Azedra® (Iobenguane I-131) 
(Intravenous) 

Last Review Date: January 1, 2019 
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Definition 

Azedra is a radioactive therapeutic agent that releases radiation resulting from radioactive decay of I-131 causing cell death and tumor necrosis. Iobenguane has a similar structure to the neurotransmitter norepinephrine. It is taken up by the norepinephrine transporter in adrenergic nerve terminals and accumulates in adrenergically innervated tissues (i.e., heart, lungs, adrenal medulla, salivary glands, liver, and spleen) as well as tumors of neural crest origin, such as pheochromocytomas and paragangliomas. These neuroendocrine tumors express high levels of the norepinephrine transporter on their cell surfaces.

Azedra (Iobenguane I-131) is FDA approved for the treatment of adult and pediatric patients 12 years and older with Iobenguane scan positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy.

Length of Authorization 

Coverage will be provided for 6 months and may be renewed.

Guideline 

I. INITIAL APPROVAL CRITERIA 

**Azedra may be considered medically necessary if one of the below conditions are met AND use is consistent with the medical necessity criteria that follows:**

Pheochromocytoma/Paraganglioma†

- The member has unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma; **AND**
- Azedra (Iobenguane I-131) is being used as a primary treatment if prior positive MIBG scan; **AND**
- The member is not a candidate for chemotherapy or surgery.
† FDA-labeled indication(s);

Limitations/Exclusions
Azedra is not considered medically necessary when any of the following selection criteria are met:

- Azedra (iobenguane I-131) is being used after disease progression with the same regimen or had previous systemic radiotherapy treatments.
- Not to be used if platelet count is less than 80,000/mcL or absolute neutrophil count is less than 1,200/mcL.
- Single dose limit of Azedra (iobenguane I-131) is based on weight:
  - Weight greater than 62.5 kg: 18,500 Megabecquerel (MBq) (500 Millicuries (mCi)).
  - Weight 62.5 kg or less: 296 MBq/kg (8 mCi/kg).
- Indications not supported by CMS recognized compendia or acceptable peer reviewed literature may be deemed as not approvable and therefore not reimbursable.

II. RENEWAL CRITERIA
Same as initial prior authorization policy criteria.

Dosage/Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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</thead>
<tbody>
<tr>
<td>Therapy consists of a dosimetric dose followed by 2 therapeutic doses given at least 90 days apart.</td>
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</tbody>
</table>
| Pheochromocytoma/Paraganglioma (Dosimetric Dose) | Weight > 50 kg  
  - Weight ≤ 50 kg  
    - 3.7 MBq/kg (0.1 mCi/kg) |
| (Therapeutic Dose)          | Weight > 62.5 kg  
  - Weight ≤ 62.5 kg  
    - 296 MBq/kg (8 mCi/kg) |

Applicable Procedure Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C9407</td>
<td>Iodine I-131 iobenguane, diagnostic, 1 millicurie</td>
</tr>
<tr>
<td>C9408</td>
<td>Iodine I-131 iobenguane, therapeutic, 1 millicurie</td>
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</tbody>
</table>

Applicable NDCs

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>71258-0015-02</td>
<td>Azedra (lobenguane I-131) 15 mci/1ml injection solution, 2 ml vial</td>
</tr>
<tr>
<td>71258-0015-22</td>
<td>Azedra (Iobenguane I-131) 15 mci/1ml injection solution, 22.5 ml vial</td>
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</tbody>
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Applicable Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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### References