



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

Description: 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 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).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-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. Assess reproductive potential and manage with LHRH agonist and/or non-hormonal birth control 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
- Dosing Guideline Summary:
 - When used in combination with either an aromatase inhibitor (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 represents a brief summary of medication uses and therapy options derived from information provided by the drug manufacturer and other resources. This platform is intended as an educational aid and 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 discussed in the platform and is not intended as a substitute for the advice of a qualified healthcare professional. The materials contained in this platform are for informational purposes only and do not constitute or imply endorsement, recommendation, or favoring of this medication by NCODA, which assumes no liability for and does not ensure the accuracy of the information presented. NCODA does not make any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.



PQI Process Continued:

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

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 program
- 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 [Abemaciclib \(Verzenio®\) Diarrhea Management](#) PQI for more information⁴
- Drink plenty of non-caffeinated fluids per day (6-8 large glasses)
- Patient Assistance:
 - [The Continuous Care program](#) may assist with insurance/ savings. It is available via hyperlink 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>.
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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=00DG000000BmPLMA0&AppDocId=a2u0f0000006nfxAAA.

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