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Positive Quality Intervention: PARP Inhibitor Eligibility in Ovarian Cancer

Description: The purpose of this PQI is to highlight effective practices to ensure ovarian cancer patients are identified, tested, tracked, and offered a PARP inhibitor when appropriate.

Background: In gynecologic cancer patients, PARP inhibitors (PARP-I), have shown increased progression free survival (PFS) and, in some cases, overall survival. Misconceptions may exist around which patients are eligible for PARP inhibitors and when these therapies should be utilized. Patients should be educated upfront about the anticipated therapy journey including the role of maintenance treatment. In ovarian cancer, maintenance therapy is rapidly becoming the new standard of care and it is imperative to identify and appropriately offer maintenance therapy to eligible patients.[3] Data presented at a 2018 ESMO conference showed that the majority of eligible patients were not on maintenance therapy.[4] A real-world data analysis by Garofalo and colleagues found that maintenance therapy was used in 49% of eligible patients; 47% of those on maintenance therapy received a PARP-I as the maintenance agent. A study done by Randall and colleagues found 50% of women with epithelial ovarian cancer underwent BRCA1/2 testing, while Buchanan and colleagues found testing rates in this patient population to be close to around 75%. Use of a PARP-I was higher in those with a BRCA mutation at 61%, vs 45% with wild-type or unknown status.[5] This study looked at maintenance after second line or greater therapy; newer data shows PFS benefit of maintenance after first line therapy, highlighting the need to accurately identify patients up front.[6,7]

PQI Process: Upon diagnosis of ovarian cancer stage II, III or IV

- Identify and track all ovarian cancer patients by utilizing the Electronic Medical Record (EMR)
  - Use Assessment Tool for Maintenance Therapy In Ovarian Cancer tool
- Determine patient's BRCA mutation status (consider genetic testing if not already completed)
  - Utilize EMR Pathways, Regimens or Patient Management Software when available
- Work with your EMR vendor to ensure PARP-I are listed as a treatment option
- Track all current or upcoming first-line platinum therapy patients with *estimated completion date*:
  - Consider use of a calendar reminder system for dates of treatment milestones
    - The treatment plan should be reviewed with the treating oncologist and a calendar should be maintained to mark the end of systemic therapy
    - Work closely and proactively with provider to determine each unique patient's anticipated treatment plan (rather than reactive after a prescription is ordered)
  - As completion date approaches, assess treatment plan regarding maintenance therapy
    - Consider re-discussing options with provider
    - Consider monthly follow-up in the EMR during surveillance
    - When appropriate, ensure prescription for a PARP inhibitor is submitted
- Consider PARP-Inhibitor utilization
  - For patients in relapsed platinum sensitive ovarian cancer maintenance therapy following partial or complete response to platinum based chemotherapy (niraparib or rucaparib)
    - See **Niraparib (Zejula®)- Dose Modifications Based On Weight And Platelet Counts**
  - For first line or relapsed platinum sensitive maintenance therapy in BRCA associated advanced ovarian cancer (olaparib)
- BRCA1 and BRCA2-positive patients have historically been more responsive to PARP-I therapy than BRCA-negative patients
- Ensure the entire medical integrated team is educated about the importance of consistent tracking in the EMR (as described above) to ensure critical appointments and calls are done, accordingly

- Consider creating a standard treatment plan and inform all potential professionals of the anticipated path and timing (genetic counselors, schedulers, assistants, pharmacists, providers, technicians, financial counselors, administrators, and more)

Patient-Centered Activities:

- Provide upfront education on the role of maintenance treatment and discuss genetic testing (including BRCA) and implications to patient
- Provide Oral Chemotherapy Education (OCE) Sheet and counsel on relevant side effects
- Emphasize the importance of adherence
- Discuss dates for anticipated treatment milestones and options for maintenance therapy
- Clarify any misconceptions around increased efficacy in IV vs. PO therapies
- Patient Assistance: NCODA Financial Assistance Tool

References:

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Supplemental Information:

Current NCCN guidelines for genetic testing describe recommendations for BRCA testing in all ovarian cancer patients and in breast cancer patients that meet specific criteria.[11]

BRCA Testing Populations in Breast and Ovarian Cancer[5]

- Individual from family with known BRCA1/2 variant
- History of breast cancer + one of the following
  - ≤ 45 years
  - 46-50 years with additional breast cancer primary OR ≥ 1 close blood relative with breast cancer or high-grade prostate cancer
  - Unknown or limited family history
- ≤ 60 with triple negative breast cancer
- Any age + one of the following
  - ≤ 45 years
  - ≥ 1 blood relative with breast cancer diagnosed at ≤ 50 years, ovarian carcinoma, male breast cancer, metastatic prostate cancer or pancreatic cancer
  - 2 or more diagnoses of breast cancer at any age in patient or close blood relatives
- Ashkenazi Jewish ancestry
- History of ovarian cancer, pancreatic cancer, male breast cancer, or metastatic prostate cancer
- Regardless of family history, in those that may benefit from targeted therapy