Mass General Brigham
Health Plan

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), Fyarro (sirolimus injection), Gavreto (pralestinib), Hyftor (sirolimus gel), Inlyta (axitinib), Koselugo (selumetinib), Lenvima (lenvatinib), Lytgobi (futibatinib), Nexavar (sorafenib), Qinlock (ripretinib), Retevmo (selpercatinib), Rezurock (belumosudil), Rydapt (midostaurin), Sutent (sunitinib), Truseltiq (infigratinib), Votrient (pazopanib), Xospata (gilteritinib)
Effective 01/02/2024

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Medical and Specialty Medications**		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	Cosela is available through medical benefit only.		

Overview

No PA	Drugs that require PA
Torisel®# (temsirolimus)	Afinitor (everolimus 2.5 mg, 5 mg, 7.5 mg, 10 mg)* BP
Zortress®# (everolimus 0.25 mg, 0.5 mg, 0.75 mg, 1 mg)	Afinitor Disperz (everolimus tablets for oral suspension) * BP
	Ayvakit (avapritinib)
	Balversa (erdafitinib)
	Caprelsa (vandetanib)
	Cometriq (cabozantinib capsule)
	Cabometyx (cabozantinib tablet)
	Cosela (trilaciclib) MB
	Fotivda (tivozanib)
	Fyarro®(sirolimus injection)
	Gavreto (pralestinib)
	Hyftor®(sirolimus gel)
	Inlyta (axitinib)
	Koselugo (selumetinib)
	Lenvima (lenvatinib)
	Lytgobi®(futibatinib)

	Nexavar (sorafenib) * BP
	Qinlock (ripretinib)
	Retevmo (selpercatinib)
	Rezurock® (belumosudil)
	Rydapt (midostaurin)
	Sutent (sunitinib) *BP
	Truseltiq (infigratinib)
	Votrient (pazopanib) *BP
	Xospata (gilteritinib)

#This is a brand-name drug with FDA "A"-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA "A"-rated generic equivalent.
*A-rated generic available, both brand and A-rated generic require a PA.
BP Brand Preferred over generic equivalents - requires a trial of the preferred drug or clinical rationale for prescribing the non-preferred drug generic equivalent.
MB This drug is available through the health care professional who administers the drug or in an outpatient or inpatient hospital setting. The plan does not pay for this drug to be dispensed through the retail pharmacy

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)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced hormone receptor-positive, HER2-negative breast cancer
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*

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. **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*

Prescriber provides documentation of **ALL** of the following:
1. 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. subependymal giant cell astrocytoma (SEGA) with TSC
2. Prescriber is a specialist (e.g., oncologist or nephrologist) or consult notes from a specialist are provided
3. Appropriate dosing
4. Quantity requested is ≤1 tablet/day*

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)

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

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of epilepsy associated with tuberous sclerosis complex (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.*

Ayvakit (avapritinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of unresectable or metastatic GIST
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*

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

1. Diagnosis of ONE of the following:
    a. advanced systemic mastocytosis (AdvSM)
    b. systemic mastocytosis (SM) with associated hematological neoplasm
    c. mast cell leukemia
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)

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. Member has clear cell histology
        ii. Requested agent will be used in combination with Opdivo (nivolumab)
    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*

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

1. Diagnosis of unresectable hepatocellular carcinoma (HCC)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to sorafenib
5. Quantity requested is ≤1 tablet/day*

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

1. Diagnosis of locally recurrent, advanced, and/or metastatic differentiated thyroid carcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. Physician documented of inadequate response, adverse reaction, or contraindication to **ONE**, or contraindication to **BOTH** 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)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of advanced renal cell carcinoma
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.*

Fyarro® (sirolimus injection)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of locally advanced or metastatic malignant perivascular epithelioid cell tumor (PEComa)
2. Appropriate dosing

Gavreto (pralestinib)
Retevmo (selpercatinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of medullary thyroid cancer (MTC) or thyroid cancer
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*

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

1. Diagnosis of non-small cell lung cancer (NSCLC)
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.*

Retevmo (selpercatinib)
Prescriber provides documentation of **ALL** of the following:

1. Diagnosis of locally advanced or metastatic solid tumor
2. Prescriber is an oncologist
3. Appropriate dosing
4. Member is ≥18 years of age

5. Physician documentation that cancer is RET fusion-positive
6. **ONE** of the following:
    a. Physician documented of inadequate response or adverse reaction to at least one prior systemic therapy OR contraindication to the use of systemic therapy
    b. Member has no satisfactory alternative treatment options
7. Requested quantity is ≤ 4 capsules/day*

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

Hyftor® (sirolimus gel)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of facial angiofibroma
2. Member is ≥ 6 years of age
3. Prescriber is a neurologist or dermatologist, or consult notes from a neurologist or dermatologist are provided
4. ONE of the following:
    a. For members < 12 years of age, requested quantity is ≤20 grams/30 days (2 tubes/30 days)
    b. For members ≥ 12 years of age, requested quantity is ≤ 30 grams/30 days (3 tubes/30 days)

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)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of Plexiform Neurofibromatosis Type 1 (NF1)
2. Prescriber is a neurologist or oncologist
3. Appropriate dosing
4. **ONE** of the following:
    a. Member is ≥ 2 years of age and < 18 years of age at the start of therapy
    b. Member is ≥ 18 years of age *(off-label)*
5. Member has at least one measurable plexiform neurofibroma with documentation that complete resection of PN is not feasible without substantial risk or morbidity *(measurable PN defined as a lesion ≥3 cm in one dimension)*

Lenvima (lenvatinib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced renal cell carcinoma

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. **BOTH** of the following:
        i. Tumor is clear cell histology
        ii. Requested agent will be used in combination with Keytruda (pembrolizumab)
    c. **BOTH** of the following:
        i. Tumor is non-clear cell histology
        ii. Physician documentation of inadequate response or adverse reaction to **ONE** or contraindication to **BOTH** Cabometyx (cabozantinib) and sunitinib

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

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of endometrial carcinoma
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)

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)
    d. FLT3-ITD mutated AML *(off-label)* and **BOTH** of the following:
        i. Member is noted to have relapsed/refractory disease
        ii. Requested agent will be used in combination with a hypomethylating agent (5-azacytidine or decitabine)
2. Prescriber is an oncologist
3. Appropriate dosing

4. Requested quantity is ≤ 4 tablets/day*

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

Truseltiq (infigratinib)
Lytgobi®(futibatinib)
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. For Lytgobi, requested quantity is ≤ four blister packs/28 days
8. For Truseltiq, requested quantity 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*

Rezurock® (belumosudil)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of chronic graft versus host disease (cGVHD)
2. Member is ≥ 12 years of age
3. Appropriate dosing
4. Prescriber is an oncologist or hematologist
5. Requested quantity is ≤1 unit/day
6. Paid claims or physician attestation of inadequate response, adverse reaction, or contraindication to systemic glucocorticoids
7. Prior therapy for the treatment of cGVHD with at least ONE prior line of non-steroid systemic therapy (See Appendix for systemic therapies for cGVHD)

Rydapt (midostaurin)
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 (quantity requested is ≤4 capsules/day)*
5. **ONE** of the following:

a. For induction therapy, requested agent will be used in combination with cytarabine and daunorubicin
b. For consolidation therapy, requested agent will be used with cytarabine

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of aggressive systemic mastocytosis, systemic mastocytosis with associated hematological neoplasm, mast cell leukemia
2. Prescriber is a hematologist/oncologist
3. Appropriate dosing (quantity requested is ≤8 capsules/day)*
4. **ONE** of the following:
    a. **BOTH** 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)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced renal cell carcinoma, advanced pancreatic neuroendocrine tumors (PNET)
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤ 1 capsule/day*

Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of renal cell carcinoma (adjuvant setting)
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*

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, adverse reaction or contraindication to imatinib
5. Quantity requested is ≤ 1 capsule/day*

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

Votrient (pazopanib)
Prescriber provides documentation of **ALL** of the following:
1. Diagnosis of advanced renal cell carcinoma
2. Prescriber is an oncologist
3. Appropriate dosing
4. Quantity requested is ≤ 4 tablets/day*

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

1. Diagnosis of soft tissue sarcoma
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*

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

1. Diagnosis of gastrointestinal stromal tumor (GIST)
2. Paid claims or physician documentation of inadequate response, adverse reaction, or contraindication to **ALL** of the following:
    a. Gleevec (imatinib)
    b. Qinlock (ripretinib)
    c. Sutent (sunitinib)
    d. Stivarga (regorafenib)
3. Requested quantity 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, Fyarro, Lytgobi, Rezurock, Truseltiq: 6 months
    c. All other agents: 12 months
2. Reauthorizations will be granted for:
    a. Ayvakit, Cabometyx , everolimus, Fotivda , Gavreto , Inlyta, Koselugo, Lenvima, Lytgobi, 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: 3 months
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
Hyftor (sirolimus gel)	10 grams per 30 days
Lenvima (12envatinib)	90 capsules per 30 days
Lytgobi (futibatinib)	4 blister packs per 28 days
Nexavar (sorafenib)	120 tablets per 30 days
Qinlock (ripretinib)	90 tablets per 30 days
Retevmo (selpercatinib)	120 capsules per 30 days
Rezurock (belumosudil)	30 tablets 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)

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:

Preferred Regimens:

- gemcitabine + cisplatin (category 1)
- durvalumab + gemcitabine + cisplatin (category 1)

Other Recommended Regimens:

- 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

Systemic Therapies for Chronic Graft-Versus-Host Disease (cGVHD)

NCCN guidelines (V1.2022) recommend corticosteroids as first-line therapy for memberswith cGVHD. For steroid-refractory cGVHD, the following therapies are recommendedin conjunction with corticosteroids:

1. ruxolitinib (category 1)
2. abatacept
3. alemtuzumab
4. belumosudilb
5. Calcineurin inhibitors (i.e., cyclosporine, tacrolimus)
6. Etanercept
7. Extracorporeal photopheresis (ECP)
8. Hydroxychloroquine
9. Ibrutinibc
10. Imatinib
11. Interleukin-2 (IL-2)
12. Low-dose methotrexate
13. mTOR inhibitors (e.g., sirolimus)
14. mycophenolate mofetil
15. pentostatin
16. rituximab

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Review History

11/16/2022 – Reviewed and updated for Nov P&T; matched MH UPPL. Effective 11/1/22. 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. Renamed policy to "Kinase Inhibitors." Updated QLs to match MH UPPL. Recent update included designating Nexavar as a brand preferred product. Effective 2/1/23. Added age limit to the Koselugo (selumetinib) for Plexiform Neurofibromas in Adult patients with Neurofibromatosis Type 1 appendix. Clarified Cosela reauthorization approval duration to 3 months. Effective 2/1/23.
01/11/2023 – Reviewed and updated for Jan P&T. Approval criteria updated for everolimus for 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- to allow appropriate specialist for the requested indication (in place of just oncology specialist). Removed step criteria of Inlyta + Keytruda for the indication of advanced RCC (clear cell histology) for Cabometyx and Lenvima approval criteria. Retevmo updated to include expanded indication of adults with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion. Ayvakit updated to require BOTH: 1) agressive SM without the D816V c-Kit mutation or with c-Kit mutation status unknown + t/f with imatinib 2) D816V c-Kit mutation positive. Several off-label indications for use of agents within this guideline moved from appendix section to Coverage Guidelines. Removed preferred status from both Inlyta and Sutent. Added 'Brand over Generic' list. Effective 3/1/23.
03/15/23 - Reviewed and updated for Mar P&T. Added Fyarro®(sirolimus injection), Hyftor®(sirolimus gel), Rezurock. Added quantity limits to Hyftor (10gm/30 days). Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Added Lytgobi as requiring PA with same criteria as Truseltiq for the indication of treatment of adult patients with previously treated, unresectable, locally advanced or metastatic

intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. Criteria update on Hyftor®(sirolimus gel) to expand eligible prescriber to neurologist, and to increase quantity limit for patients < 12 years of age to 2 tubes per 30 days and increase quantity limit for patients ≥ 12 years of age to 3 tubes per 30 days. Fyarro, Lytgobi, Rezurock, Truseltiq will be approved for 6 months for initial requests. Effective 6/5/23.
12/13/23 – Reviewed and updated for P&T. Votrient will have brand preferred designation. No clinical changes. Effective 1/2/24