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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

Advanced Imaging

Appropriate Use Criteria: MR Guided Procedures

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.

MR Guided Procedures

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

77021	Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation
77022	Magnetic resonance guidance for, and monitoring of, parenchymal tissue ablation

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

MR Guided Procedures

General Information/Overview

Scope

These guidelines address procedures performed with magnetic resonance imaging (MRI) guidance that are either performed in bore (i.e., within the MRI gantry) or that lack a more specific biopsy code (CPT 76498). This guideline therefore includes percutaneous in bore procedures and MR guided prostate biopsy. It does not include MR guided breast biopsies (CPT 19085 or 19086).

See the Coding section for a list of modalities included in these guidelines. Codes that are not listed in this section are outside the scope of this guideline.

Clinical Indications

The following section includes indications for which MR guided biopsy is considered medically necessary, along with prerequisite information and supporting evidence where available. Indications, diagnoses, or imaging modalities not specifically addressed are considered not medically necessary.

MR Guided Procedures

MRI-Transrectal Ultrasound Fusion-Guided Prostate Biopsy

For management of documented malignancy, please refer to the Oncologic Imaging guidelines.

MR Transrectal Ultrasound Fusion Guided Biopsy is considered medically necessary when **ALL** of the following apply:

- **EITHER** of the following:

    - Persistent and unexplained elevation in PSA levels* or suspicious DRE
    - One-time biopsy during active surveillance, at least 12 months after starting active surveillance
- MR-visible lesion(s) by recent multiparametric MRI (mpMRI) using prostate imaging protocol
- Mp-MRI category Prostate Imaging Reporting and Data System (PI-RADS) 3, 4, or 5

* Elevated PSA levels defined as > 3 ng/ml in patients 45-75 years or > 4.0 ng/ml in patients 75 years or older

Rationale

MRI-Transrectal ultrasound fusion-guided prostate biopsy is a procedure that uses images from a previously performed multi-parametric MRI (mpMRI) which are uploaded onto a computer and fused to transrectal ultrasound (TRUS) images which are obtained in real time to guide a prostate biopsy. Areas of interest that had been previously marked ("targets") from the mpMRI can be specifically biopsied.

MR guided prostate biopsy is recommended by several practice and evidence based guidelines.[1-3] Several studies have demonstrated that combining targeted mpMRI with TRUS biopsy detects more clinically significant prostate cancers than TRUS biopsy alone with no greater procedural harms.[4-6]A recent (to July 31, 2018) Cochrane systematic review compared the diagnostic accuracy of MRI vs systematic biopsy in a mixed population of patients both naïve to biopsy and with priors using template guidance as the criterion reference. Based on 8 studies, the pooled sensitivities and specificities of MRI targeted biopsy were 0.80 (95% CI, 0.69 to 0.87) and 0.94 (95% CI, 0.90 to 0.97; 8 studies; low certainty of evidence). Based on 4 studies, the pooled sensitivity and specificity of systematic biopsy was 0.63 (95% CI, 0.19 to 0.93) and 1.00 (95% CI, 0.91 to 1.00). The pooled detection ratio for clinically significant prostate cancer using MRI guided biopsy was 1.12 (95% CI, 1.02 to 1.23). While the evidence quality was overall low, substantial effect size differences in sensitivity and improved detection led the authors to conclude that "the MRI pathway has the most favorable diagnostic accuracy in clinically significant prostate cancer detection".[7] These findings are consistent with other systematic reviews.[8-10]

While the efficacy of MR guided prostate cancer has been suggested by several studies, the effectiveness in everyday practice is less certain. There is a substantial learning curve to the accurate interpretation of prostate MRI with evidence for inter-rater variation by practice setting and experience. Use of a standardized method of interpretation, the Prostate Imaging Reporting and Data System (PI-RADS), uses a 1-5 scale based on well defined multiparametric parameters (including T2 weighted and diffusion imaging) to define the post test likelihood of clinically significant prostate cancer. PI-RADS scores of less than 3 have a low risk of disease.[11-13] Use of PI-RADs has been shown to improve the inter-rater reliability of reporting and is widely used in the US.[12, 14-17]

MR-Guided Percutaneous Radiofrequency Ablation for Tumor

MRI is considered medically necessary to guide and monitor electrode placement for percutaneous radiofrequency ablation of established tumors.

MR-Guided Percutaneous Biopsy

MRI is considered medically necessary to direct needle placement for in-bore percutaneous biopsy.

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History

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