BOSTON MEDICAL CENTER HEALTHNet PLAN

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WELL SENSE HEALTH PLAN

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Pharmacy Policy

Kinase Inhibitors – Unified Formulary

Policy Number: 9.711
Version Number: 2.0
Version Effective Date: 9/1/2021

Product Applicability	☐ **All Plan+ Products**
Well Sense Health Plan ☐ New Hampshire Medicaid	**Boston Medical Center HealthNet Plan** ☒ MassHealth- MCO ☒ MassHealth- ACO ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct ☐ Senior Care Options
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit – temsirolimus, Cosela

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Afinitor® (everolimus 2.5 mg§, 5 mg§, 7.5 mg§, 10 mg§)*	temsirolimus
Afinitor Disperz® (everolimus tablets for oral suspension)	everolimus
Ayvakit® (avapritinib)	
Balversa® (erdafitinib)	
Caprelsa ® (vandetanib)	

+ *Plan* refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

Cometriq® (cabozantinib capsule)	
Cabometyx® (cabozantinib tablet)	
Cosela® (trilaciclib)	
Fotivda® (tivozanib)	
Gavreto® (pralsetinib)	
Inlyta® (axitinib)[PD]	
Koselugo®(selumetinib)	
Lenvima® (lenvatinib)	
Nexavar® (sorafenib)	
Qinlock® (ripretinib)	
Retevmo® (selpercatinib)	
Rydapt® (midostaurin)	
Sutent® (sunitinib)*[PD]§	
Votrient® (pazopanib)	
Xospata® (gilteritinib)	

*A-rated generic available, both brand and A-rated generic require a PA.

[PD] Preferred Drug. In general, a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class is required. **Please note, for kinase inhibitors, a trial with a preferred agent is not required prior to approval of a non-preferred agent.**

§Brand Preferred over generic equivalents. In general, a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent is required.

Approval Criteria:

Afinitor® (everolimus 2.5 mg*, 5 mg*, 7.5 mg*, 10 mg) §	1. Documented diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer; **AND** a. Prescriber is an oncologist; **AND** b. Requested regimen includes exemestane, fulvestrant, or tamoxifen; **AND** c. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following *(Claims are NOT sufficient)*: i. anastrozole ii. letrozole iii. tamoxifen iv. toremifene v. exemestane **OR** 2. Documented diagnosis of advanced renal cell carcinoma; **AND** a. Prescriber is an oncologist; **AND** b. Documentation of **ONE** of the following: i. **ALL** of the following: 1. Member has clear cell histology; **AND** 2. Requested agent will be used as monotherapy or in combination with Lenvima (Lenvatinib) **OR**

	i. **ALL** of the following: 1. Member has non-clear cell histology; **AND** 2. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** Cabometyx (cabozantinib) and sunitinib (Note: *Claims are NOT sufficient*) **OR** 3. Documented diagnosis of **ONE** of the following: a. Renal angiomyolipoma with tuberous sclerosis complex (TSC) b. Advanced pancreatic neuroendocrine tumors (PNET) c. Advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin d. Subpendymal giant cell astrocytoma (SEGA) with TSC **AND** e. Prescriber is an oncologist **OR** 4. Documented diagnosis of epilepsy associated with tuberous sclerosis complex (TSC); **AND** a. Prescriber is a neurologist or consult notes from a neurologist are provided; **AND** b. Documented inadequate response to combination therapy with at least **two** anticonvulsants or contraindication to **ALL** other anticonvulsants; **AND** c. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent
Afinitor Disperz® (everolimus tablets for oral suspension)	1. Documented diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC); **AND** a. Prescriber is an oncologist **OR** 2. Documented diagnosis of treatment-resistant epilepsy associated with TSC; **AND** a. Prescriber is a neurologist or consult notes from a neurologist are provided; **AND** b. Documented inadequate response to combination therapy with at least **two** anticonvulsants or contraindication to **ALL** other anticonvulsants; **AND** c. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent
Ayvakit® (avapritinib)	1. Documented diagnosis of unresectable or metastatic gastrointestinal stromal tumor (GIST); **AND** a. Prescriber is an oncologist b. Documentation that member has disease harboring a PDGFRA exon 18 mutation (including PDGFRA D842V mutations)

	OR 2. Documented diagnosis of **ONE** of the following: a. Advanced systemic mastocytosis (AdvSM) b. Systemic mastocytosis (SM) with associated hematological neoplasm c. Mast cell leukemia **AND** d. Prescriber is an oncologist or hematologist; **AND** e. Documentation of **ONE** of the following: i. **ALL** of the following: 1. Member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown; **AND** 2. Documented inadequate response, adverse reaction, or contraindication to imatinib *(Note: Claims are NOT sufficient)* **OR** ii. D816V c-Kit mutation positive (as determined by an FDA-approved test)
Balversa® (erdafitinib)	1. Documented diagnosis of FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma; **AND** 2. Prescriber is an oncologist; **AND** 3. Member has received prior treatment with platinum-containing chemotherapy or is ineligible for platinum-containing chemotherapy
Cabometyx® (cabozantinib tablet)	1. Documented diagnosis of advanced renal cell carcinoma; **AND** a. Prescriber is an oncologist b. Documentation of **ONE** of the following: i. Documentation of **ALL** of the following: 1. Member has clear cell histology; **AND** 2. Requested agent will be used in combination with Opdivo (nivolumab); **AND** 3. Inadequate response, adverse reaction, or contraindication to Lenvima (Lenvatinib) used in combination with Keytruda (pembrolizumab) **OR** ii. Documentation of **ALL** of the following: 1. Member has clear cell histology; **AND** 2. Member has received a previous treatment in the metastatic setting*; **AND** 3. Requested agent will be used as monotherapy **OR** iii. Member has non-clear cell histology **OR** 2. Documented diagnosis of unresectable hepatocellular carcinoma (HCC);

	AND a. Prescriber is an oncologist; **AND** b. Documented inadequate response, adverse reaction, or contraindication to Nexavar® (sorafenib) *(Note: Claims are NOT sufficient)* *Notes:* • **For clear cell RCC, cabozantinib + nivolumab, axitinib + pembrolizumab, and lenvatinib + pembrolizumab are 1st line/preferred (category 1) for favorable risk group. For poor/intermediate risk groups: Axitinib + pembrolizumab, Cabozantinib + nivolumab, Ipilimumab + nivolumab and Lenvatinib + pembrolizumab are all listed as 1st line/preferred (category 1).*
Caprelsa® (vandetanib)	1. Documented diagnosis of symptomatic or progressive medullary thyroid cancer
Cometriq® (cabozantinib capsule)	1. Documented diagnosis of symptomatic or progressive medullary thyroid cancer
Cosela® (trilaciclib)	1. Documented diagnosis of extensive-stage small cell lung cancer (ES-SCLC); **AND** 2. Prescriber is an oncologist; **AND** 3. Member is 18 years of age or older; **AND** 4. Documentation that Cosela®(trilaciclib) will be used in combination with a platinum/etoposide- or topotecan-containing regimen
Fotivda® (tivozanib)	1. Documented diagnosis of advanced renal cell carcinoma; **AND** 2. Prescriber is an oncologist; **AND** 3. Documentation that tumor is clear cell histology; **AND** 4. Documented inadequate response or adverse reaction to **TWO** or contraindication to **ALL** systemic therapies (e.g., nivolumab monotherapy or in combination with ipilimumab, cabozantinib; axitinib monotherapy or in combination with pembrolizumab; cabozantinib monotherapy; lenvatinib in combination with pembrolizumab or everolimus; pazopanib; sunitinib) (Notes: *Claims are NOT sufficient*)
Gavreto® (pralsetinib) **Retevmo®** (selpercatinib)	1. Documented diagnosis of advanced or metastatic medullary thyroid cancer; **AND** a. Documentation of RET-mutant cancer; **AND** b. Prescriber is an oncologist; **AND** c. Member is 12 years of age or older; **OR** 2. Documented diagnosis of advanced or metastatic thyroid cancer; **AND** a. Documentation of RET fusion-positive cancer; **AND**

	b. Prescriber is an oncologist; **AND** c. Member is 12 years of age or older; **AND** d. Documentation of **ONE** of the following: i. Member refractory to radioactive iodine; **OR** ii. Radioactive iodine treatment is not appropriate **OR** 3. Documented diagnosis of non-small cell lunch cancer (NSCLC); **AND** a. Prescriber is an oncologist; **AND** b. Member is 18 years of age or older
Inlyta® (axitinib)	1. Documented diagnosis of advanced renal cell carcinoma; **AND** 2. Prescriber is an oncologist; **AND** 3. **ONE** of the following: a. Documentation of **BOTH** of the following: i. Tumor is clear cell histology; **AND** ii. Inlyta® (axitinib) will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab) **OR** b. Documentation of **BOTH** of the following: i. Inlyta® (axitinib) will be used as monotherapy; **AND** ii. Member has failed one prior line of systemic therapy
Koselugo® (selumetinib)	1. Documented diagnosis of plexiform neurofibromas (PN) in patients with neurofibromatosis type 1 (NF1); **AND** 2. Prescriber is a neurologist or oncologist; **AND** 3. Documentation of **ONE** of the following: a. Member is at least 2 years of age and less than 18 years of age at the start of therapy; **AND** i. Member has at least one measurable plexiform neurofibroma with documentation that complete resection of PN is not feasible without substantial risk or morbidity
Lenvima® (lenvatinib)	1. Documented diagnosis of advanced renal cell carcinoma; **AND** a. Prescriber is an oncologist; **AND** b. Requested regimen includes everolimus or Keytruda (pembrolizumab); **AND** c. Documentation of **ONE** of the following: i. Tumor is clear cell histology; **OR** ii. **BOTH** of the following: 1. Tumor is non-clear cell histology; **AND** 2. Inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** Cabometyx (cabozantinib) and sunitinib (Note: *Claims history is NOT sufficient)* **OR**

	2. Documented diagnosis of differentiated thyroid cancer; **AND** a. Prescriber is an oncologist **OR** 3. Documented diagnosis of endometrial carcinoma; **AND** a. Prescriber is an oncologist b. Documented inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy (e.g., carboplatin, paclitaxel, doxorubicin, docetaxel, cisplatin, ifosfamide, bevacizumab); **AND** c. Requested agent will be used in combination with Keytruda® (pembrolizumab) **OR** 4. Documented diagnosis of unresectable and metastatic HCC; **AND** a. Prescriber is an oncologist
Nexavar® (sorafenib)	1. Documented diagnosis of **ONE** of the following: a. Advanced renal cell carcinoma; **OR** b. Differentiated thyroid cancer (DTC); **OR** c. Unresectable Hepatocellular Carcinoma (HCC) **AND** d. Prescriber is an oncologist **OR** 2. Documented diagnosis of FLT3-Positive Acute Myeloid Leukemia (AML); **AND** a. Documentation of FLT3-ITD mutation; **AND** b. Documentation of relapsed/refractory disease; **AND** c. Documentation that the agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine)
Qinlock® (ripretinib)	1. Documented diagnosis of Gastrointestinal Stromal Tumor (GIST); **AND** 2. Prescriber is an oncologist; **AND** 3. Documented inadequate response or adverse reaction to at least **THREE** prior kinase inhibitor therapies, one of which is imatinib *(Note: Claims history is NOT sufficient)*
Rydapt® (midostaurin)	1. Documented diagnosis of FLT3-mutated Acute Myeloid Leukemia (AML); **AND** a. Member is 18 years of age or older; **AND** b. Prescriber is a hematologist or oncologist; **AND** c. Documentation of **ONE** of the following: i. For induction therapy, medication will be used in combination with cytarabine and daunorubicin; **OR** ii. For consolidation therapy, medication will be used with cytarabine **OR** 2. Documented diagnosis of aggressive systemic mastocytosis, systemic

	mastocytosis with associated hematological neoplasm, OR mast cell leukemia; **AND** a. Member is 18 years of age or older; **AND** b. Prescriber is a hematologist or oncologist; **AND** c. Documentation of **ONE** of the following: i. If member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown, inadequate response, adverse reaction, or contraindication to imatinib (*Claims are NOT sufficient*); **OR** ii. D816V c-Kit mutation positive (as determined by an FDA-approved test)
Sutent® (sunitinib) *§	1. Documented diagnosis of advanced renal cell carcinoma or advanced pancreatic neuroendocrine tumors (PNET); **AND** a. Prescriber is an oncologist **OR** 2. Documented diagnosis of renal cell carcinoma (adjuvant setting); **AND** a. Prescriber is an oncologist b. Member has not exceeded a maximum number of nine cycles of treatment; **AND** c. Tumor is clear cell histology **OR** 3. Documented diagnosis of gastrointestinal stromal tumor (GIST); **AND** a. Prescriber is an oncologist; **AND** b. Documented inadequate response, adverse reaction or contraindication to imatinib (*Claims are NOT sufficient*)
Votrient® (pazopanib)	1. Documented diagnosis of advanced renal cell carcinoma; **AND** a. Prescriber is an oncologist **OR** 2. Documented diagnosis of soft tissue sarcoma; **AND** a. Prescriber is an oncologist; **AND** b. Documented inadequate response, adverse reaction or contraindication to prior chemotherapy (e.g. anthracycline-containing regimen) (Note: *Claims are NOT sufficient*) **OR** 3. Documented diagnosis of gastrointestinal stromal tumor (GIST); **AND** a. Prescriber is an oncologist; **AND** b. Documented trial of **ALL** of the following: Gleevec® (imatinib), Sutent® (sunitinib), Stivarga® (regorafenib), and Qinlock® (ripretinib)
Xospata®	1. Diagnosis of FLT3-mutated acute myeloid leukemia; **AND** 2. Member is age 18 years of age or older; **AND**

(gilteritinib)	3. Prescriber is a hematologist or oncologist; **AND** 4. Documentation of **ONE** of the following: a. Member has received at least one line of treatment†; **OR** b. Member has relapsed or refractory disease
Duration of Authorization:	Prior authorization for Balversa® (erdafitinib), Caprelsa® (vandetanib), and Cometriq® (cabozantinib capsule) may be issued for **3 months.** Prior authorization for Cosela® (trilaciclib) may be issued for **6 months.** Prior authorization for all other agents may be issued for **1 year**

Appendix:

Additional Information

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus. Requests for other diagnoses must be submitted with appropriate clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

HCPCS Codes

Code	Description
J1448	Injection, trilaciclib, 1 mg

References

1. Afinitor (everolimus) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2021.
2. Ayvakit (avapritinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; January 2020.
3. Balversa (erdafitinib) [prescribing information]. Horsham, PA: Janssen Products, PL; April 2019.
4. Cabometyx (cabozantinib) [prescribing information]. Alameda, CA: Exelixis, Inc.; January 2021.
5. Caprelsa (vandetanib) [prescribing information]. Wilmington, DE. AstraZeneca Pharmaceuticals LP.; July 2016.

6. Cometriq (cabozantinib) [prescribing information]. South San Francisco, CA: Exelixis, Inc.; January 2018.
7. Cosela (trilaciclib) [prescribing information]. Durham, NC: GI Therapeutics, Inc.; February 2021.
8. Fotivda (tivozanib) [prescribing information]. Boston, MA: AVEO Pharmaceuticals, Inc.; March 2021.
9. Gavreto (pralsetinib) [prescribing information]. Cambridge, MA: Blueprint Medicines Corporation; December 2020
10. Inlyta (axitinib) [prescribing information]. New York, NY: Pfizer Inc., August 2014.
11. Koselugo (selumetinib) [prescribing information]. Wilmington, Delaware: AstraZeneca Pharmaceuticals LP; April 2020.
12. Lenvima (lenvatinib) [prescribing information]. Woodcliff Lake, NJ: Eisai, Inc.; July 2021. 30 Pharmacy Medical Necessity Guidelines: Oral Cancer Medications
13. Nexavar (sorafenib) [prescribing information]. Wayne, NJ: Bayer HealthCare Pharmaceuticals Inc.; Nov 2013.
14. Qinlock (ripretinib) [prescribing information]. Waltham, MA: Deciphera Pharmaceuticals, LLC; May 2020.
15. Retevmo (selpercatinib) [prescribing information]. Indianapolis, IN: Lilly USA, LLC; May 2020.
16. Rydapt (midostaurin) [prescribing information]. East Hanover (NJ): Novartis Pharmaceuticals Corporation.; April 2017.
17. Sutent (sunitinib) [prescribing information]. New York, NY: Pfizer Labs; November 2017.
18. Votrient (pazopanib) [prescribing information] Research Triangle Park, NC: GlaxoSmithKline; August 2016.
19. Xospata (gilteritinib) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; 2018 November.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	New policy created to align with MH Unified Formulary Policy	1/1/2021	P&T Committee
1/20/2021	Updated policy to reflect PUF changes as of 10/15/20	1/20/2021	P&T Committee

Policy Revisions History			
5/13/2021	Updated policy to reflect changes dated 3/1/21 from MH. POS criteria added. Updated policy to reflect changes dated 4/15/21 from MH. Reference table updated to include Torisel.	7/1/2021	P&T Committee
5/13/2021	P&T annual review. Moved some clinical criteria from appendix to applicable criteria sections for Nexavar and Votrient.	9/1/2021	P&T Committee
7/23/2021	Updated policy to reflect changes dated 6/16/21 from MH: Clarified listing to note generic name and remove brand name of temsirolimus and everolimus	9/1/2021	P&T Committee
10/1/2021	MH UPPL Update: Policy updated to reflect updated criteria for Cabometyx (cabozantinib), Lenvima (lenvatinib) and Afinitor (everolimus). Seven new agents will be added to the UPPL. These include the following: Ayvakit® (avapritinib), Cosela® (trilaciclib), Fotivda® (tivozanib), Gavreto® (pralsetinib), Koselugo® (selumetinib), Qinlock® (ripretinib), and Retevmo® (selpercatinib). The Medullary Thyroid Cancer Agents policy was merged with the Kinase Inhibitor policy and the medullary thyroid cancer agent's policy will be discontinued. Policy updated to reflect new approval criteria for Inlyta (axitinib) Lastly, policy was updated to include the A-rated generic for Sutent (sunitinib) and this product is also brand preferred.	1/1/2022	P&T Committee

Next Review Date

5/2022

Reference to Applicable Laws and Regulations, If Any

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.