SmartPA Criteria Proposal

Drug/Drug Class:	Alpelisib Clinical Edit
First Implementation Date:	TBD
Proposed Date:	September 15, 2022
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of alpelisib agents.

Why Issue Selected: Alpelisib is a kinase inhibitor targeting phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3Kα. Pathogenic variants in the gene encoding the catalytic α-subunit of PI3K lead to activation of PI3Kα and Akt-signaling, cellular transformation and the generation of tumors in in vitro and in vivo models. Piqray® (alpelisib) was FDA-approved in 2019 in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer. Vijoice® (alpelisib) was FDA-approved on April 5, 2022, for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of *PIK3CA*-Related Overgrowth Spectrum (PROS) who require systemic therapy. PROS is a spectrum of rare disorders involving variants in the *PIK3CA* gene causing overgrowth in various parts of the body. These variants result in an abnormally active phosphatidylinositol-3-kinase (PI3K) enzyme, causing affected cells to grow and divide more than they should. The pathogenic variants in PROS are mosaic and are only present in certain body cells that affect certain areas. Manifestations include abnormal bone, soft tissue, and blood vessel growth in these affected areas. PROS has an estimated prevalence of 14 people per million. Treatment of PROS includes symptom management and treatment of complications such as bleeding, clotting, pain, and functional impairment. Vijoice is the first FDA-approved medication for PROS. Piqray and Vijoice both contain alpelisib as the active ingredient and differ solely in how they are supplied.

Due to the high cost, possible adverse events, and specific approved indications, MO HealthNet will impose clinical criteria to ensure appropriate utilization of alpelisib agents.

Program-Specific Information:

Date Range FFS 07/01/2021 to 06/30/2022			
Drug	**Claims**	**Spend**	**Cost per year (WAC)**
PIQRAY 200 MG BLISTER PACK	2	$34,879.78	$243,384.96
PIQRAY 250 MG BLISTER PACK	-	-	
PIQRAY 300 MG BLISTER PACK	29	$469,578.60	
VIJOICE 50 MG BLISTER PACK	-	-	$422,500.00
VIJOICE 125 MG BLISTER PACK			
VIJOICE 250 MG BLISTER PACK			

Type of Criteria:	☐ **Increased risk of ADE**	☐ **Preferred Drug List**
	☒ **Appropriate Indications**	☒ **Clinical Edit**
Data Sources:	☐ **Only Administrative Databases**	☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Alpelisib agents
- Age range: All appropriate MO HealthNet participants aged 2 years and older

Approval Criteria

Initial Therapy:

- Claim is for Piqray **OR**
- For Vijoice tablets:
  - Prescribed by or in consultation with an appropriate specialist in the treated disease state **AND**
  - Participant is aged ≥ 2 years **AND**
  - Participants aged ≥ 18 years: therapeutic reason why Piqray 250 mg daily dose pack cannot be utilized **AND**
  - Documented diagnosis of PROS as verified by:
    - Genetic testing **OR**
    - National Institutes of Health (NIH) Workshop Diagnostic Guidelines **AND**
  - Documentation of at least one target lesion identified on imaging with baseline measurement of target lesion volume **OR**
  - Participants who are unable to complete baseline imaging must have at least one quantifiable target lesion able to be measured, requests will be subject to clinical review **AND**
  - Initial approval for 6 months

Continuation of Therapy:

- For Vijoice:
  - Documentation of benefit of therapy by one of the following from baseline:
    - ≥ 20% reduction in measurement of target lesion volume
    - Reduction in sum of lesion volume
    - Clinically meaningful improvement in signs and symptoms of disease (i.e., vascular malformation, functional improvement, limb asymmetry, pain)
  - Continued approval for 1 year

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- For Vijoice: participant is currently pregnant

Required Documentation

Laboratory Results:		Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

6 months

References

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