NIRAPARIB

Generic	Brand	HICL	GCN	Exception/Other
NIRAPARIB TOSYLATE	ZEJULA	44177		

GUIDELINES FOR USE

1. Does the patient have a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meet **ALL** of the following criteria?
   - 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 is in complete or partial response to their most recent platinum based-chemotherapy
   - Patient has completed at least 2 or more lines of platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment
   - The patient is greater than 18 years of age

   If yes, **approve for 12 months by HICL with a quantity limit of #90 capsules per 30 days.**
   If no, do not approve.
   DENIAL TEXT: The guideline named **NIRAPARIB (Zejula)** requires a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer. In addition, the following criteria must be met:
   - The requested medication will be used as monotherapy
   - The requested medication is started no later than 8 weeks after the patient's most recent platinum-containing regimen
   - The patient is in complete or partial response to their most recent platinum based-chemotherapy
   - Patient has completed at least 2 or more lines of platinum-based chemotherapy
   - The requested medication will be used for maintenance treatment
   - The patient is greater than 18 years of age

RATIONALE
Promote appropriate utilization of **NIRAPARIB** based on FDA approved indication and dosage.

FDA APPROVED INDICATIONS
Zejula is indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

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FDA APPROVED INDICATIONS (CONTINUED)

DOSAGE AND ADMINISTRATION

The recommended dose of Zejula as monotherapy is 300 mg (three 100 mg capsules) taken orally once daily with or without food. Bedtime administration may be a potential method for managing nausea. Patients should start treatment with Zejula no later than 8 weeks after their most recent platinum-containing regimen.

Instruct patients to take their dose of Zejula at approximately the same time each day. Each capsule should be swallowed whole.

Zejula treatment should be continued until disease progression or unacceptable toxicity.
In the case of a missed dose of Zejula, instruct patients to take their next dose at its regularly scheduled time. If a patient vomits or misses a dose of Zejula, an additional dose should not be taken.

To manage adverse reactions, consider interruption of treatment or dose reduction. Recommended dose reductions are indicated in Table 1.

Table 1. Recommended Dose Adjustments

Dose Level	Dose
Starting dose	300 mg/day (three 100 mg capsules)
First dose reduction	200 mg/day (two 100 mg capsules)
Second dose reduction	100/day* (one 100 mg capsule)

REFERENCES

- Zejula [Prescribing Information]. Waltham, MA: Tesaro; 2017.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/17
Created: 08/17
Client Approval: 08/17
P&T Approval: 07/17