curative

Self-Administered Oncology Agents Prior Authorization with Quantity Limit Criteria

Preferred agent options are as follows.

Indication(s)	Number of Preferred Required	Preferred Agent(s)	Non-Preferred Agent(s)
Advanced or metastatic breast cancer	1 preferred agent	Ibrance, Verzenio	Kisqali, Kisqali Femara Pack
Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase	1 preferred agent	Imatinib (generic), Sprycel	Bosulif, Tasigna
Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase with the T315I mutation	1 preferred agent	Iclusig	Scemblix
Polycythemia Vera	1 preferred agent	Peginterferon[a]	BESREMi

*NOTE: brand Gleevec to be managed through generic before brand requirement
a- preferred agent may be targeted in another utilization management program and require Prior Authorization

FDA APPROVED INDICATIONS[3-106]
Please reference individual agent product labeling.

CLINICAL RATIONALE
For the purposes of the Self-Administered Oncology Agents criteria, indications deemed appropriate are those approved in FDA labeling and/or supported by NCCN Drugs & Biologics compendia with a category 1 or 2A recommendation, AHFS, or DrugDex with level of evidence of , 2A, 2B.

SAFETY[3-106]

Agent(s)	Contraindication(s)
Afinitor/Afinitor Disperz (everolimus)	Hypersensitivity to everolimus, to other rapamycin derivatives
Alecensa (alectinib)	None
Alunbrig (brigatinib)	None
Ayvakit (avapritinib)	None
Balversa (erdafitinib)	None
BESREMi (ropeginterferon alfa-2b-njft)	Existence of, or history of severe psychiatric disorders, particularly severe depression, suicidal ideation, or suicide attempt; Hypersensitivity to interferons including interferon alfa-2b or any of the inactive ingredients of BESREMi; Moderate (Child-Pugh B) or severe (Child-Pugh C) hepatic impairment; History or presence of

Agent(s)	Contraindication(s)
	active serious or untreated autoimmune disease; Immunosuppressed transplant recipients
Bosulif (bosutinib)	Hypersensitivity to bosutinib
Braftovi (encorafenib)	None
Brukinsa (zanubrutinib)	None
Cabometyx (cabozantinib)	None
Calquence (acalabrutinib)	None
Caprelsa (vandetanib)	Congenital long QT syndrome
Cometriq (cabozantinib)	None
Copiktra (duvelisib)	None
Cotellic (cobimetinib)	None
Daurismo (glasdegib)	None
Erivedge (vismodegib)	None
Erleada (apalutamide)	Pregnancy
Exkivity (mobocertinib)	None
Farydak (panobinostat)	None
Fotivda (tivozanib)	None
Gavreto (pralsetinib)	None
Gilotrif (afatinib)	None
Gleevec (imatinib)	None
Hycamtin (topotecan)	Severe hypersensitivity to topotecan
Ibrance (palbociclib)	None
Iclusig (ponatinib)	None
Idhifa (enasidenib)	None
Imbruvica (ibrutinib)	None
Inlyta (axitinib)	None
Inqovi (decitabine/ cedazuridine)	None
Inrebic (fedratinib)	None
Iressa (gefitinib)	None
Jakafi (ruxolitinib)	None
Kisqali (ribociclib)	None
Kisqali Femara Pack (ribociclib and letrozole co-packaged)	Hypersensitivity to letrozole, or any excipients of Femara
Koselugo (selumetinib)	None
Lenvima (lenvatinib)	None
Lonsurf (trifluridine/tipiracil)	None
Lorbrena (lorlatinib)	Concomitant use with a strong CYP3A inducer, due to potential for serious hepatotoxicity
Lumakras (sotorasib)	None
Lynparza (olaparib) tablets	None
Lysodren (mitotane)	None
Matulane (procarbazine)	Known hypersensitivity to procarbazine, inadequate marrow reserve
Mekinist (trametinib)	None
Mektovi (binimetinib)	None
Nerlynx (neratinib)	None

Agent(s)	Contraindication(s)
Nexavar (sorafenib)	Known severe hypersensitivity to sorafenib or its components, use in combination with carboplatin and paclitaxel in patients with squamous cell lung cancer
Ninlaro (ixazomib)	None
Nubeqa (darolutamide)	None
Odomzo (sonidegib)	None
Onureg (azacitidine)	Known severe hypersensitivity to azacitidine or its components
Orgovyx (relugolix)	None
Pemazyre (pemigatinib)	None
Piqray (alpelisib)	Severe hypersensitivity to Piqray or to any of its components
Pomalyst (pomalidomide)	Pregnancy
Qinlock (ripretinib)	None
Retevmo (selpercatinib)	None
Revlimid (lenalidomide)	Pregnancy, severe hypersensitivity to lenalidomide
Rozlytrek (entrectinib)	None
Rubraca (rucaparib)	None
Rydapt (midostaurin)	Hypersensitivity to midostaurin or any of the excipients
Scemblix (asciminib)	None
Sprycel (dasatinib)	None
Stivarga (regorafenib)	None
Sutent (sunitinib)	None
Tabrecta (capmatinib)	None
Tafinlar (dabrafenib)	None
Tagrisso (osimertinib)	None
Talzenna (talazoparib)	None
Tarceva (erlotinib)	None
Targretin (bexarotene) capsules	Pregnancy; known serious hypersensitivity to bexarotene or other components of the product
Targretin (bexarotene) gel	known serious hypersensitivity to bexarotene or other components of the product
Tasigna (nilotinib)	Hypokalemia, hypomagnesemia, long QT syndrome
Tazverik (tazemetostat)	None
Temodar (temozolomide)	Hypersensitivity to dacarbazine (DTIC) or Temodar components
Tepmetko (tepotinib)	None
Thalomid (thalidomide)	Pregnancy, hypersensitivity to thalidomide or its components
Tibsovo (ivosidenib)	None
Tretinoin (oral)	known hypersensitivity to tretinoin, any of its components, or other retinoids; sensitivity to parabens
Truseltiq (infigratinib)	None
Tukysa (tucatinib)	None
Turalio (pexidartinib)	None
Tykerb (lapatinib)	Known hypersensitivity to lapatinib or its components
Ukoniq (umbralisib)	None
Venclexta (venetoclax)	Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase in patients with CLL/SLL
Verzenio (abemaciclib)	None
Vitrakvi (larotrectinib)	None
Vizimpro (dacomitinib)	None
Vonjo (pacritinib)	Concomitant use of a strong CYP3A4 inhibitor or inducer
Votrient (pazopanib)	None
Welireg (belzutifan)	None

Agent(s)	Contraindication(s)
Xalkori (crizotinib)	None
Xeloda (capecitabine)	Severe renal failure, hypersensitivity to capecitabine or any of its components, hypersensitivity to 5-fluorouracil
Xospata (gilteritinib)	Hypersensitivity to gilteritinib or any of the excipients
Xpovio (selinexor)	None
Xtandi (enzalutamide)	Pregnancy
Yonsa (abiraterone acetate)	Pregnancy
Zejula (niraparib)	None
Zelboraf (vemurafenib)	None
Zolinza (vorinostat)	None
Zydelig (idelalisib)	History of serious allergic reactions including anaphylaxis and toxic epidermal necrolysis
Zykadia (ceritinib)	None
Zytiga (abiraterone)	None

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Self-Administered Oncology Agents Prior Authorization with Quantity Limit – through Preferred (optional)

TARGET AGENT(S)

Afinitor® (everolimus)[a]
Afinitor® Disperz (everolimus)[a]
Alecensa® (alectinib)
Alunbrig® (brigatinib)
Ayvakit™ (avapritinib)
Balversa® (erdafitinib)
BESREMi® (ropeginterferon alfa-2b-njft)
Bosulif® (bosutinib)
Braftovi® (encorafenib)
Brukinsa™ (zanubrutinib)
Cabometyx® (cabozantinib)
Calquence® (acalabrutinib)
Caprelsa® (vandetanib)
Cometriq® (cabozantinib)
Copiktra™ (duvelisib)
Cotellic® (cobimetinib)
Daurismo™ (glasdegib)
Erivedge® (vismodegib)
Erleada® (apalutamide)
Exkivity™ (mobocertinib)
Farydak® (panobinostat)
Fotivda® (tivozanib)
Gavreto™ (pralsetinib)
Gilotrif® (afatinib)
Gleevec® (imatinib)[a]
Hycamtin® (topotecan)
Ibrance® (palbociclib)
Iclusig® (ponatinib)
Idhifa® (enasidenib)
Imbruvica® (ibrutinib)
Inlyta® (axitinib)
Inqovi® (decitabine/cedazuridine)
Inrebic® (fedratinib)
Iressa (gefitinib)
Jakafi® (ruxolitinib)
Kisqali® (ribociclib)
Kisqali® Femara® Pack (ribociclib and letrozole co-packaged)
Koselugo™ (selumetinib)
Lenvima® (lenvatinib)
Lonsurf® (trifluridine/tipiracil)
Lorbrena® (lorlatinib)
Lumakras™ (sotorasib)
Lynparza® (olaparib)
Lysodren® (mitotane)
Matulane® (procarbazine)
Mekinist® (trametinib)
Mektovi® (binimetinib)
Nerlynx® (neratinib)
Nexavar® (sorafenib)[a]
Ninlaro® (ixazomib)
Nubeqa® (darolutamide)
Odomzo® (sonidegib)
Onureg® (azacitidine)
Orgovyx (relugolix)
Pemazyre® (pemigatinib)
Piqray® (alpelisib)
Pomalyst® (pomalidomide)
Qinlock® (ripretinib)
Retevmo™ (selpercatinib)
Revlimid® (lenalidomide)[a]
Rozlytrek™ (entrectinib)
Rubraca® (rucaparib)
Rydapt® (midostaurin)
Scemblix® (asciminib)
Sprycel® (dasatinib)
Stivarga® (regorafenib)
Sutent® (sunitinib)[a]
Tabrecta™ (capmatinib)
Tafinlar® (dabrafenib)
Tagrisso® (osimertinib)
Talzenna® (talazoparib)
Tarceva® (erlotinib)[a]
Targretin® (bexarotene)[a]
Tasigna® (nilotinib)
Tazverik® (tazemetostat)
Temodar® (temozolomide)[a]
Tepmetko® (tepotinib)
Thalomid® (thalidomide)
Tibsovo® (ivosidenib)
Tretinoin (oral)
Truseltiq™ (infigratinib)
Tukysa® (tucatinib)
Turalio® (pexidartinib)
Tykerb® (lapatinib)[a]
Ukoniq™ (umbralisib)
Venclexta® (venetoclax)
Verzenio® (abemaciclib)
Vitrakvi® (larotrectinib)
Vizimpro® (dacomitinib)
Vonjo™ (pacritinib)
Votrient® (pazopanib)
Welireg™ (belzutifan)
Xalkori® (crizotinib)
Xeloda® (capecitabine)[a]
Xospata® (gilteritinib)
Xpovio® (selinexor)
Xtandi® (enzalutamide)
Yonsa® (abiraterone acetate)
Zejula (niraparib)
Zelboraf® (vemurafenib)
Zolinza® (vorinostat)

Zydelig® (idelalisib)

Zykadia® (ceritinib)
Zytiga® (abiraterone)[a]

a-generic available

PRIOR AUTHORIZATION WITH QUANTITY LIMIT CRITERIA FOR APPROVAL – through
Preferred
Initial Evaluation
Target Agent(s) will be approved when ALL of the following are met:

1. ONE of the following:
    - **A.** Information has been provided that indicates the patient is currently being treated with the requested agent within the past 180 days
      OR
    - B. The prescriber states the patient is being treated with the requested agent within the past 180 days AND is at risk if therapy is changed
      OR
    - C. ALL of the following:
        - i. ONE of the following:
            - a. The patient's age is within FDA labeling for the requested indication for the requested agent
              OR
            - b. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication

          AND
        - ii. ONE of the following:
            - a. The patient has an FDA approved indication for the requested agent
              OR
            - b. The patient has an indication that is supported by NCCN 1, 2A, or 2B recommended use, AHFS, or DrugDex level of evidence of 1, 2A, or 2B [i.e., this indication must be supported by ALL requirements in the compendia (e.g., performance status, disease severity, previous failures, monotherapy vs combination therapy, etc.)] for the requested agent

          AND
        - iii. ONE of the following:
            - a. ALL of the following:
                1. The requested indication requires genetic/specific diagnostic testing per FDA labeling or compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested agent
                   AND
                2. Genetic/specific diagnostic testing has been completed
                   AND
                3. The results of the genetic/specific diagnostic testing indicate therapy with the requested agent is appropriate

              OR
            - b. The requested indication does NOT require specific genetic/diagnostic testing per FDA labeling or supported by compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested agent

          AND
        - iv. ONE of the following:
            - A. The requested agent is being used as monotherapy AND is approved for use as monotherapy in the FDA labeling or

compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested indication

OR

B. The requested agent will be used as combination therapy with all agent(s) and/or treatments (e.g., radiation) listed for concomitant use in the FDA labeling or compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested indication

AND

v. ONE of the following:
   a. The requested agent will be used as a first-line agent AND is FDA labeled or supported by compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) as a first-line agent for the requested indication

   OR

   b. The patient has tried and had an inadequate response to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested indication

   OR

   c. The patient has an intolerance, FDA labeled contraindication, or hypersensitivity to the appropriate number and type(s) of prerequisite agent(s) listed in the FDA labeling or compendia (NCCN 1, 2A, 2B recommended use, AHFS, DrugDex level of evidence of 1, 2A, or 2B) for the requested indication

AND

vi. If the client has preferred products* for the requested indication (*Preferred agents are determined by the client and may include both brand and generic agents), then ONE of the following:
   A. The requested agent is a preferred agent for the requested indication

   OR

   B. The requested agent is a non-preferred agent for the requested indication (as determined by the client) AND ONE of the following:
      i. The patient's medication history indicates use of a preferred agent for the requested indication

      OR

      ii. The patient has an intolerance or hypersensitivity to a preferred agent(s) for the requested indication

      OR

      iii. The patient has an FDA labeled contraindication to ALL preferred agent(s) for the requested indication

      OR

      iv. BOTH of the following:
         1. NCCN does NOT specify the plan preferred agent(s) as a preferred regimen for the requested indication

         AND

         2. NCCN specifies the requested agent as a preferred regimen for the requested indication

      OR

      v. The prescriber has provided information in support of use of the non-preferred agent over the preferred agent(s) for the requested indication

      OR

vi. If the requested agent is Bosulif or Tasigna for CML, the patient has been previously treated with either Bosulif OR Tasigna for the requested indication

Indication	Preferred Agents	Non-Preferred Agents
Advanced or metastatic breast cancer	Ibrance, Verzenio	Kisqali, Kisqali Femara Pack
Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase	Imatinib (generic), Sprycel	Bosulif, Tasigna
Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase with the T315I mutation	Iclusig	Scemblix
Polycythemia Vera	Peginterferon[a]	BESREMi

*NOTE: brand Gleevec to be managed through generic before brand requirement
a- preferred agent may be targeted in another utilization management program and require Prior Authorization

AND

vii. If the requested agent is Imbruvica 140 mg or 280 mg tablets, ONE of the following:
   a. The patient has tried and had an inadequate response to Imbruvica 140 mg capsules
      OR
   b. The patient has an intolerance or hypersensitivity to Imbruvica capsules that is not expected to occur with Imbruvica tablets
      OR
   c. The patient has an FDA labeled contraindication to Imbruvica capsules that is not expected to occur with Imbruvica tablets

AND

viii. If the requested agent is Zytiga/abiraterone 500 mg, ONE of the following:
   a. The patient has tried and had an inadequate response to generic abiraterone 250 mg tablets
      OR
   b. The patient has an intolerance or hypersensitivity to generic abiraterone 250 mg tablets that is not expected to occur with the requested agent
      OR
   c. The patient has an FDA labeled contraindication to generic abiraterone 250 mg tablets that is not expected to occur with the requested agent

AND

2. If the requested agent is for one of the following brand agents with a generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the requested brand agent
      OR

B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the requested brand agent
OR
C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent

Brand	Generic Equivalent
Afinitor	everolimus
Afinitor Disperz	everolimus
Gleevec	imatinib
Sutent	sunitinib
Tarceva	erlotinib
Targretin	bexarotene
Temodar	temozolomide
Tykerb	lapatinib
Xeloda	capecitabine
Zytiga	abiraterone

AND

3. The patient does not have any FDA labeled contraindications to the requested agent
AND
4. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
AND
5. ONE of the following:
   A. Quantity limit does NOT apply to the requested agent
   OR
   B. The requested quantity (dose) does NOT exceed the program quantity limit
   OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
      AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit
   OR
   D. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
      AND
      ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
      AND
      iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 3 months for dose titration requests over the program quantity limit and Vitrakvi
Up to 12 months for all other requests, approve loading doses where appropriate

Renewal Evaluation

Target Agent(s) will be approved when ALL of the following are met:

1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process
   AND
2. ONE of the following:
   A. The requested agent is Vitrakvi AND the patient has experienced clinical benefit (i.e., partial response, complete response, or stable disease) with the requested agent
      OR
   B. The requested agent is NOT Vitrakvi
   AND
3. If the requested agent is for one of the following brand agents with a generic equivalent (listed below), then ONE of the following:
   A. The patient has an intolerance or hypersensitivity to the generic equivalent that is not expected to occur with the requested brand agent
      OR
   B. The patient has an FDA labeled contraindication to the generic equivalent that is not expected to occur with the requested brand agent
      OR
   C. The prescriber has provided information to support the use of the requested brand agent over the generic equivalent

Brand	Generic Equivalent
Afinitor	everolimus
Afinitor Disperz	everolimus
Gleevec	imatinib
Sutent	sunitinib
Tarceva	erlotinib
Targretin	bexarotene
Temodar	temozolomide
Tykerb	lapatinib
Xeloda	capecitabine
Zytiga	abiraterone

   AND
4. The patient does not have any FDA labeled contraindications to the requested agent
   AND
5. The patient does not have any FDA labeled limitation(s) of use that is otherwise not supported in NCCN to the requested agent
   AND
6. ONE of the following:
   A. Quantity limit does NOT apply to the requested agent
      OR
   B. The requested quantity (dose) does NOT exceed the program quantity limit
      OR
   C. ALL of the following:
      i. The requested quantity (dose) is greater than the program quantity limit
         AND
      ii. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication
         AND
      iii. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit

OR

D. ALL of the following:
   i. The requested quantity (dose) is greater than the program quantity limit
   AND
   ii. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication
   AND
   iii. The prescriber has provided information in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 12 months

FDA Companion Diagnostics:
https://www.fda.gov/medical-devices/vitro-diagnostics/list-cleared-or-approved-companion-diagnostic-devices-vitro-and-imaging-tools

DOCUMENT HISTORY

Approval Date MM/YYYY	Approved By	Notes
09/2022	P&T UM Committee	Initial Criteria Review