Kinase Inhibitors:
Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg), Afinitor Disperz (everolimus tablets for oral suspension), Ayvakit (avapritinib), Balversa (erdafitinib), Caprelsa (vandetanib), Cometriq (cabozantinib capsule), Cabometyx (cabozantinib tablet), Cosela (trilaciclib), Fotivda (tivozanib), Gavreto (pralestinib), Inlyta (axitinib), Koselugo (selumetinib), Lenvima (lenvatinib), Nexavar (sorafenib), Qinlock (ripretinib), Retevmo (selpercatinib), Rydapt (midostaurin), Sutent (sunitinib), Truseltiq (infigratinib), Votrient (pazopanib), Xospata (gilteritinib)

Effective 11/01/2022

Plan	☒ MassHealth ☐ Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit (NLX)		
Specialty Limitations	This medication has 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	N/A		

Overview
Approval Diagnosis:

- Advanced hormone receptor-positive, HER2-negative breast cancer: everolimus
- Advanced neuroendocrine tumors (NET) of gastrointestinal or lung origin: everolimus
- Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) or RET-fusion positive thyroid cancer: Gavreto, Retevmo
- Advanced pancreatic neuroendocrine tumors (PNET): everolimus, sunitinib
- Advanced renal cell carcinoma: everolimus, Cabometyx, Fotivda, Inlyta, Lenvima, Nexavar, sunitinib, Votrient
- Aggressive systemic mastocytosis (ASM), SM with associated hematological neoplasm (SM-AHN), mast cell leukemia (MCL): Ayvakit, Rydapt
- Differentiated thyroid cancer (DTC): Cabometyx, Lenvima, Nexavar
- Endometrial carcinoma: Lenvima
- Epilepsy associated with tuberous sclerosis complex (TSC): everolimus
- Extensive-stage small cell lung cancer (ES-SCLC): Cosela
- FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma: Balversa
- FLT3-mutated acute myeloid leukemia (AML): Rydapt, Xospata
- Gastrointestinal Stromal Tumor (GIST): sunitinib, Qinlock

- Locally advanced or metastatic cholangiocarcinoma with a FGFR2 fusion or other rearrangement: Truseltiq
- Metastatic RET fusion-positive non-small cell lung cancer (NSCLC): Gavreto, Retevmo
- Plexiform neurofibromas in patients with neurofibromatosis type 1 (NF1): Koselugo
- Renal angiomyolipoma with tuberous sclerosis complex (TSC): everolimus
- Renal cell carcinoma (adjuvant setting): sunitinib
- Soft tissue sarcoma: Votrient
- Subependymal giant cell astrocytoma (SEGA) with TSC: everolimus
- Symptomatic or progressive medullary thyroid cancer: Caprelsa, Cometriq
- Unresectable Hepatocellular Carcinoma (HCC): Cabometyx, Lenvima, Nexavar
- Unresectable or metastatic GIST: Ayvakit

No PA	Drugs that require PA
temsirolimus	Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg §)*
everolimus	Afinitor Disperz (everolimus tablets for oral suspension) §*
	Ayvakit (avapritinib)
	Balversa (erdafitinib)
	Caprelsa (vandetanib)
	Cometriq (cabozantinib capsule)
	Cabometyx (cabozantinib tablet)
	Cosela (trilaciclib)
	Fotivda (tivozanib)
	Gavreto (pralestinib)
	Inlyta (axitinib)[PD]
	Koselugo (selumetinib)
	Lenvima (lenvatinib)
	Nexavar (sorafenib) *§
	Qinlock (ripretinib)
	Retevmo (selpercatinib)
	Rydapt (midostaurin)
	Sutent (sunitinib) *[PD]§
	Truseltiq (infigratinib)
	Votrient (pazopanib)
	Xospata (gilteritinib)

*A-rated generic available, both brand and A-rated generic require a PA.
PD Preferred Drug - 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 - requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.

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 if the member meets **ALL** following criteria and documentation has been submitted:

Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg)

Advanced hormone receptor-positive, HER2-negative breast cancer
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Requested regimen includes exemestane, fulvestrant, or tamoxifen
5. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **ALL** of the following:
    a. anastrozole
    b. letrozole
    c. tamoxifen
    d. toremifene
    e. exemestane
6. Quantity requested is ≤1 tablet/day*

Advanced renal cell carcinoma
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. **ALL** of the following:
        i. Member has clear cell histology
        ii. Requested agent will be used as monotherapy or in combination with Lenvima (Lenvatinib)
    b. **ALL** of the following:
        i. Member has non-clear cell histology
        ii. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** Cabometyx (cabozantinib) and sunitinib
5. Quantity requested is ≤1 tablet/day*

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
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤1 tablet/day*

Epilepsy associated with tuberous sclerosis complex (TSC)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of treatment-resistant epilepsy associated with TSC

2. Prescriber is a neurologist or consult notes from a neurologist are provided
3. Physician documentation of inadequate response to combination therapy with at least two anticonvulsants or contraindication to ALL other anticonvulsants
4. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent
5. Quantity requested is ≤1 tablet/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Afinitor Disperz (everolimus tablets for oral suspension)

Subependymal giant cell astrocytoma (SEGA) with tuberous sclerosis complex (TSC)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤1 tablet/day*

Epilepsy associated with tuberous sclerosis complex (TSC)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is a neurologist or consult notes from a neurologist are provided
3. Physician documentation of inadequate response to combination therapy with at least two anticonvulsants or contraindication to ALL other anticonvulsants
4. Requested agent will be used as adjunctive therapy with at least one anticonvulsant agent
5. Quantity requested is ≤1 tablet/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Ayvakit (avapritinib)

Unresectable or metastatic GIST
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member has disease harboring a PDGFRA exon 18 mutation (including PDGFRA D842V mutations)
5. Quantity requested is ≤1 tablet/day*

Advanced systemic mastocytosis (AdvSM), systemic mastocytosis (SM) with associated hematological neoplasm, mast cell leukemia
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist or hematologist
3. Appropriate dosing
4. **ONE** of the following:
    a. **ALL** of the following:

i. Member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown
ii. Physician documentation of inadequate response, adverse reaction, or contraindication to imatinib

b. D816V c-Kit mutation positive (as determined by an FDA-approved test)

5. Quantity requested is ≤1 tablet/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Balversa (erdafitinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of FGFR3 or FGFR2-mutated locally advanced or metastatic urothelial carcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member has received prior treatment with platinum-containing chemotherapy or is ineligible for platinum-containing chemotherapy *(Please refer to the Appendix: Chemotherapy Regimens for Bladder Cancer)*

Cabometyx (cabozantinib tablet)

Advanced renal cell carcinoma (RCC)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following:
   a. **ALL** of the following:
      i. Member has clear cell histology
      ii. Requested agent will be used in combination with Opdivo (nivolumab)
      iii. Physician documented of inadequate response, adverse reaction, or contraindication to Inlyta (axitinib) used in combination with Keytruda (pembrolizumab)
   b. **ALL** of the following:
      i. Member has clear cell histology
      ii. Member has received a previous treatment in the metastatic setting *(e.g., cabozanitinib + nivolumab, axitnib + pembrolizumab, lenvatinib + pembrolizumab. Other treatment options may be found in the NCCN guideline)*
      iii. Requested agent will be used as monotherapy
   c. Member has non-clear cell histology
5. Quantity requested is ≤1 tablet/day*

Unresectable Hepatocellular Carcinoma (HCC)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to Nexavar® (sorafenib)

5. Quantity requested is ≤1 tablet/day*

Locally recurrent, advanced, and/or metastatic thyroid carcinoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to **ONE** of the following:
    a. Lenvima® (lenvatinib)
    b. Nexavar® (sorafenib)
5. **ONE** of the following:
    a. Member is refractory to radioactive iodine
    b. Radioactive iodine treatment is not appropriate
6. Quantity requested is ≤1 tablet/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Caprelsa (vandetanib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of symptomatic or progressive medullary thyroid cancer
2. **ONE** of the following:
    a. Request is within quantity limit of 1 unit/day for 300 mg tablets or 2 units/day for 100 mg tablets
    b. Medical necessity for exceeding quantity limit of 1 unit/day for 300 mg tablets or 2 units/day for 100 mg tablets

Cometriq (cabozantinib capsule)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of symptomatic or progressive medullary thyroid cancer
2. **ONE** of the following:
    a. Requested dose does not exceed 140 mg/day
    b. Medical necessity for exceeding the 140 mg/day dose

Cosela (trilaciclib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of extensive-stage small cell lung cancer (ES-SCLC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member is ≥ 18 years of age
5. Requested agent will be used in combination with a platinum/etoposide- or topotecan-containing regimen

Fotivda (tivozanib)

Advanced renal cell carcinoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist

3. Appropriate dosing
4. Tumor is clear cell histology
5. Physician documentation of inadequate response or adverse reaction to **TWO** or contraindication to **ALL** systemic therapies (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)
6. Quantity requested is ≤1 capsule/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Gavreto (pralestinib) and **Retevmo** (selpercatinib)

Advanced or metastatic RET-mutant medullary thyroid cancer (MTC) or Thyroid Cancer
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member is ≥12 years of age
5. **ONE** of the following:
    a. Member has medullary thyroid cancer
    b. Member has thyroid cancer and **ONE** of the following:
        i. Member refractory to radioactive iodine
        ii. Radioactive iodine treatment is not appropriate
6. Quantity requested is ≤ 4 capsules/day*

Metastatic RET fusion-positive non-small cell lung cancer (NSCLC)
Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member is ≥18 years of age
5. Quantity requested is ≤ 4 capsules/day*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Inlyta (axitinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of advanced renal cell carcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. **ONE** of the following
    a. **BOTH** of the following:
        i. Tumor is clear cell histology
        ii. Requested agent will be used in combination with Bavencio (avelumab) or Keytruda (pembrolizumab)
    b. **BOTH** of the following:
        i. Requested agent will be used as monotherapy

ii. Member has failed one prior line of systemic therapy

Koselugo (selumetinib)

Plexiform neurofibromas (PN) in patients with neurofibromatosis type 1 (NF1)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is a neurologist or oncologist
3. Appropriate dosing
4. Member is ≥ 2 years of age and < 18 years of age at the start of therapy *(refer to the Appendix for requests for adult patients with PN due to NF1)*
5. 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)

Advanced renal cell carcinoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤3 capsules/day)*
4. **ONE** of the following:
    a. **ALL** of the following:
        i. Tumor is clear cell histology
        ii. Requested agent will be used in combination with everolimus
        iii. Member has failed one first-line therapy for advanced renal cell carcinoma
    b. **ALL** of the following:
        i. Tumor is clear cell histology
        ii. Requested agent will be used in combination with Keytruda (pembrolizumab)
        iii. Physician documentation of inadequate response, adverse reaction, or contraindication to Inlyta (axitinib) used in combination with Keytruda (pembrolizumab)
    c. **BOTH** of the following:
        i. Tumor is non-clear histology
        ii. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** Cabometyx (cabozantinib) and sunitinib

Differentiated thyroid cancer
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤3 capsules/day)*

Endometrial Carcinoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤2 capsules/day)*

4. 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, and bevacizumab)*
5. Requested agent will be used in combination with Keytruda (pembrolizumab)

Unresectable Hepatocellular Carcinoma (HCC)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable and metastatic HCC
2. Prescriber is an oncologist
3. Appropriate dosing (quantity requested is ≤3 capsules/day)*

**Please refer to the Appendix: Exceeding Quantity Limits.*

Nexavar (sorafenib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of **ONE** of the following:*
    a. Advanced renal cell carcinoma
    b. Differentiated thyroid cancer (DTC)
    c. Unresectable Hepatocellular Carcinoma (HCC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤ 4 tablets/day**

**See Appendix for acute myeloid leukemia (AML) and FLT3-positive AML*
***Please refer to the Appendix: Exceeding Quantity Limits.*

Truseltiq (infigratinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable locally advanced or metastatic cholangiocarcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. Tumor has FGFR2 fusion or other rearrangement
5. Member is ≥18 years of age
6. Member has received at least one prior treatment (refer to the Appendix for prior treatments for cholangiocarcinoma)
7. Quantity requested is ≤ one blister pack/28 days

Qinlock (ripretinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Gastrointestinal Stromal Tumor (GIST)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documentation of inadequate response or adverse reaction to at least THREE prior kinase inhibitor therapies (e.g., sunitinib and regorafenib), one of which is imatinib
5. Quantity requested is ≤3 units per day**

***Please refer to the Appendix: Exceeding Quantity Limits*

Rydapt (midostaurin)

FLT3-mutated Acute Myeloid Leukemia
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Member is ≥18 years of age
3. Prescriber is a hematologist/oncologist
4. Appropriate dosing (quantity requested is ≤4 capsules/day)*
5. **ONE** of the following:
    a. For induction therapy, medication will be used in combination with cytarabine and daunorubicin
    b. For consolidation therapy, medication will be used with cytarabine

Aggressive Systemic Mastocytosis, Systemic Mastocytosis with associated hematological neoplasm, mast cell leukemia
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is a hematologist/oncologist
3. Appropriate dosing (quantity requested is ≤8 capsules/day)*
4. **ONE** of the following:
    a. **ALL** of the following:
        i. Member has aggressive SM without the D816V c-Kit mutation (as determined by an FDA-approved test) or with c-Kit mutation status unknown
        ii. Inadequate response, adverse reaction, or contraindication to imatinib
    b. D816V c-Kit mutation positive (as determined by an FDA-approved test)

**Please refer to the Appendix: Exceeding Quantity Limits*

Sutent (sunitinib)

Advanced renal cell carcinoma, advanced pancreatic neuroendocrine tumors (PNET)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤ 1 capsule/day*

Renal cell carcinoma (adjuvant setting)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing *(limited to maximum of nine cycles of treatment)*
4. Tumor is clear cell histology
5. Quantity requested is ≤ 1 capsule/day*

Gastrointestinal stromal tumor (GIST)
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis

2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documentation of inadequate response, adverse reaction or contraindication to imatinib
5. Quantity requested is ≤ 1 capsule/day*

**Please refer to the Appendix: Exceeding Quantity Limits*

Votrient (pazopanib)

Advanced renal cell carcinoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤ 4 tablets/day*

Soft tissue sarcoma
Prescriber provides documentation of **ALL** of the following:
1. Appropriate diagnosis *(refer to appendix Votrient for treatment of GIST)*
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documentation of inadequate response, adverse reaction or contraindication to prior chemotherapy (e.g., anthracycline-containing regimen)
5. Quantity requested is ≤ 4 tablets/day*

**Please refer to the Appendix: Exceeding Quantity Limits*

Xospata (gilteritinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of FLT3-mutated acute myeloid leukemia
2. Member is ≥18 years of age
3. Prescriber is a hematologist/oncologist
4. Appropriate dosing
5. **ONE** of the following:
    a. Member has received at least one line of treatment *(refer to Appendix: Treatments for Acute Myeloid Leukemia)*
    b. Member has relapsed or refractory disease
6. Quantity requested is ≤ 3 tablets/day*

**Please refer to the Appendix: Exceeding Quantity Limits*

Continuation of Therapy
Reauthorization requires physician attestation of continuation of therapy and positive response to therapy.

Limitations
1. Initial approvals will be granted for:
    a. Balversa, Caprelsa, Cometriq: 3 months
    b. Cosela (trilaciclib): 6 months

c. All other agents: 12 months

2. Reauthorizations will be granted for:
   a. Ayvakit, Cabometyx , everolimus, Fotivda , Gavreto , Inlyta, Koselugo, Lenvima, Qinlock, Retevmo, Rydapt, sorafenib, sunitinib (all indications except adjuvant RCC), Truseltiq, Votrient, and Xospata: 12 months
   b. sunitinib (adjuvant RCC): up to a maximum of 9 cycles from when treatment began (each cycle is 6 weeks in length)
   c. Balversa if appropriate dosing: 12 months
   d. Caprelsa, Cometriq: 6 months
   e. Cosela: remaining length of the chemotherapy session
   f. Exceeding quantity limits will be handled on a case-by-case basis to promote dose consolidation
3. The following quantity limits apply:

Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg)	30 tablets per 30 days
Afinitor Disperz (everolimus tablets for oral suspension)	30 tablets per 30 days
Ayvakit (avapritinib)	30 tablets per 30 days
Caprelsa (vandetanib)	60 tablets per 30 days (100 mg) 30 tablets per 30 days (300 mg)
Cometriq (cabozantinib capsule)	60 capsules per 30 days (60 mg) 30 capsules per 30 days (100 mg) 30 capsules per 30 days (140 mg)
Cabometyx (cabozantinib tablet)	30 tablets per 30 days
Fotivda (tivozanib)	30 capsules per 30 days
Gavreto (pralestinib)	120 capsules per 30 days
Lenvima (lenvatinib)	90 capsules per 30 days
Nexavar (sorafenib)	120 tablets per 30 days
Qinlock (ripretinib)	90 tablets per 30 days
Retevmo (selpercatinib)	120 capsules per 30 days
Rydapt (midostaurin)	240 capsules per 30 days
Sutent (sunitinib)	30 capsules per 30 days
Truseltiq (infigratinib)	1 blister pack per 28 days
Votrient (pazopanib)	120 tablets per 30 days
Xospata (gilteritinib)	90 tablets per 30 days

Appendix

Exceeding Quantity Limits

Requests exceeding the quantity limit should be evaluated on a case-by-case basis (e.g., stability, past approvals at a dose exceeding the quantity limit, specific clinical rationale for dose is documented).

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

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 followed by avelumab maintenance therapy (category 1)
  - 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)

Koselugo (selumetinib) for Plexiform Neurofibromas in Adult Patients with Neurofibromatosis Type 1

Requests for adult patients can be reviewed using the following clinical criteria.

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Prescriber is a neurologist or oncologist
3. Appropriate dosing
4. Member has at least one measurable plexiform neurofibroma with documentation that complete resection of PN is not feasible without substantial risk or morbidity

Sorafenib for Acute Myeloid Leukemia (AML)

The AML NCCN guidelines recommend sorafenib plus a hypomethylating agent (5-azacytidine or decitabine) for patients with relapsed/refractory disease with FLT3-ITD disease.

Requests for sorafenib for AML may be approved if the prescriber provides documentation of **ALL** of the following:

1. Diagnosis of AML
2. Documentation of FLT3-ITD mutation
3. Documentation of relapsed/refractory disease
4. Documentation that the agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine)
5. Quantity requested is ≤120 tablets per 30 days

Votrient (pazopanib) for the treatment of GIST

Requests for Votrient (pazopanib) for the treatment of GIST may be approved if the prescriber documents trials of **ALL** of the following: Gleevec (imatinib), Sutent (sunitinib), and Stivarga (regorafenib) and Qinlock (ripretinib).

Treatments for 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

Treatment Regimens for Cholangiocarcinoma

According to the NCCN Guideline for the treatment of Hepatobiliary Cancer, section on Biliary Cancer, the following agents may be used for first-line treatment:

- gemcitabine + cisplatin (category 1)
- 5-fluorouracil + oxaliplatin
- 5-fluorouracil + cisplatin (category 2B)
- capecitabine + cisplatin (category 2B)
- capecitabine + oxaliplatin
- gemcitabine + albumin-bound paclitaxel
- gemcitabine + oxaliplatin
- gemcitabine + capecitabine•gemcitabine + cisplatin + albumin-bound paclitaxel (category 2B)
- 5-fluorouracil
- capecitabine
- gemcitabine

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Review History

11/16/2022 – Created for Nov P&T; matched MH UPPL. Combined criterias: Ayvakit, Balversa, Cabometyx, Cosela, Fotivda, Gavreto, Koselugo, Lenvima, Qinlock, Retevmo, Xospata. Added drugs: Afinitor, Afinitor Disperz, Caprelsa, Cometriq, Inlyta, Nexavar, Rydapt, Sutent, Truseltiq, Votrient. Named policy "Kinase Inhibitors." Updated QLs to match MH. Recent update included designating Nexavar as a brand preferred product. Effective 11/01/2022

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