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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: 02/08/2024

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 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.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

- 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.

Policy History												
#	Date	Change Description										
1.6	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.5	Effective Date: 02/02/2023	Annual review of criteria was performed, no changes were made										
1.4	Effective Date: 02/10/2022	Annual review of criteria was performed, no changes were made										
1.3	Effective Date: 02/04/2021	Annual review of criteria was performed, no changes were made										
1.2	Effective Date: 02/06/2020	Annual Review										
1.1	Effective Date: 02/14/2019	Updated Criteria										
1.0	Effective Date: 11/01/2018	New Policy <table border="1" data-bbox="472 1415 1382 1633"> <thead> <tr> <th>Line of Business</th> <th>PA Required in Medical Management System (Yes/No)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
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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>.

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