POLICY NUMBER UM ONC_1342	SUBJECT Azedra™ (iobenguane I-131)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 10/10/18, 10/09/19, 12/11/19, 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 10/10/18, 10/09/19, 12/11/19, 06/10/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler	COMMITTEE/BOARD APPROVAL Utilization Management Committee			
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT		
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS	APPLICABLE LINES OF BUSINESS All		

I. PURPOSE

To define and describe the accepted indications for Azedra (iobenguane I-131) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**

b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**

c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies **AND**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand name drugs.

2. Pheochromocytoma/Paraganglioma

a. The member has unresectable, locally advanced, or metastatic pheochromocytoma or paraganglioma **AND**

b. Azedra (iobenguane I-131) is being used as a primary treatment for member with a positive MIBG (meta-iodobenzylguanidine) scan **AND**

c. The member is not a candidate for chemotherapy or surgery.

III. EXCLUSION CRITERIA

1. Azedra (iobenguane I-131) is being used after disease progression while receiving Azedra.

2. Not to be used if platelet count is less than 80,000/mcL or absolute neutrophil count is less than 1,200/mcL.
3. Single dose limit of Azedra (iobenguane I-131) is based on weight:
    a. Weight greater than 62.5 kg: 18,500 Megabecquerel (MBq) (500 Millicuries (mCi).
    b. Weight 62.5 kg or less: 296 MBq/kg (8 mCi/kg).
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

None

VII. REFERENCES

1. Azedra PI prescribing information. Progenics Pharmaceuticals, Inc 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2019.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2019.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2019.