BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Lung Cancer Agents – Unified Formulary

Policy Number: 9.712
Version Number: 2
Version Effective Date: 9/1/2021

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
Alecensa® (alectinib)	
Alunbrig® (brigatinib)	
Gilotrif® (afatinib)	
Iressa® (gefitinib)	
Lorbrena® (lorlatinib)	
Tabrecta® (capmatinib)	
Tagrisso® (osimertinib)	
Tarceva® (erlotinib) *	
Vizimpro® (dacomitinib)	
Xalkori® (crizotinib)	
Zykadia® (ceritinib)	

*A-rated generic available. Both brand and A-rated generic require PA.

[+] *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 non-small cell lung cancer (All agents) • Advanced or metastatic pancreatic cancer (erlotinib) • Stage IIB to IIIA NSCLC (Tagrisso®) • Systemic anaplastic large cell lymphoma (Xalkori®)
Approval Criteria: **Alecensa®** (alectinib) **Zykadia®** (ceritinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis* 2. Prescriber is an oncologist 3. Appropriate dosing 4. Cancer is anaplastic lymphoma kinase (ALK)-positive *(Documentation must be provided on the PA request or in attached medical records)* 5. **ONE** of the following: a. If the request is for Alecensa® (alectinib), quantity requested is ≤8 units/day b. If the request is for Zykadia® (ceritinib), quantity requested is ≤3 units/day *Notes:* • **Please see Appendix for requests for Zykadia® (ceritinib) for the first-line treatment of ROS1-rearrangement NSCLC.*
Approval Criteria: **Alunbrig®** (brigatinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Cancer is anaplastic lymphoma kinase (ALK)-positive *(Documentation must be provided on the PA request or in attached medical records)* 5. **ONE** of the following: c. Quantity requested is ≤2 units/day (30 mg tablet) *a.* Quantity requested is ≤1 unit/day (90 mg, 180 mg tablets; 90 mg-180 mg tablet pack)
Approval Criteria: **Gilotrif®** (afatinib)	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. Member has epidermal growth factor receptor (EGFR) mutations *(Documentation must be provided on the PA request or in attached medical records)* b. Inadequate response or adverse reaction to at least one platinum-based chemotherapy regimen OR contraindication to the use of platinum-based chemotherapy *(History of claims is not sufficient)* 5. Quantity requested is ≤1 unit/day
Approval Criteria: **Iressa®** (gefitinib) **Vizimpro®** (dacomitinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member has epidermal growth factor receptor (EGFR) mutations *(Documentation must be provided on the PA request or in attached*

	medical records) 5. Quantity requested is ≤1 unit/day
Approval Criteria: **Lorbrena®** (lorlatinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis** 2. Prescriber is an oncologist 3. Appropriate dosing 4. Cancer is ALK-positive *(Documentation must be provided on the PA request or in attached medical records)* 5. Inadequate response, adverse reaction or contraindication to Alecensa® (alectinib) 6. Quantity requested is ≤1 unit/day *Notes:* • ***Requests for ROS1-rearrangement positive disease require clinical review (see Appendix)* • *†ALK inhibitors include: Alecensa® (alectinib), Alunbrig® (brigatinib), Zykadia® (ceritinib).*
Approval Criteria: **Tabrecta®** (capmatinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Cancer has mutation that leads to MET exon 14 skipping *(Documentation must be provided on the PA request or in attached medical records)* 5. Quantity requested is ≤4 units/day
Approval Criteria: **Tagrisso®** (osimertinib)	**<u>Advanced or metastatic NSCLC</u>** 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. Cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation *(Documentation must be provided on the PA request or in attached medical records)* b. Cancer displays the EGFR mutation and the T790M resistance mutation *(Documentation must be provided on the PA request or in attached medical records)* c. Inadequate response or adverse reaction to **ONE** of the following or contraindication to **ALL** of the following *(History of claims is not sufficient)*: a. erlotinib b. Gilotrif® (afatinib) c. Iressa® (gefitinib) d. Vizimpro® (dacomitinib) 5. Quantity requested is ≤1 unit/day **<u>Stage IIB to IIIA NSCLC</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist

	3. Appropriate dosing 4. Cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation *(Documentation must be provided on the PA request or in attached medical records)* 5. Member has completely resected disease 6. Quantity requested is ≤1 unit/day
Approval Criteria: **Tarceva®** (erlotinib) * *A-rated generic available. Both brand and A-rated generic require PA	*For advanced or metastatic non-small cell lung cancer* Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member has EGFR mutations *(Documentation must be provided on the PA request or in attached medical records)* 5. Quantity requested is ≤1 unit/day 6. If request is for BRAND NAME Tarceva® the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic erlotinib (as per the Brand Name Guideline) *For advanced or metastatic pancreatic cancer* Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Appropriate dosing 4. Member will be using the requested agent in combination with gemcitabine 5. Quantity requested is ≤1 unit/day 6. If request is for BRAND NAME Tarceva® the member must meet the above criteria and the prescriber must provide medical records documenting an inadequate response or adverse reaction to generic erlotinib (as per the Brand Name Guideline)
Approval Criteria: **Xalkori®** (crizotinib)	*Metastatic non-small cell lung cancer (NSCLC)* Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Prescriber in an oncologist 3. Appropriate dosing 4. Cancer is anaplastic lymphoma kinase (ALK)-positive or ROS1 positive *(Documentation must be provided on the PA request or in attached medical records)* 5. Quantity requested is ≤2 units/day *Systemic anaplastic large cell lymphoma (ALCL)* 1. Appropriate diagnosis 2. Prescriber is an oncologist 3. Member is ≥ 1 year of age and < 22 years of age 4. Appropriate dosing

	5. Cancer is anaplastic lymphoma kinase (ALK)-positive *(Documentation must be provided on the PA request or in attached medical records)* 6. Quantity requested is ≤4 units/day 7. **ONE** of the following: a. Cancer is relapsed or refractory to **ONE** prior regimen or agent† *(History of claims in POPS is NOT sufficient)* b. Clinical rationale as to why the other available treatment regimens cannot be used *Notes:* • *Please see appendix for patients with NSCLC with MET amplification* • †First-line options include: *Brentuximab vedotin + CHP (cyclophosphamide, doxorubicin, prednisone) (category 1), CHOP (cyclophosphamide, doxorubicin, vincristine, prednisone), CHOEP (cyclophosphamide, doxorubicin, vincristine, etoposide, prednisone), Dose-adjusted EPOCH (etoposide, prednisone, vincristine, cyclophosphamide, doxorubicin)*
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.
Duration/Quantity of Authorization:	Prior authorization may be issued for **3 months.**
Recertification Criteria:	Resubmission by prescriber will infer a positive response to therapy and request can be recertified for **6 months**.

Appendix:

Stability

Stability alone on the agents 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.

Grandfathering

N/A

Additional Information

Xalkori® (crizotinib) for patients with NSCLC with ROS1 rearrangements and MET amplification

Although there is limited evidence, the NCCN guidelines recommend additional targeted therapies for patients with other genetic alterations, including Xalkori® (crizotinib) for MET amplification. Xalkori® (crizotinib) is an inhibitor of ALK, ROS1 and MET tyrosine kinases, but it is only FDA-approved for patients with NSCLC who have ALK gene and ROS1 gene rearrangements. Both ROS1 and MET are proto-oncogene receptor tyrosine kinases. These updated recommendations were based on studies that found antitumor activity with Xalkori® (crizotinib) in patients with c-MET-amplified NSCLC and advanced ROS1-rearranged NSCLC. Specifically, the NCCN guidelines indicate that ROS1 testing should be

considered in patients with metastatic NSCLC who have tested negative for both sensitizing EGFR mutation and ALK, and that patients may be treated with Xalkori® (crizotinib) if the ROS1 test is positive.

As such, requests for of Xalkori® (crizotinib) for patients with NSCLC documenting either ROS1 rearrangements or MET amplification may be approved within quantity limits.

Requests for Zykadia® (ceritinib) for ROS1-rearrangement NSCLC

Zykadia® (ceritinib) is recommended for use in the NCCN guidelines for the first-line treatment of ROS1-rearrangement NSCLC. It is only FDA-approved for use in ALK rearrangement positive NSCLC.

If a request is received for Zykadia® (ceritinib) to use in the first-line setting of ROS1-rearrangement NSCLC, it may be approved per guideline duration.

Use in off-label indications

These agents are being evaluated in other conditions. Therefore, off-label requests should be forwarded to clinical review.

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	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
3/3/2021	Updated policy to reflect changes dated 2/6/21 from MH. Updated for new indication and criteria for Tagrisso, verbiage added for A-rated generic availability for Tarceva.	3/3/2021	P&T Committee
5/13/2021	No recommended changes or updates.	9/1/2021	P&T Committee

Policy Revisions History			
7/23/2021	Updated policy to reflect changes dated 6/24/21 from MH: Guideline updated to reflect new PA criterias for both Lorbrena (lorlatinib) and Xalkori (crizotinib) based on expanded indications.	9/1/2021	P&T Committee

Next Review Date

5/2022

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.