UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Piqray

Program	Prior Authorization
Medication	Piqray® (alpelisib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2019
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

Piqray (alpelisib) is a kinase inhibitor indicated 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, following progression on or after an endocrine-based regimen.

2. Coverage Criteria:

A. Breast Cancer

1. Initial Authorization

a. Piqray will be approved based on **all** of the following criteria:

(1) Diagnosis of breast cancer

-AND-

(2) **One** of the following:

(a) Advanced
(b) Metastatic

-AND-

(3) Disease is hormone receptor (HR)-positive

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

(5) Presence of one or more PIK3CA mutations

-AND-

(6) Patient is one of the following:

(a) Postmenopausal
(b) Male

-AND-

(7) Used in combination with fulvestrant

-AND-

(8) Disease has progressed on or after an endocrine-based regimen

Authorization will be issued for 12 months.

2. Reauthorization

a. Piqray will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Piqray** therapy.

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Piqray** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Piqray** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Piqray therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Piqray [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation. May 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed July8, 2020.

Program	Prior Authorization
Change Control	
Date	Change
8/2019	New program.
8/2020	Annual Review. Removed requirement of FDA test confirming PIK3CA mutations. Added Additional Clinical Rules section.