Mass General Brigham
Health Plan

Lung Cancer Agents:
Alecensa® (alectinib), Alunbrig® (brigatinib), Exkivity® (mobocertinib), Gilotrif® (afatinib), Iressa® (gefitinib), Krazati® (adagrasib), Lorbrena® (lorlatinib), Lumakras® (sotorasib), Portrazza® (necitumumab), Rybrevant® (amivantamab-vmjw), Tabrecta® (capmatinib), Tagrisso® (osimertinib), Tarceva® (erlotinib), Tepmetko® (tepotinib), Vizimpro® (dacomitinib), Xalkori® (crizotinib), Zepzelca® (lurbinectedin), Zykadia® (ceritinib)
Effective 06/05/2023

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	Rybrevant® (amivantamab-vmjw) is available through both pharmacy and medical benefit.		

Overview

No PA	Drugs that require PA
Alternatives vary by specific malignancy and may include systemic chemotherapy	Alecensa® (alectinib)
	Alunbrig® (brigatinib)
	Exkivity® (mobocertinib)
	Gilotrif® (afatinib)
	Iressa® (gefitinib)
	Krazati® (adagrasib)
	Lorbrena® (lorlatinib)
	Lumakras® (sotorasib)
	Portrazza® (necitumumab)
	Rybrevant® (amivantamab-vmjw)
	Tabrecta® (capmatinib)
	Tagrisso® (osimertinib)
	Tarceva® (erlotinib)*
	Tepmetko® (tepotinib)

	Vizimpro® (dacomitinib)
	Xalkori® (crizotinib)
	Zepzelca® (lurbinectedin)
	Zykadia® (ceritinib)

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

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

Alecensa® (alectinib)
Zykadia® (ceritinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of metastatic non-small cell lung cancer (NSCLC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive
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

Zykadia® (ceritinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of metastatic non-small cell lung cancer *(off-label)*
2. Prescriber is an oncologist
3. Documentation of medical records showing that cancer is ROS1-rearrangement
4. Requested quantity is ≤ 3 tablet/day

Alunbrig® (brigatinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive
5. **ONE** of the following:
    a. For the 30 mg tablet, requested quantity is ≤ 2 tablet/day
    b. For the 90 mg or 180 mg tablet, or the 90 mg-180 mg tablet pack, requested quantity is ≤ 1 tablet/day

Exkivity® (mobocertinib)
Rybrevant® (amivantamab-vmjw)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of advanced or metastatic non-small cell lung cancer
2. Prescriber is an oncologist

3. Appropriate dosing
4. Documentation of medical records showing that cancer has EGFR exon 20 insertion mutation
5. Physician attestation of an inadequate response or adverse reaction to **ONE** or contraindication to **ALL** platinum-based chemotherapies
6. If the request is for Exkivity® (mobocertinib), requested quantity is ≤ 4 units/day

Gilotrif® (afatinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Documentation of medical records showing that member has epidermal growth factor receptor (EGFR) mutations
    b. Physician attestation of an inadequate response or adverse reaction to at least **ONE** or contraindication to **ALL** platinum-based chemotherapies
5. Requested quantity is ≤ 1 tablet/day

Iressa® (gefitinib)
Vizimpro® (dacomitinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that member has epidermal growth factor receptor (EGFR) mutations
5. Requested quantity is ≤ 1 tablet/day

Lorbrena® (lorlatinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer is ALK-positive
5. Physician attestation of an inadequate response, adverse reaction or contraindication to Alecensa® (alectinib)
6. Requested quantity is ≤ 1 tablet/day

Krazati® (adagrasib)
Lumakras® (sotorasib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer has KRAS G12C mutation
5. Physician attestation of inadequate response or adverse reaction to **ONE** or contraindication to the use of **ALL** first-line systemic therapies
6. **ONE** of the following:

a. For Krazati® (adagrasib), requested quantity is ≤ 6 tablets/day
b. For Lumakras® (sotorasib), ONE of the following:
    i. For Lumakras 120 mg tablet, requested quantity is ≤ 8 tablets/day
    ii. For Lumakras 320 mg tablet, requested quantity is ≤ 3 tablets/day

Portrazza® (necitumumab)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer is of squamous cell histology
5. Member will be using the requested agent in combination with gemcitabine and cisplatin
6. Medical necessity for using the requested agent instead of all other clinically appropriate alternatives

Tabrecta® (capmatinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer has mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping
5. Requested quantity is ≤ 4 tablets/day

Tagrisso® (osimertinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic non-small cell lung cancer (NSCLC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Documentation of medical records showing that cancer displays the EGFR exon 19 deletion or exon 21 L858R mutation
    b. **BOTH** of the following:
        i. Documentation of medical records showing that cancer displays the EGFR mutation and the T790M resistance mutation
        ii. Physician attestation of an inadequate response or adverse reaction to **ONE** of the following or contraindication to **ALL** of the following:
            1. Erlotinib
            2. Gilotrif® (afatinib)
            3. Iressa® (gefitinib)
            4. Vizimpro® (dacomitinib)
5. Requested quantity is ≤ 1 tablet/day

Prescriber provides documentation of **ALL** of the following:
1. Member is using Tagrisso as an adjuvant treatment for stage IB to IIIA non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer displays the EGFR exon 19 deletions or exon 21 L858R mutation

5. Member has completely resected disease
6. Physician attestation of an inadequate response or adverse reaction to ONE or contraindication to ALL platinum-based chemotherapy
7. Requested quantity is ≤ 1 tablet/day

Tarceva® (erlotinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that member has EGFR exon 19 deletions or exon 21 (L858R) substitution mutations
5. Requested quantity is ≤ 1 tablet/day
6. If the request is for brand name Tarceva®, then prescriber must provide medical records documenting inadequate response or adverse reaction to generic erlotinib (as per the Brand Name and Non-Preferred Generic Drugs guideline)

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic pancreatic cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member will be using the requested agent in combination with gemcitabine
5. Requested quantity is ≤ 1 unit/day
6. If the request is for brand name Tarceva®, then prescriber must provide medical records documenting inadequate response or adverse reaction to generic erlotinib (as per the Brand Name and Non-Preferred Generic Drugs guideline)

Tepmetko® (tepotinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer harbors MET exon 14 skipping alterations
5. Requested quantity is ≤ 2 tablets/day

Xalkori® (crizotinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable, recurrent, or refractory inflammatory myofibroblastic tumors
2. Prescriber is an oncologist
3. Member is ≥ 1 year of age
4. Appropriate dosing (Requested quantity is ≤ 4 capsules/day)
5. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer
2. Prescriber in an oncologist
3. Appropriate dosing

4. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive or ROS1 positive
5. Requested quantity is ≤ 2 capsules/day

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of relapsed or refractory systemic anaplastic large cell lymphoma
2. Prescriber is an oncologist
3. Member is ≥ 1 year of age and < 22 years of age
4. Appropriate dosing
5. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive
6. Requested quantity is ≤ 4 capsules/day
7. **ONE** of the following:
    a. Physician attestation of cancer being relapsed or refractory to ONE prior regimen or agent†
    b. Clinical rationale why other available treatment regimens cannot be used

†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)

Tabrecta® (capmatinib)
Tepmetko® (tepotinib)
Xalkori® (crizotinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of metastatic non-small cell lung cancer *(off-label)*
2. Prescriber is an oncologist
3. Documentation of medical records showing that cancer is MET positive amplification
4. **ONE** of the following:
    a. If request is for Tepmetko or Xalkori, requested quantity is ≤ 2 units/day
    b. If request is for Tabrecta, requested quantity is ≤ 4 units/day

Zepzelca® (lurbinectedin)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic non-small cell lung cancer
2. Prescriber is an oncologist
3. Appropriate dosing (documentation of weight/height or BSA)
4. Physician attestation of inadequate response, adverse reaction, or contraindication to ONE platinum-based chemotherapy

Continuation of Therapy
Reauthorizations requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Initial approvals will be granted for 3 months.
2. Reauthorizations will be granted for 6 months.
3. The following quantity limits apply:

Alecensa® (alectinib)	240 capsules per 30 days
Alunbrig (brigatinib) 30 mg	60 tablets per 30 days

Alunbrig (brigatinib) 90 mg, 180 mg, 90-180 mg pack	30 tablets per 30 days
Exkivity® (mobocertinib)	120 capsules per 30 days
Gilotrif® (afatinib)	30 tablets per 30 days
Iressa® (gefitinib)	30 tablets per 30 days
Krazati® (adagrasib)	180 tablets per 30 days
Lorbrena® (lorlatinib)	30 tablets per 30 days
Lumakras® (sotorasib)	240 tablets per 30 days (120mg) 90 tablets per 30 days (320mg)
Tabrecta® (capmatinib)	112 tablets per 28 days
Tagrisso® (osimertinib)	30 tablets per 30 days
Tarceva® (erlotinib)	30 tablets per 30 days
Tepmetko® (tepotinib)	60 tablets per 30 days
Xalkori® (crizotinib)	120 capsules per 30 days
Zykadia® (ceritinib)	90 tablets per 30 days

References

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15. Tagrisso® [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals; 2022 Jan.
16. Tabrecta® (capmatinib) [prescribing information]. East Hanover (NJ): Novartis Pharmaceutical Corporation; 2022 Jan.

17. Tepmetko® (tepotinib) [prescribing information]. Rockland (MA): EMD Serono, Inc.; 2021 Sep.
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22. Exkivity® (mobocertinib) [prescribing information]. Lexington (MA): Takeda Pharmaceuticals America, Inc; 2021 Sep.
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Review History

09/21/2022 – Reviewed and Created for September P&T. Matched MH criteria. Effective 11/01/2022.
01/11/2023 – Reviewed and updated for Jan P&T. Matched MH UPPL criteria. Renamed criteria to Lung Cancer Agents. Retired and moved drug-specific criteria of Lumakras, Rybrevant, Tagrisso, Tepmetko, Vizimpro to Lung Cancer Agents. Retired drug-specific criteria for Lorbrena, added Lorbrena to this criteria, and step through Xalkori, other ALK inhibitor, Zykadia was removed. Added new agents and criteria for: Alecensa, Alunbrig, Gilotrif, Iressa, Portrazza, Tabrecta, Tarceva, Xalkori, Zykadia, Zepzelca. Updated references. Added quantity limits. Portrazza and Zepzelca now requires PA through pharmacy benefit. Effective 3/1/23.
05/10/23 – Reviewed and updated for P&T. New drug, Krazati (adagrasib), was added to policy. Lumakras 320mg was added to criteria. Effective 6/5/23.