

Quality ID #507: Appropriate Germline Testing for Ovarian Cancer Patients

2025 COLLECTION TYPE: MIPS CLINICAL QUALITY MEASURES (COMS)

MEASURE TYPE: Process

DESCRIPTION:
Percentage of patients aged 18 years and older diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.

INSTRUCTIONS:
This measure is to be submitted a minimum of **once per performance period** for patients seen during the performance period. This measure is intended to reflect the quality of services provided for patients aged 18 and older newly diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer. This measure may be submitted by Merit-based Incentive Payment System (MIPS) eligible clinicians who provide the measure-specific denominator coding.

NOTE: Patient encounters for this measure conducted via telehealth (e.g., encounters coded with GQ, GT, POS 02, or POS 10) modifiers are allowable.

Measure Submission Type:
Measure data may be submitted by individual MIPS eligible clinicians, groups, or third-party intermediaries. The listed denominator criteria are used to identify the intended patient population. The numerator options included in this specification are used to submit the quality actions as allowed by the measure. The quality data codes listed do not need to be submitted by MIPS eligible clinicians, groups, or third-party intermediaries that utilize this modality for submissions; however, these codes may be submitted for those third-party intermediaries that utilize Medicare Part B claims data. For more information regarding Application Programming Interface (API), please refer to the Quality Payment Program (QPP) website.

DENOMINATOR:
All patients aged 18 and older with epithelial ovarian, fallopian tube, or primary peritoneal cancer newly diagnosed between July 1st of the previous performance period through June 30th of the current performance period with two encounters during the performance period

Denominator Instructions:
Patients must receive a new diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer from July 1st of the previous performance period through June 30th of the current performance period to be denominator eligible for this measure. The new diagnosis should be the patient's initial (first-ever) diagnosis of ovarian, fallopian tube, or primary peritoneal cancer.

The measure further specifies a population of patients with unknown Breast Cancer gene (BRCA) status. The panel acknowledges patients diagnosed with ovarian cancer may have undergone germline testing for a previous breast cancer diagnosis or that patients may have ovarian cancer identified at the time of prophylactic surgery following germline testing; patients with a known BRCA status at the time of ovarian cancer diagnosis are therefore not a population for whom this measure applies.

DENOMINATOR NOTE: The patient must have two encounters during the performance period. This is intended to reflect two separate encounters with the same reporting provider/group during this timeframe. There is no specific timeframe for the requirement for the two encounters that occur during the performance period. For example, two encounters with the same provider/group could occur in the same week. However, two encounters should not be counted if they occur on the same day. For example, the patient has two encounters and one is with a different provider on the same day.

*Signifies that this CPT Category I code is a non-covered service under the Medicare Part B Physician Fee Schedule (PFS). These non-covered services should be counted in the denominator population for MIPS CQMs.

Denominator Criteria (Eligible Cases):

Patients aged 18 years and older on the date of the encounter

AND

Diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer between July 1st of the previous performance period through June 30th of the current performance period (ICD-10-CM): C56.1, C56.2, C56.3, C56.9, C57.00, C57.01, C57.02, C48.1, C48.2, C48.8

AND

Two encounters during the performance period (CPT): 98000, 98001, 98002, 98003, 98004, 98005, 98006, 98007, 98008, 98009, 98010, 98011, 98012, 98013, 98014, 98015, 98016, 99202, 99203, 99204, 99205, 99212, 99213, 99214, 99215, 99242*, 99243*, 99244*, 99245*

AND NOT

DENOMINATOR EXCLUSION:

Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer: M1408

NUMERATOR:

Patients who receive germline genetic testing for BRCA1 and BRCA2 (ideally within the context of a multigene panel) or who have genetic counseling completed within 6 months of diagnosis

NUMERATOR NOTE: The American Society of Clinical Oncology (ASCO) guideline panel recommends that germline sequencing of BRCA1 and BRCA2 be performed in the context of a multigene panel that includes BRCA1, BRCA2, RAD51C, RAD51D, BRCA1 Interacting Protein (BRIP1), DNA mismatch repair protein (MLH)1, MSH2, MSH6, PMS2, and Partner and localizer of BRCA2 (PALB2). While the technical expert panel (TEP) prefers germline genetic testing is conducted for other ovarian cancer susceptibility genes in addition to BRCA1 and BRCA2 as recommended in the guideline, this measure focuses specifically on BRCA1 and BRCA2 as there may be payer variation or other limitations in the availability of multigene panels. While the ASCO guideline recommendation calls for germline testing to be conducted at the time of diagnosis, the TEP chose to specify the time period for germline testing to occur within 6 months after diagnosis. Completion of genetic counseling is included in the numerator to account for clinical workflows in practices where BRCA1 and BRCA2 testing is ordered by a genetic counselor rather than the reporting oncologist. Completion of genetic counseling may be signified by the presence of CPT or HCPCS codes (e.g., S0265) or presence of a genetic counseling report. Referral alone to genetic counseling, without evidence the patient completed genetic counseling, does not satisfy the numerator.

The performed/collected date for BRCA testing will be used to calculate the numerator time period.

Numerator Options:

Performance Met:

Patients who received germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis (M1409)

OR

Performance Not Met:

Patients who did not have germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis (M1410)

RATIONALE:

The American Cancer Society estimated roughly 19,710 new cases of ovarian cancer would be diagnosed in 2023 in the United States and an estimated 13,270 women will die of the disease [1]. Knowledge about underlying molecular alterations in ovarian cancer could allow for more personalized diagnostic, predictive, prognostic, and therapeutic strategies for the patient but also have clinical implications for her family members. Despite current recommendations for all women diagnosed with ovarian cancer to receive genetic testing, only approximately 30 percent of women undergo any genetic testing [2].

Germline mutations in BRCA1 and BRCA2 have been identified in 13-15 percent of women diagnosed with ovarian cancer, and somatic mutations are found in an additional 7 percent. The high incidence of these mutations and the advent of therapy targeted toward BRCA mutations warrant testing in all individuals diagnosed with ovarian cancer for the purpose of determining treatment recommendations, risk of other cancers, and need for cascade testing of family members. Testing for germline mutations should be done at the time of initial diagnosis. Presence of a germline mutation in a woman with advanced cancer identifies her as eligible for maintenance treatment with a poly (ADP-ribose) polymerase (PARP) inhibitor (olaparib) after response to initial chemotherapy [2].

The NCCN Ovarian Cancer guideline similarly states that, since germline and/or somatic BRCA1/2 testing informs selection of maintenance therapy for those with stage II-IV disease who are in complete response (CR) or partial response (PR) after first-line platinum-based chemotherapy, it is important to establish BRCA1/2 mutation status for patients who may be eligible for maintenance therapy following completion of platinum-based first-line chemotherapy. The goal of tumor testing in the upfront setting is to optimize identification of molecular alterations that can inform the use of interventions with demonstrated benefit in this setting, such as PARP inhibitors. Molecular alterations that should be probed for in this setting include BRCA1/2 status, loss of heterozygosity, or homologous recombination status, in the absence of a germline BRCA mutation [3].

Although the FDA recently approved frontline maintenance therapy for patients independent of mutation status following the publication of the ASCO guideline, emerging evidence is expected to indicate an overall survival benefit in ovarian cancer patients with germline mutations. Germline mutation testing therefore provides prognostic information for ovarian cancer patients, as those with germline mutations are expected to derive greater benefit from therapy. Additionally, and consistent with other recommendations in the ASCO guideline, germline testing also informs potential clinical implications for the relatives of ovarian cancer patients with germline mutations, who should themselves be offered individualized genetic risk evaluation, counseling, and genetic testing as reflected in Recommendation 1.5 in the ASCO germline testing guideline [2].

References

1. Mundhada, P. V., Bakshi, A. M., Thipalli, N., & Yelne, S. (2024). Unveiling the Promise: A Comprehensive Review of Salpingectomy as a Vanguard for Ovarian Cancer Prevention. *Cureus*, 16(1), e53088. <https://doi.org/10.7759/cureus.53088>
2. Konstantinopoulos, P. A., Norquist, B., Lacchetti, C., Armstrong, D., Grisham, R. N., Goodfellow, P. J., Kohn, E. C., Levine, D. A., Liu, J. F., Lu, K. H., Sparacio, D., & Annunziata, C. M. (2020). Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. *Journal of Clinical Oncology: Official Journal of the American Society of Clinical Oncology*, 38(11), 1222–1245. <https://doi.org/10.1200/JCO.19.02960>
3. National Comprehensive Cancer Network (NCCN). (2024). NCCN Clinical Practice Guidelines in Oncology. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2024. Retrieved from <http://www.nccn.org>

CLINICAL RECOMMENDATION STATEMENTS:

The two evidence-based clinical guidelines listed below directly support that all women diagnosed with ovarian cancer should undergo germline testing, as mutation status informs treatment, and carries implications for the need for cascade testing in family members. The measure will enhance compliance with the clinical guidelines by assessing the rates by which eligible providers pursue germline testing in ovarian cancer patients, ideally improving patient outcomes, and identifying at-risk patient relatives.

Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline [1]

Recommendation 1.1: All women diagnosed with epithelial ovarian cancer should be offered germline genetic testing for BRCA1, BRCA2, and other ovarian cancer susceptibility genes, irrespective of their clinical features or family cancer history. Somatic tumor testing for BRCA1 and BRCA2 pathogenic or likely pathogenic variants should be performed in women who do not carry a germline pathogenic or likely pathogenic BRCA1/2 variant (Type: evidence-based, benefits outweigh harms; Evidence quality: intermediate; Strength of recommendation: strong).

Recommendation 3.1 Women with epithelial ovarian cancer should be offered testing, as outline in recommendation 1.1, at the time of diagnosis. This has implications for therapeutic decision making (Type: evidence-based, benefits outweigh harms; Evidence quality: high; Strength of recommendation: strong).

NCCN Clinical Practices Guidelines in Oncology: Ovarian Cancer Including Fallopian Tube Cancer and Primary

Peritoneal Cancer [2]

Recommendation: Because germline and/or somatic *BRCA1* and *BRCA2* status may inform future options for maintenance therapy, all patients with histologically confirmed ovarian, fallopian tube, or primary peritoneal cancer should undergo genetic risk evaluation and germline and somatic testing, if not previously performed. In the absence of a *BRCA1/2* mutation, homologous recombination deficiency testing may also be considered, as it may provide information about the magnitude of benefit of PARP inhibitor maintenance therapy following first-line chemotherapy (category 2B).

1. Panagiotis A. Konstantinopoulos, Barbara Norquist, Christina Lacchetti, Deborah Armstrong, Rachel N. Grisham, Paul J. Goodfellow, Elise C. Kohn, Douglas A. Levine, Joyce F. Liu, Karen H. Lu, Dorinda Sparacio, and Christina M. Annunziata. Germline and Somatic Tumor Testing in Epithelial Ovarian Cancer: ASCO Guideline. *Journal of Clinical Oncology* 2020 38:11, 1222-1245
2. National Comprehensive Cancer Network (NCCN). (2024). NCCN Clinical Practice Guidelines in Oncology. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer Version 1.2024. Retrieved from <http://www.nccn.org>

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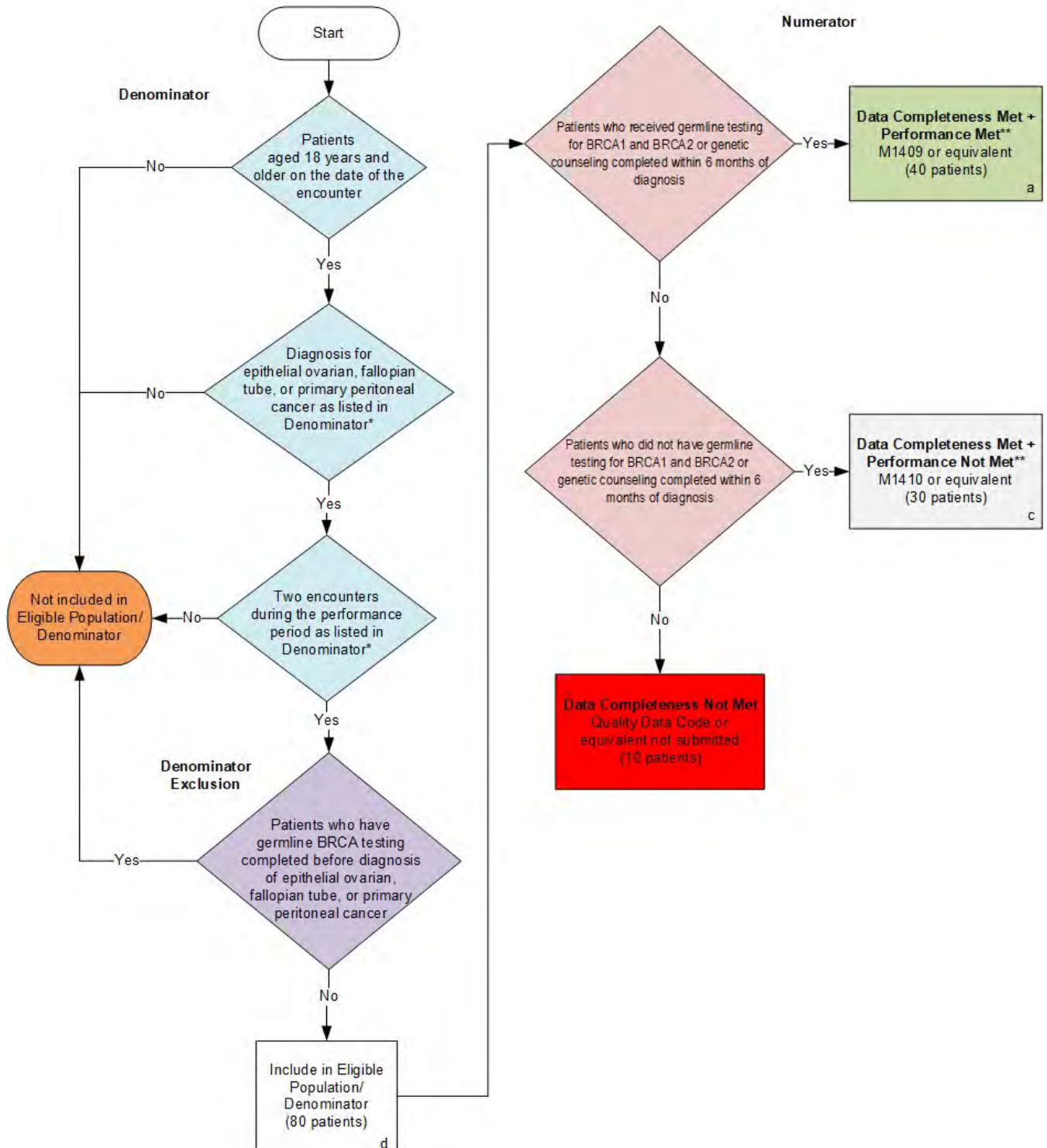
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2025 Clinical Quality Measure Flow for Quality ID #507: Appropriate Germline Testing for Ovarian Cancer Patients

Disclaimer: Refer to the measure specification for specific coding and instructions to submit this measure.



SAMPLE CALCULATIONS

Data Completeness =

$$\frac{\text{Performance Met (a=40 patients)} + \text{Performance Not Met (c=30 patients)}}{\text{Eligible Population / Denominator (d=80 patients)}} = \frac{70 \text{ patients}}{80 \text{ patients}} = 87.50\%$$

Performance Rate =**

$$\frac{\text{Performance Met (a=40 patients)}}{\text{Data Completeness Numerator (70 patients)}} = \frac{40 \text{ patients}}{70 \text{ patients}} = 57.14\%$$

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient - Process

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v9

2025 Clinical Quality Measure Flow Narrative for Quality ID #507: Appropriate Germline Testing for Ovarian Cancer Patients

Disclaimer: Refer to the measure specification for specific coding and instruction to submit this measure.

1. Start with Denominator
2. Check *Patients aged 18 years and older on the date of the encounter*:
 - a. If *Patients aged 18 years and older on the date of the encounter* equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patients aged 18 years and older on the date of the encounter* equals Yes, proceed to check *Diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer between July 1st of the previous performance period through June 30th of the current performance period as listed in Denominator**.
3. Check *Diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer as listed in Denominator**:
 - a. If *Diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Diagnosis for epithelial ovarian, fallopian tube, or primary peritoneal cancer as listed in Denominator** equals Yes, proceed to check *Two encounters during the performance period as listed in Denominator**.
4. Check *Two encounters during the performance period as listed in Denominator**:
 - a. If *Two encounters during the performance period as listed in Denominator** equals No, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Two encounters during the performance period as listed in Denominator** equals Yes, proceed to check *Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer*.
5. Check *Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer*:
 - a. If *Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer* equals Yes, do not include in *Eligible Population/Denominator*. Stop processing.
 - b. If *Patients who have germline BRCA testing completed before diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer* equals No, include in *Eligible Population/Denominator*.
6. Denominator Population:
 - Denominator Population is all Eligible Patients in the Denominator. Denominator is represented as Denominator in the Sample Calculation listed at the end of this document. Letter d equals 80 patients in the Sample Calculation.
7. Start Numerator
8. Check *Patients who received germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis*:
 - a. If *Patients who received germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis* equals Yes, include in *Data Completeness Met and Performance Met***.

- *Data Completeness Met and Performance Met*** letter is represented in the Data Completeness and Performance Rate in the Sample Calculation listed at the end of this document. Letter a equals 40 patients in the Sample Calculation.
- b. If *Patients who received germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis* equals No, proceed to check *Patients who did not have germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis*.
9. Check *Patients who did not have germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis*:
 - a. If *Patients who did not have germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis* equals Yes, include in *Data Completeness Met and Performance Not Met***.
 - *Data Completeness Met and Performance Not Met*** letter is represented in the Data Completeness in the Sample Calculation listed at the end of this document. Letter c equals 30 patients in the Sample Calculation.
 - b. If *Patients who did not have germline testing for BRCA1 and BRCA2 or genetic counseling completed within 6 months of diagnosis* equals No, proceed to check *Data Completeness Not Met*.
 10. Check *Data Completeness Not Met*:
 - If *Data Completeness Not Met*, the Quality Data Code or equivalent was not submitted. 10 patients have been subtracted from the Data Completeness Numerator in the Sample Calculation.

Sample Calculations:

Data Completeness equals Performance Met (a equals 40 patients) plus Performance Not Met (c equals 30 patients) divided by Eligible Population/Denominator (d equals 80 patients). All equals 70 patients divided by 80 patients. All equals 87.50 percent.

Performance Rate equals Performance Met (a equals 40 patients) divided by Data Completeness Numerator (70 patients). All equals 40 patients divided by 70 patients. All equals 57.14 percent.

*See the posted measure specification for specific coding and instructions to submit this measure.

NOTE: Submission Frequency: Patient - Process

The measure diagrams were developed by CMS as a supplemental resource to be used in conjunction with the measure specifications. They should not be used alone or as a substitution for the measure specification.