talazoparib (Talzenna®)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO065

Description

Talazoparib (Talzenna) is an orally administered poly (ADP-ribose) polymerase (PARP) inhibitor.

Length of Authorization

- Initial: Three months
- Renewal: Twelve months

Quantity limits

talazoparib (Talzenna)	Indication	Quantity Limit	DDID
0.25 mg capsules	BRCA-mutated breast cancer, locally advanced or metastatic	90 capsules/30 days	204472
1 mg capsules		30 capsules/30 days	204473

Initial Evaluation

I. Talazoparib (Talzenna) may be considered medically necessary when the following criteria below are met:
   A. Member is 18 years of age or older; **AND**
   B. Talazoparib (Talzenna) has been prescribed by, or in consultation with a specialist in oncology; **AND**
   C. Talazoparib (Talzenna) will be used as monotherapy; **AND**
   D. Member has not had documented disease progression on prior PARP inhibitor therapy; **AND**
   E. A diagnosis of locally advanced (stage III) or metastatic (stage IV) breast cancer when the following are met:
      1. Documented deleterious (pathogenic) or suspected deleterious (likely pathogenic) germline BRCA mutation as determined by BRCA testing; **AND**
      2. Documented HER2-negative disease; **AND**
      3. Prior treatment with an anthracycline (e.g., doxorubicin) and/or a taxane (e.g. paclitaxel) was ineffective, unless contraindicated; **AND**
      4. If treated with prior platinum chemotherapy, disease is not platinum refractory (i.e., progression of disease within 8 weeks of platinum discontinuation); **AND**
      5. Member has received no more than three previous cytotoxic regimens for advanced breast cancer (stage III or stage IV); **AND**

6. For hormone receptor positive (HR+) disease, member has had progression of disease on prior endocrine therapy, unless the patient is considered inappropriate for endocrine therapy

II. Talazoparib (Talzenna) is considered investigational when used for all other conditions, including but not limited to:
   A. When used in combination with any other chemotherapy or targeted therapy
   B. Early-stage breast cancer
   C. Ovarian cancer, fallopian tube, and peritoneal cancer
   D. Lung cancer
   E. Prostate cancer

Renewal Evaluation

I. Clinical documentation of response to treatment, such as stabilization or improvement of disease; **AND**
II. Absence of unacceptable toxicity from the medication

Supporting Evidence

I. Talazoparib (Talzenna) is FDA-approved for the treatment of adults with germline BRCA mutated, HER2-negative locally advanced or metastatic disease.
II. The efficacy and safety of talazoparib (Talzenna) monotherapy was demonstrated in an open-label trial (EMBRACA) which enrolled adult patients that had a deleterious or suspected deleterious germline BRCA1/2 mutation detected by testing with BRACAnalysis.
III. Patients in the EMBRACA study had received no more than three previous cytotoxic regimens for advanced breast cancer, and they had received previous treatment with a taxane, an anthracycline, or both, unless contraindicated.
IV. Previous neoadjuvant or adjuvant platinum-based therapy was allowed, provided the patient had a disease-free interval for at least six months after the last dose. Patients were excluded if they had disease progression while receiving platinum chemotherapy for advanced breast cancer (i.e., progression of disease within approximately eight weeks after the last dose).
V. Patients included in the study had no more than three prior therapies in the advanced breast cancer setting. More than two therapies in other settings (e.g. neoadjuvant, adjuvant) do not apply.
VI. Although prior endocrine-based therapy was not required in the EMBRACA trial, 90.4% of patients had progressed on endocrine-based therapy before being treated with talazoparib (Talzenna), and 100% had received prior chemotherapy for HR+ disease. The standard treatment

approach for HR+ disease is to first target the hormone pathway (unless considered inappropriate), then consider single agent chemotherapy or PARP inhibitor if there is progression on endocrine-based therapy.

VII. The National Comprehensive Cancer Network (NCCN) breast cancer guideline lists the PARP inhibitors [talazoparib (Talzenna) and olaparib (Lynparza)] as Category 1 options for previously treated recurrent or metastatic HER2-negative germline BRCA mutated breast cancer.

Investigational or Not Medically Necessary Uses

I. The efficacy and safety of talazoparib (Talzenna) in combination with other chemotherapy or immunotherapy agents has not been evaluated. Talazoparib (Talzenna) is indicated as monotherapy.
II. There is no evidence to support the use of a subsequent PARP inhibitor following progression of disease on another PARP inhibitor.
III. Due to its mechanism of action, there is interest in using talazoparib (Talzenna) in other cancers such as ovarian cancer, prostate cancer, and lung cancer; however, studies are still ongoing and use outside of BRCA mutated breast cancer is considered investigational.
IV. Additionally, there is a lack of evidence supporting the use of talazoparib (Talzenna) in early breast cancer (e.g., neoadjuvant treatment).

References

1. Talzenna [Prescribing Information]. New York, NY: Pfizer. October 2018.
2. Litton J, Rugo H, Ettl J, et al. Talazoparib in patients with advanced breast cancer and germline BRCA mutation. N Engl J Med 2018;379:753-63
3. NCCN Clinical Practice Guideline in Oncology: Breast Cancer. Version 3.2018. National Comprehensive Cancer Network. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Updated October 25, 2018.
4. UpToDate, Inc. Systemic treatment of metastatic breast cancer in women: Chemotherapy. UpToDate [database online]. Waltham, MA. Available at: http://www.uptodate.com/home/index.html. Updated August 21, 2017. Accessed December 27, 2018.
5. National Institutes of Health, Clinicaltrials.gov [website]. [cited periodically]; Available from: www.clinicaltrials.gov

Policy Implementation/Update:

Date Created	February 2019
Date Effective	February 2019
Last Updated	
Last Reviewed	

Action and Summary of Changes	Date