

Medicare Advantage Medical Policy



MA: MULTIMARKER TESTING RELATED TO OVARIAN CANCER

EFFECTIVE 01/01/2024

Ovarian Cancer Diagnostic Algorithmic Tests

- I. Ovarian cancer diagnostic algorithmic tests (i.e., OVA1, Overa, ROMA, and OvaWatch) (0003U, 81500, 81503, 0375U) may be considered **investigational** for all indications, including but not limited to:
 - A. Preoperative evaluation of adnexal masses to triage for malignancy
 - B. Screening for ovarian cancer
 - C. Selecting patients for surgery for an adnexal mass
 - D. Evaluation of patients with clinical or radiologic evidence of malignancy
 - E. Evaluation of patients with nonspecific signs or symptoms suggesting possible malignancy
 - F. Postoperative testing and monitoring to assess surgical outcome and/or to detect recurrent malignant disease following treatment

Ovarian Cancer Treatment Algorithmic Tests

- I. Ovarian cancer treatment algorithmic tests (0172U) may be considered **medically necessary** when:
 - A. The member has a diagnosis of ovarian cancer, **AND**
 - B. The member is being considered for PARP inhibitor therapy.
- II. Ovarian cancer treatment algorithmic tests (0172U) are considered **investigational** for all other indications.

POSITION STATEMENT

National Comprehensive Cancer Network (NCCN)

NCCN guidelines for Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer (1.2023) recognize the use of biomarker analysis for risk assessment for ovarian cancer in women with a pelvic mass as an emerging technology; however, the NCCN panel of experts currently does not recommend these biomarker tests for clinical use. (p. MS-10 and p. MS-11)

Ovarian Cancer Treatment Algorithmic Tests

National Comprehensive Cancer Network (NCCN)

NCCN guidelines for Ovarian Cancer, Fallopian Tube Cancer, and Primary Peritoneal Cancer (1.2023) recommend genetic risk evaluation, and germline and somatic testing if not previously done, including *BRCA1/2* to inform maintenance therapy for patients with ovarian, fallopian tube, or primary peritoneal cancer. If a patient does not have a germline *BRCA1/2* mutation, homologous recombination status may inform on the benefit of PARP inhibitor therapy. (p. OV-1)

American Society of Clinical Oncology (ASCO)

ASCO (2020) issued a guideline for the use of PARP inhibitors in the management of ovarian cancer, which included the following summary of recommendations:

“The guideline pertains to patients who are PARPi naïve. All patients with newly diagnosed, stage III-IV EOC (epithelial ovarian, tubal, or primary peritoneal cancer), whose disease is in complete or partial response to first-line, platinum-based chemotherapy with high-grade serous or endometrioid EOC should be offered PARPi maintenance therapy with niraparib. For patients with germline or somatic pathogenic or likely pathogenic variants in *BRCA1* (g/s*BRCA1*) or *BRCA2* (g/s*BRCA2*) genes, should be treated with olaparib. The addition of olaparib to bevacizumab may be offered to patients with stage III-IV EOC with g/s*BRCA1/2* and/or genomic instability and a partial or complete response to chemotherapy plus bevacizumab combination. Maintenance therapy (second line or more) with single-agent PARPi may be offered for patients with EOC who have not received a PARPi and have responded to platinum-based therapy regardless of *BRCA* mutation status. Treatment with a PARPi should be offered to patients with recurrent EOC that has not recurred within 6 months of platinum-based therapy, who have not received a PARPi and have a g/s*BRCA1/2*, or whose tumor demonstrates genomic instability. PARPis are not recommended for use in combination with chemotherapy, other targeted agents, or immune-oncology agents in the recurrent setting outside the context of a clinical trial. Recommendations for managing specific adverse events are presented. Data to support reuse of PARPis in any setting are needed.” (p. 3)

CODES

81503	81500	0003U	0172U	0375U
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REFERENCES

Tew WP, Lacchetti C, Ellis A, et al. PARP Inhibitors in the Management of Ovarian Cancer: ASCO Guideline. *J Clin Oncol*. 2020;38(30):3468-3493. doi:10.1200/JCO.20.01924

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High Risk Assessment: Breast, Ovarian and Pancreatic. Version 3.2023. https://www.nccn.org/professionals/physician_gls/pdf/genetics_bop.pdf

