

## Commercial/Healthcare Exchange PA Criteria

*Effective: August 13<sup>th</sup>, 2019*

**Prior Authorization:** Piqray

**Products Affected:** Piqray oral tablets

**Medication Description:** Piqray is an inhibitor of phosphatidylinositol-3-kinase (PI3K) with inhibitory activity predominantly against PI3K $\alpha$ . PI3K inhibition by alpelisib treatment has been shown to induce an increase in estrogen receptor (ER) transcription in breast cancer cells. The combination of alpelisib and fulvestrant demonstrated increased antitumor activity compared to either treatment alone in xenograft models derived from ER-positive, PIK3CA mutated breast cancer cell lines.

**Covered Uses:** Advanced or metastatic, hormone receptor-positive, HER2-negative disease, PIK3CA-mutated, breast cancer, in combination with fulvestrant in postmenopausal women, and men following progression on or after endocrine therapy.

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Diagnosis of HER2-negative, hormone receptor-positive, advanced or metastatic breast cancer.
2. Documentation of PIK3CA-mutation as detected by an FDA-approved test.
3. Previous therapies tried.
4. Current therapy regimen.

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by, or in consultation with, an oncologist.

**Coverage Duration:** 12 months

**Other Criteria:**

Approve if the patient meets the following criteria:

- A. The patient is a postmenopausal female or a male; AND
- B. The patient has 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; AND
- C. Piqray is being used in combination with fulvestrant

**References:**

Piqray® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.

## Policy Revision history

| Rev # | Type of Change | Summary of Change | Sections Affected | Date       |
|-------|----------------|-------------------|-------------------|------------|
| 1     | New Policy     | New Policy        | All               | 07/23/2019 |