Pharmacy Drug Policy

SUBJECT: Oncology Clinical Review Prior Authorization (CRPA) Rx Drug Policy
POLICY NUMBER: PHARMACY-33
EFFECTIVE DATE: 10/2013
LAST REVIEW DATE: 11/1/2026

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 are 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 (Pharmacy benefit only). 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 ongoing revision. Newly marketed drugs and existing drugs with new indications may be subject to prior authorization until formal coverage criteria are established. Inclusion of a drug in this policy does not guarantee its current availability on the market, as some agents may be discontinued, withdrawn, or otherwise unavailable. As product status changes, drugs may be removed from the policy.
3. Utilization Management is contract dependent. Refer to specific contract/benefit language for exclusions.
    a. Coverage criteria may be dependent on the contract renewal date.
    b. Coverage of drugs listed in this policy are contract dependent.
    c. Not all contracts/benefits allow coverage of healthcare professional administered drugs as part of their pharmacy benefit
    d. Not all contracts/benefits cover all medical infusible drugs.
4. Clinical documentation must be submitted for each request (initial and recertification [if applicable]) unless otherwise specified (e.g., provider attestation required). Supporting documentation includes, but is not

limited to, progress notes documenting previous treatments and treatment history, diagnostic testing, laboratory test results, genetic testing or biomarker results, imaging, and other objective or subjective measures of clinical benefit. For recertification, continued approval requires documentation demonstrating that the requested product is providing ongoing benefit to the patient, evidenced by improvement or stability in the disease state or condition, and that continued use remains medically necessary. Ongoing use of the requested product must continue to align with the current policy's preferred formulary. Recertification reviews may result in a requirement to trial more cost-effective treatment alternatives as they become available (e.g., generics, biosimilars, or other guideline-supported treatment options). Requested dosing must remain consistent with FDA-approved or off-label/guideline-supported dosing recommendations.

5. 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.
6. 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.
7. 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.
8. This policy is based on available evidence as of the last review date. Coverage determinations are subject to applicable plan documents, state and federal regulations, and individual patient circumstances. This policy does not constitute medical advice.
9. For commercial contracts, medical necessity determinations align with the Certificate of Coverage issued by the Health Plan, which states that covered services must be clinically appropriate and not primarily for the convenience of the member, the member's family, or the provider.
10. Unless otherwise stated within **Table 4. Drug Specific Approval Timeframes**, approval time periods are listed in the table below.

Approval time periods

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

11. Approval timeframes may be extended to align authorization periods for drugs administered as part of a multidrug regimen, including when regimen components are administered across different benefits. This provision does not apply when the approval timeframe reflects a drug-specific limitation on duration of therapy.

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) • Beqalzi (sonrotoclax) • Besremi (ropeginterferon alfa-2b-njft) (**NOTE**: both Rx and Medical benefit drug) • Bosulif (bosutinib) • Bosutinib (generic Bosulif) • Braftovi (encorafenib) • Brukinsa (zanubrutinib) • Cabometyx (cabozantinib tablets) • Calquence (acalabrutinib) • Caprelsa (vandetanib) • Cavhanza (nilotinib ODT) • Cometriq (cabozantinib capsules) • Copiktra (duvelisib) • Cotellic (cobimetinib) • Daurismo (glasdegib) • Danziten (nilotinib) • Ensacove (ensartinib) • Erivedge (vismodegib) • Erleada (apalutamide) • Erlotinib (generic Tarceva) • Etcamah (camizestrant) • Fotivda (tivozanib) • Fruzaqla (fruquintinib) • Gavreto (pralsetinib) • Gilotrif (afatinib) • Gomekli (mirdametinib) • Hemady (dexamethasone) • Hernexeos (zongertinib) • Hyrnuo (sevabertinib) • Ibrance (palbociclib) • Ibtrozi (taletrectinib adipate) • Iclusig (ponatinib) • Idhifa (enasidenib) • Imbruvica (ibrutinib) • Imkeldi (imatinib) • Inluriyo (imlunestrant tosylate) • Inlyta (axitinib) • Inqovi (decitabine/cedazuridine) • Inrebic (fedratinib)

- Iressa (gefitinib)
- Gefitinib (generic Iressa)
- Itovebi (inavolisib)
- Iwilfin (eflornithine)
- Jaypirca (pirtobrutinib)
- Jakafi (ruxolitinib)
- Jakafi XR (ruxolitinib ER)
- Jideytro (zidesamtinib)
- Kisqali (ribociclib)
- Komzifti (ziftomenib)
- Koselugo (selumetinib)
- Krazati (adagrasib)
- Lazcluze (lazertinib)
- Lenvima (lenvatinib)
- Lifyorli (relacorilant)
- Lonsurf (trifluridine and tipiracil)
- Lorbrena (lorlatinib)
- Lumakras (sotorasib)
- Lynparza tablets (olaparib tablets)
- Lytgobi (futibatinib)
- Mekinist (trametinib)
- Mektovi (binimetinib)
- Mimrylo (rusfertide acetate)
- Modeyso (dordaviprone hcl)
- 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)
- Phyrago (dasatinib)
- Piqray (alpelisib)
- Pomalyst (pomalidomide)
- Pomalidomide (generic for Pomalyst)
- Purixan (6-mercaptopurine)
- Mercaptopurine oral suspension (generic Purixan)
- Qinlock (ripretinib)
- Rasonque (daraxonrasib)
- 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)
- Tasigna (nilotinib)
- Nilotinib hcl (generic Tasigna)
- Nilotinib tartrate
- Targretin capsules (bexarotene capsules)
- Bexarotene capsules (generic Targretin capsules)
- Targretin gel (bexarotene gel)
- Bexarotene gel (generic 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)
- Veppanu (vepdegestrant)
- 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)
- Zegfrovy (sunvozertinib)
- Zejula (niraparib)
- Zelboraf (vemurafenib)
- Zenbexus (iberdomide)
- 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
Etcamah (camizestrant)
1. Must be 18 years of age or older AND 2. Must be prescribed by, or in consultation with an oncologist AND 3. Must have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epithelial growth receptor 2 (HER2)-negative AND 4. Must meet one of the following (a or b): a. Must be designated female at birth and must be post-menopausal or pre-menopausal/peri-menopausal treated with ovarian ablation/suppression OR b. Must be designated male at birth 5. Must have received ≥ 6 months of therapy with an aromatase inhibitor plus CDK4/6 inhibitor therapy in the front-line setting AND 6. Must have an ESR1 mutation detected via ctDNA using an FDA-authorized test AND 7. Must NOT have evidence of disease progression at the time of the *ESR1* mutation detection AND 8. Will use Etcamah in combination with a CDK4/6 inhibitor. 9. NOTE: Pre-menopausal and Peri-menopausal individuals with ovarian ablation or suppression should be treated as post-menopausal individuals. Individual designated male at birth with breast cancer should be treated similarly to post-menopausal individuals, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis. 10. Recommended dosing is 75 mg orally once daily. 11. Quantity limit is 28 tablets/28 days.
Hernexeos (zongertinib)
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 Hernexeos (zongertinib) following disease progression on Hyrnuo (sevabertinib) will be considered experimental and investigational and will be subject to an off-label review.
Hyrnuo (sevabertinib)
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 Hyrnuo (sevabertinib) following disease progression on Hernexeos (zongertinib) will be considered experimental and investigational and will be subject to an off-label review.

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.

Inluriyo (imlunestrant tosylate)

1. Must be prescribed by, or in consultation with, an oncologist **AND**
2. Must have a diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive human epidermal growth factor receptor 2 (HER2)-negative **AND**
3. Must be 18 years of age or older **AND**
4. Must have confirmed *ESR1*-mutated disease **AND**
5. Must meet one of the following (a or b):
   a. Must be designated female at birth and must be post-menopausal or pre-menopausal/peri-menopausal treated with ovarian ablation/suppression **OR**
   b. Must be designated male at birth **AND**
6. Must meet one of the following (a or b):
   a. If using as monotherapy, must have progressed following standard first-line therapy with at least one line of an aromatase inhibitor and a CDK4/6 inhibitor OR
   b. If using in combination with abemaciclib (Verzenio), must have progressed following therapy with at least one line of endocrine therapy with or without a CDK4/6 inhibitor
7. Patient must not have progressed on treatment with another selective estrogen receptor degrader (SERD)
8. NOTE: Pre-menopausal and Peri-menopausal individuals with ovarian ablation or suppression should be treated as post-menopausal individuals. Individuals designated male at birth with breast cancer should be treated similarly to post-menopausal individuals, except that use of an aromatase inhibitor is ineffective without concomitant suppression of testicular steroidogenesis.
9. Quantity limit: 56 tablets/28 days

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.

Komzifti (ziftomenib)

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 Komzifti (ziftomenib) following disease progression on another menin inhibitor will be considered experimental and investigational and will be subject to an off-label review.
   b. Komzifti must be given as monotherapy

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.

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.

Mimrylo (rusfertide)

1. Must be prescribed by or in consultation with a hematologist or oncologist **AND**
2. Must be 18 years of age or older **AND**
3. Must have a confirmed diagnosis of polycythemia vera (PV) **AND**
4. Requires therapeutic phlebotomy to maintain hematocrit < 45% **AND**
5. Must meet ONE of the following (a, b, or c):
   a. Requires ≥ 3 phlebotomies within 6 months; **OR**
   b. Requires ≥ 5 phlebotomies within 12 months; **OR**
   c. Has documented intolerance to therapeutic phlebotomy
6. Must meet ONE of the following:
   a. Patient is receiving stable cytoreductive therapy and continue to require therapeutic phlebotomy; **OR**
   b. Patient experienced inadequate response, intolerance, or contraindication to cytoreductive therapy; **OR**
   c. Per provider's assessment, cytoreductive therapy is not clinically appropriate for the patient
7. Quantity Limits:
   a. 9.5 mg, 19 mg and 28 mg vials: 4 vials per 28 days
   b. 41 mg and 57 mg vials: 8 vials per 28 days

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, or in consultation with, an oncologist **AND**
2. Must have diagnosis of advanced or metastatic breast cancer that is hormone receptor-positive and human epidermal growth factor receptor 2 (HER2)-negative **AND**
3. Must be 18 years of age or older **AND**
4. Must have confirmed *ESR1*-mutated disease **AND**
5. Must meet one of the following (a or b):

a. Must be designated female at birth and must be post-menopausal or premenopausal/perimenopausal treated with ovarian ablation/suppression **OR**
b. Must be designated male at birth **AND**

6. Must have progressed following standard first-line therapy with at least one line of an aromatase inhibitor and a CDK4/6 inhibitor **AND**
7. Must be used as monotherapy **AND**
8. Patient must not have progressed on treatment with another selective estrogen receptor degrader (SERD)
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

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.

Revuforj (revumenib)

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 Revuforj (revumenib) following disease progression on another menin inhibitor will be considered experimental and investigational and will be subject to an off-label review.
    b. Revuforj must be given as monotherapy
    c. See Step Therapy table for requirement for adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation

Tazverik (tazemetostat)

As of March 10, 2026, Ipsen has withdrawn Tazverik from the market for all approved indications following safety concerns emerging from an ongoing trial. Based on this announcement, The Health Plan will not authorize coverage of Tazverik for new patients or existing users.

Veppanu (vepdegestrant)

1. Must be prescribed by or in consultation with an oncologist **AND**
2. Must have a diagnosis of advanced or metastatic breast cancer that is hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative **AND**
3. Must be 18 years of age or older **AND**
4. Must have confirmed *ESR1*-mutated disease **AND**
5. Must meet one of the following (a or b):
    a. Must be designated female at birth and must be post-menopausal or premenopausal/peri-menopausal treated with ovarian suppression **OR**
    b. Must be designated male at birth **AND**
6. Must have progressed following at least one line of endocrine therapy and a cyclin-dependent-kinase (CDK) 4/6 inhibitor (Kisqali and Verzenio are the Health Plan's preferred CDK4/6 inhibitors) **AND**
7. Must be used as monotherapy **AND**

8. Patient must not have progressed on treatment with a selective estrogen receptor degrader (SERD) 9. NOTE: Pre-menopausal and post-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: 30 tablets/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. i. This does not apply when Verzenio is used in combination with imlunestrant (Inluriyo).

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
Cavhanza (nilotinib ODT)	For all FDA approved, and compendia supported indications	Must be a contraindication to the use of generic nilotinib Hcl capsules
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	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 **OR** • Low-volume synchronous 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: • 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.	There must be a contraindication to Kisqali **AND** Verzenio
Inluriyo (imlunestrant)	For a diagnosis of advanced 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)	For use as monotherapy, must have progressed following standard first-line therapy with at least one line of an aromatase inhibitor and a CDK4/6 inhibitor (i.e., Ibrance, Kisqali, Verzenio)
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.
Jakafi XR (ruxolitinib ER)	For all FDA approved, and compendia supported indications	Must have had serious side effects or drug failure with Jakafi (ruxolitinib). Use of Jakafi XR to reduce treatment burden (for convenience), in the absence of such clinical factors, does not meet medical necessity criteria and will not be authorized.
Koselugo (selumetinib) oral granules	For all FDA approved, and compendia supported indications	Requests for Koselugo oral granules will require documentation indicating why patient cannot use capsules or documentation of reason for difficulty swallowing.
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 advanced 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 progressed following standard first-line therapy with at least one line of an aromatase inhibitor and 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]) cannot be used (e.g., high risk for cardiovascular [CV] events or a history of a CV event)
Phyrago (dasatinib)	For all FDA approved, and compendia supported indications	Must have medical reason why dasatinib cannot be used
Revuforj (revumenib)	For adults with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation The following is an **exception** to the step therapy requirement: • If Revuforj is being used in combination with a strong CYP3A4 inhibitor (e.g., posaconazole)	Must have adequate medical justification to why Komzifti cannot be used.
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

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
Beqalzi (sonrotoclax)	Starter Dose pack: 1 pack (44 tabs)/28 days 1mg & 5mg Restart packs: 1 pack (11 tabs)/7 days 20mg Restart pack: 1 pack (14 tabs)/7 days 80mg tablets: 120/30 days
Besremi (ropeginterferon alfa-2b-njft)	2 syringes per 28 days
Braftovi (encorafenib)	75 mg: 180 capsules/30 days
Brukinsa (zanubrutinib)	120 capsules/30 days 60 tablets/30 days
Bosulif and generic bosutinib	50 mg: 30 capsules/30 days 100 mg capsules: 150 capsules/30 days 100 mg tablets: 120 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 tablets/ 30 days
Caprelsa (vandetanib)	100 mg:60 tablets/30 days 300mg: 30 tablets/30 days
Cavhanza (nilotinib ODT)	112 tablets/28 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)	25 mg: 60 tablets/30 days 100 mg: 30 tablets/30 days • For the 100 mg strength, a quantity of 60 tablets/30 days may be allowed if documentation is received that a moderate CYP3A4 inducer must be co-administered.
Danziten (nilotinib)	112 tablets/28 days
Ensacove (ensartinib)	60 capsules/30 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
Erlotinib (generic Tarceva)	30 tablets/30 days
Etcamah (camizestrant)	28 tablets per 28 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
Hernexeos (zongertinib)	90 tablets/30 days
Hyrnuo (sevabertinib)	120 tablets/30 days
Ibrance (palbociclib)	21 tablets per 28 days
Ibtrozi (taletrectinib adipate)	90 capsules/30 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 aged 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.
Inluriyo (imlunestrant tosylate)	56 tablets/28 days
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
Jakafi XR (ruxolitinib ER)	30 tablets/30 days
Jaypirca (pirtobrutinib)	50 mg: 30 tablets/30 days 100 mg: 60 tablets/30 days
Jideytro (zidesamtinib)	25 mg: 90 tablets/30 days 100 mg: 30 tablets/30 days
Kisqali (ribociclib)	63 capsules per 28 days
Komzifti (ziftomenib)	90 capsules/30 days

Koselugo (selumetinib)	10 mg: 240 capsules/30 days 25 mg: 120 capsules/30 days 5 mg: 600 oral granule capsules/30 days 7.5 mg: 360 oral granule 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
Lifyorli (relacorilant)	150 mg pack: 27 capsules/28 days 125 mg pack: 18 capsules/28 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
Mimrylo (rusfertide acetate)	9.5 mg, 19 mg and 28 mg vials: 4 vials per 28 days 41 mg and 57 mg vials: 8 vials per 28 days
Modeyso (dordaviprone hcl)	20 capsules/28 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 and generic pomalidomide	21 tablets/28 days
Qinlock (ripretinib)	90 tablet/30 days
Rasonque (daraxonrasib)	60 tablets/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 and Phyrago (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
Targretin and bexarotene capsules	300 capsules/30 days
Targretin gel and bexarotene gel	240 grams/30 days
Tasigna and generic nilotinib hcl, nilotinib tartrate	50 mg: 120 capsules/30 days 150 mg and 200 mg: 112 capsules/28 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 10mg: 56 tablets/28 days 50mg: 224 tablets/28 days 100mg: 112 tablets/28 days. a. 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.
Veppanu (vepdegestrant)	30 tablets/30 days
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	200 mg: 120 tablets/30 days
Welireg (belzutifan)	90 tablets/30 days
Xalkori (crizotinib)	Capsules: 200 mg and 250 mg capsules: 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.
Zegfrovy (sunvozertinib)	30 tablets/30 days
Zejula (niraparib)	90 capsules/30 days 30 tablets/30 days
Zelboraf (vemurafenib)	240 tablets/30 days
Zenbexus (iberdomide)	21 capsules/28 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
Alecensa (alectinib)	Adjuvant treatment following tumor resection of ALK-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive)	2 years
Brukinsa (zanubrutinib)	MCL, maintenance therapy in combination with rituximab	2 years
Calquence (acalabrutinib)	MCL, maintenance therapy in combination with rituximab	2 years
Imbruvica (ibrutinib)	MCL, maintenance therapy in combination with rituximab	2 years
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
Kisqali (ribociclib)	Adjuvant treatment, in combination with an aromatase inhibitor, in adults with HR-positive, HER2-negative stage II and III early breast cancer at high risk for recurrence	3 years
Lynparza Tablets (olaparib tablets)	Adjuvant treatment in patients with deleterious or suspected germline BRCA-mutated HER2-negative high risk early breast cancer	12 months
Mekinist (trametinib)	Adjuvant treatment, in combination with dabrafenib, for patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s) following complete resection	12 months
Nerlynx (neratinib)	Early stage of HER2-positive breast cancer	12 months
Nexavar (sorafenib)	AML, maintenance therapy	24 months
Rydapt (midostaurin)	AML, maintenance therapy	12 months
Sutent (sunitinib	Adjuvant treatment for adults at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy	54 weeks
Tafinlar (dabrafenib)	Adjuvant treatment, in combination with trametinib, for patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s) following complete resection	12 months
Tagrisso (osimertinib)	Adjuvant treatment after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations	3 years

Vanflyta (quizartinib)	AML, maintenance therapy	36 months
Venclexta (venetoclax)	CLL/SLL in combination with obinutuzumab	12 months
Venclexta (venetoclax)	CLL/SLL in combination with acalabrutinib ± obinutuzumab	14 months
Venclexta (venetoclax)	CLL/SLL in combination with rituximab	24 months
Verzenio (abemaciclib)	Adjuvant treatment, in combination with endocrine therapy, in patients with HR-positive, HER2-negative, node-positive, early breast cancer at high risk of recurrence	2 years
Xospata (gilteritinib)	AML, maintenance therapy	26 months

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 GAVRETO INLYTA INREBIC IWILFIN JAYPIRCA KRAZATI KOMZIFTI LAZCLUZE LENVIMA LORBRENA LUMAKRAS LYNPARZA MEKTOVI NEXAVAR NUBEQA ODOMZO OGSIVEO PIQRAY 250 MG AND 300 MG PAZOPANIB PHYRAGO RASONQUE RETEVMO

REVUFORJ
REZLIDHIA
ROZLYTREK
RUBRACA
SORAFENIB
SPRYCEL
TABRECTA
TALZENNA
TARGRETIN CAPSULES
TEPMETKO
TIBSOVO
TURALIO
VERZENIO
VITRAKVI
VIZIMPRO
VONJO
VOTRIENT
X/POVIO /
XTANDI
YONSA
ZYTIGA

IMPORTANT INFORMATION ON ACCELERATED APPROVALS:
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:
11/01/2026	Revised
09/15/2026	Revised; Table #5 updates approved by P&T committee on 8/13/2026
09/10/2026	Revised
08/26/2026	Revised
08/13/2026	Reviewed / P&T Committee Approval
07/16/2026	Revised
07/01/2026	Revised
05/22/2026	Revised
05/14/2026	Reviewed / P&T Committee Approval
05/01/2026	Revised
03/23/2026	Revised

03/16/2026	Revised
02/12/2026	Reviewed / P&T Committee Approval
01/15/2026	Revised
12/19/2025	Revised
11/14/2025	Revised
11/13/2025	Reviewed / P&T Committee Approval
10/31/2025	Revised
10/02/2025	Revised
08/28/2025	Revised
08/14/2025	Reviewed / P&T Committee Approval
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
12/2022	Revised
11/2022	Revised
09/2022	Revised
07/2022	Revised
6/2022	Revised
5/2022	Revised
4/2022	Revised

3/2022	Revised
2/2022	Revised / P&T Committee Approval
12/2021	Revised
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
10/20	Revised
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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12/17	Revised
11/17	Revised
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

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