Medicare Medical Policy

Surgical Site of Service

Effective Date: 1/1/2025

MEDICARE MEDICAL POLICY NUMBER: 395

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INSTRUCTIONS FOR USE: Company Medicare Medical Policies serve as guidance for the administration of plan benefits and do not constitute medical advice nor a guarantee of coverage. Company Medicare Medical Policies are reviewed annually to guide the coverage or non-coverage decision-making process for services or procedures in accordance with member benefit contracts (otherwise known as Evidence of Coverage or EOCs) and Centers of Medicare and Medicaid Services (CMS) policies, manuals, and other CMS rules and regulations. In the absence of a CMS coverage determination or specific regulation for a requested service, item or procedure, Company policy criteria or applicable utilization management vendor criteria may be applied. These are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

The Company reserves the right to determine the application of Medicare Medical Policies and make revisions to these policies at any time. Any conflict or variance between the EOC and Company Medical Policy will be resolved in favor of the EOC.

SCOPE: Providence Health Plan, Providence Health Assurance, and Providence Plan Partners as applicable (referred to individually as "Company" and collectively as "Companies").

PRODUCT AND BENEFIT APPLICATION

MEDICARE COVERAGE CRITERIA

IMPORTANT NOTE: More than one Centers for Medicare and Medicaid Services (CMS) reference may apply to the same health care service, such as when more than one coverage policy is available (e.g., both an NCD and LCD exist). All references listed should be considered for coverage decision-making. The Company uses the most current version of a Medicare reference available at the time of publication; however, these websites are not maintained by the Company, so Medicare references and their corresponding hyperlinks may change at any time. If there is a conflict between the Company Medicare Medical Policy and CMS guidance, the CMS guidance will govern.

Notes: This policy does **not** apply to services on the Centers for Medicare & Medicaid Services (CMS) Inpatient Only list.

Service	Medicare Guidelines
Centers for Medicare & Medicaid Services (CMS) Lists	CMS Lists:
Services (ems) Lists	 If the surgical procedure is found on the CMS Inpatient Only List (IOL), inpatient admission is considered medically appropriate without further review. If the procedure is found on the CMS ASC-covered surgical procedures list OR is not found on either the CMS IOL or the ASC list, then inpatient admission will be reviewed using the following since CMS has already determined these procedures do not generally require active medical monitoring or overnight stays.
General Medicare Coverage	All of the following must be considered when making inpatient
Requirements and Background for	admission decisions for the services addressed by this policy:
Inpatient Admissions	
	 The Medicare two-midnight benchmark. (Note: The expectation that the member will require a hospital stay that crosses two midnights or more must be a reasonable one and must be supported by the documentation in the medical record.)
	 Independent clinical judgment of the reviewing qualified health care professional, taking into account the individual patient's unique clinical circumstances based on the documentation in the clinical record. Company criteria for inpatient admission decision-making
	for the services in this policy (below) may also be applied.

	See <u>Policy Guidelines</u> below for additional information regarding Medicare guidelines for inpatient hospital admission decision-making.
Inpatient Setting Decision-Making	 Company medical policy for <u>Inpatient Surgical Site of Service</u> These services may be considered <u>medically necessary</u> for Medicare when the Company medical policy criteria are met. These services are considered <u>not medically necessary</u> for Medicare when the Company medical policy criteria are not met. <u>See Policy Guidelines below.</u>

IMPORTANT NOTICE: While some services or items may appear medically indicated for an individual, they may also be a direct exclusion of Medicare or the member's benefit plan. Such excluded services or items by Medicare and member EOCs include, but are not limited to, services or procedures considered to be cosmetic, not medical in nature, or those considered not medically reasonable or necessary under *Title XVIII of the Social Security Act, §1862(a)(1)(A)*. If there is uncertainty regarding coverage of a service or item, please review the member EOC or submit a pre-service organization determination request. Note that the Medicare Advance Beneficiary Notice of Noncoverage (ABN) form cannot be used for Medicare Advantage members. (Medicare Advance Written Notices of Non-coverage. MLN006266 May 2021)

POLICY CROSS REFERENCES

None

The full Company portfolio of Medicare Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to review for medical necessity, the following documentation **must** be provided. If any of these items are not submitted, the review may be delayed and the decision outcome could be affected:

- Medical records to include documentation of all of the following:
 - History
 - o Physical examination including patient weight and co-morbidities
 - Surgical plan
 - American Society of Anesthesiologists Physical Classification (ASA-PS) score

BACKGROUND

Currently, the scope of this policy is limited to review of select total knee arthroplasty (TKA), total hip arthroplasty (THA), temporomandibular joint (TMJ) arthroplasty, elbow arthroplasty, shoulder arthroplasty, wrist/hand arthroplasty and ankle arthroplasty codes, as well as some spinal procedure codes, for site of service (place of service or setting) appropriateness; however, procedures other these

may be added for site of service appropriateness review in the future. Future additions to this policy will be limited to codes **not** included on the CMS inpatient only list.

MEDICARE AND MEDICAL NECESSITY

Under Medicare, all services must be medically reasonable and necessary under §1862(a)(1)(A) of the Social Security Act in order to be covered. This includes services being provided at the appropriate level of care. Decisions on the setting for healthcare services are based on Medicare requirements (e.g., two midnight benchmark) and the unique clinical circumstances of the individual receiving the services, as well as nationally recognized guidelines. Factors include, but are not limited to, a "patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting."

For any service **not** found on the Medicare Inpatient Only list (services eligible for coverage in an outpatient setting), if an inpatient setting is anticipated, clinical documentation must support the medical need for an inpatient place of service for the individual member. CMS does allow the use of "screening instruments" such as InterQual[®] or MCG[™] guidelines, but the use of such tools is not required.³

Inpatient Only Procedures

This policy does **not** apply to services found on the Medicare Inpatient Only list. For the most current Addendum E published lists, see https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.

For **2024**, the CMS Inpatient Only list can be accessed from the Hospital Outpatient Prospective Payment- Notice of Final Rulemaking with Comment Period (NFRM) 2024 webpage. From here, click the "**2024 NFRM OPPS Addenda**" download file (you will need to accept "License agreement" when prompted). Once downloaded, open the *2024 NFRM Addendum E.11012023* excel file. (The excel spreadsheet is preferred for viewing purposes over the notepad file, which is also included.)

Addendum E is the list of "HCPCS Codes That Would Be Paid Only as Inpatient Procedures."

These same steps can be followed to find past years Inpatient Only lists as well.

- For **2023**, the above information can be accessed from the <u>Hospital Outpatient Prospective</u> <u>Payment – Notice of Final Rulemaking with Comment (NFRM) 2023</u> web page.
- For **2022**, the above information can be accessed from the <u>Hospital Outpatient Prospective</u> Payment- Notice of Final Rulemaking with Comment Period (NFRM) 2022 web page.
- For **2021**, the above information can be accessed from the <u>Hospital Outpatient Prospective</u> Payment- Notice of Final Rulemaking with Comment Period (NFRM) 2021 web page.

Background

CMS developed an "Inpatient Only" or IPO list as a collection of services which CMS has determined are not appropriate to be furnished in a hospital <u>outpatient</u> department. These "Inpatient only" services are generally surgical services which "pose significant safety risk to beneficiaries" and "require inpatient

care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged." There is no payment under the Hospital *Outpatient* Prospective Payment System (OPPS) for services that have been designated as "inpatient only" services. With limited exception, Medicare does not pay for an inpatient only service for individuals registered as an outpatient.⁵

In 2020, Medicare proposed to eliminate the Inpatient Only (IPO) list over a three-year transitional period, beginning with some 300 primarily musculoskeletal-related services. It was anticipated that the IPO list would be completely phased out by CY 2024, making these procedures eligible to be paid by Medicare when furnished in the hospital outpatient setting when outpatient care is appropriate, while still allowing a service to be payable when furnished in the hospital inpatient setting when inpatient care is appropriate. However, in 2021 it was determined to reinstate the IPO list and with a few exceptions, add back to the IPO list any services which had been removed in 2021.

Ambulatory Surgical Center (ASC) Covered Services

The yearly updated lists of ASC covered surgical procedures and payment rates are available on the CMS website.

• Addendum AA is the list of "ASC Covered Surgical Procedures."

Surgical procedures and their respective codes that are included on the ASC list of covered surgical procedures have been reviewed by CMS and "have been determined to pose no significant safety risk to Medicare beneficiaries when furnished in ASCs, and for which standard medical practice dictated that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (overnight stay)."⁴

ASC-covered surgical procedures do **not** include surgical procedures that:

- (1) generally result in extensive blood loss;
- (2) require major or prolonged invasion of body cavities;
- (3) directly involve major blood vessels;
- (4) are generally emergent or life threatening in nature;
- (5) commonly require systemic thrombolytic therapy;
- (6) are designated as requiring inpatient care under § 419.22(n);
- (7) can only be reported using a CPT unlisted surgical procedure code; or
- (8) are otherwise excluded under § 411.15.4

Additional procedures may also be included on Addendums BB, as procedures integral to a covered ASC procedure. Under the ambulatory surgical center (ASC) payment system, Medicare makes facility payments to ASCs <u>only</u> for the specific ASC covered surgical procedures on the ASC list of covered surgical procedures. "Covered ASC services are those surgical procedures that are identified by CMS on a listing that is updated at least annually. Some surgical procedures are covered by Medicare but are not on the list of ASC covered surgical procedures." In addition, services on the CMS Inpatient Only List are "deemed to pose significant safety risk to beneficiaries in ASCs" and thus would not be "eligible for designation and coverage as ASC covered surgical procedures."

Inpatient Admission Decision-Making

According to the *Medicare Benefit Policy Manual, Chapter 1 – Inpatient Hospital Services Covered Under Part A,* §10 – Covered Inpatient Hospital Services Covered Under Part A, "The physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient... the decision to admit a patient is a complex medical judgment which can be made only after the physician has considered a number of factors, including the patient's medical history and current medical needs, the types of facilities available to inpatients and to outpatients, the hospital's by-laws and admissions policies, and the relative appropriateness of treatment in each setting." This reference includes additional factors to be considered when making a decision to admit an individual or render services on an outpatient basis.

The Medicare two-midnight benchmark rule does apply to Medicare Advantage plans; however, the expectation that a patient will require a hospital stay that crosses two midnights or more must be a reasonable one, based on clinical information known of the patient at the time of admission. The Plan will review the medical records to determine if this two-midnight expectation by the admitting physician is a reasonable one.

Finally, the Medicare Program Integrity Manual, Chapter—6 - Medicare Contractor Medical Review Guidelines for Specific Services, §6—5 - Medical Review of Inpatient Hospital Claims for Part A Payment also provides guidance regarding inpatient admission reviews, specifically addressing the use of "screening instruments" such as InterQual® or MCG™ guidelines. While Medicare does allow for the use of these screening tools, the use of such tools is not required. The Company uses the criteria provided in this policy for inpatient admission decision-making for services that are eligible to be performed on an outpatient basis. Of note, regardless of what tool, instrument or criteria set may be used, Medicare requires clinical judgment be applied to each case, taking into account the patient's unique clinical circumstances, when making a medical necessity determination with the documentation in the clinical record.

The Company policy for *PHA Medicare Medical Policy Development and Application* (MP50) provides details regarding Medicare's definition of medical necessity and the hierarchy of Medicare references and resources during the development of medical policies, as well as the Plan's use of evidence-based processes for policy development. In the absence of Medicare coverage policies (e.g., manual, national coverage determination [NCD], local coverage determination [LCD], article [LCA], etc.) which addresses the medical necessity of a given medical service, Medicare regulatory guidelines do allow Medicare Advantage Organizations (MAOs) to make their own coverage determinations, as long as the MAO applies an objective, evidence-based process, based on authoritative evidence. (*Medicare Managed Care Manual, Ch. 4, §90.5*)

<u>Important Note:</u> Procedures on the Medicare Inpatient Only List and ASC list of covered surgical services are **not** guaranteed coverage or payment solely on the basis of inclusion on these lists. When applicable, medical necessity for services will be reviewed using available <u>PHP medical policies</u>.

SUMMARY

Under Medicare, all services must be medically reasonable and necessary under §1862(a)(1)(A) of the Social Security Act in order to be covered. This includes services being provided at the appropriate level of care.

Surgical services on the **CMS Inpatient Only List** are generally services which "pose significant safety risk to beneficiaries" and "require inpatient care because of the nature of the procedure, the typical underlying physical condition of patients who require the service, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged."

In contrast, surgical procedures included on the **ASC list of covered surgical procedures** "have been determined to pose no significant safety risk to Medicare beneficiaries when furnished in ASCs, and for which standard medical practice dictated that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure (overnight stay)."

Therefore, since services on the CMS Inpatient Only List are "deemed to pose significant safety risk to beneficiaries in ASCs," they are not eligible for designation and coverage as ASC covered surgical procedures. Under Medicare, these procedures are only eligible for coverage when rendered in an inpatient setting, making inpatient admissions medically necessary.

Alternatively, services on the ASC-covered surgical procedures list do **not** pose a significant safety risk to patients when performed in outpatient settings, and thus, inpatient care and overnight stays are not generally required for these services. When an inpatient stay is requested for a service found on the ASC-covered surgical procedures list, the medical record must clearly document and support the clinical need for an inpatient setting. When an inpatient stay is requested for a service which is not found on either the CMS Inpatient Only List or the ASC list of covered procedures, the medical record must also clearly support the clinical need for an inpatient setting.

REGULATORY STATUS

U.S. FOOD & DRUG ADMINISTRATION (FDA)

While clearance by the Food and Drug Administration (FDA) is a prerequisite for Medicare coverage, the 510(k) premarket clearance process does not in itself establish medical necessity. Medicare payment policy is determined by the interaction of numerous requirements, including but not limited to, the availability of a Medicare benefit category and other statutory requirements, coding and pricing guidelines, as well as national and local coverage determinations and clinical evidence.

BILLING GUIDELINES AND CODING

GENERAL

Most of the procedures below **only** require prior authorization when billed with **place of service (POS) code 21** (inpatient hospital). These codes will not require prior authorization if billed with other place of service codes.

However, some of the procedures below (e.g., CPT 27130 [THA] and the spinal procedures listed) require prior authorization **regardless of the place of service**, to review both general medical necessity of the surgical procedure, as well as additional review if anticipated to be performed in an inpatient setting to determine the medical appropriateness of an inpatient stay.

As of the most recent policy review, **all** of the procedures code below **except** for 22630, 22633, and 23473 are found on the CMS ASC-covered procedures list. CPT codes 22630, 22633, and 23473 are found on neither the CMS Inpatient Only List, nor the ASC-covered procedures list.

CODE	CODES*			
		Temporomandibular Joint Arthroplasty Codes		
CPT	21243	Arthroplasty, temporomandibular joint, with prosthetic joint replacement		
	Shoulder Arthroplasty Codes			
	23470	Arthroplasty, glenohumeral joint; hemiarthroplasty		
	23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))		
		Elbow, Wrist, and Hand Arthroplasty Codes		
	24360	Arthroplasty, elbow; with membrane (eg, fascial)		
	24366	Arthroplasty, radial head; with implant		
	25332	Arthroplasty, wrist, with or without interposition, with or without external or		
	23332	internal fixation		
	25442	Arthroplasty with prosthetic replacement; distal ulna		
	25446	Arthroplasty with prosthetic replacement; distal radius and partial or entire carpus (total wrist)		
	25447	Arthroplasty, intercarpal or carpometacarpal joints; interposition		
	25448	Arthroplasty, intercarpal or carpometacarpal joints; suspension, including transfer		
		or transplant of tendon, with interposition, when performed		
	26531	Arthroplasty, metacarpophalangeal joint; with prosthetic implant, each joint		
	26535	Arthroplasty, interphalangeal joint; each joint		
	26536	Arthroplasty, interphalangeal joint; with prosthetic implant, each joint		
		Hip Arthroplasty Codes		
	27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip		
		arthroplasty), with or without autograft or allograft		
		Knee Arthroplasty Codes		
	27446	Arthroplasty, knee, condyle and plateau; medial OR lateral compartment		
	27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)		
		Ankle Arthroplasty Codes		
	27702	Arthroplasty, ankle; with implant (total ankle)		
	,	Spinal Procedures Codes		
	22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy,		
		osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2		
	22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2		
	22612	Arthrodesis, posterior or posterolateral technique, single interspace; lumbar (with lateral transverse technique, when performed)		
	22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar		

	22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace; lumbar
	22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
	22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)
HCPCS	None	

*Coding Notes:

- The code list above is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit. According to Medicare, "presence of a payment amount in the MPFS and the Medicare physician fee schedule database (MPFSDB) does not imply that CMS has determined that the service may be covered by Medicare." The issuance of a CPT or HCPCS code or the provision of a payment or fee amount by Medicare does not make a procedure medically reasonable or necessary or a covered benefit by Medicare. (Medicare Claims Processing Manual, Chapter 23 Fee Schedule Administration and Coding Requirements, §30 Services Paid Under the Medicare Physician's Fee Schedule, A. Physician's Services)
- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be denied as not covered. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, prior authorization is recommended.
- See the non-covered and prior authorization lists on the Company <u>Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website</u> for additional information.
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling
 edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and
 Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website
 for coding guidelines and applicable code combinations.

REFERENCES

- Centers for Medicare & Medicaid Services (CMS). Medicare Program Integrity Manual, Chapter 3

 Verifying Potential Errors and Taking Corrective Actions, 3.6.2.2 Reasonable and Necessary
 Criteria. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/pim83c03.pdf. Accessed 4/8/2024.
- Centers for Medicare and Medicaid Services (CMS). Medicare Benefit Policy Manual, Chapter 1 Inpatient Hospital Services Covered Under Part A, §10 Covered Inpatient Hospital Services Covered Under Part A. https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/bp102c01.pdf. Accessed 4/6/2023.
- CMS. Medicare Program Integrity Manual, Chapter 6 Medicare Contractor Medical Review Guidelines for Specific Services, §6.5 - Medical Review of Inpatient Hospital Claims for Part A Payment. https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/Downloads/pim83c06.pdf. Accessed 4/6/2023.
- CMS. Medicare Claims Processing Manual, Chapter 14 Ambulatory Surgical Centers, § 20.2 Types of Services Included on the ASC Covered Procedures List;
 https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c14.pdf.
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 https://www.cms.gov/regulations-and-guidance/gu

- 5. CMS. Medicare Claims Processing Manual, Chapter 4 Part B Hospital (Including Inpatient Hospital Part B and OPPS), §180.7 Inpatient-Only Services. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf. Published 2020. Accessed 4/6/2023.
- 6. Noridian Healthcare. Noridian Medicare A News JF January 2021. https://med.noridianmedicare.com/documents/10529/26401685/Medicare+A+News+JF+January+2021. Published 2021. Accessed 4/6/2026.
- 7. CMS-1772-FC. https://www.cms.gov/medicaremedicare-fee-service-paymenthospitaloutpatientppshospital-outpatient-regulations-and-notices/cms-1772-fc
 Accessed 4/6/2023.
- 8. CMS. Medicare Claims Processing Manual, Chapter 14 Ambulatory Surgical Centers, §10.2 Ambulatory Surgical Center Services on ASC List; https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c14.pdf. Updated 2023. Accessed 4/6/2023.

POLICY REVISION HISTORY

DATE	REVISION SUMMARY
7/2023	New Medicare Advantage medical policy
6/2024	Annual review; added TMJ, elbow, shoulder, wrist/hand, and ankle arthroplasty codes, as well as some spinal procedure codes, to policy for inpatient POS
1/2025	Interim update; remove revision arthroplasty codes from scope of policy & Q1 2025 code updates