Pharmacy Management Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (CRPA) Rx Drugs
POLICY NUMBER: PHARMACY-33
EFFECTIVE DATE: 10/2013
LAST REVIEW DATE: 06/13/2025

If the member's subscriber contract excludes coverage for a specific service or prescription drug, it is not covered under that contract. In such cases, medical or drug policy criteria are not applied. This drug policy applies to the following line/s of business:

Policy Application

Category:	☒ Commercial Group (e.g., EPO, HMO, POS, PPO)	☐ Medicare Advantage
	☒ On Exchange Qualified Health Plans (QHP)	☐ Medicare Part D
	☒ Off Exchange Direct Pay	☒ Essential Plan (EP)
	☐ Medicaid & Health and Recovery Plans (MMC/HARP)	☒ Child Health Plus (CHP)
	☐ Federal Employee Program (FEP)	☐ Ancillary Services
	☐ Dual Eligible Special Needs Plan (D-SNP)	

POLICY:

The oncology drug Clinical Review Prior-Authorization (CRPA) process is designed to ensure newly approved (FDA) prescription drugs are used appropriately in cases where a drug poses potential efficacy, quality, toxicity, or utilization concerns for the members and the Health Plan. In addition, this policy may be used for medications that have significant concerns about safety or inappropriate use, but do not warrant a stand-alone policy. The Pharmacy Management clinical team reviews the oncology drugs falling into these categories under the process of Clinical Review Prior Authorization (CRPA). A Letter of Medical Necessity (LOMN), Exception Form, or Prior Authorization Form completion is required for consideration of drug coverage under this policy.

Prior Authorization criteria listed in this policy is based on FDA labeled indication or NCCN level of evidence 1 or 2A. For requests that do not meet the policy criteria defined below, please refer to the Off-Label Use of FDA Approved Drugs policy.

POLICY GUIDELINES:

1. This policy is applicable to drugs that are included on a specific drug formulary. If a drug referenced in this policy is non-formulary, please reference the Non-Formulary Medication Exception Review Policy for all Lines of Business policy for review guidelines.
2. This policy is subject to frequent revisions as new medications come onto the market. Some drugs will require prior authorization prior to approved language being added to the policy.
3. Utilization Management are contract dependent and coverage criteria may be dependent on the contract renewal date. Additionally, coverage of drugs listed in this policy are contract dependent. Refer to specific contract/benefit language for exclusions.
4. Drugs listed in this policy apply to the Pharmacy (Rx) benefit, unless otherwise specified.
5. Supportive documentation of previous drug use must be submitted for any criteria which require trial of a preferred agent if the preferred drug is not found in claims history.
6. Clinical documentation must be submitted for each request (initial and recertification) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not limited to, progress notes documenting previous treatments/treatment history, diagnostic testing, laboratory test results, genetic testing/biomarker results, and imaging.

7. Dose and frequency should be in accordance with the FDA label or recognized compendia (for off-label uses). When services are performed in excess of established parameters, they may be subject to review for medical necessity.
8. For contracts where Insurance Law § 4903(c-1), and Public Health Law § 4903(3-a) are applicable, if trial of preferred drug(s) is the only criterion that is not met for a given condition, and one of the following circumstances can be substantiated by the requesting provider, then trial of the preferred drug(s) will not be required. The provider must make their intent to override a trial of the preferred drugs clear and must provide rationale and supporting documentation for one of the following:
    - The required prescription drug(s) is (are) contraindicated or will likely cause an adverse reaction or physical or mental harm to the member;
    - The required prescription drug is expected to be ineffective based on the known clinical history and conditions and concurrent drug regimen;
    - The required prescription drug(s) was (were) previously tried while under the current or a previous health plan, or another prescription drug or drugs in the same pharmacologic class or with the same mechanism of action was (were) previously tried and such prescription drug(s) was (were) discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event;
    - The required prescription drug(s) is (are) not in the patient's best interest because it will likely cause a significant barrier to adherence to or compliance with the plan of care, will likely worsen a comorbid condition, or will likely decrease the ability to achieve or maintain reasonable functional ability in performing daily activities;
    - The individual is stable on the requested prescription drug. The medical profile of the individual (age, disease state, comorbidities), along with the rational for deeming stability as it relates to standard medical practice and evidence-based practice protocols for the disease state will be taken into consideration.
    - The above criteria are not applicable to requests for brand name medications that have an AB rated generic. We can require a trial of an AB-rated generic equivalent prior to providing coverage for the equivalent brand name prescription drug.
9. Unless otherwise stated below within Drug Specific Approval Timeframes table below, approval time periods are listed in the table below
    a. Continued approval at time of recertification will require documentation that the drug is providing ongoing benefit to the patient in terms of improvement or stability in disease state or condition. Such documentation may include progress notes, imaging or laboratory findings, and other objective or subjective measures of benefit which support that continued use of the requested product is medically necessary.
    b. Recertifications will be evaluated for the regimen that is currently being prescribed (monotherapy, combination therapy, etc.). If this differs from the initial review, the request will be reviewed based on the level of evidence that is available for the current regimen.
    c. Ongoing use of the requested product must continue to reflect the current policy's preferred formulary [Recertification reviews may result in the requirement to try more cost-effective treatment alternatives as they become available (i.e., generics, biosimilars, or other guideline-supported treatment options)] and the requested dose must continue to meet FDA approved or off-label/guideline supported dosing
10. All requests will be reviewed to ensure they are being used for an appropriate indication and may be subject to an off-label review in accordance with our Off-Label Use of FDA Approved Drugs Policy (Pharmacy-32). This includes any request that is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy.
11. All utilization management requirements outlined in this policy are compliant with applicable New York State insurance laws and regulations. Policies will be reviewed and updated as necessary to ensure ongoing compliance with all state and federally mandated coverage requirements.

Approval time periods

Line of Business	Initial approval	Continued approval
Commercial/Exchange	6 months	6 months

PHARMACY (Rx) ONCOLOGY DRUGS INCLUDED IN THIS POLICY:

Drug Name
• Abiraterone 500 mg tablet • Afinitor (everolimus) • Akeega (niraparib tosylate monohydrate and abiraterone acetate) • Everolimus tablets (generic Afinitor) • Afinitor Disperz (everolimus tablets for oral suspension) • Everolimus tablets for oral suspension (generic Afinitor Disperz) • Alecensa (alectinib) • Alunbrig (brigatinib) • Augtyro (repotrectinib) • Avmapki Fakzynja co-pack (avutometinib potassium and defactinib hydrochloride) • Ayvakit (avapritinib) • Balversa (erdafitinib) • Besremi (ropeginterferon alfa-2b-njft) (**NOTE**: both Rx and Medical benefit drug) • Bosulif (bosutinib) • Braftovi (encorafenib) • Brukinsa (zanubrutinib) • Cabometyx (cabozantinib tablets) • Calquence (acalabrutinib) • Caprelsa (vandetanib) • Cometriq (cabozantinib capsules) • Copiktra (duvelisib) • Cotellic (cobimetinib) • Daurismo (glasdegib) • Danziten (nilotinib) • Erivedge (vismodegib) • Erleada (apalutamide) • Fotivda (tivozanib) • Fruzaqla (fruquintinib) • Gavreto (pralsetinib) • Gilotrif (afatinib) • Gomekli (mirdametinib) • Hemady (dexamethasone) • Ibrance (palbociclib) • Iclusig (ponatinib) • Idhifa (enasidenib) • Imbruvica (ibrutinib) • Imkeldi (imatinib) • Inlyta (axitinib) • Inqovi (decitabine/cedazuridine) • Inrebic (fedratinib) • Iressa (gefitinib) • Itovebi (inavolisib) • Iwilfin (eflornithine) • Gefitinib (generic Iressa) • Jaypirca (pirtobrutinib)

- Jakafi (ruxolitinib)
- Kisqali (ribociclib)
- Koselugo (selumetinib)
- Krazati (adagrasib)
- Lazcluze (lazertinib)
- Lenvima (lenvatinib)
- Lonsurf (trifluridine and tipiracil)
- Lorbrena (lorlatinib)
- Lumakras (sotorasib)
- Lynparza tablets (olaparib tablets)
- Lytgobi (futibatinib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Nerlynx (neratinib)
- Nexavar (sorafenib)
- Sorafenib (generic Nexavar)
- Ninlaro (ixazomib)
- Nubeqa (darolutamide)
- Odomzo (sonidegib)
- Ogsiveo (nirogacestat)
- Ojjaara (momelotinib)
- Ojemda (tovorafenib)
- Onureg (oral azacitidine)
- Orgovyx (relugolix)
- Orserdu (elacestrant)
- Pemazyre (pemigatinib)
- Piqray (alpelisib)
- Pomalyst (pomalidomide)
- Purixan (6-mercaptopurine)
- Mercaptopurine oral suspension (generic Purixan)
- Qinlock (ripretinib)
- Retevmo (selpercatinib)
- Revuforj (revumenib)
- Rezlidhia (olutasidenib)
- Rezurock (belumosudil)
- Romvimza (vimseltinib)
- Rozlytrek (entrecetinib
- Rubraca (rucaparib)
- Rydapt (midostaurin)
- Scemblix (asciminib)
- Soltamox (tamoxifen citrate)
- Sprycel (dasatinib)
- Dasatinib (generic for Sprycel)
- Stivarga (regorafenib)
- Sutent (sunitinib)
- Sunitinib maleate (generic Sutent)
- Tabrecta (capmatinib)
- Tafinlar (dabrafenib)
- Tagrisso (osimertinib)
- Talzenna (talazoparib)
- Tarceva (erlotinib)
- Erlotinib (generic Tarceva)
- Tasigna (nilotinib)

- Nilotinib (generic Tasigna)
- Targretin capsules (bexarotene capsules)
- Bexarotene capsules (generic Targretin capsules)
- Targretin gel (bexarotene gel)
- Bexarotene gel (Targretin gel)
- Tazverik (tazemetostat)
- Tepmetko (tepotinib)
- Tibsovo (ivosidenib)
- Torpenz (everolimus)
- Truqap (capivasertib)
- Tukysa (tucatinib)
- Turalio (pexidartinib)
- Tykerb (lapatinib)
- Lapatinib (generic Tykerb)
- Valchlor (mechlorethamine)
- Vanflyta (quizartinib)
- Venclexta (venetoclax)
- Verzenio (abemaciclib)
- Vitrakvi (larotrectinib)
- Vizimpro (dacomitinib)
- Vonjo (pacritinib)
- Voranigo (vorasidenib)
- Votrient (pazopanib)
- Pazopanib (generic Votrient)
- Welireg (belzutifan)
- Xalkori (crizotinib)
- Xermelo (telotristate ethyl)
- Xospata (gileritinib)
- Xpovio (selinexor)
- Xtandi (enzalutamide)
- Yonsa (abiraterone acetate, micronized)
- Zejula (niraparib)
- Zelboraf (vemurafenib)
- Zolinza (vorinostat)
- Zydelig (idelalisib)
- Zykadia (ceritinib)
- Zytiga (abiraterone acetate)

UNIVERSAL CRITERIA:

The drugs listed in this policy will be reviewed in accordance with criteria described below.

Note select drugs are subject to additional and/or more comprehensive coverage criteria which can be found in the Drug Specific Criteria table:

1. Must prescribed by, or in consultation with an Oncologist, Hematologist, or appropriate specialist **AND**
2. The requested use (indication AND regimen) must meet **one** of the following:
   a. Approved by the U.S. Food and Drug Administration (FDA) **OR**
   b. A National Comprehensive Cancer Network (NCCN) category level 1 or 2A recommendation **OR**
   c. Satisfied by the criteria required for the applicable line of business (LOB) for the treatment of cancer in the Off-Label Use of FDA Approved Drugs policy (Pharmacy-32) **AND**
3. Step therapy requirements must be met for select drugs (see Drugs with Step Therapy Requirements table)

TABLE 1. DRUG SPECIFIC CRITERIA

Drug specific criteria may include, but is not limited to unique approval timeframes, step therapy requirements, and additional limitations to universal coverage criteria. Drug specific criteria will include any applicable quantity limits (quantity limits for drugs without specific criteria can be found in the Drugs with Quantity Limit Requirements table).

DRUG NAME (Rx benefit)
Drug Specific Criteria
Ibrance (palbociclib)
1. In addition to the Universal Criteria outlined above the following criteria will also apply: a. Unless otherwise explicitly stated in the NCCN compendia, the use of Ibrance (palbociclib) following disease progression on prior CDK 4/6 inhibitor therapy is considered experimental and investigational and will be subject to an off-label review.
Itovebi (inavolisib)
1. Must meet prescriber requirement as outlined in the Universal Criteria (criterion #1) **AND** 2. Must be 18 years of age or older **AND** 3. Must have a diagnosis of endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced, or metastatic breast cancer **AND** 4. Must have confirmed presence of one or more PIK3CA mutations as detected by an FDA-approved test **AND** 5. Must have recurrence on or after completing adjuvant endocrine therapy **AND** 6. Must be used in combination with Ibrance (palbociclib) and fulvestrant **AND** 7. Patient must not have experienced disease progression on any of the following: a. Protein kinase B (AKT)/ phosphatidylinositol 3-kinase (PI3K)/ mammalian target of rapamycin (mTOR) inhibitors **AND** b. Cyclin-dependent kinase (CDK) 4/6 inhibitors 8. Quantity Limit: a. 9 mg: 28 tablets/28 days b. 3 mg: 56 tablets/28 days
Kisqali (ribociclib)
1. In addition to the Universal Criteria outlined above the following criteria will also apply: a. Unless otherwise explicitly stated in the NCCN compendia, the use of Kisqali (ribociclib) following disease progression on prior CDK 4/6 inhibitor therapy is considered experimental and investigational and will be subject to an off-label review.
Lumakras (sotorasib)
1. In addition to the Universal Criteria outlined above the following criteria will also apply: a. Unless otherwise explicitly stated in the NCCN compendia, the use of Lumakras (sotorasib) following disease progression on a previous KRAS G12C-targeted therapy will be considered experimental and investigational and will be subject to an off-label review.
Ojjaara (momelotinib)
1. Must be prescribed by an oncologist or hematologist **AND** 2. Must be 18 years of age or older **AND** 3. Must have a diagnosis of intermediate or high-risk myelofibrosis (MF), including primary MF or secondary MF [post-polycythemia vera (PV) and post-essential thrombocythemia (ET)] **AND** 4. Must have anemia, defined as hemoglobin < 10 g/dL 5. Quantity Limit: 30 tablets/30 days

Orserdu (elacestrant)

1. Must be prescribed by an Oncologist **AND**
2. Must have diagnosis of unresectable recurrent, or metastatic breast cancer that is hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative **AND**
3. Must be designated female at birth **AND**
    a. Must be post-menopausal **OR**
4. Must be designated male at birth **AND**
    a. Must be 18 years of age and older **AND**
5. Must be used as a single agent (excepting ovarian ablation therapy for pre-menopausal/peri-menopausal individuals) **AND**
6. Must have confirmed *ESR1*-mutated disease **AND**
7. Must be requested as 2nd line or later therapy **AND**
8. Step therapy applies
    a. Must have had prior treatment include a CDK4/6 inhibitor (i.e., Ibrance, Kisqali, Verzenio)
9. NOTE: Pre-menopausal and Peri-menopausal individuals with ovarian ablation or suppression should be treated as postmenopausal individuals. Individuals designated male at birth with breast cancer should be treated similarly to postmenopausal individuals, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.
10. Quantity Limit:
    a. 345 mg: 30 tablets/30 days
    b. 86 mg: 90 tablets/30 days

Krazati (adagrasib)

1. In addition to the Universal Criteria outlined above the following criteria will also apply:
    a. Unless otherwise explicitly stated in the NCCN compendia, the use of Krazati (adagrasib) following disease progression on a previous KRAS G12C-targeted therapy will be considered experimental and investigational and will be subject to an off-label review.

Purixan and mercaptopurine oral suspension

1. Must be prescribed by an oncologist **AND**
2. Must have a diagnosis of acute lymphoblastic leukemia (ALL) for:
    a. Children who are unable to swallow oral pills **OR**
    b. Children or adults who require a daily dosage that cannot be obtained from 50mg tablets
3. Requests for the use of Purixan/mercaptopurine oral suspension for other indications will be evaluated based on the off-label policy for medical necessity
    a. In addition, there must be documentation as to why the individual cannot utilize oral tablets (Swallowing disorder, unique dosing, etc.)
4. Quantity limit of 100 ml per 30 days.

Verzenio (abemaciclib)

1. In addition to the Universal Criteria outlined above the following criteria will also apply:
    a. Unless otherwise explicitly stated in the NCCN compendia, the use of Verzenio (abemaciclib) following disease progression on prior CDK 4/6 inhibitor therapy is considered experimental and investigational and will be subject to an off-label review.

Exkivity (mobocertinib)

As of April 8, 2024, Takeda will no longer provide Exkivity commercially. Takeda launched a Compassionate Use Program in January 2024 to ensure patients on or prescribed Exkivity before April 1, 2024, could have access to the drug. Only patients who were prescribed Exkivity prior to April 1, 2024 will be eligible for the Compassionate Use Program.

Based on the above announcement, The Health Plan will not authorize coverage of Exkivity for new patients or existing users.

TABLE 2. DRUGS WITH STEP THERAPY REQUIREMENTS:

- Unless otherwise specified, step therapy will apply to:
  - New Starts ONLY **AND**
  - ALL Lines of Business except Medicare Part D
- Step Therapy criteria listed below applies to all shared FDA labeled indications or compendia supported indications/regimens, defined as NCCN level of evidence 1 or 2A.

Drug Name	Diagnosis	Requirement
Abiraterone 500 mg tablet	For all FDA approved, and compendia supported indications	Due to the availability of the lower costing abiraterone 250 mg tablet that is likely to produce equal therapeutic results, patients must use 250 mg abiraterone tablets unless there is adequate justification as to why this formulation is not appropriate.
Afinitor (everolimus) tablets	For all FDA approved, and compendia supported indications	Must be a contraindication to the use of generic everolimus tablets
Afinitor Disperz (everolimus tablets for oral suspension)	For all FDA approved, and compendia supported indications	Must be a contraindication to the use of generic everolimus tablets for oral suspension
Erleada (apalutamide)	For non-metastatic, castration-resistant prostate cancer	Must have had serious side effects with Nubeqa (darolutamide) **AND** Xtandi (enzalutamide)
	For a metastatic, castration-sensitive prostate cancer with: • High-volume synchronous metastases **OR** • High-volume metachronous metastases **OR** • Low-volume synchronous metastases	Must have had serious side effects or drug failure with abiraterone acetate, Nubeqa (darolutamide) in combination with docetaxel, **AND** Xtandi (enzalutamide)
	For a metastatic, castration-sensitive prostate cancer with: • Low-volume metachronous metastases	Must have had serious side effects or drug failure with abiraterone acetate **AND** Xtandi (enzalutamide)
Ibrance (palbociclib)	For treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative recurrent unresectable, advanced, or metastatic breast cancer: • As initial therapy in combination with an aromatase inhibitor or fulvestrant **OR** • Used as subsequent therapy in combination with fulvestrant The following is an **exception** to the step therapy requirement:	There must be a contraindication to Kisqali **AND** Verzenio

	• If the request is for use in combination with Itovebi (inavolisib) and fulvestrant for treatment of endocrine-resistant, *PIK3CA*-mutated, hormone receptor (HR)-positive, human epidermal growth-factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.	
Imbruvica (ibrutinib) 140 mg and 280 mg tablets	For all FDA approved, and compendia supported indications	Requests for Imbruvica 140mg tablets or 280mg tablets will **NOT** be approved unless there is a contraindication to Imbruvica 140mg capsules. This applies to both initial and continuation of therapy/recertification requests
Imbruvica (ibrutinib) oral suspension	For all FDA approved, and compendia supported indications	Requests for Imbruvica oral suspension will require use of Imbruvica capsules or tablets (NOTE: criteria must be met for 140 mg and 280 mg tablet) unless the request is for patients aged 1 to less than 12 years for the treatment of cGVHD
Imkeldi (imatinib) oral solution	For all FDA approved, and compendia supported indications	For individuals 18 years of age and older, requests for Imkeldi oral solution require documentation of a medical reason why imatinib tablets cannot be used.
Inrebic (fedratinib)	For all FDA approved, and compendia supported indications	Must have had serious side effects or drug failure with Jakafi (ruxolitinib)
Iressa (gefitinib)	For all FDA approved, and compendia supported indications	Requests for brand name Iressa will require documentation of a medical reason why gefitinib cannot be used.
Mekinist (trametinib) oral solution	For all FDA approved, and compendia supported indications	**For individuals weighing 26 kg or greater**, requests for Mekinist oral solution require documentation of a medical reason why Mekinist tablets cannot be used
Nexavar (sorafenib)	For all FDA approved, and compendia supported indications	Requests for brand name Nexavar will require documentation of a medical

		reason why sorafenib cannot be used
Orserdu (elacestrant)	For a diagnosis of unresectable recurrent, or metastatic breast cancer that is hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated disease (Note: See Drug Specific Criteria section for full criteria)	Must have had prior treatment include a CDK4/6 inhibitor (i.e., Ibrance, Kisqali, Verzenio)
Orgovyx (relugolix)	For castration-sensitive prostate cancer	Must have a medical reason why alternative GnRH (LHRH) receptor antagonist degarelix [Firmagon] or GnRH agonists (such as leuprolide [Lupron], goserelin [Zoladex], triptorelin [Trelstar], and histrelin [Vantas]) cannot be used (e.g., high risk for cardiovascular [CV] events or a history of a CV event)
Scemblix (asciminib)	For Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) with the T315I mutation	Must have adequate medical justification as to Iclusig (ponatinib) cannot be used
Sprycel (dasatinib)	For all FDA approved, and compendia supported indications	Requests for brand name Sprycel will require documentation of a medical reason why dasatinib cannot be used
Sutent (sunitinib)	For all FDA approved, and compendia supported indications	Requests for brand name Sutent will require documentation of a medical reason why sunitinib cannot be used
Tafinlar (dabrafenib) tablets for oral suspension	For all FDA approved, and compendia supported indications	**For individuals weighing 26 kg or greater**, requests for Tafinlar tablets for oral suspension require documentation of a medical reason why Tafinlar capsules cannot be used
Tarceva (erlotinib)	For all FDA approved, and compendia supported indications	Requests for brand name Tarceva will require documentation of a medical reason why erlotinib cannot be used
Targretin (bexarotene) capsules	For all FDA approved, and compendia supported indications	Requests for brand name Targretin capsules will require documentation of a medical reason why bexarotene capsules cannot be used

Targretin (bexarotene) gel	For all FDA approved, and compendia supported indications	Requests for brand name Targretin gel will require documentation of a medical reason why bexarotene gel cannot be used
Tykerb (lapatinib)	For all FDA approved, and compendia supported indications	Requests for brand name Tykerb will require documentation of a medical reason why lapatinib cannot be used
Votrient (pazopanib)	For all FDA approved, and compendia supported indications	Requests for brand name Votrient will require documentation of a medical reason why pazopanib cannot be used
Yonsa (abiraterone acetate, micronized)	For metastatic castration-resistant prostate cancer	Must have had serious side effects with abiraterone acetate **AND** Xtandi(enzalutamide)
Zytiga (abiraterone acetate)	For metastatic castration-resistant prostate cancer	Must have had serious side effects with abiraterone acetate **AND** Xtandi (enzalutamide)
	For metastatic high-risk castration-sensitive prostate cancer	Must have had serious side effects with abiraterone acetate, Nubeqa (darolutamide) in combination with docetaxel, **AND** Xtandi (enzalutamide)

TABLE 3. DRUGS WITH QUANTITY LIMIT REQUIREMENTS:

For drugs with specific criteria, applicable quantity limits will be included in the Drug Specific Criteria table.

Drug Name	Quantity Limit
Afinitor, everolimus tablets Afinitor Disperz, everolimus tablets for oral suspension	30 tablets/30 days for all strengths. Requests for everolimus 5 mg at a quantity of 60/30 require adequate justification as to why everolimus 10 mg cannot be used.
Akeega (niraparib tosylate monohydrate and abiraterone acetate)	60 tablets/30 days
Alecensa (alectinib)	240 capsules/30 days
Alunbrig (brigatinib)	30 mg: 120 tablet/30 days 90 mg and 180 mg: 30 tablets/30 days
Augtyro (repotrectinib)	160 mg: 60 capsules/30 days 40mg: 240 capsules/30 days
Avmapki Fakzynja co-pack (avutometinib potassium and defactinib hydrochloride)	1 co-pack (24 avutometinib capsules and 42 defactinib tablets)/ 28 days
Ayvakit (avapritinib)	30 tablets/30 days
Balversa (erdafitinib)	5mg: 28 tab/28 days 4mg: 56 tab/28 days 3mg: 84 tab/28 days

Besremi (ropeginterferon alfa-2b-njft)	2 syringes per 28 days
Braftovi (encorafenib)	50 mg: 120 capsules/30 days 75 mg: 180 capsules/30 days
Brukinsa (zanubrutinib)	120 capsules/30 days
Bosulif (bosutinib)	100 mg: 60 tablets/30 days 400 mg: 30 tablets/30 days 500 mg: 30 tablets/30 days
Cabometyx (cabozantinib tablets)	30 tablets/30 days
Calquence (acalabrutinib)	60 capsules or tablets/ 30 days
Caprelsa (vandetanib)	100 mg:60 tablets/30 days 300mg: 30 tablets/30 days
Cometriq (cabozantinib capsules)	140 mg capsule kit: 120 capsules/30 days 100 mg capsule kit: 60 capsules/30 days 60 mg capsule kit: 90 capsules/30 days
Copiktra (duvelisib)	60 capsules/30 days
Cotellic (cobimetinib)	63 tablets/28 days.
Daurismo (glasdegib)	100 mg: 30 tablets/30 days 25 mg: 60 tablets/30 days
Danziten (nilotinib)	112 tablets/28 days
Erivedge (vismodegib)	30 capsules/30 days. A quantity exception may be granted for a diagnosis of medulloblastoma, which would be limited to a quantity of 60 capsules/30 days.
Erleada (apalutamide)	60 mg: 120 tablets/30 days 240 mg: 30 tablets/30 days
Fotivda (tivozanib)	21 capsules/28 days
Fruzaqla (fruquintinib)	5 mg: 21 capsules/28 days 1 mg: 84 capsules/28 days
Gavreto (pralsetinib)	120 capsules/30 days
Gilotrif (afatinib)	30 tablets/30 days.
Gomekli (mirdametinib)	1 mg capsule and 1 mg tablet for oral suspension: 168 capsules or soluble tablets/28 days 2 mg capsules: 84 capsules/28 days
Ibrance (palbociclib)	21 tablets per 28 days
Iclusig (ponatinib)	30 tablets/30 days
Idhifa (enasidenib)	30 tablets/30 days
Imbruvica (ibrutinib)	• Imbruvica 70mg Capsule and 140mg, 280mg, and 420 mg tablet: 30 tablets/30 days. a. Quantity limit exceptions for **70 mg capsule** will require the following: i. The patient is age 1 to less than 12 years of age **AND** ii. The patient has a diagnosis of chronic graft versus host disease (cGVHD) **AND** iii. There must be adequate medical justification as to why the Imbruvica oral suspension cannot be used • Imbruvica 140mg Capsule: 90 capsules/30 days. a. To allow for a 560 mg daily dose, a quantity limit exception for the **140 mg capsules** may be granted for 120 capsules/ 30 days • Imbruvica oral suspension: 108 mL (1 bottle)/30 days

	a. Upon each review and dose escalation request, the allowed quantity will be reviewed in accordance with the FDA-approved BSA-based dosing and, as such, will be limited to the minimum number of whole bottles to obtain the appropriate dose/day supply.
Imkeldi (imatinib) oral solution	140 mL(1 bottle) per 28 days a. Quantity limits will be reviewed in accordance with the FDA-approved BSA-based dosing and as such, will be limited to the minimum number of full bottles to obtain the appropriate daily dose.
Inlyta (axitinib)	5 mg: 120 tablets/30 days 1mg: 240 tablets/30 days
Inqovi (decitabine/cedazuridine)	5 tablets/28 days
Inrebic (fedratinib)	120 capsules/30 days
Iressa and generic gefitinib	30 tablets/30 days
Itovebi inavolisib)	3 mg: 56 tablets/28 days 9 mg: 28 tablets/28 days
Iwilfin (eflornithine)	240 tablets/30 days
Jakafi (ruxolitinib)	60 tablets/30 days
Jaypirca (pirtobrutinib)	50 mg: 30 tablets/30 days 100 mg: 60 tablets/30 days
Kisqali (ribociclib)	63 capsules per 28 days
Koselugo (selumetinib)	10 mg: 240 capsules/30 days 25 mg: 120 capsules/30 days
Krazati (adagrasib)	180 tablets/30 days
Lazcluze (lazertinib)	80 mg: 60 tablets/30 days 240 mg: 30 tablets/30 days
Lenvima (lenvatinib)	24 mg pack: 90 capsules/30 days 20 mg pack: 60 capsules/30 days 18 mg pack: 90 capsules/30 days 14 mg pack: 60 capsules/30 days 12 mg pack: 90 capsules/30 days 10 mg pack: 30 capsules/30 days 8 mg pack: 60 capsules/30 days 4 mg pack: 30 capsules/30 days
Lonsurf (trifluridine and tipiracil)	15 mg/6.14mg: 100 tablets/28 days 20 mg/8.19mg: 80 tablets/28 days
Lorbrena (lorlatinib)	100 mg: 30 tablets/30 days 25 mg: 90 tablets/30 days
Lumakras (sotorasib)	120 mg: 240 tablets/30 days 240 mg: 120 tablets/30 days 320 mg: 90 tablets/30 days
Lynparza Tablets (olaparib tablets)	120 tablets/30 days
Lytgobi (futibatinib)	20 mg daily dose: 140 tablets/28 days 16 mg daily dose: 112 tablets/28 days 12 mg daily dose: 84 tablets/28 days

Mekinist (trametinib)	0.5 mg: 90 tablets/30 days 2 mg: 30 tablets/30 days Oral solution: 540 mL/30 days a. Quantity limits for Mekinist oral solution will be reviewed in accordance with the FDA-approved weight-based dosing and as such, will be limited to the minimum number of full bottles to obtain the appropriate daily dose. [See Drugs with Step Therapy Requirements table for additional details]
Mektovi (binimetinib)	180 tablets/30 days
Nerlynx (neratinib)	180 tablets/30 day
Nexavar and generic sorafenib	120 tablets/30 days
Ninlaro (ixazomib)	3 capsules/28 days
Nubeqa (darolutamide)	120 tablets/30 days
Odomzo (sonidegib)	30 capsules/30 days
Ogsiveo (nirogacestat)	50 mg:180 tablets/30 days 100 mg and 150 mg: 60 tablets/30 days
Ojjaara (momelotinib)	30 tablets/ 30 days
Ojemda (tovorafenib)	Tablets: 24 tablets/28 days Oral suspension: 48 mL (4 bottles)/28 days • For individuals requiring greater than 300 mg per week, a quantity limit exception of 96 mL (8 bottles)/28 days will be authorized.
Onureg (oral azacitidine)	14 tablets/28 days
Orgovyx (relugolix)	32 tablets/30 days
Orserdu (elacestrant)	345 mg: 30 tablets/30 days 86 mg: 90 tablets/30 days
Pemazyre (pemigatinib)	14 tablets/21 days for all strengths
Piqray (alpelisib)	300mg/day pack and 250mg/day pack: 56 tablets/28 days 200mg/day pack: 28 tablets/28 days
Pomalyst (pomalidomide)	21 tablets/28 days.
Qinlock (ripretinib)	90 tablet/30 days
Retevmo (selpercatinib)	40 mg: 180 capsules/30 days 80 mg: 120 capsules/30 days
Rezlidhia (olutasidenib)	60 capsules/30 days
Rezurock (belumosudil)	30 tablets/30 days a. For individuals on a proton pump inhibitor (PPI), documentation must be provided as to why the patient cannot be transitioned to an H2 blocker or tapered off the PPI before an exception will be granted for a quantity of 60 tablet/30 days b. An exception may be granted for a quantity of 60 tablets/30 days if Rezurock will be co-administered with a strong CYP3A inducers (i.e., rifampin)
Revuforj (revumenib)	110 mg strength: 120 tablets/30 days 160 mg strength: 60 tablets/30 days 25 mg strength: 240 tablets/30 days
Romvimza (vimseltinib)	8 capsules/28 days
Rozlytrek (entrecetinib)	100mg: 30 capsules/30 days a. Pediatric patients with NTRK gene fusion positive solid tumors and BSA 1.11-1.50m^2 can be approved for a quantity Limit of 150 capsules/30 days for 100mg capsules

	200 mg: 90 capsules/30 days 50 mg oral pellets: 42 packets/21 days a. Quantity limits for Rozlytrek oral pellets will be reviewed in accordance with FDA-approved BSA-based dosing and as such be limited to the minimum number of packets (each packet contains 50 mg entrectinib) to obtain the appropriate daily dose.
Rubraca (rucaparib)	120 tablets/30 days
Rydapt (midostaurin)	240 capsules/30 days
Scemblix (asciminib)	100 mg: 120 tablets/30 days 20 mg and 40 mg: 60 tablets per 30 days. • A quantity limit may be granted for a diagnosis of Ph+ CML in CP with the T315I mutation to manage adverse reactions, which would be limited to a quantity of 240 tablets per 30 days for the 40 mg strength tablet.
Soltamox (tamoxifen citrate)	300 mL/ 30 days
Sprycel (dasatinib) and generic dasatinib	20 mg: 120 tablets/30 days 50 mg, 70 mg, 80 mg, 100 mg, 140 mg: 60 tablets/30 days
Stivarga (regorafenib)	84 tablets/28 days
Sutent and generic sunitinib	12.5 mg: 90 capsules/30 days 25 mg, 37.5 mg, 50 mg: 30 capsules/30 days
Tabrecta (capmatinib)	112 tablets/28 days
Tafinlar (dabrafenib)	50 mg: 300 capsules/30 days 75 mg: 120 capsules/30 days 10 mg tablets for oral suspension: 420 tablets/30 days. a. Quantity limits for Tafinlar tablets for oral suspension will be reviewed in accordance with the FDA-approved weight-based dosing and as such, will be limited to the minimum number of full bottles to obtain the appropriate daily dose. [See Drugs with Step Therapy Requirements table for additional details]
Tagrisso (osimertinib)	30 tablets/30 days a. For the 80 mg strength, if the patient is taking a strong CYP3A inducers, a quantity limit exception may be granted to allow for 60 tablets/30 days to achieve a daily dose of 160 mg.
Talzenna (talazoparib)	30 capsules/30 days
Tarceva and generic erlotinib	30 tablets/30 days
Targretin and bexarotene capsules	300 capsules/30 days
Targretin gel and bexarotene gel	240 grams/30 days
Tasigna and generic nilotinib	50 mg: 120 capsules/30 days 150 mg and 200 mg: 112 capsules/28 days
Tazverik (tazemetostat)	240 tablets/30 days
Tepmetko (tepotinib)	60 tablets/30 days
Tibsovo (ivosidenib)	60 tablets/30 days
Torpenz (everolimus)	30 tablets/30 days
Truqap (capivasertib)	64 tablets/28 days
Tukysa (tucatinib)	50 mg: 240 tablets/30 days 150 mg: 120 tablets/30 days
Turalio (pexidartinib)	120 capsules/30 days

Tykerb and generic lapatinib	180 tablets/30 days
Valchlor (mechlorethamine)	60 grams/30 days
Vanflyta (quizartinib)	56 tablets/28 days
Venclexta (venetoclax)	Starting pack: 42 tablets/28 days 50mg: 224 tablets/28 days 100mg: 112 tablets/28 days. a. Please note: a quantity limit exception of 168 tablets/28 days for the 100 mg tablet may be approved for the treatment of AML in combination with low dose cytarabine.
Verzenio (abemaciclib)	60 tablets/30 days
Vitrakvi (larotrectinib)	100mg: 60 capsules/30 days 25 mg: 90 capsules/30 days 20 mg/mL solution: 300mL/30 days
Vizimpro (dacomitinib)	30 tablets/30 days
Vonjo (pacritinib)	120 capsules/30 days
Voranigo (vorasidenib)	10 mg: 60 tablets/30 days 40 mg: 30 tablets/30 days
Votrient and generic pazopanib	120 tablets/30 days
Welireg (belzutifan)	90 tablets/30 days
Xalkori (crizotinib)	Tablets: 200 mg and 250 mg tablets: 60 tablets/30 days. A quantity exception may be granted for a diagnosis of anaplastic large cell lymphoma (ALCL), which would be limited to a quantity of 120 tablets/30 days. Oral pellets in dispensing capsules: 20 mg: 240 capsules/30 days 50 mg: 120 capsules/30 days 150 mg:180 capsules/30 days
Xermelo (telotristate ethyl)	90 tablets/30 day
Xospata (gileritinib)	90 tablets/30 days
Xpovio (selinexor)	• 80 mg twice weekly (160 mg weekly) dose carton (20 mg strength tablet):32 tablets/28 days • 80 mg weekly dose carton (40 mg strength tablet): 8 tablets/28 days • 60 mg twice weekly (120 mg weekly) dose carton (20 mg strength tablet):24 tablets/28 days • 60 mg weekly dose carton (60 mg strength tablet): 4 tablets/28 days • 100 mg weekly dose carton (20 mg strength tablet): 20 tablets/28 days • 100 mg weekly carton (50 mg strength tablet): 8 tablets/28 days • 40 mg twice weekly or 80 mg weekly dose carton (20 mg strength tablet):16 tablets/28 days • 40 mg twice weekly dose carton (40 mg strength tablet): 8 tablet/28 days • 40 mg weekly dose carton (40 mg strength tablet): 4 tablets/ 28 days • 60 mg weekly dose carton (20 mg strength tablet): 12 tablets/28 days • 40 mg weekly dose carton (20 mg strength tablet): 8 tablets/28 days • 40 mg weekly dose carton (10 mg strength tablet): 16 tablets/28 days
Xtandi (enzalutamide)	40 mg: 120 /30 days (capsules and tablets) 80 mg: 60 tablets/30 days

Yonsa (abiraterone acetate, micronized)	120 tablets/30 days. A quantity limit of 240 tablets/30 days will be allowed if documentation is received that a strong CYP3A4 inducer must be co-administered.
Zejula (niraparib)	90 capsules/30 days 30 tablets/30 days
Zelboraf (vemurafenib)	240 tablets/30 days
Zolinza (vorinostat)	120 capsules/30 days or 136 capsules/34 days
Zydelig (idelalisib)	60 tablets/30 days
Zykadia (ceritinib)	90 capsules/30 days
Zytiga (abiraterone acetate)	250 mg: 120 tablets/30days 500mg: 60 tablets/30 days

TABLE 4. DRUG SPECIFIC APPROVAL TIMEFRAMES:

Drug Name	Initial Approval	Continued Approval
Lonsurf (trifluridine and tipiracil)	3 months	3 months
Besremi (ropeginterferon alfa-2b-njft)	12 months	12 months

TABLE 5. DRUGS WITH MAXIMUM DURATION OF THERAPY BASED ON DIAGNOSIS:

Drug Name	Diagnosis	Maximum Duration of Therapy
Lynparza Tablets (olaparib tablets)	Adjuvant treatment in patients with deleterious or suspected germline BRCA-mutated HER2-negative high risk early breast cancer	12 months
Nerlynx (neratinib)	Early stage of HER2-positive breast cancer	12 months
Iwilfin (eflornithine)	High-risk neuroblastoma (HRNB) in individuals who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy	2 years

TABLE 6. DRUGS COVERED IN SPLIT FILL PROGRAM:

For applicable lines of businesses (Commercial, Exchange, Child Health Plus), a split-fill program **will apply to new starts only** for the drugs listed below. An override to bypass the split-fill program will be provided for existing users that have been maintained on the drugs listed below.
ABIRATERONE ACETATE 500 MG TABLET AYVAKIT BALVERSA BESREMI BEXAROTENE CAPSULES BRAFTOVI CABOMETYX DAURISMO DASATINIB ERLOTINIB HCL EXKIVITY GAVRETO INLYTA INREBIC IWILFIN JAYPIRCA

KRAZATI
LAZCLUZE
LENVIMA
LORBRENA
LUMAKRAS
LYNPARZA
MEKTOVI
NEXAVAR
NUBEQA
ODOMZO
OGSIVEO
PIQRAY 250 MG AND 300 MG
PAZOPANIB
RETEVMO
REVUFORJ
REZLIDHIA
ROZLYTREK
RUBRACA
SORAFENIB
SPRYCEL
TABRECTA
TALZENNA
TARCEVA
TARGRETIN CAPSULES
TEPMETKO
TIBSOVO
TURALIO
VERZENIO
VITRAKVI
VIZIMPRO
VONJO
VOTRIENT
XPOVIO
XTANDI
YONSA
ZYTIGA

IMPORTANT INFORMATION ON ACCELERATED APPROVALS:

Please refer to the following FDA websites for up-to-date information on ongoing, verified, and withdrawn accelerated approval indications:

Ongoing Cancer Accelerated Approvals:
https://www.fda.gov/drugs/resources-information-approved-drugs/ongoing-cancer-accelerated-approvals

Verified Clinical Benefit Cancer Accelerated Approvals:
https://www.fda.gov/drugs/resources-information-approved-drugs/verified-clinical-benefit-cancer-accelerated-approvals

Withdrawn Cancer Accelerated Approvals*:
https://www.fda.gov/drugs/resources-information-approved-drugs/withdrawn-cancer-accelerated-approvals
*Note: Individuals currently receiving treatment for a withdrawn indication should consult with their healthcare provider whether to remain on treatment. Continued coverage for treatment of a withdrawn indication will only be considered should the patient be established on therapy prior to the withdrawal date listed on the FDA website.

UPDATES:

Date:	Revision:
06/13/2025	Revised
05/08/2025	Reviewed / P&T Committee Approval
04/01/2025	Revised
03/13/2025	Revised
03/06/2025	Revised
02/06/2025	P&T Committee Review & Approval
02/03/2025	Revised
01/28/2025	Revised
01/09/2025	Revised
01/01/2025	Revised
12/06/2024	Revised
11/25/2024	Revised
11/21/2024	Review / P&T Committee Approval
11/06/2024	Revised
11/01/2024	Revised
09/25/2024	Revised
08/21/2024	Revised
05/30/2024	Revised
03/11/2024	Revised
02/08/2024	Reviewed / P&T Committee Approval
01/2024	Revised
12/2023	Revised
11/2023	Revised
10/2023	Revised
09/2023	Revised
08/2023	Revised
07/2023	Revised
06/2023	Revised
05/2023	Revised
04/2023	Revised
03/2023	Revised
02/2023	P&T Committee Approval
01/2023	Revised
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11/2022	Revised
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07/2022	Revised
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3/2022	Revised
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11/2021	Revised
10/2021	Revised
9/2021	Revised
8/2021	Revised

7/2021	Revised
6/2021	Revised
4/2021	Revised
3/2021	Revised
2/2021	Revised / P&T Committee Approval
01/2021	Revised
12/20	Revised
11/20	Revised
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9/20	Revised
6/20	Revised
5/20	Revised
4/20	Revised
2/20	Revised
1/20	Revised
12/19	Revised
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10/17	Revised
8/17	Revised
6/17	Revised
5/17	Revised
4/17	Revised
3/17	Revised
1/17	Revised
11/16	Revised
10/16	Revised
9/16	Revised
8/16	Revised
7/16	Revised
6/16	Revised
5/16	Revised
4/16	Revised
3/16	Revised

2/16	Revised
1/16	Revised
12/15	Revised
11/15	Revised
10/15	Revised
8/15	Revised
7/15	Revised
6/15	Revised
5/15	Revised
3/15	Revised
2/15	Revised
1/15	Revised
11/14	Revised
10/14	Revised
9/14	Revised
8/14	Revised
7/14	Revised
6/14	Revised
5/14	Revised
10/13	Initial Policy Effective Date

REFERENCES:

In addition to the full prescribing information for each individual drug and NCCN Drugs and Biologic Compendium, the following references have been utilized in creating drug specific criteria:

Afinitor-
1. FDA approve first drug formulated for children with rare brain tumor. FDA News Release. August 2012. Available at: http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm317385.html

Nexavar-
1. Llovet J, et al. "Sorafenib improves survival in advanced Hepatocellular Carcinoma (HCC): Results of a Phase III randomized placebo-controlled trial (SHARP trial)". Proceedings from the 2007 annual meeting of the American Society of Clinical Oncology. Late-breaking Abstract (LBA) #1.

Tarceva-
1. Pham D., et al. Use of cigarette-smoking history to estimate the likelihood of mutations in epidermal growth factor receptor gene exons 19 and 21 in lung adenocarcinomas. Journal of Clinical Oncology. April 10, 2006; 24(11):1700-1704.
2. Black J, Houghton WC. Sodium Oxybate improves excessive daytime sleepiness in narcolepsy. Sleep. July 2006; 29(7):939-46.

Xalkori-
1. Triano L, Deshpande H, Gettinger S. Management of Patients with Advanced Non-Small Cell Lung Cancer. *Drugs* 2010; 70(2):167-179

Zelboraf-
1. Chapman P, Hauschild A, Robert C et al. Improved Survival with Vemurafenib in Melanoma with BRAF V600E Mutation. New England Journal of Medicine 2011; 364(26): 2507-2516.