Clinical Policy Title:	niraparib
Policy Number:	RxA.573
Drug(s) Applied:	Zejula®
Original Policy Date:	03/06/2020
Last Review Date:	8/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all):

1. Diagnosis of advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Request meets one of the following (a or b):
   a. The member's diagnosis and prior therapy meet both of the following (i and ii):
      i. Newly diagnosed stage II-IV disease;
      ii. Member completed first-line platinum-based chemotherapy regimen and is in a complete or partial response;
   b. The member's diagnosis and prior therapy meet both of the following (i and ii):
      i. Documentation of deleterious or suspected deleterious germline BRCA-mutation;
      ii. Completed platinum-based chemotherapy and is in a complete or partial response;
3. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Talzenna®).

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Uterine Cancer (off-label) (must meet all):

1. Diagnosis of advanced, recurrent/metastatic, or inoperable uterine sarcoma;
2. Member has tried one systemic regimen (examples of a systemic regimen include one or more of the following products: dacarbazine, docetaxel, doxorubicin, epirubicin, gemcitabine, ifosfamide, vinorelbine);
3. Member has BRCA2 mutation;
4. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Talzenna®).

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indication in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. 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. Available at: https://pubmed.ncbi.nlm.nih.gov/27717299/. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Ovarian Cancer Version 3.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed August 28, 2024.
3. National Comprehensive Cancer Network. Uterine Neoplasms. Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed August 28, 2024.
4. Morgan RD, Clamp AR, Evans DGR, Edmondson RJ, Jayson GC. PARP inhibitors in platinum-sensitive high-grade serous ovarian cancer. Cancer Chemother Pharmacol. 2018;81(4):647-658. Available at: https://pubmed.ncbi.nlm.nih.gov/29464354/. Accessed August 28, 2024.
5. ClinicalTrials.gov. A Maintenance Study with Niraparib Versus Placebo in Patients with Platinum Sensitive Ovarian Cancer (NOVA). Available at: https://clinicaltrials.gov/ct2/show/NCT01847274. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical policy title was updated as “niraparib”. 2. Line of business policy applies to all lines of business. 3. Initial approval criteria I.A.1 was updated to add new diagnosis criteria. 4. Continued therapy approval criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance..” 5. References were reviewed and updated.	11/05/2020	12/07/2020
Policy was reviewed: 1. References were reviewed and updated.	10/08/2021	12/07/2021
PA policy was reviewed: 1. Initial Approval Criteria I.A.4: Updated to remove Completed ≥ 2 platinum-based chemotherapy regimens and is in a complete or partial response. 2. Initial and Continued Therapy Criteria I.A.5 and II.B.3: Updated to add disclaimer Prescribed regimen must be FDA-approved or recommended by NCCN. 3. References were reviewed and updated.	07/28/2022	10/19/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria to Diagnosis of advanced or recurrent epithelial ovarian, fallopian	03/24/2023	04/13/2023

tube, or primary peritoneal cancer. 2. Initial Approval Criteria, I.A.1.c: Updated diagnostic criteria to remove "Disease is associated with HRD positive status defined by one of the following (a or b): a. Documentation of deleterious or suspected deleterious germline BRCA mutation; b. Documentation of genomic instability and disease has progressed > 6 months after response to the last platinum-based chemotherapy; 3. Initial Approval Criteria, I.A.5: Updated to include new prior therapy criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Talzenna®). 4. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, Uterine Cancer. 5. Initial Approval Duration for all indications: Updated from 6 months to 12 months. 6. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	8/28/2024	9/13/2024