hosts CMS sub-regulatory guidance, including manuals, transmittals, and other guidance on the Medicare program.

**Caution:** The CMS website does not maintain an archive of prior versions of manuals and often removes transmittals or other guidance without notice. If you rely on guidance from the CMS website, you should retain a printed or electronic copy to ensure you have it for future reference.

- B. HCPro maintains a website with extensive links to Medicare resources, including the FDsys and CMS websites at:

<https://www.revenuecycleadvisor.com/helpful-links>

1. Handout 1 is a copy of HCPro’s links page for your reference or to note links you find useful during class.

##### II. Key Sources of Authority

- A. For your reference, Handout 1A is a table with key sources of authority, or Medicare “rules”, as well as where they are published, where to find them on the internet, and example citations.

1. Handout 1A is organized in order that audit contractors should apply guidance in making medical review decisions. < *Medicare Program Integrity Manual*, Chapter 3 § 3.3 A >

## B. Statutes

### 1. Public Laws

- a. Congress adopts new statutes as Public Laws. Public Laws are found on Congress.gov, maintained by the Library of Congress.

Link: Congress.gov under Regulations and Statutes

- b. Each public law has a home page that provides information on the adoption of the bill and the final text.

Tip: Under the “Text” tab, use the “Enrolled Bill” for an easy-to-use version of the text of a bill, with embedded links to related provisions.

### 2. *United States Code (U.S.C.)*

- a. The *U.S.C.* is a compilation of the statutes of the United States.
  - i. Title 42 of the *U.S.C.*, which contains the Medicare laws, has not been enacted as positive law. Its text is prima facie evidence of the law, but the text of the Public Law, as enacted, takes precedence in the event of a conflict.

Link: Unites States Code (Federal Statutes) under Regulations and Statues

### 3. Social Security Act

- a. Frequently, Medicare laws are cited by their Social Security Act section number, rather than their *U.S.C.* section number. The Social Security Administration maintains an updated version of the Social Security Act.

Link: Social Security Act, Title 18 (Medicare) under Regulations and Statues

## C. Regulations

### 1. *Federal Register*

- a. CMS publishes proposed and final regulations in the *Federal Register*.

Regulations are first published as proposed rules with request for comment. After gathering comments, a final rule is published, which contains the final regulation and a preamble with significant commentary and responses to submitted comments.

- b. On the Federal Register site, you can browse by date or use the “Search” function at the top of the page to search for a particular volume and page number.

Link: Federal Register under Regulations and Statutes

- c. FQHCs generally are not subject to annual rule making with an FQHC specific proposed or final rule. FQHC changes through rule making are usually addressed in the Medicare Physician Fee Schedule Final Rule.

Link: IPPS – Physician Fee Schedule - Regulations under Medicare-Related Sites – Physician/Practitioner

- d. Proposed and final rules can be very large and difficult to navigate.

- i. The “Summary of the Major Provisions” section in the “Executive Summary” at the beginning of the rule can be a helpful place to start.

Tip: Use the Table of Contents to find sections of interest and the “find” feature of the software to navigate to pertinent sections.

- ii. Follow-up questions can be directed to the individuals in the “For Further Information Contact:” section.

Link: HHS Employee Directory under Medicare-Related Sites - General

### 2. *Code of Federal Regulations (C.F.R.)*

- a. The *C.F.R.* is a compilation of the regulations of the United States. Title 42 contains the Medicare regulations.
  - i. The *C.F.R.* is published in an official annual edition and a regularly updated electronic version referred to as the *eCFR*, an unofficial compilation of the *C.F.R.* and recent *Federal Register* amendments.

**Caution:** The annual edition of Title 42 is updated October 1 of each year, but the OPPS regulations are adopted around November 1. Use the *eCFR* for the most up-to-date version of federal regulations.

Link: CFR Title 42 – Electronic Version under Regulations and Statutes

Tip: Use the Federal Register citations noted at the end of each regulation to find important preamble discussion published when the regulation or amendment was adopted.

#### D. Sub-Regulatory Guidance

1. Sub-regulatory guidance, such as manuals and transmittals, is binding on Medicare contractors. Regulations require Administrative Law Judges (ALJs) give “substantial deference” to the guidance applicable to a case and if they do not follow it, explain why in their decision letter. <42 *C.F.R.* 405.1062>
2. “Paper-based” Manuals
  - a. The *Provider Reimbursement Manual* contains charging and cost reporting guidelines and is available in a “paper-based” version that can be downloaded from the CMS website.

Link: Manuals – Paper Based Manuals under Medicare-Related Sites - General

- b. The *Provider Reimbursement Manual* has two parts
  - i. Part I provides cost report information such as Medicare’s policies on “Bad Debts, Charity, and Courtesy Allowances” or the “Determination of Costs of Services”, which provides information on the structure of charges.
  - ii. Part II primarily provides cost report formats and completion instructions.

### 3. "Internet-only" Manuals (IOMs)

- a. CMS provides significant sub-regulatory guidance in "internet-only" manuals published directly on their website.

**Caution:** CMS often removes or revises manual sections without providing an archive of prior versions. As noted above, you should retain a printed or electronic copy of manual sections you rely on to ensure you have them for future reference.

Link: [Manuals – Internet Only Manuals under Medicare-Related Sites - General](#)

- b. The following IOMs may be particularly helpful:

- i. *Pub. 100-02 – Medicare Benefit Policy Manual* provides coverage requirements for various inpatient and outpatient services.
- ii. *Pub. 100-04 – Medicare Claims Processing Manual* provides coding, billing and claims guidance.
- iii. *Pub. 100-05 – Medicare Secondary Payer Manual* provides information related to Medicare as a primary or secondary payer.
- iv. *Pub. 100-07 – State Operations Manual* provides guidance on the Conditions of Participation.

Tip: To access detailed information, such as Tag numbers, Interpretive Guidelines, and Survey Procedures, open the "Appendices Table of Contents" and click on the "Appendix Letter" for the provider or survey type (e.g., "A" for "Hospitals" or "V" for "Responsibilities of Medicare Participating Hospitals in Emergency Cases", i.e., EMTALA).

- v. *Pub. 100-08 – Medicare Program Integrity Manual* provides guidance to Medicare auditors, including MACs, SMRCs, CERT, Recovery Auditors, and UPICs.

#### 4. Transmittals and Program Memoranda

- a. Transmittals communicate new or revised policies or procedures, as well as new, deleted or revised manual language.

Link: Transmittals and Program Memoranda under Medicare-Related Sites – General

Use links on the left navigation to access transmittals or program memoranda from prior years.

Note: One Time Notification (OTN) transmittals are global in nature and not tied to a particular substantive manual.

- b. Transmittal Numbers:

Format of transmittal numbers:

R (Number – in the order of publishing) (Initials for manual)

R10224CP: 224<sup>th</sup> published transmittal, related to the Claims Processing Manual

Note: the numbering system for transmittals changed on approximately March 20, 2020. Previously, the transmittals were numbered separately for each manual, rather than by date across all manuals.

- c. Change Request Numbers:

- i. Transmittals are linked to a change request (CR) number, CMS' internal tracking number, tying together documents associated with a particular policy change.

Change Request (CR) numbers:

- May be associated with multiple transmittals, e.g., one CR may have an associated Medicare Claims Processing Manual Transmittal and a Medicare Benefit Policy Manual Transmittal.
- Are used in the numbering of associated MLN Matters Articles, discussed later in this outline.
- Are often used by CMS representatives to refer to policy changes, rather than transmittal numbers.

d. Components of a Transmittal

- i. "Date" (in the header) represents the date the transmittal was published.
- ii. "Effective Date" represents the date of service the policy in the transmittal will begin to apply, unless noted otherwise.

**Caution:** The effective date of a transmittal may be prior to the date the transmittal was published, which may affect coverage, coding, billing, or payment of services already rendered.

- iii. "Implementation Date" represents the date processing systems will be able to process claims correctly according to the policies in the transmittal, unless noted otherwise.

**Caution:** The implementation date of a transmittal is generally the first business day of the quarter or year after the transmittal is effective but may be substantially after the effective date. A provider may need to hold claims affected by the transmittal until system changes are implemented.

- iv. If there are new, deleted, or revised manual sections associated with the transmittal, they will be listed in the "Changes in Manual Instructions" table at the beginning of the transmittal.

- a) The text of new or revised manual sections will appear after the attachments at the end of the transmittal.

**Caution:** New or revised text will appear in red italics; however, deleted text will not be noted. Important guidance may be removed without any indication in the transmittal. Revisions should be reviewed carefully.

- v. "Background" and "Policy" sections provide important information about the policy changes in the transmittal.
- vi. The "Business Requirements Table" contains specific instructions to CMS contractors for implementation of changes in the transmittal, including instructions related to reprocessing claims or adjusting claims brought to their attention by providers.

**Tip:** This section may be particularly helpful to providers to determine the effect of the transmittal on their claims.

vii. The “Contacts” section contains the names and email addresses of CMS staff, which may be used for follow-up questions.

viii. Transmittals may also have attachments with important tables or other important information.

## 5. MLN Matters Articles

- a. MLN Matters Articles are articles that explain Medicare policy in easy to understand format, often written for specific provider types as noted at the top of the article.

Link: [MLN Matters Articles – Overview Page under Medicare-Related Sites – General](#)

- b. There are two types of MLN Matters Articles:

- i. MLN Matters Articles linked to a particular transmittal are intended to provide practical and operational information about the transmittal.

Tip: In addition to being published on the MLN website, a link for MLN Matters Article associated with a transmittal appears below the link for the transmittal on the transmittal’s home page.

- ii. Special Edition MLN Matters Articles are not linked to a transmittal but rather provide information on topics CMS believes require additional clarification. They frequently provide information not found in transmittals or manuals.

Tip: In addition to appearing on the MLN website, Special Edition MLN Matters Articles are listed on the transmittals website for the year they were published.

Format of MLN Matters Article numbers:

Tied to a particular transmittal/change request:

MM (Change Request Number)

MM12738 is tied to CR12738

Special Edition MLN:

SE (two-digit year) (sequential number)

SE22001 is the first Special Edition MLN Article in 2021

## 6. Other Guidance

- a. CMS frequently posts other guidance on their website in the form of documents, FAQs, algorithms, or other information.
- b. FQHC helpful site:

Link: Federally Qualified Health Center (FQHC) under Medicare-Related Sites – Rural Health

## III. Ways to Stay Current (All Free)

- A. Subscribe to HCPro’s resources to receive information and updates applicable to your facility.
  1. Revenue Cycle Daily Advisor is a free daily email publication with informative articles gathered from a variety of HCPro and HealthLeaders sources.
  2. Revenue Integrity Insider is a free email publication with information from the National Association of Healthcare Revenue Integrity (NAHRI), a new association dedicated to providing revenue integrity professionals with the resources, networking, and education needed to foster this growing field and profession.

Link: HCPro Free Email Newsletters under Listserv Subscriptions

- B. Subscribe to CMS email updates.

Link: CMS Email Update Lists – Subscriber’s Main Page under Listserv Subscriptions

1. Suggested CMS mailing lists include:
  - a. CMS Coverage Email Updates
  - b. MLN Connects™ Provider eNews
  - c. Rural Health Open Door Forum

- i. The Rural Health Open Door Forum addresses Rural Health Clinic (RHC), Critical Access Hospital (CAH), and Federally Qualified Health Center (FQHC) issues.

Tip: CMS conducts periodic “Rural Health Open Door Forum” calls which provide valuable information to both RHCs and FQHCs. You can receive dial in information by signing up to this list or checking the Rural Health Open Door Forum website.

Link: Open Door Forum – Overview page under Medicare General Sites

- d. CMS News Releases (including proposed and final rule fact sheets)
- C. Subscribe to your MAC’s email list.

#### IV. 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;
  - 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 >

## V. 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 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 >
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](http://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*>

### VI. Prior Authorization

- A. For specified services, CMS requires 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>.
- 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 OPFS 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:
    - b. Rhinoplasty and Related Services:
    - 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>
- 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)>
    - i. CPT codes 64490 - 64495 Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT).
      - a) Specific to spinal region and level

#### 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 10 business days. <Operational Guide, Section 4>
  - a. 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>
  - b. 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>
    - i. A provisional affirmation is valid for 120 days from the date of the decision. <Operational Guide, Section 7.1>
    - ii. 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>
  - c. 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>
    - i. 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>
    - ii. A provisional non-affirmation is not an initial claim determination and cannot be appealed. <Operational Guide, Section 11>
    - iii. 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>
      - a) 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>
  - 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.

#### 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>
  - e. Gaining exemption if not exempt in prior year:
    - i. 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>

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

### 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 Pain 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?

## VII. 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.

- 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>
  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>

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

4. "Categorical denials" occur when the denial is based on other statutory provisions not referenced in the LOL statute. <Medicare 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

### VIII. 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. 06/30/2023)), available in English, Spanish, and large print, is the required form for providing notice of non-coverage for outpatient services. Handout 2 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>

- 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>

- 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.

#### 5. Completion of the Form

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.

- 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 >
  - 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 be 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".

## 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 FQHC 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.

## 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.

## 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 FQHC 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>

#### D. 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)>
- 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 \_\_\_\_\_.”)

## E. Advanced Beneficiary Notice and Modifier Usage

- 1. Modifier GA – Waiver of liability statement issued as required by payer policy
  - a. The GA modifier is reported when an ABN is provided to the beneficiary indicating there is a likelihood the service will deny as not reasonable and necessary under Medicare guidelines.
  - b. A mandatory ABN is issue for the service and is kept on file.
- 2. GX Modifier - Notice of liability issued, voluntary under payer policy
  - a. The GX modifier is reported when a voluntary ABN is issued for a service that Medicare never covers because it is statutorily excluded or is not a Medicare benefit.

3. GY Modifier – Item or service statutorily excluded, does not meet the definition of any Medicare benefit
  - a. The GY modifier is reported when Medicare statutorily excludes the item or service, or the item or service does not meet the definition of any Medicare benefit.
  - b. An ABN is not required for services provided with the GY modifier.
4. GZ Modifier – Item or service expected to be denied as not reasonable and necessary
  - a. The GZ modifier is informational only – indicating an ABN was not issued.

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## CASE STUDIES WITH ANALYSIS

### 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 the x-rays, and referencing the nursing pain assessment.

Turn to the *LCD – Facet Joint Interventions for Pain 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?

**Analysis:** The pain clinic physician must document that there is no untreated radiculopathy or neurogenic claudication and no non-facet pathology that could explain the source of the patient's pain, as required by the LCD.

In addition to the pain assessment, the LCD requires a disability scale at baseline for functional assessment. The billing and coding article lists some acceptable disability scales in the "Documentation Requirements" section.

The patient's history of pain and conservative care that has been tried must also be documented. The LCD requires the patient to have had pain for a minimum of 3 months with documented failure of conservative management, defined in the policy as use of NSAIDs, acetaminophen, physical therapy, acupuncture, or spinal manipulation.

The provider must also document that the patient has a covered diagnosis, supported by the medical record. The Article contains a list of covered diagnosis codes.

**Note:** This procedure will require prior authorization when performed in a PPS hospital outpatient department beginning July 1, 2023.

**Note:** This case study is based on a Novitas LCD, and billing and coding Article provided for illustrative purposes only. The LCDs and billing and coding Articles for facet joint injections vary by jurisdiction, including the documentation required to demonstrate coverage. Verify coverage, including documentation requirements, with

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CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES <b>2 33</b>

## LCD Information

### Document Information

**LCD ID**

L34892

**LCD Title**

FACET JOINT Interventions for Pain Management

**Proposed LCD in Comment Period**

N/A

**Source Proposed LCD**

[DL34892](#)

**Original Effective Date**

For services performed on or after 10/01/2015

**Revision Effective Date**

For services performed on or after 04/25/2021

**Revision Ending Date**

N/A

**Retirement Date**

N/A

**Notice Period Start Date**

03/11/2021

**Notice Period End Date**

04/24/2021

### 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

**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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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

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).<sup>1</sup>

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.<sup>1</sup>

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.<sup>1</sup>

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<sup>2</sup> and development of interventional pain management specific instrument<sup>3</sup> 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<sup>4</sup>.
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).<sup>5</sup>

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:**

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/aspersion.

 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<sup>11</sup>; **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)<sup>4,12</sup>; **AND**
3. Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by FACET JOINT synovial cyst)<sup>4,7</sup>; **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.<sup>11</sup>

 \*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.<sup>1,4,7,12,16</sup> 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).<sup>11</sup>

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.<sup>7</sup>

-  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).<sup>11</sup>

Frequency limitation: 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):

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<sup>11</sup>; **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.<sup>5,42,43,44</sup>

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<sup>11</sup> 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.<sup>11</sup>

#### 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,

- performed under ultrasound guidance,<sup>4,11</sup> or with Magnetic Resonance Imaging (MRI).<sup>4</sup>
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.<sup>4</sup>
  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.<sup>5,42,43,44</sup>
  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.<sup>56</sup>
  10. In patients with implanted electrical devices, providers must follow manufacturer instructions and extra planning as indicated to ensure safety of procedure.

The following are considered not medically reasonable and necessary:

1. Intraarticular and extraarticular FACET JOINT prolotherapy<sup>5,42,43,44</sup>
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<sup>58</sup>
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.

## 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 stimulation 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 zygapophysial joint or the two medial branch (MB) nerves that innervate that zygapophysial 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

(also called pseudoocclusion).

**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

### Diagnostic FACET JOINT Injections

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.

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATES <b>2, 42</b>

## Article Information

### General Information

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**Article Title**

Billing and Coding: FACET JOINT Interventions for Pain Management

**Article Type**

Billing and Coding

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**Revision Ending Date**

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**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).

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.

**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.

## 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

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)

### 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

### 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

**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

**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, <i>Medicare Claims Processing Manual</i> , 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



## Prior Authorization (PA) Program for Certain Hospital Outpatient Department (OPD) Services

### Operational Guide

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## Purpose

The CY 2020 OPPS/ASC Final Rule (CMS -1717-FC) established a nationwide PA process and requirements for certain hospital OPD services. CMS added additional services to the process through the CY 2021 OPPS/ASC Final Rule (CMS-1736-FC) and the **CY 2023 OPPS/ASC Final Rule (CMS-1772-FC)**. The PA program for certain hospital OPD services ensures that Medicare beneficiaries continue to receive medically necessary care while protecting the Medicare Trust Funds from unnecessary increases in the volume of covered services and improper payments. The prior authorization process does not alter existing medical necessity documentation requirements. The purpose of this Operational Guide is to interpret and clarify the review process for the hospital OPD when rendering certain OPD services for Medicare beneficiaries. This guide will advise hospital OPD providers on the process of submitting documents in support of the final claim.

Version 05/15/2023  
Check for Updates

## **1- Hospital Outpatient Department (OPD) Services Benefits**

For any service or item to be covered by Medicare, it must:

- Be eligible for a defined Medicare benefit category,
- Be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and
- Meet all other applicable Medicare statutory and regulatory requirements.

### **1.1 -Medicare statutory and regulatory requirements**

#### **Social Security Act (Title XVIII) Standard References:**

- 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 Social Security Act, Section 1862(a)(10). No payment may be made under part A or part B for any expenses incurred for items or services where such expenses are for cosmetic surgery or are incurred in connection with, except as required for the prompt repair of accidental injury or improvement of the functioning of a malformed body member.
- Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.
- Title XVIII of the Social Security Act, Section 1833(t)(2)(F) states that a method shall be developed for controlling unnecessary increases in the volume of covered OPD services.

#### **Federal Register References:**

- 42 CFR 419.8 *et seq* provides the regulatory guidance for this program, which is further explained in this operational guide.
- 42 CFR 411.15(h) Particular services excluded from coverage. Cosmetic surgery and related services.

In order to be covered under Medicare, a service shall be reasonable and necessary. A service to be considered reasonable and necessary when the service is:

- Safe and effective.
- Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000, that meet the requirements of the Clinical Trials NCD are considered reasonable and necessary).
- Appropriate, including the duration and frequency that is considered appropriate for the service, in terms of whether it is:
  - Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member.

- Furnished in a setting appropriate to the patient's medical needs and condition.
- Ordered and furnished by qualified personnel.
- One that meets, but does not exceed, the patient's medical needs.
- At least as beneficial as an existing and available medically appropriate alternative.

## 2- Program Overview

This nationwide program will include the hospital OPDs that provide certain OPD services and are enrolled in the Medicare FFS program. The term requester will be used throughout this document to describe the person or entity that submits the prior authorization request (PAR), documentation, and /or claims. The providers will be required to obtain PA before the services are provided to Medicare beneficiaries and before the provider submits claims for payment under Medicare for these services.

The hospital OPD provider will submit the PARs to their local Medicare Administrative Contractor (MAC) jurisdiction. The MAC will review the information submitted and issue the decision (affirmative or non-affirmative) to the provider.

The provider may submit a request for an expedited review of a PAR if delays in receipt of a PA decision could jeopardize the life or health of the beneficiary.

The MAC will deny a claim for a service that requires a PA if the provider has not received a provisional affirmation of coverage unless the provider is exempt. The Centers for Medicare and Medicaid Services (CMS) may elect to exempt a provider from PA upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules and that this exemption would remain in effect until CMS elects to withdraw the exemption.

The provider may resubmit a PAR with additional supporting information, upon receipt of a non-affirmation, as many times as necessary to achieve an affirmation decision.

### **Inquiries Regarding the Program:**

Hospital OPD providers who have questions about the program review process should contact their local MAC jurisdiction.

**Appendix A** includes the specific Healthcare Common Procedure Coding System (HCPCS) codes that are included in the OPD PA program.

**Note:** Codes in Appendix A may be subject to change.

### **2.1- OPD Services That Require Prior Authorization**



**CMS added Facet Joint Interventions to the nationwide prior authorization process for hospital outpatient department (OPD) services. OPD providers can start submitting the prior authorization requests (PARs) on June 15, 2023, for dates of service on or after July 1, 2023. This service category will be in addition to the existing list of services requiring prior authorization, which are**

blepharoplasty, botulinum toxin injection, rhinoplasty, panniculectomy, vein ablation, implanted neurostimulators, and cervical fusion with disc removal.

The addition of new services to the Prior Authorization program does not change Medicare benefit or coverage requirements, nor does it create new documentation requirements. The documentation required to be included with a prior authorization request is information that hospital OPDs are regularly required to maintain for Medicare payments.

### 3 – Prior Authorization Request (PAR)

The PAR must be submitted before the service is provided to the beneficiary and before the claim is submitted for processing. The PAR will not be accepted after the service has been completed. The PAR must include all documentation necessary to show that the service meets applicable Medicare coverage, coding, and payment rules.

#### 3.1-General PAR Documentation

Requesters must include the following data elements in all PARs to avoid potential delays in processing. Your MAC may request additional, optional elements for submission of the PAR.

#### Initial Submission Documentation:

##### Beneficiary Information (as written on their Medicare card)

- Beneficiary Name
- Beneficiary Medicare Number (also known as the MBI)
- Beneficiary Date of Birth

##### Hospital OPD Information

- Name of facility
- PTAN/CCN
- Facility Address
- Facility National Provider Identifier (NPI)

##### Physician/Practitioner Information

- Physician/Practitioner's Name
- Physician/Practitioner's National Provider Identifier (NPI)
- Physician/Practitioner PTAN
- Physician/Practitioner's Address
- Physician/Practitioner's Fax Number (optional)

##### Requestor Information

- Requestor Name
- Requestor Phone Number
- Requestor Email Address
- Requestor Fax Number (refer to your MAC jurisdiction)

**Other Information**

- HCPCS Code(s)
- Diagnosis Code(s)
- Type of Bill
- Units of Service
- Indicate if the request is an initial or subsequent review
- Indicate if the request is expedited and the reason why

**Resubmission(s) documentation:**

In addition to the required PAR documentation in the Initial Submission section, the resubmission of the PAR should contain an exact match of the beneficiary's first name, last name, date of birth to the previous submission, and the UTN associated with the previous submission.

**3.1.1–Sending a PAR**

Requesters have the following options for submitting PARs to the A/B MACs:

- 1) mail,
- 2) fax,
- 3) electronic submission of medical documentation (esMD), content type 8.5\*, or
- 4) CMS- approved electronic portal (A/B MAC specific).

\* For more information about submissions through esMD, see [www.cms.gov/esMD](http://www.cms.gov/esMD) or contact your A/B MAC.

**MACs Contact Information:**

**J5**

WPS GHA

Mailing Address:

WPS GHA

PO Box 7953

Madison, WI 53707-7953

Fax #: 608.223.7553

Website: [wpsgha.com](http://wpsgha.com)

esMD: indicate document/ content type 8.5

**J8**

WPS GHA

Mailing Address:

WPS GHA

PO Box 7954  
Madison, WI 53707-7954  
Fax #: 608.224.3508  
Website: [wpsgha.com](http://wpsgha.com)  
esMD: indicate document/ content type 8.5

**J15**

CGS  
Mailing Address:  
CGS Administrators, LLC  
J15 Part A Prior Authorization Requests  
PO Box 20203  
Nashville, TN 37202  
FedEx/UPS/Certified Mail (Physical Address):  
CGS Administrators, LLC  
J15 Part A Prior Authorization Requests  
26 Century Blvd., Suite ST610  
Nashville, TN 37214-3685  
Fax#: 615.782.4486  
Customer Service #: 1.866.590.6703  
Website: [cgsmedicare.com](http://cgsmedicare.com)  
esMD: indicate document/content type "8.5"

**JK**

National Government Services (NGS)  
Mailing Address:  
National Government Services  
PO BOX 1708  
Indianapolis, IN 46207-7108  
Fax#: 317.841.4530  
Website: [ngsmedicare.com](http://ngsmedicare.com)  
esMD: indicate document/ content type 8.5

**J6**

National Government Services (NGS)  
Mailing Address:  
National Government Services  
PO BOX 1708  
Indianapolis, IN 46207-7108  
Fax#: 317.841.4528  
Website: [ngsmedicare.com](http://ngsmedicare.com)  
esMD: indicate document/ content type 8.5

**JE**

Noridian Healthcare Solutions LLC  
Mailing Address:  
PO Box 6782  
Fargo, ND 58103  
Customer Service: 855.609.9960  
Fax: 701-277-2903  
Website: [med.noridianmedicare.com/web/jea](http://med.noridianmedicare.com/web/jea)  
esMD: indicate document/content type "8.5"

**JF**

Noridian Healthcare Solutions LLC  
Mailing Address:  
PO Box 6722  
Fargo, ND 58103  
Customer Service: 877.908.8431  
Fax: 701-277-2903  
Website: [med.noridianmedicare.com/web/jfa](http://med.noridianmedicare.com/web/jfa)  
esMD: indicate document/content type "8.5"

**JJ**

Palmetto GBA  
Mailing Address:  
Palmetto GBA  
Part A – Prior Authorization  
PO BOX 100212  
Columbia, SC 29202-3212  
Fax #: 803.462.7313  
Phone Number: 877.567.7271  
Website: [palmettogba.com/JJA](http://palmettogba.com/JJA)  
esMD: indicate document/content type "8.5"

**JM**

Palmetto GBA  
Mailing Address:  
Palmetto GBA  
Part A – Prior Authorization  
PO BOX 100212  
Columbia, SC 29202-3212  
Fax #: 803.462.7313  
Phone Number: **855.696.0705**  
Website: [palmettogba.com/JMA](http://palmettogba.com/JMA)  
esMD: indicate document/content type "8.5"

**JL**

Novitas Solutions  
Mailing Address (including the P.O. Box):  
Novitas Solutions  
JL Prior Authorization Requests  
PO BOX 3702  
Mechanicsburg, PA 17055  
Fax#: 1.877.439.5479  
Phone #: 855.340.5975 (Prior Auth Customer Service)  
Website: [novitas-solutions.com/](http://novitas-solutions.com/)  
esMD: indicate document/content type “8.5”

**JH**

Novitas Solutions  
Mailing Address (including the P.O. Box):  
Novitas Solutions  
JH Prior Authorization Requests  
PO BOX 3702  
Mechanicsburg, PA 17055  
Fax#: 1.877.439.5479  
Phone #: 855.340.5975 (Prior Auth Customer Service)  
Website: [novitas-solutions.com/](http://novitas-solutions.com/)  
esMD: indicate document/content type “8.5”

**JN**

First Coast  
Mailing Address (including the P.O. Box):  
First Coast Services Options, Inc.  
JN Prior Authorization  
PO Box 3033  
Mechanicsburg, PA 17055-1804  
Fax#: 1.855.815.3065  
Phone # 1.855.340.5975  
Website: [fco.com/](http://fco.com/)  
esMD: indicate document/content type “8.5”

## 4- Review of the PAR

The MAC will review the information submitted, and the decision (affirmative or non-affirmative) will be issued to the provider. A provisional affirmation will be issued to the provider if it is decided that applicable Medicare coverage, coding, and payment rules are met. A non-affirmation will be issued to the provider if it is decided that applicable Medicare coverage, coding, and payment rules are not met. A unique tracking number (UTN) will be assigned to each PAR. When the PAR results in a non-affirmative decision, the MAC will provide detailed information about all missing and/or non-compliant information that resulted in the non-affirmative decision.

### 4.1- Review Decisions and Timeframes

The timeframes for conducting PA of certain hospital OPD services will be dependent upon the service(s) selected and documentation submitted for PAR. There are 3 types of review timeframes:

- **Initial Submission**—the first PAR sent to the contractor for review and decision. The MAC will complete its review of medical records and send an initial decision letter that is either postmarked or faxed within **10 business days** following the receipt of the initial request.
- **Resubmission**—any subsequent resubmissions to correct an error or omission identified during a PA decision. A resubmitted PAR is a request submitted with additional/updated documentation after the initial PAR was non-affirmed. The MAC will postmark or fax notification of the decision of these resubmitted requests to the provider or beneficiary (if specifically requested by the beneficiary) within **10 business days** of receipt of the resubmission request.
- **Expedited**—a PA decision that is performed on an accelerated timeframe based on the MAC determination that delays in review and response could jeopardize the life or health of the beneficiary. If the MAC substantiates the need for an expedited decision, the MAC will make reasonable efforts to communicate a decision within **2 business days** of receipt of the expedited request.

#### 4.1.1- Validation Period for Prior Authorization Decisions

PAR decisions and UTNs for these services are valid for 120 days. The decision date shall be counted as the first day of the 120 days. For example: if the PAR is affirmed on January 1, 2021, the PAR will be valid for dates of service through April 30, 2021. Otherwise, the provider will need to submit a new PAR.

#### 4.1.2 –Resubmission of PAR

The provider should review the detailed decision letter that was provided. A provider may resubmit a PAR an unlimited number of times upon receipt of a non-affirmative decision. The UTN will be assigned with each PA resubmission request.

#### 4.2- Expedited Review of a PAR

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

To prevent the claim from denying upon submission, the provider should ***hold their claim and not submit it*** until such time as the UTN is provided. The MAC will follow the normal process to obtain a UTN from CMS shared systems.

A provider may resubmit a request for expedited review.

#### 4.3- Decision Letter(s)

The MAC will send decision letters with the UTN to the requester using the method the PAR was received postmarked within the timeframes described in Section 4.1 of this guide. The MAC will have the option to send a copy of the decision to the requester via fax if a valid fax number was provided, even if the submission was sent via mail. The requester(s) will be notified to hold their claim and not submit it until the UTN is received (in order to avoid a claims payment denial) if the MAC exercises the option to send the PA decision without the UTN.

While the PA process is applicable to hospital OPDs, as specified in CMS-1717-FC, CMS allows the PAR to be sent by the physician/practitioner on behalf of the hospital OPD.

Physicians/practitioners who submit the PAR on behalf of the OPD should include their contact information on the PAR cover sheet, in addition to the hospital OPD's contact information. If the physician/practitioner is not the requester and would like to obtain a copy of the decision letter, they should contact the hospital OPD.

Decision letters sent via electronic submission of medical documentation (esMD) are not available at this time.

A copy of the decision letter will be sent to the beneficiary as well.

## 5- Exemption(s)

The CMS may elect to exempt a hospital OPD provider from PA upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules. This exemption would remain in effect until CMS elects to withdraw the exemption. CMS or its contractors would exempt providers that submitted at least 10 requests and achieve a PA provisional affirmation threshold of at least 90 percent during an annual assessment. By achieving this percentage of provisional affirmations, the provider would be demonstrating an understanding of the requirements for submitting accurate claims. Notice of an exemption or withdraw of an exemption will be provided at least 60 days prior to the effective date.

### 5.1- Exemption Timeline Example

Hospital outpatient departments can expect the following process:

#### January 1, 2023:

- The exemption cycle begins for providers who met **the 90% or greater** compliance rate threshold. Exempt providers should not submit PARs.
- PARs received during an exemption period for exempt providers will be rejected.
- Providers who did not meet the compliance rate threshold should continue submitting PARs as usual.

#### August 1, 2023:

- Exempt providers will receive a postpayment Additional Document Request (ADR) for a 10-claim sample from the period such providers were exempt to determine continued compliance. Providers must have at least 10 claims submitted and paid by June 30 in order to be considered for the exemption. If the exempt providers have less than 10 claims submitted, their exemption status will be withdrawn.
- Providers have 45 days to submit documentation, and MACs will complete their review within 45 days of receipt of the requested documentation.
- Providers who submit additional documentation after the initial 45-day response timeframe will not have their compliance rate changed if the MAC has already finalized their compliance rate and sent a notification to the provider. The MAC will still review late documentation, issue a review determination, and make a claim adjustment, if necessary. Claim denials are subject to the normal appeals process; however, overturned appeals will not change the provider's exemption status.

#### October 1, 2023- October 31, 2023:

April 11, 2023

- MACs calculate the affirmation rate of initial PARs for non-exempt providers for all eight service categories combined, and notify those providers with an affirmation rate of 90% or greater.

#### **October 1, 2023- November 30, 2023:**

- Hospital OPDs have the option to opt out of the exemption process and continue submitting PARs. Hospital OPDs that choose to opt out of this exemption process must submit an opt-out request to their MAC no later than November 30. Late submissions will be rejected.

#### **November 2, 2023:**

- On or after November 2, 2023, providers will receive a Notice of Withdrawal of Exemption if they receive less than a 90% claim approval rate during their exemption cycle.
- Providers who *continue* to demonstrate a 90% or greater claim approval rate based upon the 10-claim review will receive a Notice of Continued Exemption and do not need to submit PARs.

#### **December 18, 2023:**

- Providers who did not meet the 90% claim approval rate will no longer be exempt and may start submitting PARs in advance of the January 1 review cycle.

#### **January 1, 2024:**

- The exemption cycle begins for providers who met the compliance rate threshold. Exempt providers should not submit PARs.
- PARs received during an exemption period for exempt providers will be rejected.
- Providers who are not exempt must have an associated PAR for any claim submitted on or after this date.

For providers who are not exempt, CMS will continue assessing a provider's compliance through their PAR affirmation rates starting January of each year. For exempt providers, CMS will continue to evaluate their claim approval rate through ADRs sent on August 1 of each year.

## **6- Program Specifics**

### **6.1 – Implementation of Prior Authorization**

The MACs began accepting PARs for hospital OPD services requiring PA on June 17, 2020 and rendered on or after July 1, 2020.

### **6.2 – Required Documentation**

For detailed documentation requirements, the hospital OPD providers should refer to their MAC jurisdiction's Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs), where applicable. To meet coverage criteria, the patient's medical record must contain documentation that fully supports the medical necessity for services<sup>1</sup>.

The following hospital OPD services require PA:

- (i) Blepharoplasty
- (ii) Botulinum toxin injections
- (iii) Panniculectomy
- (iv) Rhinoplasty
- (v) Vein ablation

### 6.2.1- Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair

General Documentation Requirements for Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair:

- Documented subjective patient complaints which justify functional surgery (vision obstruction, unable to do daily tasks, etc.);
- Documented excessive upper/ lower lid skin;
- Signed clinical notes support a decrease in peripheral vision and/or upper field vision causing the functional deficit (when applicable);
- Signed physician's or non-physician practitioner's documentation of functional impairment and recommendations;
- Supporting pre-op photos (when applicable);
- Visual field studies/exams (when applicable).

### 6.2.2 - Botulinum Toxin Injections

PA is only required when one of the required Botulinum Toxin codes (J0585, J0586, J0587, or J0588) is used **in conjunction with** one of the required CPT injection codes (64612, injection of chemical for destruction of nerve muscles on one side of face, or 64615, injection of chemical for destruction of facial and neck nerve muscles on both sides of face). Use of these Botulinum Toxin codes in conjunction/paired with procedure codes other than 64612 or 64615 will not require PA under this program.

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<sup>1</sup> The MACs will review all PARs in accordance with the policy in place at the time of the anticipated date of service, including any waivers, flexibilities, and/or revised guidance issued as a result of the COVID-19 Public Health Emergency.

### General Documentation Requirements for Botulinum Toxin Injections:

- A covered diagnosis;
- Dosage and frequency of planned injections;
- Specific site(s) injected (refer to your MAC's LCD/LCA);
- Documentation to support the medical necessity when electromyography procedures performed in conjunction with botulinum toxin type A injections to determine the proper injection site(s) (when applicable);
- To support continuous treatment, the documentation should include the clinical effectiveness of two consecutive treatments that preceded the anticipated procedure (refer to your MAC's LCD/LCA);
- Documentation of the management of a chronic migraine diagnosis. A medical record must include a history of migraine and experiencing frequent headaches on most days of the month;
- Documentation of traditional treatments such as medication, physical therapy, and other appropriate methods have been tried and proven unsuccessful (when applicable).

### 6.2.3- Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services

#### General Documentation Requirements for Panniculectomy, Excision of Excess Skin and Subcutaneous Tissue (Including Lipectomy), and related services:

- Stable weight loss with BMI less than 35 be obtained prior to authorization of coverage for panniculectomy surgery (when applicable);
- Description of the pannis and the underlying skin;
- Description of conservative treatment undertaken and its results;
- The medical records document(s) that the panniculus causes chronic intertrigo or candidiasis or tissue necrosis that consistently recurs over three months and is unresponsive to oral or topical medication (when applicable);
- Pre-op photograph (if requested);
- Copies of consultations (when applicable);
- Related Operative report(s) (when applicable);
- Any other pertinent information.

### 6.2.4 - Rhinoplasty, and related services



#### General Documentation Requirements for Rhinoplasty and related services:

- Medical documentation, with evaluation and management, supporting medical necessity of the service that is to be performed;
- Radiologic imaging if done;
- Photographs that document the nasal deformity (if applicable);
- Documentation supporting unresponsiveness to conservative medical management (if applicable).

## 6.2.5 - Vein Ablation, and related services

General Documentation Requirements for Vein Ablation and related services:

- Doppler ultrasound;
- Documentation stating the presence or absence of DVT (deep vein thrombosis), aneurysm, and/or tortuosity (when applicable);
- Documented Incompetence of the Valves of the Saphenous, Perforator or Deep venous systems consistent with the patient's symptoms and findings (when applicable);
- Photographs, if the clinical documentation received, is inconclusive;
- Documentation supporting the diagnosis of symptomatic varicose veins (evaluation and complaints), and the failure of an adequate trial of conservative management (before the initial procedure) (refer to your MAC's LCD/LCA).

## 6.3 – Program Specifics for Additional Hospital OPD Services

### 6.3.1- Implementation of Prior Authorization

The MACs began accepting PARs for two new services on June 17, 2021, for services rendered on or after July 1, 2021.

### 6.3.2- Required Documentation

For detailed documentation requirements, the hospital OPD providers should refer to National Coverage Determinations (NCDs) and their MAC jurisdiction's LCDs/LCAs, where applicable. To meet coverage criteria, the patient's medical record must contain documentation that fully supports the medical necessity for services.

The following additional hospital OPD services will require PA:

- i. Cervical Fusion with Disc Removal
- ii. Implanted Spinal Neurostimulators

#### 6.3.2.1- Cervical Fusion with Disc Removal

General Documentation Requirements for Cervical Fusion with Disc Removal:

- Condition requiring procedure
- Physical examination
- Duration/character/location/radiation of pain
- Activity of daily living (ADL) limitations
- Imaging reports pertinent to performed procedure
- Operative report(s) (when applicable)
- Conservative treatment modalities include but are not limited to\*:

- Physical Therapy
- Occupational Therapy
- Injections
- Medications
- Assistive device use
- Activity modification

\* When imminent surgery is required, and the medical records are submitted without conservative treatment documentation, supporting documentation must be received in the form of imaging report(s), physical findings correlated to the imaging, and the surgeon's note(s).

### 6.3.2.2 - Implanted Spinal Neurostimulators<sup>2</sup>

Providers who plan to perform **both** the trial and permanent implantation procedures using CPT 63650 in the hospital OPD will **only** be required to submit a PAR for the trial procedure. To avoid a claim denial, providers must place the Unique Tracking Number (UTN) received for the trial procedure on the claim submitted for the permanent implantation procedure. When the trial is rendered in a setting other than hospital OPD, providers will need to request PA for CPT 63650 as part of the permanent implantation procedure in the hospital OPD.

General Documentation Requirements for trial **or** permanent Implanted Spinal Neurostimulators:

- Indicate if this request is for a trial or permanent placement
- Physician office notes including:
  - Condition requiring procedure
  - Physical examination
  - Treatments tried and failed including but are not limited to:
    - Spine surgery
    - Physical therapy
    - Medications
    - Injections
    - Psychological therapy
- Documentation of **appropriate** psychological evaluation<sup>3</sup>
- For permanent placement, include all the above documentation, as well as documentation of pain relief with the temporary implanted electrode(s).
  - A successful trial should be associated with at least 50% reduction of target pain or 50% reduction of analgesic medications.

<sup>2</sup> 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 CMS-1736-FC.

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

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

## 6.4 – Program Specifics for an Additional Hospital OPD Service

### 6.4.1- Implementation of Prior Authorization

The MACs will begin accepting PARs for the new service category on June 15, 2023, for dates of service on or after July 1, 2023.

### 6.4.2- Required Documentation

For detailed documentation requirements, the hospital OPD providers should refer to their local MAC jurisdiction's LCDs/LCAs, where applicable. To meet coverage criteria, the patient's medical record must contain documentation that fully supports the medical necessity for services.

The following additional hospital OPD service category will require PA: Facet Joint Interventions.

#### 6.4.2.1- Facet Joint Interventions

 General Documentation Requirements for Facet Joint Interventions- Intraarticular (IA) Facet Joint Injections, Medial Branch Blocks (MBB), and Radiofrequency Ablations (RFA):

- Moderate to severe chronic neck or low back pain, predominantly axial, that causes functional deficit measured on pain or disability scale, **and**
- Presence of pain for minimum of 3 months with documented failure to respond to conservative management, **and**
- Absence of untreated radiculopathy or neurogenic claudication (except for radiculopathy caused by facet joint synovial cyst), **and**
- Non-facet pathology must be ruled out based on clinical evaluation or radiology studies
- The scales used to assess the measurement of pain and/or disability must be obtained at baseline and documented in the medical record for each assessment (refer to your MAC's LCD/LCA).

Diagnostic Facet Joint Procedures (IA or MBB):

- Indicate if this request is for an initial or second diagnostic procedure
- For the first diagnostic facet joint procedure, documentation must support the criteria outlined in general documentation requirements for facet joint interventions
- Diagnostic procedures should be performed with the intent that if successful, RFA would be considered the primary treatment goal at the diagnosed level(s)
- For the second diagnostic facet joint procedure(s), documentation must support the

following:

- Documentation must support the requirements for the first diagnostic procedure at the same level, **and**
- After the first diagnostic procedure, there must be at least 80% of pain relief, **and**
- The second diagnostic procedure may only be performed a minimum of 2 weeks after the initial diagnostic procedure. Exception to the two-weeks duration may be considered on an individual basis and must be clearly documented in the medical record

Frequency limitation for IA/MBB: 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.

Therapeutic Facet Joint Procedures (IA):

- Indicate if this request is for an initial or subsequent therapeutic procedure
- Documentation of two (2) diagnostic facet joint procedures with each providing at least 80% of pain relief, **and**
- Subsequent therapeutic facet joint procedures at the same anatomic site with at least 50% pain relief for at least 3 months from the prior therapeutic procedure or at least 50% improvement in the ability to perform previously painful movements and ADLs, compared to baseline measurement using the same scale, **and**
- Documentation of why the beneficiary is not a candidate for radiofrequency ablation (RFA)

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.

Facet Joint Denervation (RFA):

- Indicate if this request is for an initial or subsequent facet joint denervation procedure
- For the initial thermal RFA, documentation must support at least two (2) diagnostic MBBs with each one providing at least 80% of pain relief, **and**
- Subsequent thermal facet joint RFA at the same anatomic site with at least 50% of pain improvement for at least six (6) months or at least 50% improvement in the ability to perform previously painful movements and ADLs, 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.

## 7 – Decisions

### 7.1 - Provisional Affirmation PA Decision

A provisional affirmation PA decision is a preliminary finding that a future claim submitted to Medicare for the service (s) likely meets Medicare’s coverage, coding, and payment requirements. The provisional affirmation PA decision is valid for 120 days from the date decision was made.

### 7.2 - Non-Affirmation PA Decision

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

The MAC will provide the PAR requester notification of what required documentation is missing or noncompliant with Medicare requirements via fax, mail, or the MAC provider portal (when available). The decision letter for an incomplete PAR will be detailed and postmarked within the applicable timeframes described in Section 4.1 as it pertains to each hospital's OPD service.

### 7.3 - Provisional Partial Affirmation PA Decision

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

The MAC will follow the same process for any service(s) within the PA request that is given a provisional affirmation decision as is described in § 7.1 and for any service(s) that are given a non-affirmation decision as is described in § 7.2.

### 7.4 - Resubmitting PAR



The requestor may resubmit another complete PAR with all documentation required and whatever modifications are needed, as noted in the detailed decision letter. Unlimited resubmissions are permitted. The requestor is encouraged to include the original non-affirmed UTN on the resubmitted PAR.

## 8 - Claim Submission

### 8.1 – Affirmed PA Decision on File

Cases where a PAR was submitted, and a provisional affirmation PA decision was granted, including any service(s) that was part of a partially affirmed decision.

- The submission of the prior authorized claim is to have the 14 bytes UTN that is located on the decision letter. For submission of electronic claims, the UTN must be in positions 1 through 18. When the claim enters the Fiscal Intermediary Shared System (FISS), the UTN will move to positions 19 through 32, and zeros will autofill the first field. For providers submitting electronic claims, the Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at the loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.
- For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN. If information is entered into the first field (positions 1 through 18), it will come into FISS as zeros. If the Treatment Authorization Code is entered into the first field, FISS changes the Treatment Authorization code to zeros, and the claim will not be accepted. If the UTN is entered into the first Treatment Authorization field, FISS will change the UTN to all zeros. The claim is accepted into FISS with the zeros and without the UTN. The claim will process without the UTN but will edit for the OPD UTN.
- Should be submitted to the applicable MAC for adjudication.

**Note:** If all Medicare coverage, coding, and payment requirements are met, the claim will likely be paid.

- Claims receiving a provisional affirmation may be denied based on either of the following:
- Technical requirements that can only be evaluated after the claim has been submitted for formal processing; or
- Information was not available at the time of a PAR.
- We note claims for which there is a provisional affirmation PA decision will be afforded some protection from future audits, both pre- and postpayment; however, review contractors may audit claims if potential fraud, inappropriate utilization, or changes in billing patterns are identified.

### 8.2 – Non-Affirmed PA Decision on File

Cases where a PAR was submitted, and a non-affirmed PA decision was granted, including any non-affirmed service(s) that was part of a partially affirmed decision.

- The submission of the prior authorized claim is to have the 14-byte UTN that is located on the decision letter. For submission of electronic claims, the UTN must be in positions 1 through 18. When the claim enters the Fiscal Intermediary Shared System (FISS), the UTN will move to positions 19 through 32, and zeros will autofill the first field. For providers submitting electronic claims, the Medicare Treatment Authorization field must contain blanks or valid Medicare data in the first 14 bytes of the treatment authorization field at the loop 2300 REF02 (REF01=G1) segment for the ASC X12 837 claim.
  - For all other submissions, the provider must TAB to the second field of the treatment authorization field (positions 19–32) and key the UTN. If information is entered into the first field (positions 1 through 18), it will come into FISS as zeros. If the Treatment Authorization Code is entered into the first field, FISS changes the Treatment Authorization code to zeros, and the claim will not be accepted. If the UTN is entered into the first Treatment Authorization field, FISS will change the UTN to all zeros. The claim is accepted into FISS with the zeros and without the UTN. The claim will process without the UTN but will edit for the OPD UTN.
  - Should be submitted to the applicable MAC for adjudication.
-  • If the claim is submitted to the MAC for payment with a non-affirmative PA decision, it will be denied.
- All appeal rights are then available.
  - This claim could then be submitted to secondary insurance, if applicable.

### 8.3- Claims Submitted without a PA Decision on File

-  • As described in 42 CFR §419.82, if a service requires PA under this program, submitting a PAR is a **condition of payment**.
-  • Claims for HCPCS code subject to required PA submitted without a PA determination and a corresponding UTN will be automatically denied.

### 8.4 – Denials for Related Services

Claims related to or associated with services that require PA as a condition of payment will not be paid if the service requiring PA is not also paid. These related services include, but are not limited to, services such as anesthesiology services, physician services, and/or facility services. Only associated services performed in the OPD setting will be affected.

Depending on the timing of claim submission for any related services, claims may be automatically denied or denied on a postpayment basis.

#### 8.4.1 –Associated Services Codes

CMS intends to deny services that are associated with OPD services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, vein ablation, cervical fusion with disc removal, and implanted spinal neurostimulators) that require PA as a condition of payment and have received non-affirmation decisions and/or have denied claims. The codes for these associated services are listed in the table located in Appendix B (OPD PA Part B Associated Codes List). This list is subject to change in the future.

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## 9 – Special Claim Considerations

### 9.1 – Advanced Beneficiary Notice (ABN)

If the hospital OPD receives a non-affirmed PA decision because the service was determined to be not medically reasonable and necessary, the provider should issue an ABN in advance of performing the service if it is expected that payment will be denied. The provider should submit the claim with the GA modifier appended to it. The Contractor will determine the validity of the ABN in accordance with standard ABN policies. (See IOM 100-04, Chapter 30)

If an applicable claim is submitted without a PA decision and is flagged as having an ABN, it will be stopped for additional documentation to be requested, and a review of the ABN will be performed (to determine the validity of the ABN) following standard claim review guidelines and timelines.

The provider should issue ABN and submit the claim with a GX modifier if it is expected that Medicare would deny payment for a service under the statutory exclusion for purely cosmetic services. Under those circumstances, ABN is voluntary and is not required to bill the patient for the service that is denied under the cosmetic services exclusion. However, CMS encourages providers to issue an ABN in this situation to inform the beneficiary of the likelihood of financial liability.

### 9.2 – Claims Exclusions

The following claim types are excluded from the PA program described in this operational guide unless otherwise specified:

- Veterans Affairs
- Indian Health Services
- Medicare Advantage
- Part A and Part B Demonstration
- Medicare Advantage sub-category IME only claims
- Part A/B rebilling
- Claims for Emergency Department services when the claim is submitted with an ET modifier or 045x revenue code. (This does not exclude these claims from regular medical review.)

## 10 – Secondary Insurance

This section pertains to the instances where the beneficiary has more than one insurance. In these instances, Medicare must be either the first or the secondary insurance company.

### 10.1 – Medicare is Primary Insurance

In cases where Medicare is primary, and another insurance company is secondary:

 The contractors will suspend claims to request documentation and conduct a review of the Advanced Beneficiary Notice (ABN) when there is no PAR and the claim is submitted with the GA modifier appended.

The Contractor will determine the validity of the ABN in accordance with standard ABN policies. (See IOM 100-04, Chapter 30, Section 40).

 Providers who choose to use the PA process to obtain a claim denial should follow the below process:

- The requester may submit the **PAR** with complete documentation as appropriate. If all relevant Medicare coverage requirements are **not** met for the service, then a non-affirmative PA decision will be sent to the provider and beneficiary, advising that Medicare will not pay for the item.
- After receiving a non-affirmative decision for the PAR, if the associated **claim** is submitted by the provider to the MAC for payment, it will be denied.
- The provider or beneficiary may forward the denied claim to his/her secondary insurance payer as appropriate to determine payment for the service.

In cases where a beneficiary is dually eligible for Medicaid and Medicare, a non-affirmed PA decision is sufficient for meeting states' obligation to pursue other coverage before considering Medicaid coverage. The provider may need to submit the claim to Medicare first and obtain a denial before submitting the claim to Medicaid for payment<sup>4</sup>.

### 10.2 – Another Insurance Company is Primary

Cases where another insurance company is primary and Medicare is secondary:

- The requester submits the PAR with complete documentation as appropriate. If all relevant Medicare coverage requirements **are** met for the item(s), then a provisional affirmative PA decision will be sent to the provider and to the beneficiary, if specifically requested by the beneficiary, advising them that Medicare **will** pay for the service.

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<sup>4</sup> <https://www.medicaid.gov/federal-policy-guidance/downloads/cib011317.pdf>

- The provider submits a claim to the other insurance company.
- If the other insurance company denies the claim, the provider or beneficiary can submit a claim to the MAC for payment (listing the unique tracking number on the claim).

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## 11- Claim Appeals

Claims subject to PA requirements under the hospital OPD program follow all current appeals procedures. A PAR that is non-affirmed is not an initial determination on a claim for payment for services provided and, therefore, would not be appealable; however, the provider has an unlimited number of opportunities to resubmit a PAR, provided the claim has not yet been submitted and denied.



A non-affirmation PA decision does not prevent the provider from submitting a claim. Submission of such a claim and resulting denial by the MAC would constitute an initial payment determination, which makes the appeal rights available.

For further information, please consult the Medicare Claims Processing Manual publication, Chapter 29, Appeals of Claims Decision.

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## **12- Suspension of PA process**

CMS may suspend the OPD services PA process requirements generally or for a particular service(s) at any time by issuing a notification on the CMS website.

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## Appendix A

## Final List of Outpatient Department Services That Require Prior Authorization

The following is the list of codes associated with the list of hospital outpatient department services contained in 42 CFR 419.83(a)(1) and (2).	
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after <i>July 1, 2020</i> :	
<ul style="list-style-type: none"> <li>(i) Blepharoplasty</li> <li>(ii) Botulinum toxin injections</li> <li>(iii) Panniculectomy</li> <li>(iv) Rhinoplasty</li> <li>(v) Vein ablation</li> </ul>	
Code	(i) Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair <sup>1</sup>
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

<sup>1</sup> CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

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 <sup>2</sup>
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

<sup>2</sup> CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

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
The following service categories comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2021:	
(i) Cervical Fusion with Disc Removal	
(ii) Implanted Spinal Neurostimulators	
Code	Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators <sup>3</sup>
63650	Percutaneous implantation of neurostimulator electrode array, epidural
The following service category comprise the list of hospital outpatient department services requiring prior authorization beginning for service dates on or after July 1, 2023: Facet Joint Interventions.	
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;



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

<sup>3</sup>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 CMS-1736-FC.

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## Appendix B

## OPD PA Part B Associated Codes List

## Blepharoplasty, Blepharoptosis Repair, and Brow Ptosis Repair

HCPCS Codes	HCPCS Description
00103	Anesthesia for reconstructive procedures of eyelid (eg, blepharoplasty, ptosis surgery)
14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
15260	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
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
21282	Lateral canthopexy
67830	Correction of trichiasis; incision of lid margin
67840	Excision of lesion of eyelid (except chalazion) without closure or with simple direct closure
67875	Temporary closure of eyelids by suture (eg, Frost suture)
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)
67912	Correction of lagophthalmos, with implantation of upper eyelid lid load (eg, gold weight)
67917	Repair of ectropion; extensive (eg, tarsal strip operations)
67921	Repair of entropion; suture
67924	Repair of entropion; extensive (eg, tarsal strip or capsulopalpebral fascia repairs operation)
67950	Canthoplasty (reconstruction of canthus)
67966	Excision and repair of eyelid, involving lid margin, tarsus, conjunctiva, canthus, or full thickness, may include preparation for skin graft or pedicle flap with adjacent tissue transfer or rearrangement; over one-fourth of lid margin
67973	Reconstruction of eyelid, full thickness by transfer of tarsoconjunctival flap from opposing eyelid; total eyelid, lower, 1 stage or first stage

<b>HCPCS Codes</b>	<b>HCPCS Description</b>
88300	Level I - Surgical pathology, gross examination only
88302	Level II - Surgical pathology, gross and microscopic examination: Appendix, incidental; Fallopian tube, sterilization; Fingers/toes, amputation, traumatic; Foreskin, newborn; Hernia sac, any location; Hydrocele sac; Nerve; Skin, plastic repair; Sympathetic ganglion; Testis, castration; Vaginal mucosa, incidental; Vas deferens, sterilization
88304	Level III - Surgical pathology, gross and microscopic examination: Abortion, induced; Abscess; Aneurysm - arterial/ventricular; Anus, tag; Appendix, other than incidental; Artery, atheromatous plaque; Bartholin's gland cyst; Bone fragment(s), other than pathologic fracture; Bursa/synovial cyst; Carpal tunnel tissue; Cartilage, shavings; Cholesteatoma; Colon, colostomy stoma; Conjunctiva - biopsy/pterygium; Cornea; Diverticulum - esophagus/small intestine; Dupuytren's contracture tissue; Femoral head, other than fracture; Fissure/fistula; Foreskin, other than newborn; Gallbladder; Ganglion cyst; Hematoma; Hemorrhoids; Hydatid of Morgagni; Intervertebral disc; Joint, loose body; Meniscus; Mucocele, salivary; Neuroma - Morton's/traumatic; Pilonidal cyst/sinus; Polyps, inflammatory - nasal/sinusoidal; Skin - cyst/tag/debridement; Soft tissue, debridement; Soft tissue, lipoma; Spermatocoele; Tendon/tendon sheath; Testicular appendage; Thrombus or embolus; Tonsil and/or adenoids; Varicocele; Vas deferens, other than sterilization; Vein, varicosity;
88331	Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen

### Botulinum Toxin Injections

<b>HCPCS Codes</b>	<b>HCPCS Description</b>
20553	Injection(s); single or multiple trigger point(s), 3 or more muscles
31573	Laryngoscopy, flexible; with therapeutic injection(s) (eg, chemodenervation agent or corticosteroid, injected percutaneous, transoral, or via endoscope channel), unilateral
31575	Laryngoscopy, flexible; diagnostic
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve
64450	Injection(s), anesthetic agent(s) and/or steroid; other peripheral nerve or branch
64611	Chemodenervation of parotid and submandibular salivary glands, bilateral
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)
64616	Chemodenervation of muscle(s); neck muscle(s), excluding muscles of the larynx, unilateral (eg, for cervical dystonia, spasmodic torticollis)
64617	Chemodenervation of muscle(s); larynx, unilateral, percutaneous (eg, for spasmodic dysphonia), includes guidance by needle electromyography, when performed
76942	Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device), imaging supervision and interpretation

<b>HCPCS Codes</b>	<b>HCPCS Description</b>
92012	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; intermediate, established patient
92014	Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits
92285	External ocular photography with interpretation and report for documentation of medical progress (eg, close-up photography, slit lamp photography, gonioscopy, stereo-photography)
95874	Needle electromyography for guidance in conjunction with chemodenervation
96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular
J0585	Injection, onabotulinumtoxin A, 1 unit
J0586	Injection, abobotulinumtoxin A, 5 units
J0587	Injection, rimabotulinumtoxin B, 100 units
J0588	Injection, incobotulinumtoxin A, 1 unit

### Panniculectomy

<b>HCPCS Codes</b>	<b>HCPCS Description</b>
00802	Anesthesia for procedures on lower anterior abdominal wall; panniculectomy
11406	Excision, benign lesion including margins, except skin tag (unless listed elsewhere), trunk, arms or legs; excised diameter over 4.0 cm
13101	Repair, complex, trunk; 2.6 cm to 7.5 cm
13102	Repair, complex, trunk; each additional 5 cm or less
14301	Adjacent tissue transfer or rearrangement, any area; defect 30.1 sq cm to 60.0 sq cm
14302	Adjacent tissue transfer or rearrangement, any area; each additional 30.0 sq cm, or part thereof
15777	Implantation of biologic implant (eg, acellular dermal matrix) for soft tissue reinforcement (ie, breast, trunk)
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
31571	Laryngoscopy, direct, with injection into vocal cord(s), therapeutic; with operating microscope or telescope
33286	Removal, subcutaneous cardiac rhythm monitor
49561	Repair initial incisional or ventral hernia; incarcerated or strangulated
49566	Repair recurrent incisional or ventral hernia; incarcerated or strangulated
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed)
88300	Level I - Surgical pathology, gross examination only
88302	Level II - Surgical pathology, gross and microscopic examination: Appendix, incidental; Fallopian tube, sterilization; Fingers/toes, amputation, traumatic;

HCPCS Codes	HCPCS Description
	Foreskin, newborn; Hernia sac, any location; Hydrocele sac; Nerve; Skin, plastic repair; Sympathetic ganglion; Testis, castration; Vaginal mucosa, incidental; Vas deferens, sterilization
88304	Level III - Surgical pathology, gross and microscopic examination: Abortion, induced; Abscess; Aneurysm - arterial/ventricular; Anus, tag; Appendix, other than incidental; Artery, atheromatous plaque; Bartholin's gland cyst; Bone fragment(s), other than pathologic fracture; Bursa/synovial cyst; Carpal tunnel tissue; Cartilage, shavings; Cholesteatoma; Colon, colostomy stoma; Conjunctiva - biopsy/pterygium; Cornea; Diverticulum - esophagus/small intestine; Dupuytren's contracture tissue; Femoral head, other than fracture; Fissure/fistula; Foreskin, other than newborn; Gallbladder; Ganglion cyst; Hematoma; Hemorrhoids; Hydatid of Morgagni; Intervertebral disc; Joint, loose body; Meniscus; Mucocele, salivary; Neuroma - Morton's/traumatic; Pilonidal cyst/sinus; Polyps, inflammatory - nasal/sinusoidal; Skin - cyst/tag/debridement; Soft tissue, debridement; Soft tissue, lipoma; Spermatocele; Tendon/tendon sheath; Testicular appendage; Thrombus or embolus; Tonsil and/or adenoids; Varicocele; Vas deferens, other than sterilization; Vein, varicosity
88312	Special stain including interpretation and report; Group I for microorganisms (eg, acid fast, methenamine silver)

### Rhinoplasty

HCPCS Codes	HCPCS Description
00160	Anesthesia for procedures on nose and accessory sinuses; not otherwise specified
13132	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; 2.6 cm to 7.5 cm
13133	Repair, complex, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; each additional 5 cm or less
14040	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10 sq cm or less
14041	Adjacent tissue transfer or rearrangement, forehead, cheeks, chin, mouth, neck, axillae, genitalia, hands and/or feet; defect 10.1 sq cm to 30.0 sq cm
14060	Adjacent tissue transfer or rearrangement, eyelids, nose, ears and/or lips; defect 10 sq cm or less
15260	Full thickness graft, free, including direct closure of donor site, nose, ears, eyelids, and/or lips; 20 sq cm or less
15275	Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area
15730	Midface flap (ie, zygomaticofacial flap) with preservation of vascular pedicle(s)
15733	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)
20912	Cartilage graft; nasal septum
21016	Radical resection of tumor (eg, sarcoma), soft tissue of face or scalp; 2 cm or greater
21210	Graft, bone; nasal, maxillary or malar areas (includes obtaining graft)

<b>HCPCS Codes</b>	<b>HCPCS Description</b>
21235	Graft; ear cartilage, autogenous, to nose or ear (includes obtaining graft)
21282	Lateral canthopexy
30120	Excision or surgical planing of skin of nose for rhinophyma
30140	Submucous resection inferior turbinate, partial or complete, any method
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
31253	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including frontal sinus exploration, with removal of tissue from frontal sinus, when performed
31259	Nasal/sinus endoscopy, surgical with ethmoidectomy; total (anterior and posterior), including sphenoidotomy, with removal of tissue from the sphenoid sinus
31267	Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus
31276	Nasal/sinus endoscopy, surgical, with frontal sinus exploration, including removal of tissue from frontal sinus, when performed
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural
88300	Level I - Surgical pathology, gross examination only
88302	Level II - Surgical pathology, gross and microscopic examination: Appendix, incidental; Fallopian tube, sterilization; Fingers/toes, amputation, traumatic; Foreskin, newborn; Hernia sac, any location; Hydrocele sac; Nerve; Skin, plastic repair; Sympathetic ganglion; Testis, castration; Vaginal mucosa, incidental; Vas deferens, sterilization;
88304	Level III - Surgical pathology, gross and microscopic examination: Abortion, induced; Abscess; Aneurysm - arterial/ventricular; Anus, tag; Appendix, other than incidental; Artery, atheromatous plaque; Bartholin's gland cyst; Bone fragment(s), other than pathologic fracture; Bursa/synovial cyst; Carpal tunnel tissue; Cartilage, shavings; Cholesteatoma; Colon, colostomy stoma; Conjunctiva - biopsy/pterygium; Cornea; Diverticulum - esophagus/small intestine; Dupuytren's contracture tissue; Femoral head, other than fracture; Fissure/fistula; Foreskin, other than newborn; Gallbladder; Ganglion cyst; Hematoma; Hemorrhoids; Hydatid of Morgagni; Intervertebral disc; Joint, loose body; Meniscus; Mucocele, salivary; Neuroma - Morton's/traumatic; Pilonidal cyst/sinus; Polyps, inflammatory - nasal/sinusoidal; Skin - cyst/tag/debridement; Soft tissue, debridement; Soft tissue,

HCPCS Codes	HCPCS Description
	lipoma; Spermatocele; Tendon/tendon sheath; Testicular appendage; Thrombus or embolus; Tonsil and/or adenoids; Varicocele; Vas deferens, other than sterilization; Vein, varicosity;
88331	Pathology consultation during surgery; first tissue block, with frozen section(s), single specimen

### Vein Ablation

HCPCS Codes	HCPCS Description
01930	Anesthesia for therapeutic interventional radiological procedures involving the venous/lymphatic system (not to include access to the central circulation); not otherwise specified
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg
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
37761	Ligation of perforator vein(s), subfascial, open, including ultrasound guidance, when performed, 1 leg
37765	Stab phlebectomy of varicose veins, 1 extremity; 10-20 stab incisions
37766	Stab phlebectomy of varicose veins, 1 extremity; more than 20 incisions
37799	Unlisted procedure, vascular surgery
88304	Level III - Surgical pathology, gross and microscopic examination: Abortion, induced; Abscess; Aneurysm - arterial/ventricular; Anus, tag; Appendix, other than incidental; Artery, atheromatous plaque; Bartholin's gland cyst; Bone fragment(s), other than pathologic fracture; Bursa/synovial cyst; Carpal tunnel tissue; Cartilage, shavings; Cholesteatoma; Colon, colostomy stoma; Conjunctiva - biopsy/pterygium;

HCPCS Codes	HCPCS Description
	Cornea; Diverticulum - esophagus/small intestine; Dupuytren's contracture tissue; Femoral head, other than fracture; Fissure/fistula; Foreskin, other than newborn; Gallbladder; Ganglion cyst; Hematoma; Hemorrhoids; Hydatid of Morgagni; Intervertebral disc; Joint, loose body; Meniscus; Mucocele, salivary; Neuroma - Morton's/traumatic; Pilonidal cyst/sinus; Polyps, inflammatory - nasal/sinusoidal; Skin - cyst/tag/debridement; Soft tissue, debridement; Soft tissue, lipoma; Spermatocele; Tendon/tendon sheath; Testicular appendage; Thrombus or embolus; Tonsil and/or adenoids; Varicocele; Vas deferens, other than sterilization; Vein, varicosity;
93922	Limited bilateral noninvasive physiologic studies of upper or lower extremity arteries, (eg, for lower extremity: ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus bidirectional, Doppler waveform recording and analysis at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries plus volume plethysmography at 1-2 levels, or ankle/brachial indices at distal posterior tibial and anterior tibial/dorsalis pedis arteries with, transcutaneous oxygen tension measurement at 1-2 levels)
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study

### Cervical Fusion with Disc Removal

HCPCS Codes	HCPCS Description
00600	Anesthesia for procedures on cervical spine and cord; not otherwise specified
20930	Allograft, morselized, or placement of osteopromotive material, for spine surgery only
20931	Allograft, structural, for spine surgery only
20936	Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminae fragments) obtained from same incision
20937	Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision)
20939	Bone marrow aspiration for bone grafting, spine surgery only, through separate skin or fascial incision
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophyctomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
22830	Exploration of spinal fusion
22845	Anterior instrumentation; 2 to 3 vertebral segments
22846	Anterior instrumentation; 4 to 7 vertebral segments
22849	Reinsertion of spinal fixation device
22853	Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to intervertebral disc space in conjunction with interbody arthrodesis, each interspace

HCPCS Codes	HCPCS Description
22854	Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges), when performed, to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect
22855	Removal of anterior instrumentation
36620	Arterial catheterization or cannulation for sampling, monitoring or transfusion (separate procedure); percutaneous
63081	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, single segment
63082	Vertebral corpectomy (vertebral body resection), partial or complete, anterior approach with decompression of spinal cord and/or nerve root(s); cervical, each additional segment
72020	Radiologic examination, spine, single view, specify level
72040	Radiologic examination, spine, cervical; 2 or 3 views
72050	Radiologic examination, spine, cervical; 4 or 5 views
72125	Computed tomography, cervical spine; without contrast material
76937	Ultrasound guidance for vascular access requiring ultrasound evaluation of potential access sites, documentation of selected vessel patency, concurrent realtime ultrasound visualization of vascular needle entry, with permanent recording and reporting
88300	Level I - Surgical pathology, gross examination only
95861	Needle electromyography; 2 extremities with or without related paraspinal areas
95865	Needle electromyography; larynx
95868	Needle electromyography; cranial nerve supplied muscles, bilateral
95870	Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters
95928	Central motor evoked potential study (transcranial motor stimulation); upper limbs
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs

### Implanted Spinal Neurostimulators

HCPCS Codes	HCPCS Description
00620	Anesthesia for procedures on thoracic spine and cord, not otherwise specified
00630	Anesthesia for procedures in lumbar region; not otherwise specified
01992	Anesthesia for diagnostic or therapeutic nerve blocks and injections (when block or injection is performed by a different physician or other qualified health care professional); prone position

HCPCS Codes	HCPCS Description
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)
63650	Percutaneous implantation of neurostimulator electrode array, epidural
63655	Laminectomy for implantation of neurostimulator electrodes, plate/paddle, epidural
63663	Revision including replacement, when performed, of spinal neurostimulator electrode percutaneous array(s), including fluoroscopy, when performed
63685	Insertion or replacement of spinal neurostimulator pulse generator or receiver, direct or inductive coupling
63688	Revision or removal of implanted spinal neurostimulator pulse generator or receiver
69990	Microsurgical techniques, requiring use of operating microscope
72020	Radiologic examination, spine, single view, specify level
72070	Radiologic examination, spine; thoracic, 2 views
72074	Radiologic examination, spine; thoracic, minimum of 4 views
72080	Radiologic examination, spine; thoracolumbar junction, minimum of 2 views
72100	Radiologic examination, spine, lumbosacral; 2 or 3 views
75705	Angiography, spinal, selective, radiological supervision and interpretation
75894	Transcatheter therapy, embolization, any method, radiological supervision and interpretation
77003	Fluoroscopic guidance and localization of needle or catheter tip for spine or paraspinal diagnostic or therapeutic injection procedures (epidural or subarachnoid)
95861	Needle electromyography; 2 extremities with or without related paraspinal areas
95870	Needle electromyography; limited study of muscles in 1 extremity or non-limb (axial) muscles (unilateral or bilateral), other than thoracic paraspinal, cranial nerve supplied muscles, or sphincters
95926	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in lower limbs
95937	Neuromuscular junction testing (repetitive stimulation, paired stimuli), each nerve, any 1 method
95938	Short-latency somatosensory evoked potential study, stimulation of any/all peripheral nerves or skin sites, recording from the central nervous system; in upper and lower limbs
95939	Central motor evoked potential study (transcranial motor stimulation); in upper and lower limbs
95970	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming
95971	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional

HCPCS Codes	HCPCS Description
95972	Electronic analysis of implanted neurostimulator pulse generator/transmitter (eg, contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with complex spinal cord or peripheral nerve (eg, sacral nerve) neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional
96374	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); intravenous push, single or initial substance/drug
96375	Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); each additional sequential intravenous push of a new substance/drug
99152	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; initial 15 minutes of intraservice time, patient age 5 years or older
99153	Moderate sedation services provided by the same physician or other qualified health care professional performing the diagnostic or therapeutic service that the sedation supports, requiring the presence of an independent trained observer to assist in the monitoring of the patient's level of consciousness and physiological status; each additional 15 minutes intraservice time

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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.

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**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 <sup>330</sup>
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, onabotulinumtoxin a, 1 unit
J0586	Injection, abobotulinumtoxin a, 5 units
J0587	Injection, rimabotulinumtoxin b, 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
Code	(iv) Rhinoplasty, and related services <sup>331</sup>
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
<b>Beginning for service dates on or after July 1, 2021</b>	
Code	(i) Cervical Fusion with Disc Removal
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2
22552	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophylectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace
Code	(ii) Implanted Spinal Neurostimulators <sup>332</sup>
63650	Percutaneous implantation of neurostimulator electrode array, epidural
<b>Beginning for service dates on or after July 1, 2023</b>	
Code	Facet Joint Interventions
64490	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; single level
64491	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; second level
64492	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), cervical or thoracic; third and any additional level(s)
64493	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; single level
64494	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; second level
64495	Injection(s), diagnostic or therapeutic agent, paravertebral facet (zygapophyseal) joint (or nerves innervating that joint) with image guidance (fluoroscopy or CT), lumbar or sacral; third and any additional level(s)
64633	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, single facet joint

64634	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); cervical or thoracic, each additional facet joint
64635	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, single facet joint
64636	Destruction by neurolytic agent, paravertebral facet joint nerve(s), with imaging guidance (fluoroscopy or CT); lumbar or sacral, each additional facet joint

## BILLING CODE 4120-01-C

**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<sup>333</sup> (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.<sup>334 335 336 337 338 339 340</sup> In the CY

<sup>330</sup>CPT 67911 (Correction of lid retraction) was removed on January 7, 2022.

<sup>331</sup>CPT 21235 (Obtaining ear cartilage for grafting) was removed on June 10, 2020.

<sup>332</sup>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.

<sup>333</sup>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>.

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

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

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

<sup>337</sup>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](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

<sup>338</sup>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](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

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

<sup>339</sup>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](https://qualitynet.org/outpatient/public-reporting/overall-ratings/resources).

<sup>340</sup>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](https://qualitynet.org/inpatient/public-reporting/overall-ratings/resources#tab2).

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

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

**Prior Authorization (General)**

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

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

**2. Q: When did the Prior Authorization Process for OPD Services begin?**

A: Prior Authorization for the initial five services (blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation) started on June 17, 2020, for dates of service on or after July 1, 2020. Two additional hospital OPD services (cervical fusion with disc removal and implanted spinal neurostimulators) requiring prior authorization started on June 17, 2020, for dates of service on or after July 1, 2021. **Facet joint interventions will require prior authorization for dates of service on or after July 1, 2023.**

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

A: As part of the Calendar Year 2020 OPPS/ASC Final Rule (CMS-1717-FC), CMS required prior authorization for the following service **categories**: blepharoplasty, botulinum toxin injections, panniculectomy, rhinoplasty, and vein ablation. As part of the Calendar Year 2021 OPPS/ASC Final Rule (CMS-1736-FC), CMS required prior authorization for two additional service **categories**: cervical fusion with disc removal and implanted spinal neurostimulators. **As announced in the Calendar Year 2023 OPPS/ASC Final Rule (CMS-1772-FC), for dates of service on or after July 1, 2023, CMS will require prior authorization for a new service category: Facet joint interventions.** The Final List of Outpatient Services that Require Prior Authorization is located [here](#).

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

A: CMS will only require prior authorization for CPT code 63650 (Implantation of

spinal neurostimulator electrodes, accessed through the skin) at this time. CMS is temporarily removing CPT codes 63685 and 63688 from the list of OPD services that require prior authorization.

**5. Q: Why is CMS temporarily removing CPT codes 63685 and 63688 from the list of OPD services that require prior authorization?**

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

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

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

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

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

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

A: The CMS has observed significant increases in the utilization volume of some covered OPD services. Our analysis and research showed that increases in the volume of these OPD services are unnecessary, and further program integrity action is warranted. As part of our responsibility to protect the Medicare Trust Funds, we continually analyze data to determine if there are additional covered OPD services that are exhibiting unnecessary increases in volume for which prior authorization would be appropriate. We believe prior authorization for these services will be an effective method for controlling unnecessary increases in volume and will reduce instances in which Medicare pays for services that do not meet Medicare requirements.

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

A: Suppliers, providers, and other Medicare practitioners can be confident that the items

and services that their patients need will be covered without time delays, subsequent paperwork, or the need to file an appeal for a claim that was later deemed not payable. In addition, paid claims for which there is an associated provisional affirmation decision will be afforded some protection from future audits.

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

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

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

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

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



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

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

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

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

A: Yes. The Maryland hospital waiver does not affect their OPD requirement to

participate in this program. Maryland OPDs are required to submit prior authorization requests for the services listed in this program.

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

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

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

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

**Prior Authorization Request Process**

**17. Q: What form do I use to submit a prior authorization request, and is it available on the website?**

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

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

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

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

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

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



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



**21. Q: Do the botulinum toxin J-codes listed in this program require prior**

**authorization when they are used for injection procedures other than 64612 and 64615?**

A: No. Prior authorization is only required when one of the required Botulinum Toxin codes (J0585, J0586, J0587, or J0588) is used in conjunction with one of the required CPT injection codes (64612, injection of chemical for destruction of nerve muscles on one side of face, or 64615, injection of chemical for destruction of facial and neck nerve muscles on both sides of face). Use of these Botulinum Toxin codes in conjunction/paired with procedure codes other than 64612 or 64615 will not require prior authorization under this program.

**Prior Authorization Request Process-Medical Review**

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

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

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

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

- A provisional affirmation decision is a preliminary finding that a future claim submitted to Medicare for the item or service meets Medicare's coverage, coding, and payment requirements.
- A non-affirmation decision is a preliminary finding that, if a future claim is submitted for the item or service, it does not meet Medicare's coverage, coding, and payment requirements.
- A provisional partial affirmation decision means that one or more service(s) on the request received a provisional affirmation decision, and one or more service(s) received a non-affirmation decision.
- The MAC will send the hospital OPD provider a written decision (i.e., provisional affirmation, provisional partial affirmation, or non-affirmation) and, if applicable, provide the detailed reasons for the non-affirmation decision. The MAC will also share such information with beneficiaries.

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

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



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

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

**26. Q: What is a resubmitted request?**

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

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

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

**28. Q: Can I appeal a claim that did not go through prior authorization and does not have UTN?**

A: Failure to submit a prior authorization request for a service on the prior authorization list will result in the denial of the service. These denials are considered initial determinations that are subject to appeal. In processing an appeal of a claim for which there was no submission of a prior authorization request, MACs will acknowledge the issues raised by a party in the redetermination notice. MACs will consider whether there was, in fact, a prior authorization request submitted for the OPD service as required in regulation. If no prior authorization request was submitted, payment shall not be made due to the failure to comply with a mandatory condition of payment, even if the item or service is otherwise covered.

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

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

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

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

**Prior Authorization Request Process-Unique Tracking Number (UTN)****31. Q: Will there be a tracking number for each prior authorization decision?**

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

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

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

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

**33. Q: For how long is the UTN valid?**

A: Each UTN is valid for 120 days. The decision date is counted as the first day of the

120 days. For example: if the prior authorization request affirmation decision is documented on January 1, 2021, the prior authorization will be valid for dates of service through April 30, 2021. After that, the provider will need to submit a new request.

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

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

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

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

 **36. Q: Facet joint injections can be performed up to 4 times per rolling 12 months. If the second or subsequent procedures occur within 120 days, do providers need to submit a separate prior authorization request for each procedure?**

A: Each procedure requires a new prior authorization request regardless of whether the next service falls within 120 days. Each UTN for facet joint injections is valid for one claim.

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

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

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

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

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

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

### **Exemption Process**

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

A: The CMS may elect to exempt a Part A provider from the prior authorization process upon a provider's demonstration of compliance with Medicare coverage, coding, and payment rules, and that this exemption would remain in effect until CMS elects to withdraw the exemption. Your MAC will calculate the affirmation rate of initial prior authorization requests for all **eight** service categories combined and hospital OPD providers will be notified if their affirmation rate is 90% or greater. Providers who met the above compliance rate threshold will receive a written Notice of Exemption through the US mail or MAC provider portal. Those hospital OPDs will be exempt from submitting prior authorization requests. More detailed information about the exemption process is available in the Operational Guide.

#### **41. Q: Was the exemption cycle extended?**

A: Yes. The exemption cycle for the hospital OPD providers was extended. The exemption cycle will be year-long instead of biannually. Providers who are not exempt and will meet the PAR compliance rate of 90% or greater will receive a written Notice of Exemption through the US mail or MAC provider portal on or after November 2, 2022.

#### **42. Q: When will I receive my Additional Documentation Request (ADR) to determine continued compliance to remain exempt?**

A: Exempt providers will receive a postpayment ADR for a 10-claim sample from the period such providers were exempt on August 1 of each year to determine continued compliance. Providers must have at least 10 claims submitted and paid by June 30 in order to be considered for the continued exemption. If the exempt providers have less than 10 claims submitted, their exemption status will be withdrawn.

#### **43. Q: How can I opt out of the exemption process?**

A: Hospital OPDs have the option to opt out of the exemption process and continue

submitting prior authorization requests. Hospital OPDs that choose to opt out must submit an opt-out request to their MAC starting October 1 and no later than November 30 of each year. Late submissions will be rejected. OPD providers should contact their MACs for more detailed information on the opt-out process.

### **Claims Submission and Processing**

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

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

**45. Q: Are physicians and other associated providers required to submit the UTN on their claims?**

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

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

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

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

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

services requested.

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

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

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

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

**50. Q: If a hospital OPD submits a claim for a non-affirmed procedure and the claim is denied, as well as claims for related physician services, must the physician appeal separately, or can the hospital OPD appeal the associated physician claim as well?**

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

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

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

**52. Q: Can we submit prior authorizations retroactively – meaning that the service was already provided, but the claim has not yet been billed?**

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

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

A: An ABN must be issued in advance of performing the procedure if it is expected that payment for a service will be denied by Medicare because the service is not medically

reasonable and necessary. (See Claims Processing Manual, Pub. 100-04, Chapter 30 for additional information on ABNs.) The provider must submit the claim with a GA modifier, and the MAC will review it to determine if the ABN was issued appropriately.

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

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

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

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

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

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

**57. Q: If the hospital performs an applicable procedure that is ordinarily considered cosmetic but could be determined medically reasonable and necessary for the patient's specific condition, and the physician or hospital believes that Medicare will deny the procedure as not medically reasonable and necessary, should the beneficiary be given an ABN in order to be billed for the services?**

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

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

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

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

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

**60. Q: Is prior authorization required for CPT 67911 (Correction of lid retraction)?**

A: No. CPT 67911 was originally on the list of hospital OPD services that require prior authorization; however, in response to stakeholders' feedback and additional data analysis, we are removing this code from the list, as it is not likely to be cosmetic in nature, and commonly occurs secondary to another condition. This code will not require prior authorization as a condition of payment.



**61. Q: Why was my claim for a facet joint intervention service denied when I had a UTN with a provisional affirmation?**

A: A claim with a provisionally affirmed UTN may be denied for technical requirements that can only be evaluated after the claim has been submitted for formal processing or for information not available at the time of a prior authorization request, including if the frequency of the facet joint interventions exceeds the allowed limit. Please see your local MAC's LCD/LCA or [OPD Operational Guide](#) for more details.

# Medicare Claims Processing Manual

## Chapter 30 - Financial Liability Protections

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## 10 - Financial Liability Protections (FLP) Provisions of Title XVIII (Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

The FLP provisions of the Social Security Act (hereinafter referred to as the Act) protect beneficiaries, healthcare providers, and suppliers under certain circumstances from unexpected liability for charges associated with claims that Medicare does not pay. The FLP provisions apply after an item or service's coverage determination is made. This chapter discusses the following FLP provisions:



- Limitation On Liability (LOL) under §1879(a)-(g) of the Act.
- Refund Requirements (RR) for Non-assigned Claims for Physicians Services under §1842(l) of the Act.
- Refund Requirements (RR) for Assigned and Non-assigned Claims for Medical Equipment and Supplies under §§1834(a)(18), 1834(j)(4), and 1879(h) of the Act.

In most cases, the FLP provisions apply only to beneficiaries enrolled in the Original Medicare FFS program Parts A and B.

The FLP provisions apply only when both of the following are met:

- Items and/or services are denied on the basis of specific statutory or regulatory provisions.; and
- Involve determinations about beneficiary and/or healthcare provider/supplier knowledge of whether Medicare was likely to deny payment for the items and/or services.

The LOL provisions apply to all Part A services and all assigned claims for Part B services. The RR apply to both assigned and unassigned claims for medical equipment and supplies and to unassigned claims for physicians' services. However, RR do not apply to claims for Part A services.

## 20 - Limitation On Liability (LOL) Under §1879 Where Medicare Claims Are Denied

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

In general, application of the LOL provisions depends upon two primary factors:



1. Whether the claim for the item and/or service provided was denied for certain specific reasons. See §21 of this chapter for more examples.

Type of Denial	Description	Example
Statutory Basis	The LOL provisions apply only to claims for items and/or services submitted by healthcare providers or suppliers that have	Items and services found to be not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the

Type of Denial	Description	Example
	taken assignment, and only to claims for items and/or services not otherwise statutorily excluded, that are denied on the basis of §1862(a)(1), §1862(a)(9), §1879(e), or §1879(g) of the Act.	functioning of a malformed body member. (§1862(a)(1)(A) of the Act)
<b>Dependent Services</b>	When Medicare payment is made under the LOL provisions, the payment determination includes claims for any dependent services that are denied as an indirect result of the original denial. Thus, where a particular qualifying service is denied as not reasonable and necessary under §1862(a)(1)(A) of the Act, any dependent services are also denied as not reasonable and necessary under §1862(a)(1)(A) of the Act. If the LOL provisions apply to the denial of the qualifying service, it will also apply to the dependent service, and Medicare will make payment for both services, provided all other conditions for coverage and payment are met.	Under §§1814(a)(2)(C) and 1835(a)(2)(A) of the Act, home health aide services can be covered only if a beneficiary needs intermittent skilled nursing care. When coverage is denied for intermittent skilled nursing services (the qualifying primary services) under §1862(a)(1) or (9) of the Act, home health aide services (the dependent services) likewise are not covered. In such cases, if Medicare payment is made under the LOL provision for the primary services, it would be made for the dependent services as well, provided the services meet all conditions for coverage and payment (i.e. a physician's certification of the need for the dependent services and proof that the services are reasonable and necessary).
<b>Higher Levels of Care and "Excess Components"</b>	Normally, Medicare payment is denied for items and/or services that are not reasonable and necessary on the basis of §1862(a)(1)(A) of the Act. However, the LOL provisions may apply if a reduction in payment occurs because the furnished items or services are at a higher level of care and provide more extensive items or services than was reasonable and necessary to meet the needs of the beneficiary.	A deluxe or aesthetic feature of an upgraded item of medical equipment is an "excess component." Charge increases on the basis of purported premium quality services are not considered to be "excess components" since that would constitute circumvention of payment limits and applicable charging limits (e.g., limiting charges in the case of unassigned claims for physicians' services and fee schedule amounts in the case of assigned claims).



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.

<b>Knowledge of the Non-covered Item/Service</b>	<b>Liability</b>	<b>Payment Responsibility</b>
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:

<b>Statutory Provision (section of the Act)</b>	<b>Description</b>
§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.

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.

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.

## 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)
<b>Categorical</b>	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.	<ul style="list-style-type: none"> <li>• Personal comfort items (§1862(a)(6) of the Act).</li> <li>• Routine physicals and most screening tests (§1862(a)(7) of the Act).</li> <li>• Most immunizations (vaccinations) (§1862(a)(7) of the Act).</li> <li>• Routine eye care, most eyeglasses and examinations (§1862(a)(7) of the Act).</li> <li>• Hearing aids and hearing aid examinations (§1862(a)(7) of the Act).</li> <li>• Cosmetic surgery (§1862(a)(10) of the Act).</li> <li>• Orthopedic shoes and foot supports (orthotics) (§1862(a)(8) of the Act).</li> </ul>

Type of Denial	Description	Example(s)
		<p><b>NOTE:</b> §22.1 of this chapter provides a more expansive list of examples.</p>
<p><b>Technical</b></p>	<p>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.</p>	<ul style="list-style-type: none"> <li>• 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).</li> <li>• Payment for a dressing is denied because it does not meet the definition for “surgical dressings” (§1861(s)(5) of the Act).</li> <li>• 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).</li> <li>• Drugs and biologicals which are usually self-administered by the patient.</li> <li>• 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)</li> <li>• Other items or services that must be denied under 42 CFR 410.12 through 410.105 of the Medicare regulations.</li> </ul>

### 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.

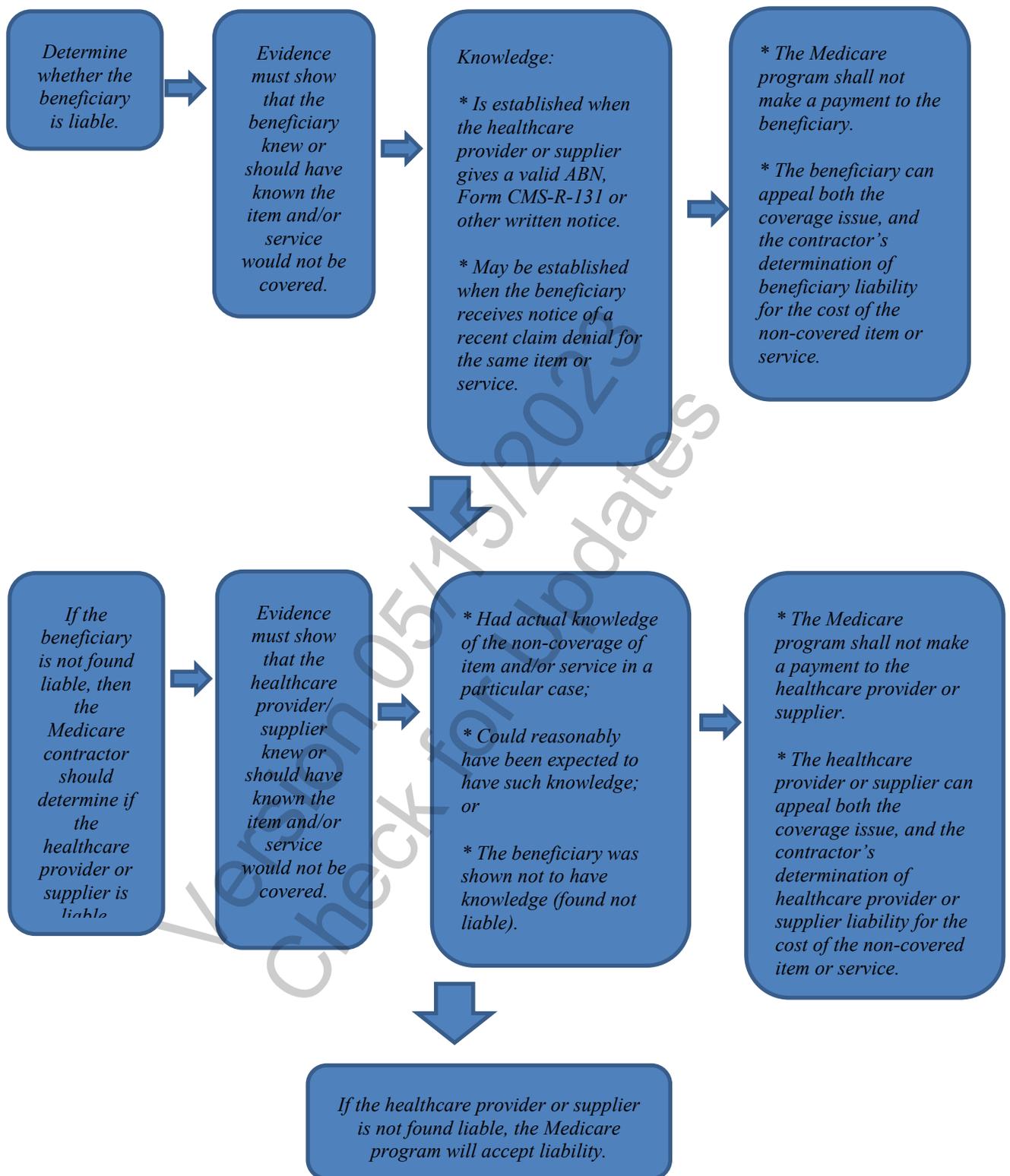
Statutory Provision (section of the Act)	Description
§1862(a)(23)	Claims for the technical component of advanced diagnostic imaging services described in §1834(e)(1)(B) of the Act for which payment is made under the fee schedule established under §1848(b) of the Act and that are furnished by a supplier (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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Check for updates



**NOTE:** If both the beneficiary and the healthcare provider or supplier are found to have knowledge, the beneficiary will be held liable.

### 30.1 - Beneficiary's Knowledge and Liability

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



Beneficiary knowledge standards vary between the §1879 LOL provision and the two Refund Requirement (RR) provisions as shown in the table below.

Provision	Description	Beneficiary Knowledge
<b>Limitation On Liability</b>	§1879(a)(2) of the Act requires that the beneficiary “did not know, and could not reasonably have been expected to know, that payment would not be made* * *,” for items or services that are excluded from coverage.	<ul style="list-style-type: none"> <li>• Knowledge based on written notice having been provided to the beneficiary.</li> <li>• Knowledge based on any other means from which it is determined that the beneficiary knew, or should have known, that payment would not be made.</li> </ul>
<b>Medical Equipment and Supplies RR</b>	§1834(a)(18)(A)(ii) of the Act [which is incorporated by reference into §1834(j)(4) and §1879(h) of the Act] requires that “before the item was furnished, the patient was informed that payment under this part may not be made for that item and the patient has agreed to pay for that item,” that is, for medical equipment and supplies denied on the basis of §1834(a)(17)(B), §1834(j)(1), §1834(a)(15), or §1862(a)(1) of the Act.	<ul style="list-style-type: none"> <li>• Knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.</li> </ul>
<b>Physician RR</b>	§1842(l)(1)(C)(ii) of the Act requires that “before the service was provided, the individual was informed that payment under this part may not be made for the specific service and the individual has agreed to pay for that service,” that is, for physician services that are denied because they were not reasonable and necessary under §1862(a)(1) of the Act.	<ul style="list-style-type: none"> <li>• Knowledge must be evidenced by a signed written notice and agreement to pay personally in case of a denial.</li> </ul>

Knowledge is determined on a case by case basis. In certain circumstances, being in receipt of a valid ABN or other written notice does not guarantee that the beneficiary had knowledge that an item or service would not be covered. For instance, in a case where a beneficiary received a valid ABN and then, upon initial determination, the claim was paid as covered, that original ABN cannot be used as evidence of knowledge for future claims relating to a similar or reasonably comparable item or service, since the original ABN was belied by the favorable payment decision.

In reviewing a determination of liability on appeal, a beneficiary's allegation that s/he did not know, in the absence of evidence to the contrary, is acceptable evidence for LOL purposes.

### **30.1.1 - Other Evidence of Knowledge** (Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

While 42 CFR 411.404 provides criteria for beneficiary knowledge based on written notice, §1879(a)(2) of the Act specifies only that knowledge must not exist in order to apply the LOL provision. If it is clear and obvious that a beneficiary in fact did know, prior to receiving an item or service, that Medicare payment for that item or service would be denied, the administrative presumption favorable to the beneficiary is rebutted. For example, if the beneficiary admits that s/he had prior knowledge that payment for an item or service would be denied, no further evidence is required.

In the case in which the Medicare contractor has such evidence of prior knowledge on the beneficiary's part, the beneficiary must be held liable under the LOL provision, even if no written notice was given by the appropriate source.

### **30.2 - Healthcare Provider or Supplier Knowledge and Liability** (Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

In order to determine whether the healthcare provider or supplier had prior knowledge that the item and/or service furnished to the beneficiary would likely be denied or whether knowledge of the denial could have been expected, the Medicare contractors review the information they maintain and/or disseminate to a particular healthcare provider or supplier and the denial's relevant facts.

If the healthcare provider or supplier cannot show that the beneficiary received proper written notice, the healthcare provider or supplier will be presumed to have knowledge (and, thereby, liability) unless s/he can prove that s/he did not know, and could not reasonably have been expected to know, that Medicare would not pay for the item and/or service. If the healthcare provider or supplier can make such a convincing showing, the Medicare contractor will find that the healthcare provider or supplier did not have the requisite knowledge and Medicare will be liable for the payment.



### **30.2.1 - Evidence of Healthcare Provider or Supplier Knowledge** (Rev.: 4197; Issued: 01-11-19; Effective: 04-15-19; Implementation: 04-15-19)

In accordance with regulations at 42 CFR 411.406, evidence that the healthcare provider or supplier did, in fact, know or should have known that Medicare would not pay for an item or service includes:

- A Medicare contractor's prior written notice to the healthcare provider or supplier of Medicare denial of payment for similar or reasonably comparable item or service. This also includes notification of Quality Improvement Organization (QIO) screening criteria specific to the condition of the beneficiary for whom the furnished item and/or service are at issue and of medical procedures subject to preadmission review by the QIO. Instructions for application of the LOL provision to QIO determinations are in the QIO Manual;
- Medicare's general notices to the medical community of Medicare payment denial of item or service under all or certain circumstances (such notices include, but are not limited to, manual instructions, bulletins, and Medicare contractors' written guidance);
- Provision of the item and service being inconsistent with acceptable standards of practice in the local medical community.
- Written notification from the healthcare provider or supplier's utilization review committee informing the healthcare provider or supplier that the item and/or service was not covered;
- The healthcare provider or supplier issuing a written notice of the likelihood of Medicare payment denial for an item and/or service to the beneficiary; or
- The healthcare provider or supplier being previously notified by telephone and/or in writing that an item or service is not covered or that coverage has ended.

If any of the circumstances described above exists, a healthcare provider or supplier is held to have knowledge.

### **30.2.2 - Medical Record Evidence of Healthcare Provider or Supplier Knowledge**

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

The healthcare provider or supplier is also accountable for information contained in the beneficiary's medical records, such as the beneficiary's medical chart, attending physicians' notes, or similar records. When the medical records clearly show that the beneficiary received only non-covered services as described in the Medicare Benefit

Policy Manual, the healthcare provider or supplier will be presumed to have knowledge of non-coverage.

**Examples:**

- A physician clearly indicated in the beneficiary’s medical record that the patient no longer needed the services or the level of care provided;
- The physician indicated the patient could be discharged;
- The attending physician refused to certify or recertify the beneficiary’s need for a particular level of care covered by Medicare because he/she determined that the patient does not require a covered level of care; or
- The contractor requested additional medical evidence after a certain number of days to determine whether continued coverage is warranted. However, the healthcare provider or supplier did not submit the evidence within the stipulated time.

**30.2.3 - Acceptable Standards of Practice**

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

When an item and/or service furnished do not meet locally acceptable standards of practice, the healthcare provider or supplier is considered to have known that Medicare payment would be denied. Because healthcare provider and supplier licensure is premised on the assumption that they are knowledgeable about locally acceptable standards of practice, healthcare providers and suppliers are presumed to have knowledge about locally acceptable standards of practice for liability determinations. No other evidence of knowledge of local medical standards of practice is necessary.

In order to determine what “acceptable standards of practice” exist within the local medical community, Medicare contractors will rely on the following:

- published medical literature;<sup>1</sup>
- a consensus of expert medical opinion;<sup>2</sup> and

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<sup>1</sup> *“Published medical literature” refers generally to scientific data or research studies that have been published in peer-reviewed medical journals or other specialty journals that are well recognized by the medical profession, such as the “New England Journal of Medicine” and the “Journal of the American Medical Association.”*

<sup>2</sup>*Consensus of expert medical opinion might include recommendations that are derived from technology assessment processes conducted by organizations such as the Blue Cross and Blue Shield Association or the American College of Physicians, or findings published by the Institute of Medicine.*

**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 minor change has been made to update the nondiscriminatory language.

## 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.

### **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.”

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.

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.~~ If Medicare does pay, you will refund any payments I made to you, less co-pays or deductibles.

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](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf)

- **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.

 **\*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 should 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.

### **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.

Version 05/15/2023  
Check for Updates

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Version 05/16/2023  
Check for Updates