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 deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.

B. Compendial uses
1. Ovarian, fallopian tube, or primary peritoneal cancer – maintenance therapy for stage II-IV disease with germline or somatic BRCA mutation
2. 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:
Documentation of laboratory report confirming BRCA mutation status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer
Authorization of 12 months may be granted for maintenance treatment of epithelial ovarian, fallopian tube, or primary peritoneal cancer when the member is in a complete or partial response to platinum-based chemotherapy and any of the following criteria are met:
1. Member has advanced (stage II-IV) disease and requested medication will be used as a single agent or in combination with bevacizumab
2. Member has recurrent disease with a deleterious or suspected deleterious germline BRCA mutation and requested medication will be used as a single agent

B. Uterine Leiomyosarcoma
Authorization of 12 months may be granted for subsequent treatment of BRCA2-altered uterine leiomyosarcoma (uLMS) when used as a single agent for advanced, recurrent, metastatic, or inoperable disease.

Reference number(s)
1687-A

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]. Durham, NC: GlaxoSmithKline; April 2023.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 25, 2024.