Pharmacy Policy

Breast Cancer Therapies – Unified Formulary

Policy Number: 9.708
Version Number: 1
Version Effective Date: 1/1/2021

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

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

†Afinitor® (everolimus) products are reviewed in the Kinase Inhibitors guideline.
*A-rated generic available. Both brand and A-rated generic require PA.
[PD] Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. 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, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

[+] *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.

Procedure:

Approval Diagnosis:	• Advanced or metastatic HER2-positive breast cancer (Nerlynx®) • Extended adjuvant treatment of adult patients with early stage HER2-positive breast cancer (Nerlynx®) • HER2-negative ER-positive breast cancer in women (Ibrance®, Kisqali®, Kisqali-Femara® Co-Pack) • HER2-negative ER-positive breast cancer in men (Ibrance®) • HER2-negative, HR-positive, PIK3CA-mutated breast cancer in men and postmenopausal women (Piqray®) • HR-positive, HER2-negative advanced or metastatic breast cancer (Verzenio®)
Approval Criteria: **Ibrance®** (palbociclib)	**<u>HER2-negative, ER-positive breast cancer</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. If applicable, member is postmenopausal or has received ovarian ablation or suppression** 5. **ONE** of the following: a. Concomitant drug therapy with an aromatase inhibitor‡ b. Concomitant drug therapy with fulvestrant 6. Quantity requested of ≤1 unit/day *Notes:* • ***Please refer to appendix for requests which do not clearly document postmenopausal status or outreach to the office if unclear.* • ‡*Acceptable aromatase inhibitors include anastrozole, letrozole, exemestane.*
Approval Criteria: **Kisqali®** (ribociclib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. **ONE** of the following: a. Concomitant drug therapy with an aromatase inhibitor‡ b. Concomitant drug therapy with fulvestrant *Notes:* • ‡*Acceptable aromatase inhibitors include anastrozole, letrozole, exemestane.*
Approval Criteria: **Kisqali-Femara® Co-Pack** (ribociclib/letrozole)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member is postmenopausal or has received ovarian ablation or suppression**

	Notes: • ***Please refer to appendix for requests which do not clearly document postmenopausal status or outreach to the office if unclear.*
Approval Criteria: **Nerlynx®** (neratinib)	**<u>Adjuvant Therapy for Early Stage Disease*</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member received trastuzumab therapy within the past two years 5. Quantity requested is ≤ 6 units/day **<u>Treatment of Metastatic Disease</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Inadequate response or adverse reaction to two anti-HER2-based regimens** 5. Requested agent will be used in combination with capecitabine 6. Quantity requested is ≤ 6 units/day *Notes:* • **Member is limited to one year total therapy with neratinib for adjuvant treatment.* • ***Anti-HER2 directed therapies include Herceptin® (trastuzumab), Kadcyla® (ado-trastuzumab emtansine), and Perjeta® (pertuzumab). Please note that if these agents are used in combination (e.g., Herceptin® [trastuzumab] and Perjeta® [pertuzumab]), this would count as one regimen.* • *History of claims are sufficient for failed trials.*
Approval Criteria: **Piqray®** (alpelisib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member has disease that progressed following treatment with endocrine-based therapy† 5. Requested agent will be used in combination with fulvestrant *Notes:* • *†Endocrine therapy may include aromatase inhibitor (e.g., letrozole, anastrazole), tamoxifen, fulvestrant. Of note, according to the NCCN guidelines, CDK4/6 inhibitors in combination with aromatase inhibitors or fulvestrant are preferred, category 1 options that meet criteria.*
Approval Criteria: **Verzenio®**	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist

(abemaciclib)	3. Appropriate dosing 4. Member is postmenopausal or has received ovarian suppression or ablation** 5. **ONE** of the following: a. Concomitant treatment with an aromatase inhibitor‡ b. Concomitant drug therapy with fulvestrant c. Requested agent will be used as monotherapy when disease has progressed after both hormonal therapy and chemotherapy 6. Quantity requested is ≤ 2 tablets/day *Notes:* • *History of claims are sufficient for failed trial.* • ***Please refer to appendix for requests which do not clearly document postmenopausal status or outreach to the office if unclear.* • ‡*Acceptable aromatase inhibitors include anastrozole, letrozole, exemestane.*
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a new prior authorization request must be submitted.
Brand Preferred over Generic:	• In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are included on the MassHealth Brand Name Preferred Over Generic List. Requests for generic versions require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent prior to approval: o everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg
Recertification Criteria:	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**.

Appendix:

Stability

Stability alone on an agent in this guideline is not a reason to bypass approval criteria. However, requests for members who have already started treatment on these agents should be reviewed with clinical review and approval is strongly considered for any member with any FDA-approved indication. **Nerlynx® (neratinib) for adjuvant treatment may only be approved for a maximum total duration of one year.**

Grandfathering

Information is not applicable.

Additional Information

Clinical Background Information and References

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

Next Review Date

2021

Reference to Applicable Laws and Regulations, If Any

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.