**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** | **Boston Medical Center HealthNet Plan** |
| ☐ New Hampshire Medicaid | ☒ MassHealth- MCO |
| | ☒ MassHealth- ACO |
| | ☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct |
| | ☐ Senior Care Options |

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

## Prior Authorization Policy

**Reference Table:**

| Drugs that require PA | No PA |
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| Afinitor® (everolimus 2.5 mg§, 5 mg§, 7.5 mg§, 10 mg§) | temsirolimus |
| Afinitor Disperz® (everolimus tablets for oral suspension) | everolimus |
| Balversa® (erdafitinib) | |
| Cabometyx® (cabozantinib tablet) | |
| Inlyta® (axitinib)[PD] | |
| Lenvima® (lenvatinib) | |
| Nexavar® (sorafenib) | |
| Rydapt® (midostaurin) | |
| Sutent® (sunitinib)[PD] | |
| Votrient® (pazopanib) | |
| Xospata® (gilteritinib) | |

[+] *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.

[PD] Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. **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, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

**Procedure:**

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| **Approval Diagnosis:** | • Advanced hormone receptor-positive, HER2-negative breast cancer: everolimus<br>• Advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin: everolimus<br>• Advanced pancreatic neuroendocrine tumors (PNET): everolimus, Sutent®<br>• Advanced renal cell carcinoma: everolimus, Cabometyx®, Inlyta®, Lenvima®, Nexavar®, Sutent®, Votrient®<br>• Aggressive systemic mastocytosis (ASM), SM with associated hematological neoplasm (SM-AHN), mast cell leukemia (MCL): Rydapt®<br>• Differentiated thyroid cancer (DTC): Lenvima®, Nexavar®<br>• Endometrial carcinoma: Lenvima®<br>• Epilepsy associated with tuberous sclerosis complex (TSC): everolimus<br>• FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma: Balversa®<br>• FLT3-mutated acute myeloid leukemia (AML): Nexavar®, Rydapt®, Xospata®<br>• Gastrointestinal Stromal Tumor (GIST): Sutent®, Votrient®<br>• Renal angiomyolipoma with tuberous sclerosis complex (TSC): everolimus<br>• Renal cell carcinoma (adjuvant setting): Sutent®<br>• Soft tissue sarcoma: Votrient®<br>• Subependymal giant cell astrocytoma (SEGA) with TSC: everolimus<br>• Unresectable Hepatocellular Carcinoma (HCC): Cabometyx®, Lenvima®, Nexavar®<br><br>Requests for all other diagnoses – consult clinical reviewer |
| **Approval Criteria:**<br><br>**Afinitor®** (everolimus 2.5 mg*, 5 mg*, 7.5 mg*, 10 mg) §<br><br>*A-rated generic available, both brand and A-rated generic require a PA<br><br>§Brand Preferred over generic equivalents. In | **<u>Advanced hormone receptor-positive, HER2-negative breast cancer</u>**<br><br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Requested regimen includes exemestane, fulvestrant, or tamoxifen<br>5. Inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following *(Claims are NOT sufficient)*:<br>a. anastrozole<br>b. letrozole<br>c. tamoxifen<br>d. toremifene<br>e. exemestane<br>6. Quantity requested is ≤1 tablet/day*<br><br>**<u>Advanced renal cell carcinoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist |

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| general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent. | 3. Appropriate dosing<br>4. **ONE** of the following:<br>a. Tumor is non-clear cell histology<br>b. Tumor is clear cell histology and inadequate response or adverse reaction to **ONE** or contraindication to **ALL** first-line therapies (pazopanib, sunitinib, temsirolimus, axitinib monotherapy or in combination with pembrolizumab, ipilimumab + nivolumab, cabozantinib, high-dose IL-2, sorafenib) (*Claims are NOT sufficient*)<br>5. Quantity requested is ≤1 tablet/day*<br><br>**Renal angiomyolipoma with tuberous sclerosis complex (TSC), advanced pancreatic neuroendocrine tumors (PNET), advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin, or subependymal giant cell astrocytoma (SEGA) with TSC**<br><br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Quantity requested is ≤1 tablet/day*<br><br>**Epilepsy associated with tuberous sclerosis complex (TSC)**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of treatment-resistant epilepsy associated with TSC<br>2. Prescriber is a neurologist or consult notes from a neurologist are provided<br>3. Inadequate response to combination therapy with at least two anticonvulsants or contraindication to ALL other anticonvulsants<br>4. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent<br>5. Quantity requested is ≤1 tablet/day*<br><br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria:**<br><br>**Afinitor Disperz®** (everolimus tablets for oral suspension) | **Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC)**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC)<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Quantity requested is ≤1 tablet/day*<br><br>**Epilepsy associated with tuberous sclerosis complex (TSC)**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of treatment-resistant epilepsy associated with TSC<br>2. Prescriber is a neurologist or consult notes from a neurologist are provided<br>3. Inadequate response to combination therapy with at least two |

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| | anticonvulsants or contraindication to ALL other anticonvulsants<br>4. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent<br>5. Quantity requested is ≤1 tablet/day*<br><br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria:**<br><br>**Balversa®** (erdafitinib) | Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Member has received prior treatment with platinum-containing chemotherapy or is ineligible for platinum-containing chemotherapy*<br><br>*Notes:*<br>• **Please refer to the Appendix: Chemotherapy Regimens for Bladder Cancer for more information.* |
| **Approval Criteria:**<br><br>**Cabometyx®** (cabozantinib tablet) | **<u>Advanced renal cell carcinoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. **ONE** of the following:<br>a. Member has poor/intermediate risk and the request is for first-line treatment of clear cell histology<br>b. Member has favorable risk and clear cell histology and inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** of the following *(Claims are NOT sufficient)*:<br>i. Votrient® (pazopanib)<br>ii. Sutent® (sunitinib)<br>c. Member has clear cell histology and has received a previous treatment in the metastatic setting**<br>d. Member has non-clear cell histology and member has an inadequate response, adverse reaction, or contraindication to Sutent® (sunitinib)<br>5. Quantity requested is ≤1 tablet/day*<br><br>**<u>Unresectable Hepatocellular Carcinoma (HCC)</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Inadequate response, adverse reaction, or contraindication to Nexavar® (sorafenib) *(Claims are NOT sufficient)*<br>5. Quantity requested is ≤1 tablet/day* |

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| | *Notes:*<br>• *For clear cell renal cell carcinoma (RCC), Sutent® (sunitinib) and Votrient® (pazopanib) are 1st line/preferred and are less costly on a net basis and Cabometyx® (cabozantinib tablet) is listed as a treatment option (for poor- and intermediate-risk groups – 1st line preferred); Cabometyx® (cabozantinib tablet) is 2nd line and preferred. For non-clear cell RCC, Sutent® (sunitinib) is preferred and Cabometyx® (cabozantinib tablet) and Votrient® (pazopanib) are listed on the same level (category 2A), but Votrient® (pazopanib) is less costly on a net basis.*<br>• ***Example of previous treatments include Inlyta® (axitinib) + Keytruda® (pembrolizumab), Sutent® (sunitinib), Votrient® (pazopanib), and Yervoy® (ipilimumab) + Opdivo® (nivolumab). Other treatment options may be found in the NCCN guideline. Please consult the Clinical Reviewer as needed.*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria:**<br><br>**Inlyta®** (axitinib) | Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of advanced renal cell carcinoma<br>2. Prescriber is an oncologist<br>3. Appropriate dosing |
| **Approval Criteria:**<br><br>**Lenvima®** (lenvatinib) | **<u>Advanced renal cell carcinoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing (quantity requested is ≤3 capsules/day)*<br>4. Requested regimen includes everolimus<br>5. **ONE** of the following:<br>a. Tumor is clear cell histology and inadequate response or adverse reaction to **ONE** or contraindication to **ALL** first-line therapies (pazopanib, sunitinib, temsirolimus, axitinib monotherapy or in combination with pembrolizumab, ipilimumab + nivolumab, cabozantinib, high-dose IL-2, sorafenib) (*Claims are NOT sufficient*)<br>b. Tumor is non-clear cell histology and inadequate response or adverse reaction to **ONE** or contraindication to **ALL** systemic therapies (e.g., sunitinib, axitinib, bevacizumab or biosimilar, cabozantinib, erlotinib, everolimus, nivolumab, pazopanib, sorafenib, temsirolimus) (*Claims are NOT sufficient*)<br><br>**<u>Differentiated thyroid cancer</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing (quantity requested is ≤3 capsules/day)*<br><br>**<u>Endometrial Carcinoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist |

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| | 3. Appropriate dosing (quantity requested is ≤2 capsules/day)*<br>4. Inadequate response or adverse reaction to one prior line of systemic therapy or contraindication to systemic therapy**<br>5. Requested agent will be used in combination with Keytruda® (pembrolizumab)<br><br>**Unresectable Hepatocellular Carcinoma (HCC)**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of unresectable and metastatic HCC<br>2. Prescriber is an oncologist<br>3. Appropriate dosing (quantity requested is ≤3 capsules/day)*<br><br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.*<br>• ***Examples of systemic therapy for endometrial carcinoma include carboplatin, paclitaxel, doxorubicin, docetaxel, cisplatin, ifosfamide, and bevacizumab. These may be used as monotherapy or as combination therapy. If you are unsure whether a treatment was appropriate to meet this criteria point, please forward to the Clinical Reviewer of the Day.* |
| **Approval Criteria:**<br><br>**Nexavar®** (sorafenib) | **Advanced Renal Cell Carcinoma, Differentiate Thyroid Cancer, Unresectable Hepatocellular Carcinoma**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of **ONE** of the following:*<br>a. Advanced renal cell carcinoma<br>b. Differentiated thyroid cancer (DTC)<br>c. Unresectable Hepatocellular Carcinoma (HCC)<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Quantity requested is ≤ 4 tablets/day**<br><br>**FLT3-Positive Acute Myeloid Leukemia (AML)**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of AML<br>2. Documentation of FLT3-ITD mutation<br>3. Documentation of relapsed/refractory disease<br>4. Documentation that the agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine)<br>Quantity requested is ≤120 tablets per 30 days<br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria**<br><br>**Rydapt®** (midostaurin) | **FLT3-mutated Acute Myeloid Leukemia**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Age ≥18 years<br>3. Prescriber is a hematologist/oncologist<br>4. Appropriate dosing (quantity requested is ≤2 capsules/day)*<br>5. **ONE** of the following: |

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| | a. For induction therapy, medication will be used in combination with cytarabine and daunorubicin<br>b. For consolidation therapy, medication will be used with cytarabine<br><br>**<u>Aggressive Systemic Mastocytosis, Systemic Mastocytosis with associated hematological neoplasm, mast cell leukemia</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Age ≥18 years<br>3. Prescriber is a hematologist/oncologist<br>4. Appropriate dosing (quantity requested is ≤8 capsules/day)*<br>5. **ONE** of the following:<br>a. 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*)<br>b. D816V c-Kit mutation positive (as determined by an FDA-approved test)<br><br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria**<br><br>**Sutent®**<br>(sunitinib) | **<u>Advanced renal cell carcinoma, advanced pancreatic neuroendocrine tumors (PNET)</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Quantity requested is ≤ 1 capsule/day*<br><br>---<br><br>**<u>Renal cell carcinoma (adjuvant setting)</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing *(limited to maximum of nine cycles of treatment)*<br>4. Tumor is clear cell histology<br>5. Quantity requested is ≤ 1 capsule/day*<br><br>**<u>Gastrointestinal stromal tumor (GIST)</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing†<br>4. Inadequate response, adverse reaction or contraindication to imatinib (*Claims are NOT sufficient*)<br>5. Quantity requested is ≤ 1 capsule/day*<br><br>*Notes:* |

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| | • †*Off-label 37.5 mg once daily, continuous daily dosing has also been found effective for GIST, but is more costly than FDA-approved dosing. Please refer to the Appendix: Exceeding Quantity Limits for guidance on these requests.*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Approval Criteria**<br><br>**Votrient®** (pazopanib) | **<u>Advanced renal cell carcinoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Quantity requested is ≤ 4 tablets/day*<br><br>**<u>Soft tissue sarcoma</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis**<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Inadequate response, adverse reaction or contraindication to prior chemotherapy (e.g. anthracycline-containing regimen) (*Claims are NOT sufficient*)<br>5. Quantity requested is ≤ 4 tablets/day*<br><br>**<u>Gastrointestinal stromal tumor (GIST)</u>**<br>Prescriber provides documentation of **ALL** of the following:<br>1. Appropriate diagnosis<br>2. Prescriber is an oncologist<br>3. Appropriate dosing<br>4. Documented trial of **ALL** of the following: Gleevec® (imatinib), Sutent® (sunitinib), and Stivarga® (regorafenib)<br><br>*Notes:*<br>• **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.*<br>• |
| **Approval Criteria**<br><br>**Xospata®** (gilteritinib) | Prescriber provides documentation of **ALL** of the following:<br>1. Diagnosis of FLT3-mutated acute myeloid leukemia<br>2. Age ≥18 years<br>3. Prescriber is a hematologist/oncologist<br>4. Appropriate dosing<br>5. **ONE** of the following:<br>a. Member has received at least one line of treatment†<br>b. Member has relapsed or refractory disease<br>6. Quantity requested is ≤ 3 tablets/day*<br><br>*Notes:*<br>• *†Please refer to Appendix: Treatments for Acute Myeloid Leukemia for additional information.* |

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| | • **Requests exceeding the quantity limit should be evaluated on a case-by-case basis. Please refer to the Appendix: Exceeding Quantity Limits.* |
| **Brand Preferred over Generic:** | • In addition to any prior authorization requirements that may be listed above, generic medications listed below have Brand name products that are included on the MassHealth Brand Name Preferred Over Generic List. Requests for generic versions require a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent prior to approval:<br>o everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg |
| **Denial Criteria:** | Cases that do not meet the approval criteria will be denied. |
| | If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted. |
| **Duration of Authorization:** | Prior authorization for Balversa® (erdafitinib) may be issued for **3 months.**<br><br>Prior authorization for all other agents may be issued for **1 year** |
| **Recertification Criteria:** | Resubmission for Cabometyx® (cabozantinib tablet), everolimus, Inlyta® (axitinib), Lenvima® (lenvatinib), Nexavar® (sorafenib), Rydapt® (midostaurin), Sutent® (sunitinib), Votrient® (pazopanib), and Xospata® (gilteritinib) will infer a positive response to therapy and request can be recertified for **1 year.**<br><br>Resubmission for Balversa® (erdafitinib) should be verified for appropriate dosing based on phosphate levels. The dose should have been increased to 9 mg once daily if the serum phosphate level is <5.5 mg/dL and drug is tolerable 14 to 21 days after start of therapy on 8 mg once daily. If appropriate, the request can be recertified for **1 year**.<br><br>Recertifications for exceeding quantity limits will be handled on a case-by-case basis to promote dose consolidation. |

**Appendix:**

**Stability**

Stability on a medication requiring a prior authorization is not a reason to bypass approval criteria. However, requests for members who have already started treatment on these agents should be forwarded to clinical review and approval should be strongly considered for any member with any FDA-approved indication.

**Grandfathering**

N/A

**Additional Information**

**Exceeding Quantity Limits**

Requests exceeding the quantity limit should be evaluated on a case-by-case basis. If there is compelling rationale for exceeding the quantity limit, please forward to clinical review for case-by-case evaluation (e.g., stability, past approvals at a dose exceeding the quantity limit, specific clinical rationale for dose is documented).

In addition to criteria in the procedure table above, requests exceeding the quantity limit must have **ALL** of the following:

- Dose is appropriate
- Dose is consolidated
- Appropriate clinical rationale for exceeding the quantity limit

**Appropriate Clinical Rationale**

Examples of appropriate rationale are provided below but is not all inclusive. Please review each request individually based on patient-specific factors.

Stability

Stability on a dose exceeding the quantity limit should be evaluated case-by-case based on information provided. Clinical rationale for exceeding the quantity limit should be documented.

Drug-Drug Interactions

Several agents have drug-drug interactions that may require exceeding the quantity limit. Please refer to the package insert or online database for guidance on appropriate dosing. Consider approval if drug-drug interaction requires increased quantity and concomitant agent cannot be discontinued.

everolimus tablet, Afinitor Disperz® (everolimus)

For diagnoses that are dosed based on trough concentrations (SEGA associated with TSC and Epilepsy associated with TSC) an increased quantity may be required if there is a low trough concentration at max dose of one tablet QD (10 mg QD). Consider approval if there is low trough concentration (< 5 ng/mL) on max dose of one tablet QD (10 mg) or one tablet for suspension QD (5 mg).

Sutent® (sunitinib)

Quantities exceeding the limit may be required in patients with end-stage renal disease (ESRD) on hemodialysis. No adjustment to the starting dose is required. However, compared to patients with normal renal function, the sunitinib exposure is 47% lower in patients with ESRD on hemodialysis. Therefore, the subsequent doses may be increased gradually up to 2-fold based on safety and tolerability. Consider approval if member has ESRD and is on dialysis.

Requests may be received for Sutent® (sunitinib) for the treatment of GIST for off-label dosing of 37.5 mg once daily continuously, which is more costly than the FDA-approved dosing of 50 mg once daily for four weeks and off treatment for two weeks per six-week cycle. Although there is insufficient data to support one dosing regimen over the other, researchers and prescribers have noted that the continuous dosing may be better tolerated and pharmacokinetically similar to the 50 mg dose and patients would not have the two weeks off schedule where the patient is drug free and the tumor can potentially flare. These dosing regimens have not been compared head-to-head in terms of efficacy, but the continuous daily dosing could possess better safety.

Please forward requests for continuous dosing for GIST to the Clinical Reviewer of the Day. The Clinical Reviewer may consider the rationale for the dosing and approve as appropriate (e.g., low performance status, safety concerns).

**Treatments for Acute Myeloid Leukemia**

Depending on the patient's age and risk status, a variety of treatments could be used for first-line therapy of acute myeloid leukemia.

Patients less than 60 years of age may receive the following treatment for induction therapy before receiving consolidation therapy:

- Cytarabine with idarubicin or daunorubicin
- Cytarabine with daunorubicin and gemtuzumab ozogamicin
- Cytarabine with daunorubicin and midostaurin (FLT3-mutated)
- Cytarabine with daunorubicin and cladribine
- Daunorubicin and cytarabine
- High-dose cytarabine with daunorubicin or idarubicin
- Fludarabine and idarubicin

Patients who are 60 years of age or older may receive the following treatment for induction therapy before receiving consolidation therapy:

- Cytarabine with daunorubicin and gemtuzumab ozogamicin (CD33-positive)
- Cytarabine with idarubicin or daunorubicin or mitoxantrone
- Daunorubicin and cytarabine
- Cytarabine with daunorubicin and midostaurin (FLT3-mutated)
- Venetoclax and decitabine
- Venetoclax and azacitidine
- Venetoclax and cytarabine
- Azacitidine
- Decitabine

**Chemotherapy Regimens for Bladder Cancer (First-line Setting)**

For first-line systemic therapy for locally advanced or metastatic bladder cancer, patients who are cisplatin eligible may receive the following preferred regimens:

- Gemcitabine and cisplatin
- Dose-dense combination of methotrexate, vinblastine, doxorubicin, and cisplatin (DDMVAC) with growth factor support.

Patients who are cisplatin ineligible may receive the following regimens:

- Preferred
    - Gemcitabine and carboplatin
    - Atezolizumab (only for patients whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression)
    - Pembrolizumab (only for patients whose tumors express PD-L1 or who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 expression)
- Other recommended regimen
    - Gemcitabine
    - Gemcitabine and paclitaxel
- Useful under certain circumstances
    - Ifosfamide, doxorubicin, and gemcitabine (for patients with good kidney function and good performance status)

**Point of Sale (POS) Criteria**

**Criteria:**

1. Claims for Balversa® (erdafitinib) (079650, 079651, 079652), Cabometyx® (075944, 075945, 075946), Inlyta® (068497, 068498), Lenvima® (074284, 073484, 073485, 073486, 078769, 073487, 076126, 076127), Rydapt® (077344), Sutent® (060326, 060327, 060328, 071671), and Xospata® (gilteritinib) (079318) will usually reject at the pharmacy as prior authorization required.
2. Claims for everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg (064994, 064995, 066495, 068582), Afinitor® Disperz (070919, 070920, 070921), and Nexavar® (060199) within established quantity limits will usually process and pay at the pharmacy if there is a claim in all claims history prior to 10/26/15 (excluding emergency).
3. Claims for Votrient® (065777) within established quantity limits will usually process and pay at the pharmacy if there is a claim in all claims history prior to 5/30/17 (excluding emergency).

**Clinical Background Information and References**

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

| Policy Revisions History | | | |
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| **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 |
| 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 |

## Next Review Date

5/2022

## Reference to Applicable Laws and Regulations, If Any

### 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.