Olaparib (LYNPARZA)
Criteria for Use
September 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at *www.pbm.va.gov* or *PBM INTRAnet* for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive olaparib.

- ☐ Creatinine clearance less than or equal to 30 mL/min
- ☐ Concomitant Strong or Moderate CYP3A inducers
- ☐ Concomitant Strong or Moderate CYP3A inhibitors- if unavoidable, reduce olaparib dose per labeling
- ☐ Untreated or uncontrolled brain metastases
- ☐ Pregnancy (i.e. known pregnancy or positive pregnancy test)
- ☐ Breastfeeding

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Care is provided by a VA/VA purchased care oncology provider
- ☐ Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- ☐ Goals of care and role of Palliative Care consult have been discussed and documented
- ☐ Male patients with partners of reproductive potential or who are pregnant should use effective contraception during treatment and for 3 months following the last dose.

Additional Inclusion Criteria

The answer to one of the following conditions must be fulfilled in order to meet criteria:

- ☐ Metastatic Castration-Resistant Prostate cancer with radiographic disease progression following treatment with enzalutamide or abiraterone/prednisone (prior use of docetaxel allowed) and both of the following:
  - ☐ Mutation in Homologous Recombination Repair (HRR) gene confirmed by FDA-approved companion diagnostic[1].
  - ☐ Ongoing castration with prior surgical castration or concomitant LHRH analogue

OR

- ☐ Other indication(s) – please provide evidence to support use (as appropriate).

[1] For HRR gene mutations other than BRCA2 consider a clinical trial if available and patient is eligible

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