STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

NIRAPARIB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		GPI-10 (2153555020)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to first-line platinum based-chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #1 per day.**
   If no, continue to #2.

2. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient is in complete or partial response to platinum-based chemotherapy (e.g., cisplatin, carboplatin)
   - The requested medication will be used for maintenance treatment
   - The patient's cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*) based on an FDA-approved companion diagnostic for Zejula
   - The requested medication will be used as monotherapy
   - The requested medication will be started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient has completed at least 2 or more lines of platinum-based chemotherapy (e.g., cisplatin, carboplatin)

   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.

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NIRAPARIB

GUIDELINES FOR USE (CONTINUED)

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 **NIRAPARIB (Zejula)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Advanced epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)
   2. Recurrent (returning) epithelial ovarian (cancer that forms on the surface of the ovary), fallopian tube, or primary peritoneal cancer (type of abdominal cancer)

B. **If you have advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to first-line platinum based-chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)

C. **If you have recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, approval also requires:**
   1. You are 18 years of age or older
   2. You are in complete or partial response to platinum-based chemotherapy (such as cisplatin, carboplatin)
   3. The requested medication will be used for maintenance treatment (treatment to prevent cancer from coming back after it has disappeared after initial therapy)
   4. Your cancer has deleterious or suspected deleterious germline *BRCA*-mutation (*gBRCAmut*: a type of gene mutation [abnormal change]) based on a Food and Drug Administration (FDA)-approved companion diagnostic for Zejula
   5. The requested medication will be used as monotherapy (used by itself for treatment)
   6. The requested medication is started no later than 8 weeks after your most recent platinum-containing regimen (such as cisplatin, carboplatin)
   7. You have completed at least two lines of platinum-based chemotherapy (such as cisplatin, carboplatin)

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.

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NIRAPARIB

RATIONALE

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

REFERENCES

- Zejula [Prescribing Information]. Durham, NC: GlaxoSmithKline; April 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
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