

ONCOLOGY CARE VALUE POLICY

POLICY: Oncology Care Value – Breast Cancer (Oral) Agents

TAC APPROVAL DATE: 03/14/2018

LAY CRITERIA EFFECTIVE DATE: 04/01/2018

DRUGS AFFECTED:

- Ibrance® (palbociclib capsules – Pfizer Inc.)
 - Kisqali® (ribociclib tablets – Novartis Pharmaceuticals)
 - Kisqali® Femara® Co-Pack (ribociclib tablets; letrozole tablets, co-packaged for oral use – Novartis Pharmaceuticals)
 - Verzenio™ (abemaciclib tablets – Eli Lilly and Company)
-

OVERVIEW

Ibrance, Kisqali/Kisqali Femara Co-Pack, and Verzenio are cyclin-dependent kinase (CDK) 4/6 inhibitors indicated for use in patients with hormone receptor (HR)-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in the following settings¹⁻⁴:

- All three agents are indicated in combination with an aromatase inhibitor (AI) as initial endocrine-based therapy for the treatment of postmenopausal women.
- Ibrance and Verzenio are also indicated in combination with Faslodex® (fulvestrant intramuscular injection) for the treatment of women with disease progression following endocrine therapy. Pre/perimenopausal women treated with Ibrance or Verzenio plus Faslodex should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards.
- Verzenio is the only agent indicated for use as monotherapy for the treatment of patients with disease progression following endocrine therapy in the advanced or metastatic setting and prior chemotherapy in the metastatic setting.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on breast cancer (version 4.2017) have not been updated to include the new indication of Verzenio in combination with AI.⁵ Ibrance + AI (i.e., letrozole, anastrozole, exemestane), and Kisqali + AI may be considered as first-line treatment options for postmenopausal patients with HR+, HER2-negative metastatic breast cancer who have not received endocrine therapy within 1 year (both combinations are category 1). Ibrance + Faslodex is a category 1 recommended option in postmenopausal or premenopausal women (receiving ovarian suppression with GnRH agonist) with HR+/HER2-negative metastatic breast cancer that has progressed on or after prior adjuvant or metastatic endocrine therapy. Verzenio + Faslodex is also a category 1 recommended option in this patient population (HR+/HER2-negative, postmenopausal patients) after progression on prior endocrine therapy. Verzenio as monotherapy is a category 2A recommended option in postmenopausal patients who progress on prior endocrine therapy and prior chemotherapy in the HR+/HER2-negative metastatic setting. If there is disease progression on CDK 4/6 inhibitor therapy, there are no data to support using an additional line of therapy with another CDK 4/6 inhibitor regimen.

POLICY STATEMENT

The Breast Cancer (Oral) Agents Oncology Care Value Policy requires the patient to meet the *ESI Standard Prior Authorization Policy* criteria and to try one of the participating products when clinically appropriate, and/or to meet the specified exception criteria prior to the approval of the non-participating product. All approvals are provided for 1 year in duration.

Automation: None

Documentation: Documentation will be required where noted in the criteria as [documentation required]. The prescriber must provide written documentation and it may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Participating Products: Ibrance, Verzenio
Non-Participating Product: Kisqali, Kisqali Femara Co-Pack

RECOMMENDED EXCEPTION CRITERIA

Trade Name	Exception
Kisqali (ribociclib tablets)	1. Breast Cancer A) Approve Kisqali or Kisqali Femara Co-Pack if the patient meets BOTH of the following criteria (i and ii): i. Patient meets the <i>ESI Standard Oncology – Kisqali and Kisqali Femara Co-Pack Prior Authorization Policy</i> criteria; AND ii. Patient has been taking Kisqali or Kisqali Femara Co-Pack and is continuing therapy [documentation required]. B) If the above criteria is not met and Kisqali/Kisqali Femara Co-Pack is not approved, offer to review for either Ibrance or Verzenio if the patient meets one of the <i>ESI Standard Oncology – Ibrance</i> or <i>Oncology – Verzenio Prior Authorization Policy</i> criteria for breast cancer.
Kisqali Femara Co-Pack (ribociclib tablets; letrozole tablets co- packaged)	

REFERENCES

1. Ibrance® capsules [prescribing information]. New York, NY: Pfizer Labs; February 2018.
2. Kisqali® tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2017.
3. Kisqali® Femara® Co-Pack tablets [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2017.
4. Verzenio™ tablets [prescribing information]. Indianapolis, IN: Eli Lilly and Company; February 2018.
5. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 4.2017). © 2018 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 8, 2018.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date	Lay Criteria Effective Date
New Policy	--	03/14/2018	In Progress

TAC – Therapeutic Assessment Committee; * For a further summary of criteria changes, refer to respective TAC minutes available at: <http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx>.