Mass General Brigham
Health Plan

Lung Cancer Agents:
Alecensa (alectinib), Alunbrig (brigatinib), 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 05/06/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy when obtained through the pharmacy benefit.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	The following medications are available through the medical benefit only: • Portrazza (necitumumab) • Rybrevant (amivantamab-vmjw) • Zepzelca (lurbinectedin)		

Overview

No PA	Drugs that require PA
Alternatives vary by specific malignancy and may include systemic chemotherapy	Alecensa (alectinib)
	Alunbrig (brigatinib)
	Gilotrif (afatinib)
	Iressa (gefitinib)*
	Krazati (adagrasib)
	Lorbrena (lorlatinib)
	Lumakras (sotorasib)
	Portrazza (necitumumab)[MB]
	Rybrevant (amivantamab-vmjw)[MB]
	Tabrecta (capmatinib)
	Tagrisso (osimertinib)
	Tarceva (erlotinib)*
	Tepmetko (tepotinib)
	Vizimpro (dacomitinib)
	Xalkori (crizotinib)
	Zepzelca (lurbinectedin)[MB]

	Zykadia (ceritinib)

*A-rated generic available. Both brand and A-rated generic require PA.
MB – Medical Benefit. This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting.

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 (NSCLC) *(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 tablet pack, requested quantity is ≤ 1 tablet/day

Rybrevant (amivantamab-vmjw)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of locally 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. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** platinum-based chemotherapies

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. 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
6. For BRAND NAME ("no substitution") Iressa prescriber must also provide medical records documenting inadequate response or adverse reaction to generic gefitinib.

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. 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. 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

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced or metastatic colorectal cancer
2. Prescriber is an oncologist
3. Appropriate dosing
4. Documentation of medical records showing that cancer has KRAS G12C mutation
5. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** platinum-based chemotherapy
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 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. **ONE** of the following: (Documentation must be provided on the PA request or in attached medical records)
    a. Cancer has mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping
    b. Cancer is MET positive amplification
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. Diagnosis of 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. 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 ("no substitution") 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 ("no substitution") 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. **ONE** of the following: (Documentation must be provided on the PA request or in attached medical records)

    a. Cancer harbors MET exon 14 skipping alterations
    b. Cancer is MET positive amplification
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
6. For Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by **ONE** of the following:
    a. Member is < 13 years of age
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Requested dose cannot be obtained from capsule formulation

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. **ONE** of the following: (Documentation must be provided on the PA request or in attached medical records)
    a. Cancer is anaplastic lymphoma kinase (ALK)-positive or ROS1 positive
    b. Cancer is MET positive amplification
5. For Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by **ONE** of the following:
    a. Member is < 13 years of age
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Requested dose cannot be obtained from capsule formulation

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. Appropriate dosing
4. Documentation of medical records showing that cancer is anaplastic lymphoma kinase (ALK)-positive
5. **ONE** of the following:
    a. Cancer is relapsed or refractory to **ONE** prior regimen or agent†
    b. Clinical rationale why other available treatment regimens cannot be used
6. For Xalkori (crizotinib) oral pellets, medical necessity for the use of the oral pellet formulation instead of the capsule as noted by **ONE** of the following:
    a. Member is < 13 years of age
    b. Member has a swallowing disorder or condition affecting ability to swallow
    c. Requested dose cannot be obtained from capsule formulation

†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)

Zepzelca (lurbinectedin)
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 (documentation of weight/height or BSA)
4. 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.

References

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4. Gilotrif® [package insert]. Ridgefield (CT): Boehringer Ingelheim Pharmaceuticals, Inc; 2019 Oct.
5. Iressa® [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals LP; 2021 May.
6. Vizimpro® (dacomitinib) [prescribing information]. New York (NY): Pfizer; 2020 Dec.
7. Tarceva® [package insert]. South San Francisco (MA): Genentech; 2018 Dec.
8. AstraZeneca Pharmaceuticals LP; Withdrawal of Approval of a New Drug Application for IRESSA [press release on the internet]. Federal Registrar. 2012 Apr 25 [cited 2019 Dec 23]. Available from: https://www.federalregister.gov/documents/2012/04/25/2012-9944/astrazeneca-pharmaceuticals-lp-withdrawal-of-approval-of-a-new-drug-application-for-iressa.
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12. Alunbrig® [package insert]. Cambridge (MA): Takeda Pharmaceuticals; 2021 Sep.
13. Lorbrena® (lorlatinib) [prescribing information]. New York (NY): Pfizer; 2021 Mar.
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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.
18. NCCN. Small Cell Lung Cancer Version 2.2022; 2021 Nov 24 [cited 2022 Mar 3]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/sclc.pdf.
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20. FDA Approves First Targeted Therapy for Lung Cancer Mutation Previously Considered Resistant to Drug Therapy [press release on the internet]. FDA; 2021 May 28 [cited 2021 Jul 26]. Available from: https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-lung-cancer-mutation-previously-considered-resistant-drug.
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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.
04/10/24 – Reviewed and updated for P&T. Exkivity removed from policy due to removal from market. Removed age range for Xalkori (crizotinib) for the indication of systemic ALCL per the NCCN guidelines. Portrazza (necitumumab), Rybrevant (amivantamab-vmjw) and Zepzelca (lurbinectedin) all changed to Medical Benefit only. Off-label criteria added to the guideline for the use of Krazati (adagrasib) and Lumakras (sotorasib) for advanced or metastatic colorectal cancer. Xalkori criteria updated within guideline to highlight criteria for medical necessity of pellet formulation over capsules. Effective 5/6/24.