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Positive Quality Intervention: Advanced Breast Cancer: Appropriate Patient Identification with Abemaciclib (Verzenio®)

Description: The goal of this PQI is to identify appropriate eligible patients for abemaciclib therapy based upon specific prognostic factors.

Background: Abemaciclib is indicated for the treatment of postmenopausal women with HR-Positive, HER2-Negative in early high-risk, advanced, or metastatic breast cancer. Abemaciclib may be used as monotherapy or in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy and in combination with fulvestrant with disease progression following endocrine therapy. In an exploratory analysis of the Monarch 3 and Monarch 2 (placebo + fulvestrant vs abemaciclib + fulvestrant) benefit was seen specifically in prognosis concerning: liver metastases, P-gR negative tumors, or high-grade tumors. The greatest benefit over placebo was seen in Monarch 2 among the subsection of patients with baseline liver metastases; the median progression free survival increased from 3.09 months (placebo) to 11.64 months (abemaciclib).[1]

PQI Process:[2]

- Obtain CBC with differential and platelets at baseline, every 2 weeks for the first 2 months, monthly for the next 2 months, then as clinically indicated
- Identify patients with prognostic factors that may benefit patient outcomes in areas such as:
  - Visceral Liver Metastases
  - P-gR Negative Tumors
  - High-grade Tumors
- Consider review of EMR for all current advanced breast cancer patients and those already on CDK4/6 inhibitors to assess for the prognostic factors above
- Provide input with medically integrated team as needed to help benefit patient
- Check liver function following the same schedule as CBC
- Abemaciclib should not be given to pregnant women
  - Ensure proper use of birth control prior to and during therapy and 3 weeks past last dose
- Monitor and educate patient to be aware of signs and symptoms of diarrhea, dehydration, venous thrombosis, or pulmonary embolism
- Dosing Guideline Summary:
  - When used in combination with either an AI or fulvestrant, abemaciclib 150 mg orally twice daily with or without food
  - When used as monotherapy abemaciclib 200 mg orally twice daily with or without food
  - See dose modification based on strong CYP3A4 inhibition
  - Be aware of dose adjustments for patients with severe hepatic impairment
  - Significant adverse effects to monitor include neutropenia and venous thromboembolism
  - Continue treatment until disease progression or unacceptable toxicity

Patient Centered Activities:[2]

- Provide Oral Chemotherapy Education (OCE) Sheet

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- How to take: Swallow whole with or without food, ideally at the same time each day
  - If vomiting occurs after taking a, do NOT repeat the dose; take next dose at the scheduled time
- Provide Loperamide (OTC) or RX antidiarrheal and counsel on diarrhea management
  - Please refer to the **Abemaciclib (Verzenio®) Diarrhea Management** PQI for more information
  - Provide Oral Chemotherapy Education Supplemental Sheet
- Drink plenty of non-caffeinated fluids per day (6-8 large glasses)
- Patient Assistance: NCODA Financial Assistance Tool

References:

1. The benefit of abemaciclib in prognostic subgroups, presented by Matthew P. Goetz 12-/5/2017.
2. VERZENIO ® [Package Insert].