



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

- HR+ HER2- 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+ HER2- early, high risk, node-positive early breast cancer, at high risk of recurrence
 - In combination with endocrine therapy (AI or tamoxifen)

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.^{1,2} 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:³

- 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

IMPORTANT NOTICE: NCODA has developed this Positive Quality Intervention platform. This platform is intended as an educational aid, does not provide individual medical advice, and does not substitute for the advice of a qualified healthcare professional. This platform does not cover all existing information related to the possible uses, directions, doses, precautions, warning, interactions, adverse effects, or risks associated with the medication. The materials contained in this platform do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA. NCODA does not ensure the accuracy of the information presented and assumes no liability relating to its accuracy. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional. It is the individual's sole responsibility to seek guidance from a qualified healthcare professional. *Updated 3.15.24*

- Significant adverse effects to monitor include neutropenia and venous thromboembolism
- Continue treatment until disease progression or unacceptable toxicity

Patient-Centered Activities:³

- Provide [Oral Chemotherapy Education \(OCE\) 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 [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. Sledge GW Jr., Toi M, Neven P, et al. MONARCH2: Abemaciclib in combination with fulvestrant 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, Compton M, et al. MONARCH 3: abemaciclib as initial therapy for advanced breast cancer. Clin Oncol. 2017;35(32): 3638-3634.
3. [VERZENIO® \[Package Insert\]](#).