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Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Outpatient Surgical Services

Appropriate Use Criteria: Site of Care for Surgical Procedures

Proprietary

Table of Contents

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 advocate for 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 ongoing 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.

Site 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.

General Information

Scope

These guidelines address site of care for a select group of outpatient surgical services that are routinely performed outside of a hospital setting. Specifically, the guideline addresses the medical necessity of performing an outpatient surgical procedure at a hospital outpatient department (HOPD) where a higher level of support may be available. The appropriate place of care is defined as the facility (HOPD or freestanding) with the proper equipment and level of support to perform select outpatient surgical services that meet applicable clinical guidelines for appropriate use.

This guideline does not address the clinical appropriateness of individual procedures but rather restricts its focus to the selection of optimal site of care where the service is rendered. Some procedures may also be subject to clinical appropriateness review; in which case, a separate clinical guideline will be used to adjudicate clinical appropriateness.*

This guideline does not address the availability of alternative non-hospital sites to perform an individual procedure. The purpose of this guideline is to define the clinical scenarios in which hospital-based care is medically necessary and, by exclusion, when it is clinically reasonable to provide services in a non-hospital setting.

The guideline does not address provider (or ancillary staff) qualification or credentialing to perform any procedure, nor does it attempt to define the adequacy of facilities or equipment used in rendering procedures. Although the accreditation and licensing of surgical facilities are not addressed in this document, it is assumed that facilities where services are rendered meet all required state and national requirements.

See the Codes section for a list of procedures included in these guidelines.

**Note: Not all services that are subject to Site of Service review also require medical necessity review of the service itself. Some may only be subject to Site of Care review.*

Definitions

Hospital outpatient department (HOPD): Hospital department at which services are rendered to outpatients

Nonhospital: Freestanding surgical facility or provider office that is not owned/operated by a hospital

Surgical procedure: For purposes of this guideline, this term encompasses procedures (see Codes section for a list) that can be safely rendered outside the hospital outpatient setting, including traditional surgical procedures (e.g., cataract extraction) and both diagnostic and therapeutic endoscopic procedures. The term excludes procedures that routinely require post-procedure admission to the hospital.

Acute coronary syndrome: Acute myocardial infarction (either ST elevation or non-ST elevation) or unstable angina pectoris

Asthma – moderate or severe: When any of the following are present, the patient can be considered to have moderate or severe asthma:

- Daytime symptoms every day
- Nocturnal symptoms at least once per week
- At least daily use of "rescue" inhaler to relieve symptoms
- FEV1 < 80% of predicted despite medical management

Chronic obstructive airways disease (COPD) – moderate or severe: Forced expiratory volume in 1 second/Forced vital capacity (FEV1/FVC) ratio of ≤ 0.7 *and* FEV1 < 80% of predicted

Diabetes – poorly controlled: Diabetes with hemoglobin A1c > 9 for more than one year, hospitalization for management of diabetic ketoacidosis within the past 6 months or requiring treatment for hypoglycemia within the past month

Hypertension – treatment resistant: Persistent hypertension in a patient taking three or more antihypertensive medications

Increased bleeding risk: Prior history of abnormal bleeding, established diagnosis of a condition which predisposes to bleeding (e.g., thrombocytopenia, hemophilia, prolonged INR despite treatment with vitamin K, need to continue anticoagulants or antiplatelet agents through to perioperative period), anticipated need for blood transfusion, blood products or other substances to control bleeding risk.

New York Heart Association (NYHA) Functional Classification: Symptom-based classification of the severity of heart failure as outlined below:

- Class I. Individuals with cardiac disease but without resulting limitation of physical activity; ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain; symptoms only occur on severe exertion.
- Class II. Individuals with cardiac disease resulting in slight limitation of physical activity; they are comfortable at rest; ordinary physical activity (e.g., moderate physical exertion, such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
- Class III. Individuals with cardiac disease resulting in marked limitation of physical activity; they are comfortable at rest; less than ordinary activity causes fatigue, palpitation, dyspnea, or anginal pain.
- Class IV. Individuals with cardiac disease resulting in inability to carry on any physical activity without discomfort; symptoms of heart failure or the anginal syndrome may be present even at rest; if any physical activity is undertaken, discomfort is increased.

Obstructive sleep apnea (OSA) – moderate or severe: OSA diagnosed by either polysomnography or home sleep testing with Apnea Hypopnea Index (AHI) or Respiratory Disturbance Index (RDI) ≥ 15

Renal disease – end-stage: Patient is on regular hemodialysis or has glomerular filtration rate of < 15 mL/min per 1.73 m^2

Clinical Indications

Site of Care

A hospital outpatient department (HOPD) is considered medically necessary for requests that meet applicable medical necessity criteria for the service being performed in **ANY** of the following scenarios:

- Procedures requiring ancillary resources that are not available outside of a HOPD related to **ANY** of the following:
    - Duration of surgical procedure is expected to exceed 3 hours
    - Anticipated difficulty with establishment or maintenance of an airway based on preoperative airway assessment, such as prior history of difficult intubation, craniofacial abnormalities, limitation of neck extension, etc.
    - Prior unanticipated surgical or anesthetic complication resulting in instability requiring unplanned admission or additional care beyond what is routinely rendered for that procedure (e.g., resuscitation, management of hemodynamic instability, prolonged observation, transfusion, etc.)
- Clinical comorbidities and/or complexities that require access to services and/or higher acuity resources that are not available outside of a HOPD due to **ANY** of the following:

  - Age ≤ 18 or ≥ 75 years
  - Pregnant
  - Increased bleeding risk
  - Intellectual disability or cognitive impairment
  - Presence of an ASA class 3 or above comorbidity, such as:
    - Body mass index (BMI) ≥ 40
    - Treatment resistant hypertension
    - Poorly controlled diabetes
    - End-stage renal disease
    - Documented history of stroke or transient ischemic attack (TIA)
    - Documented history of myocardial infarction to acute coronary syndrome
    - Established diagnosis of severe valvular heart disease
    - Sustained, symptomatic cardiac arrhythmia despite treatment
    - NYHA Class III or IV congestive heart failure
    - Moderate or severe asthma
    - Moderate or severe COPD
    - Moderate or severe OSA
    - Liver cirrhosis (with MELD score > 8)
- When performing a procedure outside the HOPD would reasonably be expected to create clinically significant delays in care
- Absence of a geographically accessible* alternative non-HOPD facility capable of performing the requested procedure

**Note: The definition of "inaccessibility" may vary per individual health plan policy.*

Rationale

Over the past several decades, services that were previously rendered solely in hospital settings have become available at non-hospital locations, such as freestanding facilities and physician offices. This shift in site of care, particularly for surgical and endoscopic procedures, has been fueled by the development of less invasive surgical approaches, improvement in anesthetic techniques, and availability of equipment outside of the hospital setting. Patient demand has similarly grown for the convenience of neighborhood services, ease of scheduling outside of the hospital, and an increasing focus on patient experience. The lower cost of non-hospital services and the economic advantage of global billing (from a provider perspective) have also contributed to the increased availability of non-hospital sites of care.

While there is growing literature demonstrating which patients and procedures can safely be moved from an inpatient to an outpatient setting, high quality, prospective, randomized controlled studies are lacking to answer the clinical question of which patients can safely receive the same services outside of a hospital setting all together. Current literature shows equivalent safety profiles for a variety of outpatient procedures performed in and out of the hospital, ranging from endoscopies to orthopedic procedures. However, these results likely rely on careful patient selection, which has largely been established retrospectively. Therefore, many of the criteria outlined in this guideline reflect clinical scenarios with demonstrated safety in the outpatient setting, with additional considerations made for performance outside of the hospital.

This guideline is intended to apply to a subset of outpatient procedures routinely performed outside of a hospital setting with an expected same-day discharge plan that includes post-discharge home care and pain control that meets the clinical needs of the procedure performed. The criteria outlined in this guideline provide a clinical

framework in which the use of a HOPD is considered medically necessary. These criteria do not require any service to be performed within a HOPD and many patients included in the outlined scenarios routinely receive care outside of a HOPD.

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

See link below for CPT code list.

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

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

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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.

History

Status	Review Date	Effective Date	Action
Revised	04/15/2024	11/17/2024	Independent Multispecialty Physician Panel (IMPP) review. Broadened clinical comorbidities to include ASA Class III+ level to be allowable for cardiovascular and cerebrovascular disease. Added criteria to allow for a HOPD when there is clinical risk of delay or lack of geographically accessible alternatives. Removed criteria for mental status change as redundant with existing criteria for intellectual disability or cognitive impairment. Scope and Rationale sections updated and aligned with all Carelon MBM Site of Care Guidelines. Expanded Site of Care guideline title for clarity. Added an Appendix explaining ASA physical status classification.
Updated	01/23/2024	Unchanged	IMPP review of General Clinical Guideline. Added required language per new Medicare regulations.
Created, reaffirmed	04/12/2023, 08/31/2021, 07/08/2020	12/30/2023	IMPP review. Added medical necessity language for clarification. Added reference. Added site of service terminology disclaimer. Original effective date.