

Talazoparib (TALZENNA)

Criteria for Use

September 2024

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at www.pbm.va.gov or <http://vawww.pbm.va.gov> for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive talazoparib.

- Absolute Neutrophil Count < 1500/ μ L; Platelet count < 75,000/ μ L; Hemoglobin < 9 g/dL (unless caused by bone marrow invasion)
- Unmanageable drug-drug interaction
- History of Myelodysplastic Syndrome or Acute Myeloid Leukemia
- Pregnancy
- Lactating

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- Care is provided by a VA/VA purchased care oncology provider
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- Goals of care and role of Palliative Care consult have been discussed and documented

Additional Inclusion Criteria

The answer to one the following must be fulfilled to meet criteria:

- Locally advanced or metastatic HER2-negative breast cancer with germline *BRCA* mutation (*gBRCAm*)
- In combination with enzalutamide for Metastatic Castration-Resistant Prostate Cancer (mCRPC) with Homologous Recombination Repair (HRR) gene mutation, in patients without prior novel androgen receptor inhibitor therapy in the mCRPC setting ¹

¹ Novel androgen receptor inhibitor therapy includes abiraterone, enzalutamide, darolutamide, apalutamide

Additional Inclusion Criteria *if applicable*

- For patients who can become pregnant and patients with partners who can become pregnant: Counseling provided on potential risks vs benefits of treatment and the use of effective contraception during therapy and for 7 months after stopping treatment.

Other Considerations
