Part B Prior Authorization Guidelines

Radioactive Agents

Iodine I-131 (iobenguane) A9590
Radium RA-223 dichloride A9606

Prior Authorization Request
Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Radioactive iodine (I-131):**

- ☐ Thyroid disease, as indicated by **1 or more** of the following:
  - ☐ Differentiated thyroid cancer (eg, follicular, papillary), as indicated by **ALL of the following**:
    - ☐ Thyroidectomy performed (total or near total)
    - ☐ Ablation of postoperative remnant of thyroid or adjuvant therapy needed, as indicated by **1 or more** of the following:
      - ☐ Extrathyroidal extension of tumor
      - ☐ Known metastases (eg, lymph node metastases)
      - ☐ Papillary thyroid cancer with **1 or more** of the following:
        - ☐ Concomitant BRAF V600E and TERT mutations
        - ☐ High-risk histology (columnar cell, diffuse sclerosing, hobnail variant, insular, poorly differentiated, tall cell)
        - ☐ Tumor-related symptoms (eg, dysphagia, hemoptysis)

☐ Postoperative (ie, 6 to 12 weeks after thyroidectomy) unstimulated thyroglobulin greater than 1 ng/mL (mcg/L)
☐ Primary tumor size 1 cm to 4 cm, and high risk of recurrence based on **1 or more** of the following:
☐ High-risk histology (eg, tall or columnar cell variants of papillary thyroid carcinoma, insular carcinoma)
☐ Known BRAF V600E mutation
☐ Multifocal tumors
☐ Primary tumor size greater than 4 cm
☐ Vascular or lymphatic invasion

☐ Hyperthyroidism, as indicated by **1 or more** of the following):
☐ Graves disease
☐ Hyperfunctioning thyroid nodule (toxic nodule, hot nodule, toxic adenoma) with benign biopsy results
☐ Multinodular goiter
☐ Persistent hyperthyroidism despite previous radioactive iodine treatment administered 6 or more months ago
☐ Recurrence of clinical hyperthyroidism following treatment with antithyroid drugs or thyroid surgery
- **Nontoxic (euthyroid) multinodular goiter with symptoms of airway, esophageal, or great vessel compression when surgery is not indicated (eg, high surgical risk or patient refusal)**

☐ **Radium RA-223 dichloride:**
☐ Radionuclide therapy of bone metastases may be indicated when ALL of the following are present:
☐ Advanced cancer (eg, prostate, breast, or lung) with multiple bone metastases
☐ Bone scan positive (ie, bone lesions predominantly osteoblastic)
☐ Pain control with conventional analgesic regimens unsatisfactory
☐ No current pathologic fracture of weight-bearing bone
☐ No severe or end-stage renal disease (glomerular filtration rate less than 30 mL/min/1.73m^2 (0.5 mL/sec/1.73m^2))

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**
☐ Patient had an adequate response or while on this product.
If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Radioactive Agents PA

Drug Name(s):
IODINE I-131 **RADIUM RA-223**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested product.

- If the member meets all these criteria, they may be approved by the Plan for the requested product.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
N/A

Coverage Duration:
Approval will be for 6 months.

FDA Indications:
Iodine I-131

- Thyroid Disease

Radium RA-223

- Advanced cancer (eg, prostate, breast, or lung) with multiple bone metastases

Off-Label Uses:
N/A

Age Restrictions:
N/A

Other Clinical Considerations:
N/A

Resources:
https://careweb.careguidelines.com/ed28/ac/ac03_033.htm#top
https://careweb.careguidelines.com/ed28/ac/ac03_182.htm#top