Washington State Health Care Authority

Antineoplastics and Adjunctive Therapies – Tyrosine Kinase Inhibitors - Oral

Medical policy no. 21.53.40-1 Effective Date: TBD

Related medical policies: Antineoplastic and Adjunctive Therapy, Oral Agents

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

Background:

The antineoplastics and adjunctive therapies are classes of medications used for the treatment of cancer and cancer-related conditions.

Medical necessity:

Drug	Medical Necessity
Acalabrutinib **(CALQUENCE)** Afatinib dimaleate **(GILOTRIF)** Alectinib **(ALECENSA)** Axitinib **(INLYTA)** Bosutinib **(BOSULIF)** Brigatinib **(ALUNBRIG)** Cabozantinib **(COMETRIQ, CABOMETYX)** Capmatinib **(TABRECTA)** Ceritinib **(ZYKADIA)** Crizotinib **(XALKORI)** Dacomitinib **(VIZIMPRO)** Dasatinib **(SPRYCEL)** Erlotinib **(TARCEVA)** Gefitinib **(IRESSA)** Gilteritinib **(XOSPATA)** Ibrutinib **(IMBRUVICA)** Imatinib **(GLEEVEC)** Lapatinib **(TYKERB)** Lenvatinib **(LENVIMA)** Lorlatinib **(LORBRENA)** Neratinib **(NERLYNX)** Nilotinib **(TASIGNA)** Osimertinib **(TAGRISSO)** Pazopanib **(VOTRIENT)** Pexidartinib **(TURALIO)** Ponatinib **(ICLUSIG)** Ripretinib **(QINLOCK)** Selpercatinib (**RETEVMO)**	Tyrosine Kinase Inhibitors may be considered medically necessary when used for: 1. conditions listed under Indications and Usage in approved drug labeling (prescribing information) from the Food and Drug Administration (FDA); OR 2. conditions listed as medically-accepted indications in any of the compendia of drug information recognized by Medicaid; OR 3. conditions supported by the National Comprehensive Cancer Network (NCCN) clinical practice guidelines;

Vandetanib **(CAPRELSA)**	

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Acalabrutinib **(CALQUENCE)** Afatinib dimaleate **(GILOTRIF)** Alectinib **(ALECENSA)** Axitinib **(INLYTA)** Bosutinib **(BOSULIF)** Brigatinib **(ALUNBRIG)** Cabozantinib **(COMETRIQ, CABOMETYX)** Capmatinib **(TABRECTA)** Ceritinib **(ZYKADIA)** Crizotinib **(XALKORI)** Dacomitinib **(VIZIMPRO)** Dasatinib **(SPRYCEL)** Erlotinib **(TARCEVA)** Gefitinib **(IRESSA)** Gilteritinib **(XOSPATA)** Ibrutinib **(IMBRUVICA)** Imatinib **(GLEEVEC)** Lapatinib **(TYKERB)** Lenvatinib **(LENVIMA)** Lorlatinib **(LORBRENA)** Neratinib **(NERLYNX)** Nilotinib **(TASIGNA)** Osimertinib **(TAGRISSO)** Pazopanib **(VOTRIENT)** Pexidartinib **(TURALIO)** Ponatinib **(ICLUSIG)** Ripretinib **(QINLOCK)** Selpercatinib (**RETEVMO)** Vandetanib **(CAPRELSA)**	Tyrosine Kinase Inhibitors may be covered when all of the following criteria are met: 1. Patient has a diagnosis and staging of a cancer that: a. the requested medication is indicated for in either: i. listed in the approved drug labeling (prescribing information); OR ii. listed as a medically-accepted indication in compendia recognized by Medicaid b. if the requested medication is to be used in combination with other chemotherapeutic or adjuvant agents according to the approved drug labeling or medically-accepted indication, then documentation of all other appropriate chemotherapy agents, including those concurrently requested, for this regimen is required c. if the requested medication is not indicated as a first line agent according to the approved drug labeling or medically-accepted indication, then documentation of all previous therapies tried and failed, the duration, and reasons for stopping the therapy are required; i. if the agent was stopped for lack of benefit, documentation of what measures were used to define positive clinical response and what was the change at end of therapy from baseline; 2. Patient has received tests that confirm the diagnosis and staging including but not limited to: a. if an FDA-approved companion diagnostic test exists for the requested agent, then documentation that the test(s) were performed to confirm the diagnosis is required b. if a test with adequate ability to confirm a gene-mutation exists, then documentation that the test(s) were performed to confirm the mutation as part of the diagnosis is required c. if any other companion tests have been used for concurrent or previous treatments, the documentation that the test(s) were performed is required 3. The requested medication is prescribed by, or in consultation with, a specialist in oncology or hematology 4. The patient does not have any contraindications to the requested medication or any other medications as part of the regimen 5. The prescribed quantity and dosing regimen for the patient's age and other factors is within the manufacturer's published dosing guidelines or compendia recognized by Medicaid

	6. Documentation from the provider on how they will monitor and measure the patient and their condition to determine tolerability and patient-specific positive clinical response **If ALL criteria are met, the request will be approved for 3 months.**
	Criteria (Reauthorization)
	Tyrosine Kinase Inhibitors may be reauthorized when all of the following criteria are met: 1. Documentation of the change from baseline of the measures used to determine tolerability and patient specific positive clinical response 2. If the requested medication is to be used in combination with other chemotherapeutic or adjuvant agents according to the approved drug labeling or medically-accepted indication, then documentation of all other appropriate chemotherapy agents, including those concurrently requested, for this regimen is required **If ALL criteria are met, the request will be approved for 6 months.**

Dosage and quantity limits:

Drug Name	Dose and Quantity Limits
Acalabrutinib **(CALQUENCE)**	100mg twice daily
Afatinib dimaleate **(GILOTRIF)**	Non-small cell lung cancer/Squamous non-small cell lung cancer: 40mg per day Squamous cell carcinoma of head and neck: 50mg per day
Alectinib **(ALECENSA)**	600mg twice daily
Axitinib **(INLYTA)**	10mg twice daily
Bosutinib **(BOSULIF)**	600mg per day
Brigatinib (**ALUNBRIG)**	180mg per day
Cabozantinib **(COMETRIQ)**	140mg per day
Cabozantinib **(CABOMETYX)**	60mg per day
Capmatinib **(TABRECTA)**	400mg twice daily
Ceritinib **(ZYKADIA)**	450mg per day
Crizotinib **(XALKORI)**	250mg twice daily
Dacomitinib **(VIZIMPRO)**	45mg per day
Dasatinib **(SPRYCEL)**	• Adults with chronic phase CML: 140mg per day • Adults with accelerated phase CML, myeloid or lymphoid blast phase CML, or Ph+ ALL: 180mg per day • Pediatrics with ALL: maximum 100mg per day (weight based dosing) • Pediatrics with chronic phase CML: maximum 120mg per day (weight based dosing)
Erlotinib **(TARCEVA)**	• Non-small cell lung cancer: 150mg per day

	• Pancreatic cancer: 100mg per day
Gefitinib **(IRESSA)**	250mg per day
Gilteritinib **(XOSPATA)**	120mg per day
Ibrutinib **(IMBRUVICA)**	• MCL and MZL: 560mg per day • CLL/SLL, WM) and cGVHD: 420mg per day
Imatinib **(GLEEVEC)**	• Adults with Ph+ CML-CP: 600 mg/day • Adults with Ph+ CML-AP or BC: 800 mg/day • Pediatrics with Ph+ CML-CP: 340 mg/m2/day, not to exceed 600mg • Adults with Ph+ ALL: 600 mg/day • Pediatrics with Ph+ ALL: 340 mg/m2/day, not to exceed 600mg • Adults with MDS/MPD: 400 mg/day • Adults with ASM: 100 mg/day or 400 mg/day • Adults with HES/CEL: 100 mg/day or 400 mg/day • Adults with DFSP: 800 mg/day • Adults with metastatic and/or unresectable GIST: 800 mg/day • Adjuvant treatment of adults with GIST: 400 mg/day • Mild renal impairment: 600mg/day • Moderate renal impairment: 400mg/day
Lapatinib **(TYKERB)**	• Advanced or metastatic breast cancer with capecitabine: 1,250 per day per day • Postmenopausal breast cancer in combination with letrozole: 1,500mg per day
Lenvatinib **(LENVIMA)**	• DTC: 24mg per day • Endometrial Carcinoma: 20mg per day • RCC: 18mg per day • HCC: Maximum 12mg per day (weight based dosing)
Lorlatinib **(LORBRENA)**	100mg per day
Neratinib **(NERLYNX)**	240mg per day
Nilotinib **(TASIGNA)**	• Adults Ph+ CML-AP, Ph+ CMP-CP resistant/intolerant to prior therapy: 400mg twice daily • Adults Ph+ CML-CP newly diagnosed: 300mg twice daily • Pediatrics Ph+ CML-CP: 230mg/m^2 twice daily, maximum 400mg/dose
Osimertinib **(TAGRISSO)**	80mg per day
Pazopanib **(VOTRIENT)**	800mg per day
Pexidartinib **(TURALIO)**	800mg per day
Ponatinib **(ICLUSIG)**	45mg per day
Ripretinib **(QINLOCK)**	150mg per day
Selpercatinib **(RETEVMO)**	• Medullary thyroid carcinoma, less than 50kg: 120mg twice daily • Medullary thyroid carcinoma, 50kg or greater: 160mg twice daily • Non-small cell lung cancer, less than 50kg: 120mg twice daily • Non-small cell lung cancer, 50kg or greater: 160mg twice daily • Thyroid cancer, less than 50 kg: 120mg twice daily • Thyroid cancer, 50kg or greater: 160mg twice daily
Vandetanib **(CAPRELSA)**	300mg per day

Coding:

HCPCS Code	Description
J8565	Gefitinib, oral, 250 mg
J9999	Not otherwise classified, antineoplastic drugs
S0088	Imatinib, 100 mg

Definitions:

Term	Description
ASM	Aggressive systemic mastocytosis
CEL	Chronic eosinophilic leukemia
cGVHD	Chronic graft versus host disease
CLL/SLL	Chronic lymphocytic leukemia/Small lymphocytic lymphoma
CML	Chronic myeloid leukemia
DFSP	Dermatofibrosarcoma protuberans
DTC	Differentiated thyroid cancer
GIST	Gastrointestinal stromal tumors
HCC	Hepatocellular carcinoma
HES	Hypereosinophilic syndrome
MCL	Marginal zone lymphoma
MDS/MPD	Myelodysplastic/myeloproliferative diseases
MZL	Marginal zone lymphoma
Ph+ ALL	Philadelphia chromosome-positive acute lymphoblastic leukemia
Ph+ CML	Philadelphia chromosome positive chronic myeloid leukemia
Ph+ CML-AP	Philadelphia chromosome positive chronic myeloid leukemia accelerated phase (AP),
Ph+ CML-BC	Philadelphia chromosome positive chronic myeloid leukemia in blast crisis
Ph+ CML-CP	Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (CP)
RCC	Renal cell carcinoma
WM	Waldenström's macroglobulinemia

References:

1. Alecensa [package insert]. South San Francisco, CA; Genentech; November 2017.
2. Alunbrig [package insert] Cambridge, MA; Takeda; December 2018.
3. Bosulif [package insert] New York, NY; Pfizer; October 2018.
4. Cabometyx [package insert]. Alameda, CA; Exelixis; January 2019.
5. Calquence [package insert] Wilmington, DE; AstraZeneca; November 2017.
6. Caprelsa [package insert] Cambridge, MA; Genzyme; October 2018.
7. Cometriq [package insert]. South San Francisco, CA; Exelixis; January 2018.
8. Gleevec [package insert]. East Hanover, NJ; Novartis; July 2018.
9. Gilotrif [package insert] Ridgefield, CT; Boehringer Ingelheim; January 2018.
10. Iclusig [package insert] Cambridge, MA; Takeda; October 2018.
11. Imbruvica [package insert] Horsham, PA; Janssen Biotech; January 2019.

12. Inlyta [package insert] New York, NY; Pfizer; August 2018.
13. Iressa [package insert] Wilmington, DE; AstraZeneca; May 2003.
14. Lenvima [package insert] Woodcliff Lake, NJ; Eisai; December 2018.
15. Lorbrena [package insert]. New York, NY; Pfizer; November 2018.
16. Nerlynx [package insert]. Los Angeles, CA; Puma Biotechnology; June 2018.
17. Qinlock [package insert]. Waltham, MA; Deciphera Pharmaceuticals. May 2020.
18. Retevmo [package insert]. Indianapolis, IN; Lilly USA;
19. Sprycel[package insert] Princeton, NJ; Bristol-Myers Squibb; December 2018.
20. Stivarga [package insert]. Whippany, NJ; Bayer; June 2018.
21. Sutent [package insert]. New York, NY; Pfizer; November 2017.
22. Tabrecta [package insert] East Hanover, NJ; Novartis; May 2020.
23. Tarissio [package insert] Wilmington, DE; AstraZeneca; August 2018.
24. Tarceva [package insert]. South San Francisco, CA; Genentech; October 2016.
25. Tasigna [package insert]. East Hanover, NJ; Novartis; July 2018.
26. Turalio [package insert]. Basking Ridge, NJ; Daiichi Sankyo; August 2019.
27. Tykerb [package insert]. East Hanover, NJ; Novartis; December 2018.
28. Votrient [package insert]. East Hanover, NJ; Novartis; May 2017.
29. Vizimpro [package insert]. New York, NY; Pfizer; September 2018.
30. Xalkori [package insert]. New York, NY; Pfizer; January 2019.
31. Xospata [package insert]. Northbrook, IL; Pfizer; May 2019.
32. Zykadia [package insert]. East Hanover, NJ; Novartis; March 2019.
33. National Comprehensive Cancer Network. Plymouth Meeting, PA. 2020. https://www.nccn.org/

History:

Date	Action and Summary of Changes
06.24.2020	Revised language in Medical Necessity section
06.01.2020	Added new products to class; Updated dosing limits
07.25.2019	Formatting changes
07.01.2019	New Policy

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Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. What is the patient's diagnosis (ICD code plus description)?

   Indicate stage:

   Indicate disease type**:**

1. Is patient currently being treated with this medication? ☐ Yes ☐ No
   If yes:
   When was treatment with the requested dose started?

   What measures were used to define positive clinical response?

   What is the change from baseline?

2. Will this medication be used in combination with other chemotherapeutic or adjuvant agents?
   If yes, list all therapies:

3. What is the patient's planned dosing regimen?

4. List treatments patient has previously tried and dates these treatments were started?

   How long were they on these treatments?

   Why were they discontinued?

5. Has diagnosis and disease mutation been confirmed with an FDA approved companion diagnostic test?
   ☐ Yes ☐ No ☐ Not applicable

6. Does the patient have a contraindication to the requested oral oncology medication regimen? ☐ Yes ☐ No
   If yes, indicate contraindication(s):

7. Indicate if prescribed by or in consultation with:
   ☐ Hematologist ☐ Oncologist ☐ Other. Specify:

8. Indicate for the patient:

Height (cm):	Date taken:
Weight (kg):	Date taken:
Body surface area (m^2):	Date taken:

CHART NOTES, LABS AND TEST RESULTS, INCLUDING ALL DIAGNOSTIC TESTS, ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date