BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Medical Necessity Policy

Breast Cancer Therapies – Unified Formulary

Policy Number: 9.708
Version Number: 2.1
Version Effective Date: 1/1/2022

Product Applicability	☐ **All Plan[+] Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Afinitor® (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg) †§	Tykerb® (lapatinib)
Afinitor Disperz® (everolimus tablets for oral suspension) †	
Ibrance® (palbociclib)[PD]	
Kisqali® (ribociclib)	

[+] *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Kisqali-Femara® Co-Pack (ribociclib/letrozole)	
Nerlynx® (neratinib)	
Piqray® (alpelisib)	
Tukysa® (tucatinib)	
Verzenio® (abemaciclib)	

†Afinitor® (everolimus) products are reviewed in the Kinase Inhibitors guideline.
PD Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required. Please note, for Breast Cancer therapies, a trial with a preferred agent is not required prior to approval of a non-preferred agent.
§ Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required.

Approval Criteria:

Ibrance® (palbociclib)	1. Member has a diagnosis of HER2-negative, HR-positive breast cancer; **AND** 2. The prescriber is an oncologist; **AND** 3. Member will be using **ONE** of the following: a. Concomitant drug therapy with an aromatase inhibitor (e.g., anastrozole, letrozole, or exemestane); **OR** b. Concomitant drug therapy with fulvestrant **AND** 4. If applicable, documentation that member is postmenopausal or has received ovarian ablation or suppression
Kisqali® (ribociclib)	1. Member has a diagnosis of HER2-negative, HR-positive breast cancer ; **AND** 2. The prescriber is an oncologist; **AND** 3. Member will be using **ONE** of the following: a. Concomitant drug therapy with an aromatase inhibitor(e.g., anastrozole, letrozole, or exemestane); **OR** b. Concomitant drug therapy with fulvestrant
Kisqali-Femara® Co-Pack (ribociclib/letrozole)	1. Member has a diagnosis of HER2-negative, HR-positive breast cancer ; **AND** 2. The prescriber is an oncologist; **AND** 3. Documentation that member is postmenopausal or has received ovarian ablation or suppression
Nerlynx® (neratinib)	1. The prescriber is an oncologist; **AND** 2. Member has **ONE** of the following diagnoses: a. Extended adjuvant treatment for early stage HER2-positive breast cancer; **AND** i. Member has not exceeded one year of total therapy with neratinib for adjuvant; **AND**

	ii. Member has received trastuzumab therapy within the past two years **OR** b. Advanced or metastatic HER2-positive breast cancer; **AND** i. Documentation that member has had an inadequate response or adverse reaction to two anti-HER2-based regimens (e.g. Herceptin® [trastuzumab], Kadcyla® [ado-trastuzumab emtansine], and Perjecta® [Pertuzumab])** *Notes:* • ***Please note that if these agents are used in combination (e.g., Herceptin® [trastuzumab] and Perjeta® [pertuzumab]), this would count as one regimen.*
Piqray® (alpelisib)	1. Member has a diagnosis of HER2-negative, HR-positive, PIK3CA-mutated breast cancer; **AND** 2. The prescriber is an oncologist; **AND** 3. Documentation the member has disease that progressed following treatment with endocrine-based therapy†; **AND** 4. Piqray will be used in combination with fulvestrant *Notes:* • †*Endocrine therapy may include aromatase inhibitor (e.g., letrozole, anastrazole), tamoxifen, fulvestrant. According to the NCCN guidelines, CDK4/6 inhibitors in combination with aromatase inhibitors or fulvestrant are preferred, category 1 options that meet criteria.*
Tukysa® (tucatinib)	1. Member has a diagnosis of advanced unresectable or metastatic HER2-positive breast cancer; **AND** 2. The prescriber is an oncologist; **AND** 3. Tukysa will be used in combination with trastuzamab and capecitabine; **AND** 4. Documentation that the member has had an inadequate response or adverse reaction to one anti-HER2-based regimen (e.g., Herceptin® [trastuzumab], Kadcyla® (ado-trastuzumab emtasine), and Perjeta® [pertuzumab])
Verzenio®	1. Member has a diagnosis of advanced or metastatic HR-positive, HER2-negative breast cancer; **AND**

(abemaciclib)	2. The prescriber is an oncologist; **AND** 3. Documentation that member is postmenopausal or has received ovarian suppression or ablation; **AND** 4. Member will be using **ONE** of the following: a. Concomitant treatment with an aromatase inhibitor (e.g., anastrozole, letrozole, exemestane); **OR** b. Concomitant drug therapy with fulvestrant ; **OR** c. Requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy
Duration of Authorization	Prior authorization may be issued for **1 year** Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **up to 1 year.** Requests for Nerlynx® (neratinib) for adjuvant treatment may be approved for a **maximum total duration of 1 year only**.

Codes

None

References

1. Afinitor (everolimus) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2021.
2. Ibrance (palbociclib) [prescribing information]. New York, NY:Pfizer, Inc.; April 2019. 23. Iclusig (ponatinib) [prescribing information]. Cambridge, MA: ARIAD Pharmaceuticals, Inc., November 2016.
3. Kisqali (ribociclib) [prescribing information]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; July 2018.
4. National Comprehensive Cancer Network (NCCN). Breast cancer. V4.2020. URL: nccn.org/professionals/physician_gls/pdf/breast.pdf. Available from Internet. Accessed 2020 June 26.
5. Nerlynx (neratinib) [prescribing information]. Los Angeles, CA: Puma Biotechnology, Inc; February 2020.
6. Piqray (alpelisib) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; May 2019.
7. Tukysa (tucatinib) [prescribing information]. Bothell, WA: Seattle Genetics, Inc; April 2020.

8. Tykerb (lapatinib) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline. April 2017.
9. Verzenio (abemaciclib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; February 2018.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
5/13/2021	P&T annual review. No changes.	9/1/2021	P&T Committee
10/1/2021	UPPL 1/1/2022 Update: One new agent Tukysa® added to UPPL. Guideline updated to reflect Ibrance® diagnosis as HR-positive breast cancer in women (previously noted as ER-positive).	1/1/2022	P&T Committee

Next Review Date

5/2022

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe

when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.