STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TALAZOPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TALAZOPARIB TOSYLATE	TALZENNA	45368		GPI-10 (2153558040)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*) as confirmed by a FDA-approved test
   - The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting

   If yes, continue to #2**.**
   If no, continue to #3.

2. Does the patient meet **ONE** of the following criteria?
   - The patient does NOT have hormone receptor (HR)-positive breast cancer
   - The patient has hormone receptor (HR)-positive breast cancer AND has received prior treatment with endocrine therapy or be considered inappropriate for endocrine therapy

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

3. Does the patient have a diagnosis of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Talzenna will be used in combination with Xtandi (enzalutamide)

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

4. Does the patient meet **ONE** of the following criteria?
   - The patient had a bilateral orchiectomy
   - The patient has a castrate level of testosterone (i.e., less than 50 ng/dL)
   - Talzenna will be used concurrently with a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron-Depot [leuprolide], Zoladex [goserelin], Supprelin [histrelin], Firmagon [degarelix])

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, do not approve.
   DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TALAZOPARIB (TALZENNA)** requires the following rule(s) be met for approval:
   A. You have ONE of the following diagnoses:
      1. Human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer (cancer that does not have a type of protein and has spread from where it started to nearby tissue or lymph nodes or has spread to other parts of the body)
      2. HRR gene-mutated (abnormal change in the homologous recombination repair gene) metastatic castration-resistant prostate cancer (mCRPC: prostate cancer that has spread to other parts of the body and no longer responds to testosterone lowering treatment)
   B. You are 18 years of age or older
   C. **If you have breast cancer, approval also requires:**
      1. You have a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutation (*gBRCAm*: a type of gene mutation [abnormal change]) as confirmed by a Food and Drug Administration-approved test
      2. You have been treated with chemotherapy in the neoadjuvant (drugs used to treat cancer given before main treatment), adjuvant (add-on to main treatment), or metastatic setting (treating disease that has spread)
      3. If you have hormone receptor (HR)-positive breast cancer, you had additional treatment with endocrine (hormone) therapy or are considered inappropriate for endocrine therapy

   (Denial text continued on next page)

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GUIDELINES FOR USE (CONTINUED)

D. **If you have prostate cancer, approval also requires:**
   1. Talzenna will be used in combination with Xtandi (enzalutamide)
   2. You meet ONE of the following:
      a. You had a bilateral orchiectomy (both testicles have been surgically removed)
      b. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
      c. Talzenna will be used together with a gonadotropin-releasing hormone (GnRH) analog (such as Lupron-Depot [leuprolide], Zoladex [goserelin], Supprelin [histrelin], Firmagon [degarelix])

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Talzenna.

REFERENCES

- Talzenna [Prescribing Information]. New York, NY: Pfizer Labs; June 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/01/23
Created: 02/19
Client Approval: 06/23
P&T Approval: 07/23