envolve Pharmacy Solutions

Clinical Policy: Niraparib (Zejula)
Reference Number: ERX.SPA.54
Effective Date: 06.01.17
Last Review Date: 05/17
Line of Business: Commercial [Prescription Drug Plan] Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Niraparib (Zejula™) is a poly(ADP-ribose) polymerase (PARP) inhibitor.

FDA approved indication
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.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Zejula is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all)**:**
1. Diagnosis of epithelial ovarian cancer including fallopian tube or primary peritoneal cancer;
2. Documentation of complete or partial response to prior platinum-based chemotherapy regimen;
3. Dose does not exceed 300 mg/day (3 capsules/day).

Approval duration: Length of Benefit

B. Other diagnoses/indications
1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg/day (3 capsules/day).

Approval duration: Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Drug	Dosing Regimen	Dose Limit/ Maximum Dose
Rubraca® (rucaparib)	600 mg orally twice daily	1200 mg per day
Lynparza™ (olaparib)	400 mg orally twice daily	800 mg per day
carboplatin (Paraplatin®)	Varies	Varies
cisplatin (Platinol®-AQ)	Varies	Varies
carboplatin/docetaxel	Varies	Varies
carboplatin/gemcitabine		
carboplatin/gemcitabine/ bevacizumb	Varies	Varies
carboplatin/liposomal doxorubicin	Varies	Varies
carboplatin/paclitaxel	Varies	Varies
cisplatin/gemcitabine	Varies	Varies

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Ovarian, fallopian tube, or primary peritoneal cancer	300 mg PO QD	300 mg per day

VI. Product Availability

Capsules: 100 mg

VII. References

1. Zejula Prescribing Information. Waltham, MA: Tesaro, Inc., March 2017. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/208447lbl.pdf. Accessed March 30, 2017.
2. Mirza MR, Monk BJ, Herrstedt J et al. Niraparib Maintenance Therapy in Platinum-Sensitive, Recurrent Ovarian Cancer. N Engl J Med. 2016 Dec 1;375(22):2154-2164. Epub 2016 Oct 7.
3. National Comprehensive Cancer Network. Ovarian Cancer Version 1.2016. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed March 29, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04/17	05/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional

medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.

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