



Positive Quality Intervention: Advanced Breast Cancer: Appropriate Patient Identification with Abemaciclib

Description of PQI: To identify appropriate eligible patients for abemaciclib (Verzenio®) therapy based upon specific prognostic factors.

Background: Abemaciclib is indicated for the treatment of postmenopausal women with HR-Positive, HER2-Negative advanced or metastatic breast cancer. A 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-gp 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 PFS increased from 3.09 months (placebo) to 11.64 (abemaciclib).^[6]

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-gp 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. Assess reproductive potential and manage with LHRH agonist as appropriate
- Ensure proper use of birth control prior to, and during therapy
- Monitor and educate patient to be aware of signs and symptoms of diarrhea, dehydration, venous thrombosis, or pulmonary embolism

Patient Centered Activities^[3]:

- Provide Oncology Chemotherapy Education (OCE) Sheet
- Storage: Room temperature; cool dry place
- Disposal: Do not flush. Dispose of unused or expired medications or contact a local pharmacy to inquire about drug-take back programs

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- How to take: Swallow whole with or without food, ideally at the same time each day. Drink plenty of non-caffeinated liquids. If vomiting occurs after taking a dose, do NOT repeat the dose; take your next dose at your scheduled time
- Provide Loperamide (OTC) or RX antidiarrheal and counsel on diarrhea management
 - Please refer to the **NCODA Abemaciclib Diarrhea Management PQI** for more information^[4]
- Drink plenty of non-caffeinated fluids per day (6-8 large glasses)

Dosing Guideline Summary:

- When used in combination with either an aromatase inhibitor (AI) or fulvestrant, the recommended dose of abemaciclib is 150 mg orally twice daily with or without food
- When used as monotherapy the recommended dose of abemaciclib is 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
- Refer to full prescribing information for more information

Patient Assistance:

- May be available for uninsured, qualifying patients. Sign up at <https://www.verzenio.com/savings-support/savings-card>
- The Continuous Care™ program may assist with insurance/ savings. It is available at the site above or by calling: 1-844-837-9364 (1-844-VERZENIO)

References:

1. VERZENIO [Package Insert]. Eli Lilly and Company , Indianapolis, IN; 2018. Accessed at: <http://uspl.lilly.com/verzenio/verzenio.html#pi>
2. https://www.nccn.org/professionals/physician_gls/default.aspx#breast
3. [Lexicomp Online, Hudson, Ohio: Lexi-Comp, Inc.; updated 8/1/18; accessed 8/2/18](#)
4. <https://www.ncoda.org/Management-of-Abemaciclib-Associated-Diarrhea/>
5. Gold Standard, Inc. Abemaciclib. Clinical Pharmacology [database online]. Available at: <http://www.clinicalpharmacology.com>. Accessed: 8/2/18
6. The benefit of abemaciclib in prognostic subgroups, presented by Matthew P. Goetz 12-/5/2017. Available at: https://lilly-medcomms.veevavault.com/ui/approved_viewer?token=1904-23eda912-9a67-4a3a-847c-dab99ef3e133&email=a300f000005In3MAAS&orgid=00DG0000000BmPLMA0&AppDocId=a2u0f0000006nfxAAA

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