Blue Cross Blue Shield Blue Care Network of Michigan

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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 06/06/2024
Retired

Azedra® (iobenguane I-131)

HCPCS: A9590

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved indication
   b. FDA approved age
   c. Prescribed by or in consultation with an oncologist
   d. Submission of official pathology report documenting pheochromocytoma or paraganglioma
   e. Submission of official radiology report of positive iobenguane scan
   f. In the absence of metastatic disease, submission of a surgical or medical consult documenting the reason for inoperability

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Quantity Limit: Align with FDA approved dosing
   b. Initial Authorization Period: 6 months (3 total doses: 1 dosimetric dose, 2 therapeutic doses given at least 90 days apart)
   c. Renewal Criteria: Not applicable as no further authorization will be provided

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Pheochromocytomas are rare tumors of the adrenal glands. When this type of tumor occurs outside the adrenal gland, it is called a paraganglioma. The adrenal glands are located right above the kidneys and make hormones including the stress hormones epinephrine and norepinephrine. Pheochromocytomas increase the production of these hormones, leading to hypertension (high blood pressure) and symptoms such as headaches, irritability, sweating, rapid heart rate, nausea, vomiting, weight loss, weakness, chest pain or anxiety.

- Azedra is a radioactive drug indicated 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. It is similar in structure to norepinephrine (NE) and is taken up by tumor cells due to high levels of NE transporters on their cell surfaces. The radiation resulting from I-131 causes cell death.

- The National Comprehensive Cancer Network 2023 treatment guidelines for neuroendocrine and adrenal tumors recommend Azedra or Lutathera® plus octreotide or lanreotide, chemotherapy, or radiation for local, unresectable tumors or metastatic disease.

References:

1. Azedra [prescribing information]. New York, NY: Progenics Pharmaceuticals, Inc.; March 2021.
2. National Comprehensive Cancer Network. Neuroendocrine and adrenal tumors (Version 1.2023). 2023 August 2. Available at: https://www.nccn.org/professionals/physician_gls/pdf/neuroendocrine.pdf. Accessed on December 21, 2023.
3. Clinicaltrials.gov. A study evaluating ultratrace iobenguane I131 in patients with malignant relapsed/refractory pheochromocytoma/paraganglioma (NCT00874614). Available at: https://clinicaltrials.gov/ct2/show/NCT00874614?term=azedra&rank=2. Accessed on November 9, 2020.
4. Clinicaltrials.gov. Expanded access program of ultratrace iobenguane I131 for malignant relapsed/refractory pheochromocytoma/paraganglioma (NCT02961491). Available at: https://clinicaltrials.gov/ct2/show/NCT02961491. Accessed on November 9, 2020.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.7</td><td>Effective Date: 06/06/2024</td><td>Policy to be retired as the drug is being discontinued and removed from the market</td></tr>
<tr><td>1.6</td><td>Effective Date: 02/08/2024</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.5</td><td>Effective Date: 02/02/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.4</td><td>Effective Date: 02/10/2022</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.3</td><td>Effective Date: 02/04/2021</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>1.2</td><td>Effective Date: 02/06/2020</td><td>Annual Review</td></tr>
<tr><td>1.1</td><td>Effective Date: 02/14/2019</td><td>Updated Criteria</td></tr>
<tr><td>1.0</td><td>Effective Date: 11/01/2018</td><td>New Policy
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*