Reference number(s)
1687-A

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.

A. FDA-Approved Indications
   1. Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.
   2. 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.
   3. Treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status defined by either:
      a. a deleterious or suspected deleterious BRCA mutation, or
      b. genomic instability and who have progressed more than six months after response to the last platinum-based chemotherapy.

      Select patients for therapy based on an FDA-approved companion diagnostic for Zejula.

B. Compendial uses
   1. Ovarian, fallopian tube, or primary peritoneal cancer - single agent for maintenance treatment
   2. Epithelial ovarian, fallopian tube, or primary peritoneal cancer - in combination with bevacizumab for platinum-sensitive persistent or recurrent disease
   3. Uterine Leiomyosarcoma (uLMS)

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of laboratory report confirming BRCA mutation status, where applicable.
B. Documentation of laboratory report confirming homologous recombination deficiency status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
   1. Authorization of 12 months may be granted for maintenance treatment of recurrent or advanced (stage II-IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer as a single agent when the member is in a complete or partial response to chemotherapy.
   2. Authorization of 12 months may be granted for the treatment of persistent, recurrent, or advanced ovarian, fallopian tube, or primary peritoneal cancer as a single agent when all of the following criteria are met:
      a. Member has been treated with three or more prior chemotherapy regimens

b. Member's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following:
   i. Member has a deleterious or suspected deleterious BRCA mutation
   ii. Member has genomic instability and has progressed more than six months after response to the last platinum-based chemotherapy

3. Authorization of 12 months may be granted for the treatment of persistent or recurrent ovarian, fallopian tube, or primary peritoneal cancer, in combination with bevacizumab for platinum-sensitive disease.

B. Uterine Leiomyosarcoma

Authorization of 12 months may be granted for treatment of BRCA altered uterine leiomyosarcoma (uLMS) as second-line therapy when used as a single agent.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Zejula [package insert]. Research Triangle Park, NC: GlaxoSmithKline; May 2021.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 5, 2022.