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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 a cyclin-dependent kinase 4 and 6 (CDK4 and CDK6) inhibitor. Inhibition of these kinases prevents activation by cyclin D1 in estrogen receptor-positive breast cancer cells, thereby preventing retinoblastoma protein (Rb) phosphorylation, cell cycle progression, and cell proliferation in patients with:[1]

- Hormone receptor (HR)- positive, human epidermal growth factor receptor 2 (HER2)-negative, advanced or metastatic breast cancer
    - In combination with an aromatase inhibitor (AI) in postmenopausal females and in males
    - As a single agent with progressive disease following endocrine therapy and prior chemotherapy
    - In combination with fulvestrant (and gonadotropin-releasing hormone agonist in pre/perimenopausal females) with progressive disease on prior endocrine therapy
- HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence
    - In combination with endocrine therapy (AI or tamoxifen)

Most common adverse reactions (≥ 20%):[1]

- Increased: infections
- Decreased: neutrophils, lymphocytes, platelets, appetite
- Other: diarrhea, nausea, abdominal pain, fatigue, vomiting, headache, alopecia

PQI Process:

- 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
- Monitor patients for pulmonary symptoms indicative of ILD or pneumonitis
    - Symptoms may include hypoxia, cough, dyspnea, or interstitial infiltrates on radiologic exams
- 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:

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

References:

1. Sledge GW Jr., Toi M, Neven P, et al. MONARCH2: Abemaciclib in combination with fulvestratnt in women with HR+/HER2- advanced breast cancer who had progressed while receiving endocrine therapy. J Clin Oncol 2017 35:25, 2875-2884.
2. Goetz. J, Toi M, Compone M, et al. MONARCH 3: abemaciclib as initial therapy for advanced breast cancer. Clin Oncol. 2017;35(32): 3638-3634.
3. VERZENIO ® [Package Insert].