

Clinical Appropriateness Guidelines: Radiation Oncology

Radiopharmaceutical Therapy Guideline

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Proprietary

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Description and Application of the Guidelines



AIM's Clinical Appropriateness Guidelines (hereinafter "AIM's 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, where possible, criteria for medical necessity determinations. 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 healthcare
- To promote the most efficient and cost-effective use of services

AIM's 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 AIM's 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 AIM's 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.

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Commonly Used Radiopharmaceuticals

Ibritumomab tiuxetan (Zevalin®)

Radium (Ra)-223 dichloride (Xofigo®)

Radiopharmaceutical Therapy Considerations

Radioimmunotherapy is a systemic therapy that involves a targeting monoclonal antibody linked with a radiation-emitting radionuclide to treat certain types of cancer. These agents are most commonly used for treatment of certain types of B-cell non-Hodgkin's lymphoma, as it binds to the CD20 antigen found on the surface of B cells. One such radioimmunotherapy agent, Bexxar (I131 Tositumomab), was discontinued February 2014. Ibritumomab tiuxetan (Zevalin) has 3 components to treatment: rituximab (Rituxan, an anti-CD20 monoclonal antibody) is given for 2 treatments, and Yttrium-90 (Y-90), or Zevalin, is given as the third component.

Radium (Ra)-223 dichloride (Xofigo) is an alpha-emitting radiopharmaceutical that has been shown to prolong survival in men with prostate cancer. In particular, it is used for the treatment of castration-resistant prostate cancer with symptomatic bone metastases. The drug causes double-stranded DNA breaks, but has a low risk of hematologic toxicity. It is administered monthly for 6 months, and should be used as monotherapy (though it can be combined with hormonal agents or ablation). It has not been evaluated for safety in combination with chemotherapy. It should be reserved for individuals with good functional status. It may cause bone marrow failure or prolonged pancytopenia, including risk of related death. Adequate bone marrow reserves should be confirmed prior to initial and subsequent administration and the drug should be discontinued if hematologic parameters do not recover within 6 to 8 weeks of a provided dose. Furthermore, in order to minimize the risk to the bone marrow, it is recommended that the patient meets the following requirements for safety purposes:

- No radioisotopes (such as Strontium or Samarium) over the previous 6 months (24 weeks) **AND**
- No chemotherapy or biologic therapy (hormonal therapy or ablation not included in biologic therapy) in the last 4 weeks

Somatostatin receptor therapeutic targeted radiotherapy remains under active investigation, and its role for therapeutic use is yet to be clarified. It will not be reviewed under the AIM program at this time.

Radiopharmaceutical Therapy Indications

Lymphoma

Zevalin

A single course of Zevalin is appropriate for lymphoma **when ANY of the following conditions are met**

- Any CD20 positive lymphoma as a part of a pre-autologous transplant conditioning regimen **OR**
- Follicular B-cell NHL, CD20 positive
 - Relapsed or refractory **OR**
 - After initial therapy when individual demonstrates a partial or complete response **OR**
- Other low-grade B-cell NHL (such as marginal zone lymphomas or MALT)
 - Relapsed or refractory

Prostate Cancer

Xofigo

A single course of Xofigo (as monotherapy*), for up to 6 planned monthly injections, is appropriate for prostate cancer **if ALL of the following conditions are met**

- Metastatic, castrate-resistant prostate cancer **AND**
- Symptomatic bone metastases only, with no visceral involvement **AND**
- Disease is worsening or progressing
 - Based on imaging demonstrating worsening bone metastases **OR**
 - Based on PSA over 5 ng/mL and rising over 2 consecutive lab evaluations **AND**
- Individual has a good performance status of ECOG 0-2

Note: *Xofigo cannot be combined with chemotherapy; however, it can be combined with hormonal agents or ablation.

Coding

Ibritumomab tiuxetan (Zevalin)

CPT

79403..... Radiopharmaceutical therapy, radiolabeled monoclonal antibody by intravenous infusion

ICD-10 Diagnoses

C88.4 Marginal zone lymphoma (MALT)

HCPCS

A9543 Yttrium Y-90 ibritumomab tiuxetan, therapeutic, per treatment dose, up to 40 millicuries

ICD-10 Diagnoses

C82.00 – C82.99 Nodular lymphoma (or follicular)

C83.80 – C83.89 Other named variants of lymphosarcoma and reticulosarcoma

C83.90 – C88.9 Other malignant lymphomas

Radium (RA)-223 dichloride (Xofigo)

CPT

79101..... Radiopharmaceutical therapy, by intravenous administration

ICD-10 Diagnoses

C61 Malignant neoplasm of the prostate

HCPCS

A9606 Radium ra-223 dichloride, therapeutic, per microcurie

ICD-10 Diagnoses

C79.82 Secondary malignant neoplasm, prostate

C80.1 Malignant (primary) neoplasm, unspecified

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These Guidelines are a work in progress that may be refined as often as new significant data becomes available.

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