CLINICAL APPROPRIATENESS GUIDELINES

ONCOLOGIC IMAGING

Appropriate Use Criteria: PET Radiotracers

Proprietary

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Description and Application of the Guidelines

The AIM Clinical Appropriateness Guidelines (hereinafter “the AIM 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 AIM, 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
- 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 AIM 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. AIM reviews all of its Guidelines at least annually.

AIM makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the AIM Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, AIM considers the Guidelines to be important, proprietary information of AIM, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of AIM.

AIM 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 AIM 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. If requested by a health plan, AIM will review requests based on health plan medical policy/guidelines in lieu of the AIM Guidelines.

The Guidelines may also be used by the health plan or by AIM 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.

History

Status	Date	Action
Revised	03/09/2019	Retitled Pretest Requirements to “Clinical Appropriateness Framework” to summarize the components of a decision to pursue diagnostic testing. To expand applicability beyond diagnostic imaging, retitled Ordering of Multiple Studies to “Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions” and replaced imaging-specific terms with “diagnostic or therapeutic intervention.” Repeated Imaging split into two subsections, “repeat diagnostic intervention” and “repeat therapeutic intervention.”
Reviewed	07/11/2018	Last Independent Multispecialty Physician Panel review
Revised	07/26/2016	Independent Multispecialty Physician Panel revised
Created	03/30/2005	Original effective date

PET Radiotracers

11C-Choline PET-CT

Initial treatment strategy

- Not indicated

Subsequent treatment strategy

11C-Choline is **medically necessary** in adult patients when ALL of the following criteria are met:

- Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy
  - Biochemically recurrent/persistent disease*
  - Results of conventional imaging are negative for metastasis or conventional imaging is not indicated†
  - MRI of the pelvis is negative or non-diagnostic for local recurrence
  - Patient is a candidate for local salvage therapy‡
  - PSA level is > 1 ng/ml

Surveillance

- Not indicated

Notes

* *The Radiation Therapy Oncology Group-American Society of Therapeutic Radiology and Oncology (RTOG-ASTRO) Phoenix Consensus defines biochemical recurrence as a rise by 2 ng/mL or more above the nadir PSA after local radiation therapy with or without hormone therapy. The American Urological Association defines biochemical recurrence as a PSA >0.2 ng/ml after prostatectomy with a second confirmatory level of PSA >0.2 ng/mL.*
† *Prior imaging to detect distant metastases not required for low-risk disease (T1-T3, PSA <10 ng/ml, Gleason 6).*
‡ *External beam radiation therapy ± androgen deprivation therapy after prostatectomy OR radical prostatectomy, cryosurgery, high-intensity focused ultrasound, or brachytherapy after external beam radiation therapy.*

18F-Fluciclovine (Axumin®) PET-CT

Initial treatment strategy

- Not indicated

Subsequent treatment strategy

18F Fluciclovine PET is **medically necessary** in adult patients when ALL of the following criteria are met:

- Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy
  - Biochemically recurrent/persistent disease*
  - Results of conventional imaging are negative for metastasis or conventional imaging is not indicated†
  - MRI of the pelvis is negative or non-diagnostic for local recurrence
  - Patient is a candidate for local salvage therapy‡
  - PSA level is > 1 ng/ml

Surveillance

- Not indicated

Notes

* *The Radiation Therapy Oncology Group-American Society of Therapeutic Radiology and Oncology (RTOG-ASTRO) Phoenix Consensus defines biochemical recurrence/persistence as a rise by 2 ng/mL or more above the nadir PSA after local radiation therapy with or without hormone therapy. The American Urological Association defines biochemical recurrence as a PSA >0.2 ng/ml after prostatectomy with a second confirmatory level of PSA >0.2 ng/mL.*
† *Prior conventional imaging to detect distant metastases not required for low-risk disease (T1-T3, PSA <10 ng/ml, Gleason 6).*
‡ *External beam radiation therapy ± androgen deprivation therapy after prostatectomy OR radical prostatectomy, cryosurgery, high-intensity focused ultrasound, or brachytherapy after external beam radiation therapy.*

68Ga-Dotatate (Netspot®) PET-CT

68Ga dotatate is **medically necessary** in adult and pediatric patients for the following indications:

Initial treatment strategy when ANY of the following criteria apply

- Biopsy-proven well-differentiated neuroendocrine tumor
- Suspected well-differentiated neuroendocrine tumor based on endoscopy, conventional imaging*, or biochemical markers† not amenable to biopsy

Subsequent treatment strategy of well-differentiated neuroendocrine tumor

- Prior to planned peptide receptor radioligand therapy (PRRT) for well-differentiated neuroendocrine tumor; OR
- When identification of more extensive disease will change management and one of the following criteria is met:
  - Equivocal findings of disease progression on conventional imaging
  - Clinical or biochemical progression with negative conventional imaging
  - When the original disease was only detectable by 68Ga dotatate

Surveillance

- Not indicated

Notes

** Conventional imaging includes MRI or contrast-enhanced CT with or without octreotide scintigraphy.*
† Biochemical evidence for suspected neuroendocrine cancers may include elevated levels of chromogranin A, pancreatic polypeptide, neuron-specific enolase, vasoactive intestinal polypeptide, serotonin (urinary 5-HIAA), gastrin, somatostatin, catecholamines, metanephrines, calcitonin, fasting insulin, C-peptide (proinsulin), or glucagon.

Codes

The following codes may be applicable to PET and PET-CT imaging and may not be all-inclusive.

CPT

78811	PET imaging, limited area
78812	PET imaging, skull to mid-thigh
78813	PET imaging, whole body
78814	PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; limited area
78815	PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; skull base to mid-thigh
78816	PET imaging, with concurrently acquired CT for attenuation correction and anatomic localization; whole body

HCPCS

A9515	Choline c-11, diagnostic, per study dose up to 20 millicuries
A9587	Gallium ga-68, dotatate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie

ICD-10 Diagnosis

Refer to the ICD-10 CM manual

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History

Status	Date	Action
Reviewed	09/12/2018	Independent Multispecialty Physician Panel review