carelon

Status: Created
Doc ID: RBM12-300-0121.1

Effective Date: 01/01/2021
Last Review Date: 07/08/2020

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

Clinical Appropriateness Guidelines

New and Emerging Healthcare Interventions

Appropriate Use Criteria

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. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- 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 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. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. 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. 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 should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

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 supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

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.

New and Emerging Healthcare Interventions

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

76497	Unlisted computed tomography procedure
76498	Unlisted magnetic resonance procedure
78499	Unlisted cardiovascular px dx nuclear medicine
81599	Unlisted multianalyte assay algorithmic analysis
84999	Unlisted chemistry procedure

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

New and Emerging Healthcare Overview

General Information/Overview

Scope

This guideline addresses healthcare interventions defined as drugs, devices, tests, medical and /or surgical procedures, that are new and/or emerging. In most cases, the technologies required by these interventions have either only recently been approved by the Food and Drug Administration (FDA) or have not yet become an established part of the standard of care in the majority of markets.

This guideline covers new healthcare technology that is managed by Carelon, but that is not otherwise addressed by Carelon's solution specific guidelines. New and emerging healthcare interventions often lack a recognized current procedural terminology (CPT) Category 1 code and this guideline covers **ANY** of the following scenarios:

- Category 1 not otherwise specified codes
- Category 3 temporary codes
- **EITHER** of the following scenarios:
    - Interventions that evolve too quickly for more specific criteria development
    - Interventions that are too recent for more specific criteria development

This guideline can be used for both Adult and Pediatric patients. See the Coding section for a non inclusive list of codes included in this guideline.

Definitions

Complete clinical evaluation includes a history and when possible physical exam along with a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.

Quality evidence based literature usually refers to one or more peer reviewed clinical studies of at least moderate quality by GRADE, although exceptions may be made in certain clinical scenarios. Moderate quality evidence by GRADE requires a moderate confidence that future research will not significantly alter the estimate of effect.

Analytic validity refers to the accuracy with which a particular genetic characteristic, such as a DNA sequence variant, chromosomal deletion, or biochemical indicator, is identified in a given laboratory test.

Technical efficacy refers to the ability of a diagnostic test, typically an imaging test, to reliably distinguish signal from noise.

Clinical validity refers to the ability of a diagnostic test to accurately detect the condition of interest.

Clinical utility refers to the ability of an intervention to improve outcomes directly relevant to the patient or to impact patient management in a way that improves patient outcomes.

Best alternative intervention is the current standard of care procedure or service that would otherwise be performed for the clinical scenario in question.

Clinical Indications

A new or emerging healthcare intervention is considered medically necessary when it is anticipated to offer net benefit by satisfying **ALL** of the following criteria:

- Diagnosis has been confirmed or reasonable pretest probability of disease has been established based on a complete clinical evaluation of the patient
- Technology required by the intervention has been approved by the Food and Drug Administration (FDA) or other responsible regulatory agency, where applicable, and has analytic validity or technical efficacy
- Benefit over the best alternative intervention has been established by quality evidence based literature in **EITHER** of the following scenarios:
    - For diagnostic interventions: comparable or superior clinical validity and clinical utility showing impact of patient management that would reasonably be expected to improve patient centered outcomes
    - For therapeutic interventions: clinical utility showing improvement in patient centered outcomes
- Harms are either reduced relative to the best alternative intervention or are offset by superior benefit

Rationale

A central purpose of new technology assessment is to determine whether there is sufficient evidence that an intervention meets requirements for medically necessity. An intervention refers to any medical or surgical test, procedure or service used to diagnose, test and/or manage known or suspected disease. Interventions are usually appropriately used and hence medically necessary when they offer net patient benefit. Net benefit is defined as the magnitude of assessed benefits less the magnitude of assessed harms.[8] Benefits refer to clinically significant improvement in outcomes that are meaningful to patients, whereas harms refer to outcomes that would be detrimental.[5]

Evidence based medicine plays an especially important role in the assessment of new and emerging interventions, since the majority are not in widespread clinical use or considered the standard of care. Evidence comes primarily from the peer reviewed medical literature and consists of studies where the intervention (independent variable) is compared to the current standard of care using one or more outcome measures (dependent variables). Appropriate outcome assessment is therefore an essential part of new technology assessment and appropriate outcome assessment depends on the nature of the intervention. For therapeutic interventions, studies should show an improvement in outcomes that are directly relevant to patients. Common direct outcomes include morbidity, mortality, and patient centered measures. For diagnostic interventions it may be difficult to design a trial that establishes a causal link with direct outcomes because a number of intermediary therapeutic steps can confound results.[5] In this case, intermediate (“indirect”) outcome measures such as biomarkers, diagnostic accuracy, and impact on clinical management may be an acceptable alternative when other lines of evidence support a causal link between indirect and direct outcome measures.[3] In rewiewing evidence for new interventions, it is

important to assess the body of evidence overall in addition to its quality. The GRADE group has developed a systematic and widely accepted method for doing so. For a given outcome, GRADE defines a way to assess the quality of a body of evidence based on the likelihood that future research will change the estimate of effect.

Analytic frameworks are used to define the pieces of evidence required to assess the net benefit of an intervention in a given clinical scenario.[1] A common analytic framework in laboratory medicine is to require analytic validity, clinical validity, and clinical utility.[6] A similar framework proposed by Fryback and Thornbury is commonly used in advanced imaging. The framework requires evidence for technical validity, diagnostic accuracy, and impact on diagnostic thinking (clinical validity), as well as impact on patient management, patient outcomes, and societal benefit (clinical utility).[3] Therapeutic analytic frameworks make use of similar principles.[5, 7, 8]

The real world effectiveness of new and emerging interventions is often uncertain, as they are less frequently performed and less well established than the standard of care. Hence, new and emerging interventions should always offer comparative efficacy, i.e. a body of evidence in controlled circumstances for a clinically significant net benefit above and beyond the standard of care.

References

1. Agency for Healthcare Research and Quality. Methods Guide for Medical Test Reviews. AHRQ Publication No. 12-EC017. Rockville, MD: Agency for Healthcare Research and Quality; 2012. p. 188.
2. American Medical Association. Specialty Guide: Pathology. Chicago, IL: American Medical Association; 2020. p. 4.
3. BMJ Best Practice. EBM Toolkit: What is GRADE? United Kingdom: BMJ Publishing Group Limited; 2020. https://bestpractice.bmj.com/info/us/toolkit/learn-ebm/what-is-grade/
4. Cochrane Community. Glossary. London (UK): Cochrane; 2020. https://community.cochrane.org/glossary
5. Fryback DG, Thornbury JR. The efficacy of diagnostic imaging. Medical decision making : an international journal of the Society for Medical Decision Making. 1991;11(2):88-94.
6. Gazelle GS, Kessler L, Lee DW, et al. A framework for assessing the value of diagnostic imaging in the era of comparative effectiveness research. Radiology. 2011;261(3):692-8.
7. Herndon JH, Hwang R, Bozic KJ. Healthcare technology and technology assessment. European spine journal : official publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society. 2007;16(8):1293-302.
8. Institute of Medicine (US) Committee for Evaluating Medical Technologies in Clinical Use. Assessing Medical Technologies. 3, Methods of Technology Assessment. Washington (DC): National Academies Press (US); 1985.
9. Lee DW, Neumann PJ, Rizzo JA. Understanding the medical and nonmedical value of diagnostic testing. Value in health : the journal of the International Society for Pharmacoeconomics and Outcomes Research. 2010;13(2):310-4.
10. Singal AG, Higgins PD, Waljee AK. A primer on effectiveness and efficacy trials. Clinical and translational gastroenterology. 2014;5:e45.
11. Slomiany M, Madhavan P, Kuehn M, et al. Value Frameworks in Oncology: Comparative Analysis and Implications to the Pharmaceutical Industry. American health & drug benefits. 2017;10(5):253-60.
12. U.S. Preventive Services Task Force. U.S. Preventive Services Task Force Procedure Manual. Rockville, MD: U.S. Preventive Services Task Force; 2015. p. 85.
13. World Health Organization. 2015 Report of global survey on Health Technology Assessment Geneva, Switzerland: World Health Organization; 2015. p. 40.

History

Status	Review Date	Effective Date	Action
Created	07/08/2020	01/01/2021	Original effective date.