

Lung Cancer Agents:

Alecensa® (alectinib), Alunbrig® (brigatinib), Exkivity® (mobocertinib), Gilotrif® (afatinib), Iressa® (gefitinib), 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 03/01/2023

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|------------------------------|---|---------------------|---|
| Plan | <input checked="" type="checkbox"/> MassHealth <input type="checkbox"/> Commercial/Exchange | Program Type | <input checked="" type="checkbox"/> Prior Authorization |
| Benefit | <input checked="" type="checkbox"/> Pharmacy Benefit <input checked="" type="checkbox"/> Medical Benefit (NLX) | | <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy |
| 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) |
| | Lorbrena® (lorlatinib) |
| | Lumakras® (sotorasib) |
| | Portrazza® (necitumumab) |
| | Rybrevant® (amivantamab-vmjw) |
| | Tabrecta® (capmatinib) |
| | Tagrisso® (osimertinib) |
| | Tarceva® (erlotinib)* |
| | Tepmetko® (tepotinib) |
| | Vizimpro® (dacomitinib) |
| | Xalkori® (crizotinib) |
| Zepzelca® (lurbinectedin) | |

*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 at least one platinum-based chemotherapy regimen or contraindication to the use of platinum-based chemotherapy
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 platinum-based chemotherapy regimen OR contraindication to the use of platinum-based chemotherapy
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

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 at least one prior systemic therapy OR contraindication to the use of systemic therapy



6. Requested quantity is \leq 8 units/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 \leq 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 \leq 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 at least one platinum-based chemotherapy regimen OR contraindication to the use of 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 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:

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| 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 |
| Lorbrena® (lorlatinib) | 30 tablets per 30 days |
| Lumakras® (sotorasib) | 240 tablets per 30 days |
| 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 |

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15. Tagrisso® [package insert]. Wilmington (DE): AstraZeneca Pharmaceuticals; 2022 Jan.

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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 Lorbrina, added Lorbrina 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.

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