

Status: Revised Effective Date: 11/15/2025

Doc ID: SUR03-1125.1 **Last Review Date:** 04/21/2025

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Clinical Appropriateness Guidelines

Surgical Services

Appropriate Use Criteria: Level of Care for Surgical Procedures

"Site of Care," "Site of Service" or another term such as "Setting" or "Place of Service" may be terms used in benefit plans, provider contracts, or other materials instead of or in addition to "Level of Care" and, in some plans, these terms may be used interchangeably.

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter "the Carelon Clinical Appropriateness Guidelines" or the "Guidelines") are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. The Guidelines establish objective and evidence-based criteria for medical necessity determinations, where possible, that can be used in support of the following:

- To establish criteria for when services are medically necessary
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To address patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation and legal standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Resources reviewed include widely used treatment guidelines, randomized controlled trials or prospective cohort studies, and large systematic reviews or meta-analyses. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website. Copies of the Guidelines are also available upon oral or written request. Additional details, such as summaries of evidence, a list of the sources of evidence, and an explanation of the rationale that supports the adoption of the Guidelines, are included in each guideline document.

Although the Guidelines are publicly available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient's unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient's condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient's care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines, and in the case of reviews for Medicare Advantage Plans, the Guidelines are only applied where there are not fully established CMS criteria. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention is likely to outweigh any potential harms, including from delay or decreased access to services that may result (net benefit).
- Widely used treatment guidelines and/or current clinical literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- There exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

Providers may be required to submit clinical documentation in support of a request for services. Such documentation must a) accurately reflect the clinical situation at the time of the requested service, and b) sufficiently document the ordering provider's clinical intent.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would justify a finding of clinical appropriateness. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account to the extent permitted by law.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns

- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

Level of Care for Surgical Procedures

"Site of Care," "Site of Service" or another term such as "Setting" or "Place of Service" may be terms used in benefit plans, provider contracts, or other materials instead of or in addition to "Level of Care" and, in some plans, these terms may be used interchangeably.

Scope

Evidence is growing that supports the safety and effectiveness of the outpatient surgery setting for many surgical procedures. Procedures that have historically been performed in the inpatient setting are now being successfully performed in the outpatient surgery setting. Factors that have contributed to this movement include:

- Equal or better outcomes compared to inpatient setting
- Minimal invasive techniques and improved surgical technologies
- Improved anesthesia techniques and more effective postoperative pain management
- Lower costs and operational efficiency

Appropriate patient selection for the outpatient setting is paramount. It may be medically necessary for patients with certain risk factors and/or undergoing certain procedures to have an inpatient setting admission postoperatively.

The intent of this guideline is to identify clinical scenarios in which pre-planned inpatient admission is medically necessary for non-emergent procedures. It is expected that a patient undergoing a scheduled, non-emergent procedure will be medically optimized, and that inpatient admission would not be required due solely to any social determinants of health that could reasonably be expected to be mitigated through preoperative planning (such as equipment or supervision required at home, etc.).

- This guideline does not attempt to address the indications that warrant either planned or unplanned admission for an observation-level stay, which may be needed to monitor for immediate post-operative complications or meet discharge criteria.
- This guideline does not address the clinical appropriateness of an inpatient admission that results from a patient's intraoperative or observation-stay course that was not known or anticipated prior to surgery.
- This guideline is intended to be used for procedures that are routinely performed on an outpatient basis. It is expected that as surgical techniques and clinical evidence advances, a greater variety of procedures may be eligible for review under this guideline. The applicable code set that falls within the scope of this guideline is at the discretion of the managing health plan.

In order to support a pre-planned inpatient admission, a provider may be asked to submit supporting medical documentation such as:

- Provider office notes detailing preoperative medical optimization
- List of managed or unmanaged comorbidities and/or other surgical risk factors
- If requested, the specific reason for an inpatient preoperative day
- Copies of medical consultations or clearances
- American Society of Anesthesiologists (ASA) physical status (see <u>Appendix</u>), Charlson Comorbidity Index score, or other validated surgical risk score, if necessary, to support the requested level of care

This guideline does not address the medical necessity of the procedure itself. The prior authorization process for medical necessity of the surgical procedure is completed separately and precedes the level of care determination. The procedure must meet any applicable clinical appropriateness guideline for prior to level of care determination.

Definitions

Outpatient Surgical Setting

An outpatient surgical procedure is defined as one where a patient arrives and is registered at a setting other than the acute inpatient hospital setting, undergoes the procedure, and is discharged the same day or within the timeframe for observation defined by patient's health plan contract and/or local government regulatory agency. Such settings may include Observation Care, Hospital Outpatient Department (on or off campus), Ambulatory Surgical Center, or Physician Office. For the purposes of this guideline, procedures performed in a Physician Office are out of scope.

Observation Surgical Setting

Observation is a special form of hospital outpatient care that provides interim services in place of an inpatient admission to allow for a reasonable period of time to evaluate and determine the need for further treatment or for inpatient admission. There is evidence that the characteristics of observation care in clinical practice differ from the Centers for Medicare & Medicaid Services definition and that use of observation care is growing with short inpatient stays being the third most common reason to admit for observation. Individual cases admitted to Observation Care may undergo concurrent clinical review to assess the need for transfer to acute inpatient setting. Maximum length of stay in Observation Care is governed by the patient's health plan contract and/or local government regulatory agency.

Surgeons who request inpatient admission for an outpatient procedure and who decline Observation Care will need to provide clinical documentation to support the need for direct admission to an acute inpatient setting.

Inpatient Surgical Setting

The inpatient surgical setting, rather than the outpatient setting, is required only if the patient's safety or health would be significantly and directly threatened if care were provided in a less intensive setting. The selection of surgical setting is not justified when it is solely for the convenience of the patient, the patient's family, or the provider.

Guidelines

Acute Inpatient Surgical Setting

The acute inpatient surgical setting may be considered medically necessary when **ONE** of the following requirements are met:

- Current postoperative care requirements are of such intensity or duration that they cannot be met in an observation or outpatient surgical setting such as:
 - Monitoring or management of hemodynamic, cardiorespiratory, vascular, neurologic, or laboratory status
- Anticipated postoperative care requirements cannot be met, even initially, in an observational surgical setting due to the complexity, duration, or extent of the planned procedure or substantial preoperative patient risk such as:
 - Required hemodynamic, cardiorespiratory, vascular, neurologic, or laboratory monitoring and/or management
 - o Preoperative ASA status ≥ IV
 - Patient's home (or other discharge location such as family, friend, or other accommodations) will be of such significant distance from the nearest hospital emergency room as to pose a clinically significant risk should an emergent or urgent post-operative complication develop
 - Inability to establish clinically appropriate supervision and support within the patient's home (or other discharge location such as family, friend, or other accommodations) despite expected preoperative care coordination efforts even after hospital-based observation

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Appendix

ASA Physical Status Classification System

Classification	Definition	Adult examples, including, but not limited to:	
ASA I	A normal healthy patient	Healthy, non-smoking, no or minimal alcohol use	
ASA II	A patient with mild systemic disease	Mild diseases only without substantive functional limitations. Current smoker, social alcohol drinker, pregnancy, obesity (30 < BMI < 40), well-controlled DM/HTN, mild lung disease	
ASA III	A patient with severe systemic disease	Substantive functional limitations; One or more moderate to severe diseases. Poorly controlled DM or HTN, COPD, morbid obesity (BMI ≥ 40), active hepatitis, alcohol dependence or abuse, implanted pacemaker, moderate reduction of ejection fraction, ESRD undergoing regularly scheduled dialysis, premature infant PCA < 60 weeks, history (> 3 months) of MI, CVA, TIA, or CAD/stents.	
ASA IV	A patient with severe systemic disease that is a constant threat to life	Recent (< 3 months) MI, CVA, TIA, or CAD/stents, ongoing cardiac ischemia or severe valve dysfunction, severe reduction of ejection fraction, sepsis, DIC, ARD or ESRD not undergoing regularly scheduled dialysis	
ASA V	A moribund patient who is not expected to survive without the operation	Ruptured abdominal/thoracic aneurysm, massive trauma, intracranial bleed with mass effect, ischemic bowel in the face of significant cardiac pathology or multiple organ/system dysfunction	
ASA VI	A declared brain-dead patient whose organs are being removed for donor purposes	_	

^{*}The addition of "E" denotes Emergency surgery: (An emergency is defined as existing when delay in treatment of the patient would lead to a significant increase in the threat to life or body part)

Source: 2014 ASA Physical Status Classification System (Amended December 13, 2020) available at the American Society of Anesthesiologists website; Accessed March 3, 2022.

Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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See link below for CPT code list.

https://providers.carelonmedicalbenefitsmanagement.com/surgicalprocedures/resources/

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

History

Status	Review Date	Effective Date	Action
Revised	04/21/2025	11/15/2025	Independent Multispecialty Physician Panel (IMPP) review. Level of Care criteria and code list expanded beyond its prior musculoskeletal scope to include additional surgical procedures. Guideline renamed to reflect this change in scope. Added references.
Reaffirmed	04/15/2024	Unchanged	IMPP review. Guideline reaffirmed. Removed "and Procedures" from the title. Added references.
Updated	n/a	01/01/2024	Annual CPT code update. Description changes for 28292, 28295, 28296, 28297, 28298, 28299. Added guidance for correct coding to code section.
Revised	04/12/2023	11/05/2023 for commercial, Medicare and Medicaid except IA and LA; 04/14/2024 for IA Medicaid	IMPP review. Added Total or partial primary shoulder arthroplasty for Ambulatory surgery center with 23-hour observation. Added Shoulder arthroplasty CPT codes: 23470 and 23472. Updated references. Added required language to General Clinical Guideline per new Medicare regulations.
Updated	_	01/01/2023	2023 Annual CPT code update: description change for 22633.
Updated	_	01/01/2022	2022 Annual CPT code update: description changes for 22633, 22634, 63048. Updated access date to ASA physical status chart.
Reaffirmed	11/11/2021	Unchanged	IMPP review. Guideline reaffirmed.
Updated	_	01/01/2021	2021 Annual CPT code update: description changes for 23466, 29822, 29823.
Revised	02/03/2020	11/01/2020	IMPP review. Added clarifications for thoracic and sacral spine. Added CPT codes for joint surgery: 27702, 27703, 27704, 27870, 28110, 28285, 28286, 28289, 28291, 28292, 28295, 28296, 28297, 28298, 28299, 28306, 28307, 28308, 28310, 28312, 28315, 28750, 29871, 29892. Added CPT codes for spine surgery: 22633, 22634, 63265, 63267.
Revised	07/11/2018	03/09/2019	IMPP review. Added the General Clinical Guideline.
Revised	07/11/2018	01/28/2019	IMPP review. Added observation surgical setting.
Created	12/12/2017	03/01/2018	IMPP review. Original effective date.