Maryland
DEPARTMENT OF HEALTH

myChoice CDx (Clinical Criteria)

myChoice CDx® is a next-generation sequencing based assay that determines homologous recombination deficiency (HRD) status by the detection of "single nucleotide variants, insertions and deletions, and large rearrangement variants in protein coding regions and intron/exon boundaries of the BRCA1 and BRCA2 genes and the determination of Genomic Instability Score (GIS) which is an algorithmic measurement of Loss of Heterozygosity (LOH), Telomeric Allelic Imbalance (TAI), and Large-scale State Transitions (LST) using DNA isolated from formalin-fixed paraffin embedded (FFPE) tumor tissue specimens." The results of the assay are used to identify individuals with ovarian cancer who may be eligible for treatment with Niraparib (Zejula®) or Olaparib (Lynparza®).

I. Criteria for Approval

Preauthorization Required:

myChoice Cdx will be considered for coverage when ALL of the criteria below are met, confirmed with supporting medical documentation:

- Patient is 18 years old or older.
- Patient has advanced epithelial ovarian cancer, fallopian tube or primary peritoneal cancer and ONE of the following:
    - Treatment with Niraparib (Zejula), Olaparib (Lynparza), or other medication for which myChoice CDx is an FDA-approved companion diagnostic, is being considered.
    - FDA label for the drug and indication being considered states companion diagnostic testing for HRD status is necessary for patient selection*.
    - Has been treated with three or more lines of chemotherapy and are being considered for treatment with Niraparib (Zejula).
    - Is in complete or partial response to two or more lines of platinum-based chemotherapy and is being considered for maintenance treatment with Niraparib (Zejula).
    - Is being considered for first line maintenance treatment with Olaparib (Lynparza) and Bevacizumab. **

*Not all indications for medications with an FDA-approved companion diagnostic test require the results of that test prior to prescribing. myChoice testing would not be considered medically necessary when prescribed for indications that do not require a companion diagnostic.

** In 2020, the FDA approved olaparib (Lynparza) in combination with bevacizumab (Avastatin) "for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status."

II. Billing Code/Information

CPT Code: 0172U - myChoice CDx®

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 8/31/2021
Last Reviewed Date: 8/31/2021