Medical Policy

BlueCross BlueShield of Kansas
An independent licensee of the Blue Cross Blue Shield Association

Title: Self Administered Oncology Agents

- **Prime Therapeutics will review Prior Authorization requests.**
  Prior Authorization Form:
  http://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6106KS-ORON.pdf

  Link to Drug List (Formulary):
  https://www.bcbsks.com/drugs/

Professional
Original Effective Date: January 1, 2011
Revision Date(s): February 1, 2012; July 1, 2012; March 1, 2013; September 1, 2013; February 28, 2014; August 28, 2014; October 1, 2014; October 1, 2015; January 1, 2016; February 24, 2016, April 1, 2016; July 1, 2016; November 1, 2016; February 1, 2017; April 1, 2017, May 1, 2017; July 1, 2017; July 15, 2017; October 1, 2017; November 1, 2017; November 27, 2017; December 11, 2017; January 1, 2018; February 5, 2018; March 12, 2018; March 26, 2018; April 23, 2018; June 25, 2018; July 23, 2018; August 20, 2018; October 22, 2018; October 29, 2018; December 1, 2018; December 3, 2018, December 17, 2018; December 24, 2018
Current Effective Date: December 24, 2018

Institutional
Original Effective Date: January 1, 2011
Revision Date(s): February 1, 2012; July 1, 2012; March 1, 2013; September 1, 2013; February 28, 2014; August 28, 2014; October 1, 2014; October 1, 2015; January 1, 2016; February 24, 2016, April 1, 2016; July 1, 2016; November 1, 2016; February 1, 2017; April 1, 2017; May 1, 2017; July 1, 2017; July 15, 2017; October 1, 2017; November 1, 2017; November 27, 2017; December 11, 2017; January 1, 2018; February 5, 2018; March 12, 2018; March 26, 2018; April 23, 2018; June 25, 2018; July 23, 2018; August 20, 2018; October 22, 2018; October 29, 2018; December 1, 2018; December 3, 2018; December 17, 2018; December 24, 2018
Current Effective Date: December 24, 2018

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member's benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health isurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.

DESCRIPTION

The intent of the Self Administered Oncology Agents Prior Authorization (PA) program is to ensure appropriate selection of patients for treatment according to product labeling and/or clinical studies and/or clinical guidelines. The criteria considers appropriate indications as those supported in FDA approved labeling, National Comprehensive Cancer Network (NCCN) with level of evidence of 1 or 2A recommendation, AHFS, or Drugdex with level of evidence of 1 or IIa. If there are preferred agents, as determined by the client, the criteria will require use of the preferred agent before the non-preferred agent.

Target Agents

Afinitor® (everolimus)	**Nerlynx™** (neratinib)
Afinitor® Disperz (everolimus)	**Nexavar®** (sorafenib)
Alecensa® (alectinib)	**Ninlaro®** (ixazomib)
Alunbrig™ (brigatinib)	**Odomzo®** (sonidegib)
Bosulif® (bosutinib)	**Pomalyst®** (pomalidomide)
Braftovi™ (encorafenib)	**Revlimid®** (lenalidomide)
Cabometyx™ (cabozantinib)	**Rubraca™** (rucaparib)
Calquence® (acalabrutinib)	**Rydapt®** (midostaurin)
Caprelsa® (vandetanib)	**Sprycel®** (dasatinib)
Cometriq™ (cabozantinib)	**Stivarga®** (regorafenib)
Copiktra™ (duvelisib)	**Sutent®** (sunitinib)
Cotellic™ (cobimetinib)	**Sylatron®** (peginterferon alfa-2b)
Daurismo™ (glasdegib)	**Tafinlar®** (dabrafenib)
Erleada™ (apalutamide)	**Tagrisso™** (osimertinib)
Erivedge™ (vismodegib)	**Tarceva®** (erlotinib)
Farydak® (panobinostat)	**Targretin®** (bexarotene) [a]
Gilotrif® (afatinib)	**Tasigna®** (nilotinib)
Gleevec® (imatinib) [a]	**Temodar®** (temozolomide) [a]
Hexalen® (altretamine)	**Thalomid®** (thalidomide)
Hycamtin® (topotecan)	**Tibsovo®** (ivosidenib)
Ibrance® (palbociclib)	**Tretinoin®** (oral)
Iclusig™ (ponatinib)	**Tykerb®** (lapatinib)
Idhifa® (enasibenib)	**Venclexta™** (venetoclax)
Imbruvica™ (ibrutinib)	**Verzenio™** (abemaciclib)
Inlyta® (axitinib)	**Vitrakvi®** (larotrectinib)
Iressa® (gefitinib)	**Vizimpro®** (dacomitinib)
Jakafi™ (ruxolitinib)	**Votrient®** (pazopanib)
Kisqali® (ribociclib)	**Xalkori®** (crizotinib)
Kisqali® Femara® Pack (ribociclib and letrozole co-packaged)	**Xeloda®** (capecitabine) [a]
	Xospata® (gilteritinib)
Lenvima™ (lenvatinib)	**Xtandi®** (enzalutamide)
Lonsurf® (trifluridine/tipiracil)	**Yonsa®** (abiraterone acetate)
Lorbrena® (lorlatinib)	**Zejula™** (niraparib)
Lynparza (olaparib) capsules	**Zelboraf®** (vemurafenib)
Lynparza (olaparib) tablets	**Zolinza®** (vorinostat)
Lysodren® (mitotane)	**Zydelig** (idelalisib)
Matulane® (procarbazine)	**Zykadia™** (ceritinib)
Mekinist® (trametinib)	**Zytiga™** (abiraterone) [a]
Mektovi® (binimetinib)	

[a] generic available

FDA Approved Indications[1-69,72-78]

Please reference individual agent product labeling.

POLICY

Prior Authorization Criteria for Approval

A **Target Agent** will be approved when ALL of the following are met:

1. ONE of the following:
   - A. There is documentation that the patient is currently being treated with the requested agent
     OR
   - B. The prescriber states the patient is currently being treated with the requested agent AND is at risk if therapy is changed
     OR
   - C. ALL of the following:
     - i. ONE of the following:
       - a. The patient has an FDA approved diagnosis for the requested agent (evidence of a paid claim within the past 180 days, or patient is new to the claim system within the past 120 days and a statement by the physician that patient is currently taking the requested medication in the past 180 days)
         OR
       - b. The use of the requested agent is for an indication that is supported by compendia. (NCCN Compendium™ level of evidence 1 or 2A, AHFS (American Hospital Formulary Service), DrugDex level of evidence 1 or 2A

       AND
     - ii. Genetic testing has been completed (if applicable) using an FDA approved genetic test if required for therapy with the requested agent and results indicate therapy with requested agent is appropriate
       AND
     - iii. ONE of the following:
       - a. The requested agent is a first line agent for the intended indication
         OR
       - b. The patient has tried and failed the first line agent for the intended indication (if applicable)
         OR
       - c. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first line agent

       AND

iv. ONE of the following:
   a. The requested agent is a preferred agent* (*preferred agents are determined by the client and may include both brand and generic agents)
   OR
   b. The requested agent is a non-preferred agent (as determined by the client) and the patient meets ONE of the following:
      1) The patient's medication history indicates use of a preferred agent for the requested indication
      OR
      2) The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent
      OR
      3) The prescriber has provided documentation in support of use of the non-preferred agent over the preferred agent

AND

2. The patient does not have an FDA labeled contraindication to the requested agent
AND
3. The patient does not have an FDA labeled limitation of use for the requested agent that is otherwise not supported in National Comprehensive Cancer Network (NCCN)
AND
4. ONE of the following:
   a. The dose is within FDA labeling
   OR
   b. The dose is not within FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the requested indication

Length of Approval: Up to 12 months

FDA Companion Diagnostics:
http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/InVitroDiagnostics/ucm301431.htm

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 1 or IIa.

Safety[1-69,72-78]

Agent	Contraindications
Afinitor / Afinitor Disperz (everolimus)	Hypersensitivity to everolimus, to other rapamycin derivatives
Alecensa (alectinib)	None

Agent	Contraindications
Alunbrig (brigatinib)	None
Bosulif (bosutinib)	Hypersensitivity to bosutinib
Braftovi (encorafenib)	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
Farydak (panobinostat)	None
Gilotrif (afatinib)	None
Gleevec (imatinib)	None
Hexalen (altretamine)	Hypersensitivity to altretamine, preexisting severe bone marrow depression, severe neurological toxicity
Hycamtin (topotecan	severe hypersensitivity to topotecan
Ibrance (palbociclib)	None
Iclusig (ponatinib)	None
Idhifa (enasidenib)	None
Imbruvica (ibrutinib)	None
Inlyta (axitinib)	None
Iressa (gefitinib)	None
Jakafi (ruxolitinib)	None
Kisqali (ribociclib)	None
Kisqali Femara Pack (ribociclib and letrozole co-packaged)	None
Lenvima (lenvatinib)	None
Lonsurf (trifluridine/tipiracil)	None
Lorbrena (lorlatinib)	Concomitant use with a strong CYP3A inducer, due to potential for serious hepatotoxicity
Lynparza (olaparib) capsules	None
Lynparza (olaparib) tablets	None
Lysodren (mitotane)	None
Matulane (procarbazine)	Known hypersensitivity to procarbazine, inadequate marrow reserve
Mekinist (trametinib)	None
Mektovi (binimetinib)	None
Nerlynx (nertinib)	None
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
Odomzo (sonidegib)	None
Pomalyst (pomalidomide)	Pregnancy
Revlimid (lenalidomide)	Pregnancy, severe hypersensitivity to lenalidomide
Rubraca (rucaparib)	None
Rydapt (midostaurin)	Hypersensitivity to midostaurin or any of the excipients
Sprycel (dasatinib)	None

Agent	Contraindications
Stivarga (regorafenib)	None
Sutent (sunitinib)	None
Sylatron (peginterferon alfa-2b)	Autoimmune hepatitis, hepatic decompensation (Child-Pugh score >6, Class B and C), hypersensitivity to peginterferon alfa-2b or interfon alfa-2b
Tafinlar (dabrafenib)	None
Tagrisso (osimertinib)	None
Tarceva (erlotinib)	None
Targretin (bexarotene)	Pregnancy; known serious hypersensitivity to bexarotene or other components of the product
Tasigna (nilotinib)	Hypokalemia, hypomagnesemia, long QT syndrome
Temodar (temozolomide)	Hypersensitivity to dacarbazine (DTIC) or Temodar components
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
Tykerb (lapatinib)	Known hypersensitivity to lapatinib or its components
Venclexta (venetoclax)	Concomitant use with strong CYP3A inhibitors at initiation and during ramp-up phase
Verzenio (abemaciclib)	None
Vitrakvi (larotrectinib)	None
Vizimpro (dacomitinib)	None
Votrient (pazopanib)	None
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
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)	Pregnancy

REVISIONS	
02-28-2014	Description section updated to include update to FDA Approved Indications chart.
	In Policy section: ▪ In Item 3 a i added Look-back period information. ▪ Moved the Kansas State Mandate information from being its own Item 4 to Item 3 a ii. ▪ Added in 3 c ii "The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the first line agent" ▪ Updated Genetic Testing chart for required results.
	Rationale section updated to include updates to the Safety chart.
	In Coding section: ▪ HCPCS Code nomenclature correction: J8705 ▪ Added HCPCS code: J9351
	References updated

REVISIONS	
08-28-2014	In Description section: ▪ Added Zykadia (ceritinib) to the FDA Approved Indications chart ▪ Updated FDA Approved Indications chart for Imbruvica ((ibrutinib), Mekinist (trametinib), Nexavar (sorafenib), Revlimid (lenalidomide), Tykerb (lapatinib)
	In Policy section: ▪ Added Item 3 d "The patient does not have any FDA labeled limitations of use" ▪ Added to Length of Approval "1 month for dose titration requests" ▪ Added to Length of Approval "for all other requests" to read "12 months for all other requests" ▪ Added FDA Labeled Limitation of Use chart ▪ Updated Genetic Testing chart
	In Rationale section: ▪ Added Zykadia (ceritinib) to the Safety chart on Toxicities, Side Effects, Warnings, Precautions and Contraindications / Boxed Warnings
	Coding section reviewed
	References updated
10-01-2014	Policy posted 10-28-2014 and effective 10-01-2014.
	Administrative Update
	In Description section: Added Zydelig (idelalisib) to the FDA Approved Indications chart.
	Coding section removed as codes are not used for pharmacy benefit.
	Rationale section updated
	References updated
10-01-2015	Policy published 10-2-2015. Policy effective 10-01-2015.
	Description updated to include: ▪ The addition of a list of the Target Drugs ▪ Updated the FDA Approved Indications chart including the addition of the following drugs; Afinitor Disperz, Farydak (panobinostat), Ibrance (palbociclib), Lenvima (lenvatinib), Lynparza (olaparib).
	In Policy section: ▪ In initial statement replaced "ONE" with "ALL" to read, "A Target Agent will be approved when ALL of the following are met:" ▪ Added "1. ONE of the following:" ▪ In 1 C b replaced the Kansas State mandate wording of "Meets the off-labeled use of an FDA approved prescription drug for cancer treatment 'if the prescription drug is recognized for treatment of the indication in one of the standard reference compendia or in substantially accepted peer reviewed medical literature. The prescribing physician shall submit to the insurer documentation supporting the proposed off-label use or uses if requested by the insurer.' (State mandate 40-2, 168 article 2 General Provisions) (History: L. 1999, ch. 128, § 2; May 6.)" with "The use of the target agent is for an indication that is supported by compendia. (NCCN CompendiumTM level of evidence 1, 2A, or 2B, AHFS (American Hospital Formulary Service), DrugDex, Clinical Pharmacology) or the prescriber has submitted additional documentation supporting the requested therapeutic use" ▪ In 1 C removed "The patient does NOT have any FDA labeled contraindication(s)" as it is placed elsewhere in the policy language. ▪ In 2 removed "limitations of use" and added "contraindication" to read, The patient does not have an FDA labeled contraindication" ▪ Added 3 "The patient does not have an FDA labeled limitation of use that is otherwise not supported in National Comprehensive Cancer Network (NCCN)" ▪ In Length of Approval added "Up to" to read, "Up to 12 months for all other requests" ▪ Removed the "FDA Labeled Limitation of Use" chart

REVISIONS	
	▪ Removed the "FDA Approved Genetic Test" chart, leaving the "FDA Approved Genetic Tests" link for more up to date reference
	Rationale section updated to include updating the Safety chart,
	In Revision section: Removed Revision information for 01-01-2011, 02-01-2012, 07-01-2012.
	References updated
01-01-2016	Description section updated to include updates to the Target Drugs and FDA Approved Indications charts. ▪ Added: Iressa® (gefitinib), Lonsurf® (trifluridine/tipiracil), Odomzo® (sonidegib) ▪ Removed: Oforta® (fludarabine)
	In Policy section: ▪ In Item C added, "AND iv. If the requested agent is a non-preferred agent (as determined by the client) ONE of the following: a. The patient's medication history indicates use of a preferred agent for the requested indication OR b. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the preferred agent OR c. The patient's genetic mutational status of the tumor supports use of the non-preferred agent" ▪ In Item 3 add, "for the requested agent" to read, "The patient does not have an FDA labeled limitation of use for the requested agent that is otherwise not supported in National Comprehensive Cancer Network (NCCN)" ▪ In Length of Approval removed "1 month for dose titration requests", "Up to" and "for all other requests" to read "12 months"
	Rationale section Safety chart updated
	References updated
02-24-2016	Published 02-24-2016. Retro-effective to 01-01-2016.
	▪ The following target drugs were added to the Target Drugs, FDA Approved Indications, and Safety charts: "Cotellic™ (cobimetinib)", "Ninlaro® (ixazomib)" and "Tagrisso™ (osimertinib)".
	References updated
04-01-2016	Published 04-29-2016. Retro-effective to 04-01-2016.
	▪ The following target drug was added to the Target Drugs, FDA Approved Indications, and Safety charts: "Alecensa (alectinib)"
	References updated.
07-01-2016	Published June 8, 2016. Effective July 1, 2016.
	Description section updated: ▪ Added "Venclexta (venetoclax)" to Target Drugs ▪ Revised indication and/or dosing for Afinitor (everolimus), Gilotrif (afatinib), Ibrance (palbociclib), Iressa (gefitinib), and Xalkori (crizotinib)
	Rationale section updated
	References updated
07-01-2016	Published August 4-2016. Effective July 1, 2016.
	Description section updated ▪ Added Cabometyx (cabozantinib) to the Target Drugs and FDA Approved Indications charts. ▪ On FDA Approved Indications chart: ▪ Updated indications for Gilotrif and Lenvima ▪ Updated references

REVISIONS	
	In Rationale section: ▪ Added Cabometyx (cabozantinib) to the Safety chart.
	References updated
11-01-2016	In the Description section: ▪ In the FDA Approved Indications chart added that "Zydelig is not indicated and is not recommended for first line treatment of any patient"
02-01-2017	Description section updated including FDA Approved Indications and Dosing chart update
	In Policy section: ▪ In Item 1 C iv added "ONE of the following: a. The requested agent is a preferred agent*(*preferred agents are determined by the client and may include both brand and generic agents)" ▪ In Item 1 C iv b added "and the patient meets" to read "The requested agent is a non-preferred agent (as determined by the client), and the patient meets ONE of the following:" ▪ In Item 1 C iv b 3) removed "genetic mutational status of the tumor supports use of the non-preferred agent" and added "The prescriber has provided documentation in support of use of the non-preferred agent over the preferred agent" ▪ Added Item 4 "ONE of the following: a. The dose is within FDA labeling OR b. The dose is not within FDA approved labeling and the prescriber has submitted documentation in support of therapy with a higher dose for the intended diagnosis which has been reviewed and approved by the Clinical Review Pharmacist. ▪ In Length of Approval added "Up to" to read "Up to 12 months"
	Updated Rationale section
	Updated References
04-01-2017	In Description section: ▪ Added Rubraca (rucaparib) to the Target Drugs and FDA Approved Indications charts. ▪ Updated FDA Approved Indications for Imbruvica (ibrutinib) and Tarceva (erlotinib).
	Rationale section updated
	In Revision section: ▪ Removed revision details for the following dates: 03-01-2013, 09-01-2013
	References updated
05-01-2017	Policy published 05-10-2017. Policy retro-effective to 05-01-2017.
	In Description section: ▪ Target Drugs and FDA Approved Indications charts updated to add Kisqali® (ribociclib)
	Rationale section updated
	References updated
06-01-2017	Policy published 06-09-2017. Policy retro-effective to 06-01-2017.
	In Description section ▪ Updated Target Drugs chart adding Zejula ▪ Updated FDA Approved Indications chart adding Zejula and updating Stivarga with a new indication
	Updated Rationale section
	Updated References
07-01-2017	Policy published 06-09-2017. Policy effective to 07-01-2017.
	In Description section ▪ Updated Target Drugs chart adding Alunbrig and Rydapt ▪ Updated FDA Approved Indications chart adding Alunbrig and Rydapt
	Updated Rationale section
	Updated References
07-01-2017	Policy published 07-14-2017. Policy retro-effective to 07-01-2017.

REVISIONS	
	In Description section: ▪ Added to Target Drugs "Kisqali® Femara® Pack (ribociclib and letrozole co-packaged)". ▪ Added to FDA Approved Indications and Dosage chart information pertaining to Kisqali Femara Pack and updated Zykadia indications.
	Updated Rationale section
	Updated References
07-15-2017	Policy published 08-01-2017. Policy retro-effective to 07-15-2017.
	In Description section: ▪ Updated FDA Approved Indications and Dosage chart adding new indications for Mekinist and Tafinlar.
10-01-2017	In Description section: ▪ To Target Drugs added to Target Drugs Idhifa (enasibenib) and Nerlynx (neratinib). Distinguished between Lynparza (olaparib) capsules and Lynparza (olaparib) tablets. ▪ To FDA Approved Indications and Dosage chart added information pertaining to Idhifa and Nerlynx. Distinguished between Lynparza (olaparib) capsules and Lynparza (olaparib) tablets. Updated the indication for Imbruvica.
	Updated Rationale section
	Updated References
11-01-2017	Policy published 11-21-2017. Policy retro-effective to 11-01-2017.
	In Description section: ▪ To Target Drugs and FDA Approved Indications added Verzenio (abemaciclib)
	In Rationale section: ▪ To Safety chart added Verzenio (abemaciclib).
	References updated
11-27-2017	Policy published 12-20-2017. Policy retro-effective to 11-27-2017.
	In Description section: ▪ Added Calquence (acalabrutinib) as a target drug ▪ In FDA Approved Indications chart added Calquence (acalabrutinib) and updated Zelboraf indications
	Rationale section updated
	References updated
12-11-2017	Policy correction posted 01-05-2018 adding the 12-11-2017 revision into the Revision section, which had not been added at the original publication on 01-01-2018.
	Policy posted 01-01-2018. Policy retro-effective to 12-11-2017.
	In Description section: ▪ In FDA Approved Indications chart updated Sprycel indications
01-01-2018	Description section updated with updates to the FDA Approved Indications chart
	In Policy section: ▪ Removed "or 2B" and "Clinical Pharmacology) or the prescriber has submitted additional documentation supporting the requested therapeutic use" and added "level of evidence 1 or 2A" to read "The use of the target agent is for an indication that is supported by compendia. (NCCN Compendium™ level of evidence 1 or 2A, AHFS (American Hospital Formulary Service), DrugDex level of evidence 1 or 2A)"
	Rationale section updated
	References updated
02-05-2018	In Description section: ▪ In FDA Approved Indications chart updated indication for Cabometyx and Gilotrif; added new indication for Lynparza tabs; and updated chart key.
	References updated
03-12-2018	Policy posted 04-11-2018. Policy retro-effective to 03-12-2018.
	In Description section:

REVISIONS	
	▪ In FDA Approved Indications chart added Erleada (apalutamide) and updated Zytiga indications
	Updated Rationale section
	Updated References
03-26-2018	Policy posted 04-11-2018. Policy retro-effective to 03-26-2018.
	▪ Imbruvica 70mg capsules, 140 mg tablet, 280 mg tablet, 420 mg tablet, 560 mg tablet now available. (The policy does not reflect dosages, so no policy document updates were made.)
04-23-2018	Policy posted 05-23-2018. Policy retro-effective to 04-23-2018.
	In Description section: ▪ Updated the FDA Indications and Dosage chart to add Tasigna 50mg dosage and new pediatric indication
06-25-2018	Policy posted 07-18-2018. Policy retro-effective to 06-25-2018.
	In Description section: ▪ In FDA Indications and Dosage chart added the new drug Yonsa (abiraterone acetate).
	Rationale section updated
	References updated
07-23-2018	Policy posted 08-15-2018. Policy retro-effective to 07-23-2018.
	In Description section: ▪ In FDA Indications and Dosage chart added the new drugs Braftovi (encorafenib) and Mektovi (binimetinib).
	Rationale section updated
	References updated
08-20-2018	Policy published 09-26-2018. Policy retro-effective to 08-20-2018.
	In Description section: ▪ FDA Indications and Dosage chart added the new Target drug Tibsovo (ivosidenib).
	Rationale section updated
	References updated
10-22-2018	Policy Published November 7, 2018. Policy retro-effective to October 22, 2018.
	Description section updated to add Copiktra as a target agent.
	Rationale section updated
	References updated
10-29-2018	Policy Published November 7, 2018. Policy retro-effective to October 29, 2018.
	Description section updated to add Vizimpro as a target agent.
	Rationale section updated
	References updated
12-01-2018	Summary of Revisions: • Removed FDA labeled indications table – no change to clinical intent • Included the requirement that the requested agent is first line • Updated contraindications table with new contraindications and to match labeling
	Description section updated
	In Policy Section: ▪ Throughout the policy language replaced "target" with "requested" to read "requested agent". ▪ In 1 A replaced "receiving" with "being treated with" ▪ In 1 B replaced "using" with "currently being treated with" ▪ In 1 C iii added "a. The requested agent is a first line agent for the intended indication" ▪ In Item 4 b replaced "intended diagnosis" with "requested indication" ▪ Replaced "FDA Approved Genetic Tests" with "FDA Companion Diagnostics"
	Rational section updated
	References updated

REVISIONS	
12-03-2018	Policy Published 01-01-2019. Policy retro-effective to 12-03-2018.
	Description section updated to add Lorbrena as a target agent.
	Rationale section updated
	References updated
12-17-2018	Policy Published 01-01-2019. Policy retro-effective to 12-17-2018.
	Description section updated to note generic availability of Zytiga 250mg
12-24-2018	Policy Published 01-01-2019. Policy retro-effective to 12-24-2018.
	Description section updated to add Daurismo, Vitrakvi, and Xospata as target agents
	Rationale section updated
	References updated

REFERENCES

1. Afinitor/Afinitor Disperz prescribing information. Novartis. April 2018.
2. Alecensa prescribing information. Genentech. June 2018.
3. Alunbrig prescribing information. Ariad Pharmaceuticals Inc. April 2017.
4. Bosulif prescribing information. Pfizer Inc. December 2017.
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