

SPECIALTY GUIDELINE MANAGEMENT

ZEJULA (niraparib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Zejula 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

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer when all of the following criteria are met:

- A. The member is in a complete or partial response to platinum-based chemotherapy.
- B. Treatment is being started or was started no later than 8 weeks after the most recent platinum-based chemotherapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Zejula [package insert]. Waltham, MA: Tesaro, Inc.; March 2017.