Washington State Health Care Authority

Antineoplastics and Adjunctive Therapies – Tyrosine Kinase Inhibitors - Oral

Medical policy no. 21.53.40-1 Effective Date: March 1, 2021

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.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

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)** Asciminib **(SCEMBLIX)** Avapritinib **(AYVAKIT)** 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)** Mobocertinib **(EXKIVITY)** Neratinib **(NERLYNX)** Nilotinib **(TASIGNA)** Osimertinib **(TAGRISSO)**	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; If all criteria are not met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration. Clients new to Apple Health or new to an MCO, who are requesting regimens for continuation of therapy should be reviewed following the reauthorization criteria listed below.

Pazopanib **(VOTRIENT)** Pexidartinib **(TURALIO)** Pirtobrutinib **(JAYPIRCA)** Ponatinib **(ICLUSIG)** Pralsetinib **(Gavreto)** Ripretinib **(QINLOCK)** Selpercatinib **(RETEVMO)** Tucatinib **(TUKYSA)** Vandetanib **(CAPRELSA)** Zanubrutinib **(BRUKINSA)**	

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
Acalabrutinib **(CALQUENCE)** Afatinib dimaleate **(GILOTRIF)** Alectinib **(ALECENSA)** Asciminib **(SCEMBLIX)** Avapritinib **(AYVAKIT)** 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)** Mobocertinib **(EXKIVITY)** Neratinib **(NERLYNX)** Nilotinib **(TASIGNA)** Osimertinib **(TAGRISSO)** Pazopanib **(VOTRIENT)** Pexidartinib **(TURALIO)** Pirtobrutinib **(JAYPIRCA)** Ponatinib **(ICLUSIG)** Pralsetinib **(GAVRETO)** Ripretinib **(QINLOCK)** Selpercatinib (**RETEVMO)** Tucatinib **(TUKYSA)** Vandetanib **(CAPRELSA)** Zanubrutinib **(BRUKINSA)**	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 6 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	Maximum Dose and Quantity Limits
Acalabrutinib **(CALQUENCE)**	200mg per day
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)**	1200 mg per day
Asciminib (SCEMBLIX)	• Ph+ CML in CP: 80mg per day • Ph+ CML in CP with T3151 Mutation: 400mg per day
Avapritinib **(AYVAKIT)**	300mg per day
Axitinib **(INLYTA)**	20mg per day
Bosutinib **(BOSULIF)**	600mg per day
Brigatinib (**ALUNBRIG)**	180mg per day
Cabozantinib **(COMETRIQ)**	140mg per day
Cabozantinib **(CABOMETYX)**	60mg per day
Capmatinib **(TABRECTA)**	800mg per day
Ceritinib **(ZYKADIA)**	450mg per day

Crizotinib **(XALKORI)**	• Metastatic NSCLC: 500mg per day • Systemic ALCL: 280mg/m^2 orally twice daily based on BSA • Unresectable IMT: 500 mg per day
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 • Postmenopausal breast cancer in combination with letrozole: 1,500mg per day
Lenvatinib **(LENVIMA)**	• Differentiated Thyroid Cancer (DTC): 24mg per day • Endometrial Carcinoma (EC): 20mg per day in combination with pembrolizumab • Renal Cell Carcinoma (RCC): 18mg per day with everolimus 20mg per day with pembrolizumab • Hepatocellular Carcinoma (HCC): Weight ≥ 60 kg = 12mg per day Weight ≤ 60 kg= 8mg per day
Lorlatinib **(LORBRENA)**	100mg per day
Mobocertinib (EXKIVITY)	160mg per day
Neratinib **(NERLYNX)**	240mg per day
Nilotinib **(TASIGNA)**	• Adults Ph+ CML-AP, Ph+ CMP-CP resistant/intolerant to prior therapy: 800mg per day

	• Adults Ph+ CML-CP newly diagnosed: 600mg per day • Pediatrics Ph+ CML-CP: 230mg/m^2 twice daily, maximum 400mg/dose
Osimertinib **(TAGRISSO)**	80mg per day
Pazopanib **(VOTRIENT)**	800mg per day
Pexidartinib **(TURALIO)**	500mg per day
Pirtobrutinib **(JAYPIRCA)**	200mg per day
Ponatinib **(ICLUSIG)**	45mg per day
Pralsetinib **(GAVRETO)**	400mg per day
Ripretinib **(QINLOCK)**	150mg per day
Selpercatinib **(RETEVMO)**	• Medullary thyroid carcinoma, less than 50kg: 240mg per day • Medullary thyroid carcinoma, 50kg or greater: 320mg per day • Non-small cell lung cancer, less than 50kg: 240mg per day • Non-small cell lung cancer, 50kg or greater: 320mg per day • Thyroid cancer, less than 50 kg: 240mg per day • Thyroid cancer, 50kg or greater: 320mg per day
Tucatinib **(TUKYSA)**	600mg per day
Vandetanib **(CAPRELSA)**	300mg per day
Zanubrutinib **(BRUKINSA)**	320mg 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. Ayvakit [package insert] Cambridge, MA; Blueprint Medicines Corporation; 2020.
4. Bosulif [package insert] New York, NY; Pfizer; October 2018.
5. Brukinsa {package insert]. San Mateo, CA; BeiGene; November 2019.
6. Cabometyx [package insert]. Alameda, CA; Exelixis; January 2019.
7. Calquence [package insert] Wilmington, DE; AstraZeneca; November 2017.
8. Caprelsa [package insert] Cambridge, MA; Genzyme; October 2018.
9. Cometriq [package insert]. South San Francisco, CA; Exelixis; January 2018.
10. Exkivity [package insert]. Cambridge, MA; Takeda; September 2021
11. Gilotrif [package insert] Ridgefield, CT; Boehringer Ingelheim; January 2018.
12. Gleevec [package insert]. East Hanover, NJ; Novartis; July 2018.
13. Iclusig [package insert] Cambridge, MA; Takeda; October 2018.
14. Imbruvica [package insert] Horsham, PA; Janssen Biotech; January 2019.
15. Inlyta [package insert] New York, NY; Pfizer; August 2018.
16. Iressa [package insert] Wilmington, DE; AstraZeneca; May 2003.
17. Jaypirca [package insert] Indianapolis, IN; Lily USA; 2023
18. Lenvima [package insert] Woodcliff Lake, NJ; Eisai; November 2022.
19. Lorbrena [package insert]. New York, NY; Pfizer; November 2018.
20. Nerlynx [package insert]. Los Angeles, CA; Puma Biotechnology; June 2018.
21. Qinlock [package insert]. Waltham, MA; Deciphera Pharmaceuticals. May 2020.
22. Retevmo [package insert]. Indianapolis, IN; Lilly USA; 2022
23. Scemblix [package insert]. East Hanover, NJ; Novartis; October 2022
24. Sprycel [package insert] Princeton, NJ; Bristol-Myers Squibb; December 2018.
25. Tabrecta [package insert] East Hanover, NJ; Novartis; May 2020.
26. Tagrissio [package insert] Wilmington, DE; AstraZeneca; August 2018.
27. Tarceva [package insert]. South San Francisco, CA; Genentech; October 2016.
28. Tasigna [package insert]. East Hanover, NJ; Novartis; July 2018.
29. Tukysa [package insert]. Bothell, WA; Seattle Genetics. April 2020.
30. Turalio [package insert]. Basking Ridge, NJ; Daiichi Sankyo; August 2019.
31. Tykerb [package insert]. East Hanover, NJ; Novartis; December 2018.
32. Vizimpro [package insert]. New York, NY; Pfizer; September 2018.
33. Votrient [package insert]. East Hanover, NJ; Novartis; May 2017.
34. Xalkori [package insert]. New York, NY; Pfizer; January 2019.
35. Xospata [package insert]. Northbrook, IL; Pfizer; May 2019.
36. Zykadia [package insert]. East Hanover, NJ; Novartis; March 2019.

History:

Date	Action and Summary of Changes
02.08.2023	Version 1 Updates: 1. Updated general formatting 2. Added Exkivity, Scemblix, and Jaypirca 3. Updated dosing for Lenvima, Turalio, Xalkori
11.30.2020	Added link to AHPDL publication
11.12.2020	Added language in clinical policy section for cases which do not meet policy criteria
10.16.2020	Updated drug list and dosing and quantity limits
08.20.2020	Updated drug list and dosing and quantity limits
08.19.2020	Approved by DUR Board
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