



Drug and Biologic Coverage Policy

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Oncology Medications

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Related Coverage Resources

[Link to find Cigna - Oncology Medication and Code List](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This coverage policy addresses medications used for the primary treatment of cancer. The use of oncology agents for non-oncology uses are addressed in separate coverage policies.

Coverage of select oncology products varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Receipt of sample product does not satisfy any criteria requirements for coverage.

For a list of medications included in the oncology medications coverage policy, refer to the **Cigna - Oncology Medication and Code List** document [see Related Coverage Resources section].

Medical Necessity Criteria

Oncology Medications are considered medically necessary when the use is an approved indication by the Food and Drug Administration (FDA) OR is a category 1, 2A, or 2B recommendation by the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®) or its derivative information product, The NCCN Drugs & Biologics Compendium (NCCN Compendium®).

Additionally, Oncology Medications are considered medically necessary for Pediatric Oncology use when **ALL** of the following are met:

1. The drug is FDA approved for at least one indication
2. The drug has not been contraindicated or not recommended by the FDA for the off-label use
3. Supported by **ONE** of the following:
 - A. Compendia recognized by federal Centers for Medicare and Medicare Services (CMS) as part of an anticancer chemotherapeutic regimen (AHFS, Clinical Pharmacology, DrugDex, etc.)
 - B. Results of at least two different controlled clinical studies published in peer reviewed English-language, biomedical journal(s) analyzed as supporting the off-label use where consideration is given to quality of evidence, validity of the data, efficacy, and safety of the drug in specific patient populations and how well the study was designed to assess the intervention, including analysis of baseline patient characteristics, patient withdrawals, and meaningful clinical outcome
 - C. Established as standard of care as analyzed in clinical practice guidelines from professional or medical specialty societies, national government supported evidence assessments or guidelines

Additional Preferred Product criteria may be required, see below table.

Product	Criteria
Abraxane intravenous infusion (paclitaxel albumin-bound)	<p><u>Cigna Pathwell Specialty Drug List Plans</u></p> <p>Abraxane is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> a. For <u>Breast Cancer</u>, ONE of the following: <ol style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient has a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient had a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) b. For <u>Cervical Cancer</u>, ONE of the following: <ol style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient has a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient had a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) c. For <u>Endometrial Cancer</u>, ONE of the following: <ol style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient has a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient had a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) d. For <u>Melanoma</u>, ONE of the following:

	<ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) <p>e. For Non-Small Cell Lung Cancer, ONE of the following:</p> <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) iv. Abraxane or paclitaxel albumin-bound intravenous infusion is being used as subsequent therapy in patients with advanced or metastatic disease <p>f. For Ovarian Cancer, ONE of the following:</p> <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine)
Afinitor tablets (everolimus)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Afinitor (everolimus) tablets is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of everolimus tablets (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Akeega (niraparib and abiraterone)	<p><u>Employer Plans</u></p> <p>Akeega is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For BRCA-mutated Prostate Cancer, documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of, contraindication, or intolerance to Lynparza (olaparib), with or without, generic abiraterone [may require prior authorization] B. Currently receiving Akeega
Alunbrig (brigatinib)	<p><u>Employer Group Plans and Individual and Family Plans:</u></p> <p>Alunbrig (brigatinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (ALK)-positive, documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of, contraindication, or intolerance to Alecensa (alectinib) [may require prior authorization] B. Patient is currently receiving Alunbrig
Alymsys (bevacizumab-maly)	<p><u>Employer Plans and Individual and Family Plans</u></p>

	<p>AlymSYS (bevacizumab-maly) is considered medically necessary when BOTH of the follow are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of <u>AND</u> cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to BOTH of the following: <ol style="list-style-type: none"> i. Mvasi (bevacizumab-awwb) [may require prior authorization] ii. Zirabev (bevacizumab-bvzr) [may require prior authorization] B. Currently receiving AlymSYS
<p>Augtyro (repotrectinib)</p>	<p><u>Employer Plans</u></p> <p>Augtyro (repotrectinib) is considered medically necessary when BOTH of the follow are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>ROS1-positive non-small cell lung cancer</u>, documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of, contraindication, or intolerance to Rozlytrek (entrectinib) B. If Augtyro has not been tried previously, approve if the patient has symptomatic systemic progression (multiple lesions) on Rozlytrek (entrectinib capsules and pellet packet), Xalkori (crizotinib capsules), or Zykadia (ceritinib capsules and tablets) C. Patient has congestive heart failure or, according to the prescriber, the patient has a risk of QT prolongation D. Patient is currently receiving therapy with Augtyro
<p>Avastin® (bevacizumab)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Avastin (bevacizumab) is considered medically necessary when BOTH of the follow are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to BOTH of the following: <ol style="list-style-type: none"> i. Mvasi (bevacizumab-awwb) [may require prior authorization] ii. Zirabev (bevacizumab-bvzr) [may require prior authorization] B. Currently receiving Avastin
<p>Besremi (ropeginterferon- alfa-2b-njft)</p>	<p><u>Employer Plans and</u></p> <p>Besremi (ropeginterferon-alfa-2b-njft) is considered medically when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Polycythemia Vera</u>, documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of, contraindication, or intolerance to BOTH of the following: <ol style="list-style-type: none"> i. Hydroxyurea ii. Pegasys (peginterferon alfa-2a) [may require prior authorization] B. Has low-risk polycythemia vera C. Currently receiving Besremi
<p>Bosulif</p>	<p><u>Employer Group Plans:</u></p>

(bosutinib tablets)

Bosulif (bosutinib tablets) is considered medically necessary when BOTH of the following are met:

1. When the Oncology Medications criteria above the table are met
2. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive**, documentation of **ONE** the following:
 - A. Trial of, contraindication, or significant intolerance to **ONE** of the following:
 - i. **Generic imatinib**
 - ii. **Scemblix** [may require prior authorization]
 - iii. **Sprycel** [may require prior authorization]
 - iv. **Tasigna** [may require prior authorization]
Note: Prior use of Gleevec or Phyrago (dasatinib) counts.
 - B. Patient is currently receiving therapy with Bosulif
 - C. Patient meets **BOTH** of the following:
 - i. Patient meets **ONE** of the following:
 1. Patient has intermediate- to high-risk chronic phase CML
 2. Patient has accelerated phase CML or blast phase CML
 - ii. Patient meets **ONE** of the following:
 1. Patient is at risk of bleeding
Note: An example of a patient with an increased risk of bleeding as if a patient has thrombocytopenia or is receiving a medication that inhibits platelet function or anticoagulants.
 2. Patient has a prolonged QT interval or is at risk of developing QT interval prolongation
 - D. Patient has a resistance mutation in which imatinib, Scemblix, a dasatinib product and Tasigna should not be used
Note: Examples of dasatinib products include Sprycel and Phyrago.

Individual and Family Plans

Bosulif (bosutinib tablets) is considered medically necessary when BOTH of the following are met:

1. When the Oncology Medications criteria above the table are met
2. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive**, documentation of **ONE** the following:
 - A. Trial of, contraindication, or significant intolerance to **ONE** of the following:
 - i. **Generic imatinib**
 - ii. **Sprycel** [may require prior authorization]
Note: Prior use of Gleevec or Phyrago (dasatinib) counts.
 - B. Patient is currently receiving therapy with Bosulif
 - C. Patient meets **BOTH** of the following:
 - i. Patient meets **ONE** of the following
 - a. Patient has intermediate- to high-risk chronic phase CML
 - b. Patient has accelerated phase CML or blast phase CML
 - ii. Patient meets **ONE** of the following:
 - a. Patient has a history of a serious, chronic lung disease or has had or is at risk of pleural effusion
Note: Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis.
 - b. Patient is at risk of bleeding
Note: An example of a patient with an increased risk of bleeding as if a patient has thrombocytopenia or is receiving a medication that inhibits platelet function or anticoagulants.

	<p>c. Patient has a prolonged QT interval or is at risk of developing QT interval prolongation</p> <p>D. Patient has a resistance mutation in which one of imatinib and a dasatinib product should not be used</p> <p><u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago.</p>
<p>Braftovi® (encorafenib)</p>	<p><u>Employer Group Plans:</u></p> <p>Braftovi is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met For <u>Melanoma, Unresectable or Metastatic, Treatment of BRAF V600 Mutation-Positive Disease</u>, documentation of ONE of the following: <ol style="list-style-type: none"> Trial of, contraindication, significant intolerance, or other exceptional clinical circumstance to ONE of the following: <ol style="list-style-type: none"> Tafinlar Zelboraf Patient is currently receiving Braftovi
<p>Cyclophosphamide tablets</p> <p><i>This applies to oncology and non-oncology uses of cyclophosphamide.</i></p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Cyclophosphamide tablets is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Documented trial of, contraindication, or intolerance to cyclophosphamide capsules
<p>Fruzaqla™ (fruquintinib)</p>	<p><u>Employer Plans</u></p> <p>Fruzaqla (fruquintinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met For <u>Appendiceal, Colon or Rectal Cancer in an individual 18 years of age or older</u>, ONE of the following: <ol style="list-style-type: none"> Trial of, contraindication, or intolerance to Lonsurf (trifluridine-tipiracil) tablets According to the prescriber, the patient has or is at risk of myelosuppression Patient has already been started on therapy with Fruzaqla
<p>Fusilev® (levoleucovorin)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Fusilev (levoleucovorin) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Inability to obtain leucovorin injection due to a documented drug shortage (Food and Drug Administration [FDA] Drug Shortage database or American Society of Health-Systems Pharmacists [ASHP] Drug Shortage list)
<p>Gleevec® (imatinib)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Gleevec (imatinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Patient has tried imatinib (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers,

	preservatives] between the brand and bioequivalent generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction
Herceptin® (trastuzumab)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Herceptin (trastuzumab) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to ALL of the following: <ol style="list-style-type: none"> i. Kanjinti (trastuzumab-anns) [may require prior authorization] ii. Ogivri (trastuzumab-dkst) [may require prior authorization] iii. Trazimera (trastuzumab-qyyp) [may require prior authorization] B. Currently receiving Herceptin
Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to ONE of the following: <ol style="list-style-type: none"> i. Kanjinti (trastuzumab-anns) [may require prior authorization] ii. Ogivri (trastuzumab-dkst) [may require prior authorization] iii. Trazimera (trastuzumab-qyyp) [may require prior authorization] B. Unable to obtain or maintain intravenous access C. Currently receiving Herceptin Hylecta
Herzuma® (trastuzumab-pkrb)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Herzuma (trastuzumab-pkrb) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to ALL of the following: <ol style="list-style-type: none"> i. Kanjinti (trastuzumab-anns) [may require prior authorization] ii. Ogivri (trastuzumab-dkst) [may require prior authorization] iii. Trazimera (trastuzumab-qyyp) [may require prior authorization] B. Currently receiving Herzuma
Ibrance® (palbociclib)	<p><u>Employer Plans</u></p> <p>Ibrance (palbociclib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For Breast Cancer, documentation of ONE of the following:

	<p>A. Trial of, contraindication, or intolerance to ONE of the following:</p> <ol style="list-style-type: none"> i. Kisqali (ribociclib) [may require prior authorization] ii. Verzenio (abemaciclib) [may require prior authorization] <p>B. Currently receiving Ibrance</p>
<p>Iclusig (ponatinib tablets)</p>	<p><u>Employer Plans</u></p> <p>Iclusig (ponatinib tablets) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Meets ONE of the following: <ol style="list-style-type: none"> A. Patient is currently receiving Iclusig B. <u>For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, documentation of ONE of the following: <ol style="list-style-type: none"> i. Trial of, contraindication, significant intolerance to TWO of the following: <ol style="list-style-type: none"> 1) Generic imatinib 2) Scemblix [may require prior authorization] 3) Sprycel [may require prior authorization] 4) Tasigna [may require prior authorization] <p><u>Note:</u> Prior use of Gleevec (imatinib) or Phyrago (dasatinib) also counts.</p> ii. Patient meets BOTH of the following: <ol style="list-style-type: none"> 1) Patient has intermediate- to high-risk chronic phase CML, accelerated phase CML, or blast phase CML 2) Patient has tried at least two other tyrosine kinase inhibitors for CML <p><u>Note:</u> Examples of tyrosine kinase inhibitors include: Sprycel, Phyrago, Bosulif, Tasigna and Scemblix.</p> iii. Patient has a resistance mutation in which imatinib, Scemblix, a dasatinib product, and Tasigna should not be used <p><u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago.</p> iv. Patient has the <i>T315I</i> mutation C. For <u>Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive</u>, documentation of ONE of the following: <ol style="list-style-type: none"> i. Trial of, contraindication, significant intolerance to ONE of the following: <ol style="list-style-type: none"> 1) Generic imatinib <p><u>Note:</u> Prior use of brand Gleevec counts.</p> 2) Sprycel [may require prior authorization] ii. Patient has a history of serious, chronic lung disease or has had or is a risk of pleural effusion <p><u>Note:</u> Examples of lung diseases include pulmonary arterial hypertension and interstitial pneumonitis.</p> iii. Patient has a resistance mutation in which imatinib and a dasatinib product should not be used <p><u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago.</p> <p><u>Individual and Family Plans</u></p>

Iclusig (ponatinib tablets) is considered medically necessary when BOTH of the following are met:

1. When the Oncology Medications criteria above the table are met

2. Meets **ONE** of the following:

A. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive**, documentation of **ONE** of the following:

i. Patient meets **BOTH** of the following:

1) Patient meets **ONE** of the following:

a. Trial of, contraindication, significant intolerance to **generic Imatinib**

Note: Prior use of Gleevec (imatinib) also counts.

b. Patient has intermediate- to high-risk chronic phase CML, accelerated phase CML, or blast phase CML

c. Patient has tried at least one other tyrosine kinase inhibitor for CML

Note: Examples of tyrosine kinase inhibitors include: Sprycel, Phyrago, Bosulif, Tasigna, and Scemblix.

d. Patient has a resistance mutation in which imatinib not be used

2) Patient meets **ONE** of the following:

a. Trial of, contraindication, significant intolerance to **Sprycel** [may require prior authorization]

Note: Prior use of Phyrago (dasatinib tablets) also counts.

b. Patient has tried at least two other tyrosine kinase inhibitors for CML

Note: Examples of tyrosine kinase inhibitors include: Sprycel, Phyrago, Bosulif, Tasigna and Scemblix.

c. Patient has a history of serious, chronic lung disease or has had or is a risk of pleural effusion

Note: Examples of lung diseases include pulmonary arterial hypertension and interstitial pneumonitis.

d. Patient is at risk of bleeding

Note: Examples of increased risk of bleeding are if a patient has thrombocytopenia or is receiving a medication that inhibits platelet function or anticoagulants.

e. Patient has a resistance mutation in which a dasatinib product should not be used

Note: Examples of dasatinib products include Sprycel and Phyrago.

ii. Patient has the *T315I* mutation

iii. Patient is currently receiving Iclusig

B. For **Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive**, documentation of **ONE** of the following:

i. According to the prescriber, patient has had a trial of, contraindication, significant intolerance to **ONE** of the following:

	<p>1) Generic imatinib <u>Note:</u> Prior use of brand Gleevec counts.</p> <p>2) Sprycel [may require prior authorization]</p> <p>ii. Patient has a history of serious, chronic lung disease or has had or is a risk of pleural effusion <u>Note:</u> Examples of lung diseases include pulmonary arterial hypertension and interstitial pneumonitis.</p> <p>iii. Patient has a resistance mutation in which imatinib and a dasatinib product should not be used <u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago.</p> <p>iv. Patient is currently receiving Iclusig</p>
<p>Infugem™ (gemcitabine)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Infugem (gemcitabine) is considered medically necessary when BOTH of the following is met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Documented trial of, contraindication, or intolerance to generic gemcitabine
<p>Jemperli™ (dostarlimab)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Jemperli (dostarlimab) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met ONE of the following: <ol style="list-style-type: none"> For <u>Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Endometrial Cancer - Monotherapy</u>, documentation of ONE of the following: <ol style="list-style-type: none"> Trial of, contraindication, or intolerance to Keytruda (pembrolizumab) [may require prior authorization] Currently receiving Jemperli For <u>Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors - Monotherapy</u>, documentation of ONE of the following: <ol style="list-style-type: none"> Trial of, contraindication, or intolerance to Keytruda (pembrolizumab) [may require prior authorization] Currently receiving Jemperli
<p>Khapzory™ (levoleucovorin)</p>	<p><u>Employer Group Plans and Individual and Family Plans</u></p> <p>Khapzory (levoleucovorin) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Inability to obtain leucovorin injection due to a documented drug shortage (Food and Drug Administration [FDA] Drug Shortage database or American Society of Health-Systems Pharmacists [ASHP] Drug Shortage list)
<p>Krazati (adagrasib)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Krazati (adagrasib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met

	<p>2. For <u>KRAS G12C-mutated Non-Small Cell Lung Cancer</u>, documentation of ONE of the following:</p> <ul style="list-style-type: none"> A. Trial of, contraindication, or intolerance to sotorasib (Lumakras) [may require prior authorization] B. Patient has brain metastases C. Patient has already been started on therapy with Krazati
<p>lanreotide acetate (by Cipla)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Lanreotide acetate [by Cipla] is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas) and for Pheochromocytoma and Paraganglioma</u>, documented trial of, contraindication, or intolerance to Somatuline Depot (lanreotide) injection [may require prior authorization]
<p>Mektovi® (binimetinib)</p>	<p><u>Employer Group Plans:</u></p> <p>Mektovi is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Melanoma, Unresectable or Metastatic, Treatment of BRAF V600 Mutation-Positive Disease</u>, documentation of ONE of the following: <ul style="list-style-type: none"> A. Trial of, contraindication, significant intolerance, or other exceptional clinical circumstance to ONE of the following: <ul style="list-style-type: none"> i. Cotellic ii. Mekinist B. Patient is currently receiving Mektovi
<p>Nexavar (sorafenib)</p>	<p><u>Employer Plans</u></p> <p>Nexavar (sorafenib) is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of sorafenib (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction <p><u>Individual and Family Plans</u></p> <p>Nexavar (sorafenib) is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of sorafenib (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
<p>Nilandron® (nilutamide)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Nilandron (nilutamide) is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of BOTH of the following:

	<p>A. Trial of nilutamide (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p> <p>B. Trial of, contraindication, or intolerance to ONE of the following:</p> <ul style="list-style-type: none"> i. Bicalutamide ii. Flutamide
<p>Ontruzant® (trastuzumab-dttb)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Ontruzant (trastuzumab-dttb) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ul style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to ALL of the following: <ul style="list-style-type: none"> i. Kanjinti (trastuzumab-anns) [may require prior authorization] ii. Ogivri (trastuzumab-dkst) [may require prior authorization] iii. Trazimera (trastuzumab-qyyp) [may require prior authorization] B. Currently receiving Ontruzant
<p>Orgovyx® (relugolix)</p>	<p><u>Individual and Family Plans</u></p> <p>Orgovyx (relugolix) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ul style="list-style-type: none"> A. Trial of, contraindication, or intolerance to ONE of the following: <ul style="list-style-type: none"> i. Eligard [may require prior authorization] ii. Firmagon [may require prior authorization] iii. Lupron Depot [may require prior authorization] iv. Trelstar [may require prior authorization] B. According to the prescriber, is at risk of cardiovascular disease C. Using for intermittent androgen deprivation therapy D. Currently receiving Orgovyx
<p>Paclitaxel albumin-bound intravenous infusion</p>	<p><u>Cigna Pathwell Specialty Drug List Plans</u></p> <p>Paclitaxel albumin-bound intravenous infusion is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ul style="list-style-type: none"> A. For Breast Cancer, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) B. For Cervical Cancer, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion

	<ul style="list-style-type: none"> iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) C. For Endometrial Cancer, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) D. For Melanoma, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) E. For Non-Small Cell Lung Cancer, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) iv. Abraxane or paclitaxel albumin-bound intravenous infusion is being used as subsequent therapy in patients with advanced or metastatic disease F. For Ovarian Cancer, ONE of the following: <ul style="list-style-type: none"> i. Patient is currently receiving Abraxane or paclitaxel albumin-bound intravenous infusion ii. Patient had a hypersensitivity to paclitaxel intravenous infusion or docetaxel intravenous infusion iii. Patient has a contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine)
Provenge® (sipuleucel-T)	<p><u>Cigna Pathwell Specialty Drug List Plans</u></p> <p>Sipuleucel-T (Provenge) is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For Metastatic Castration-Resistant Prostate Cancer (mCRPC), documentation of ONE of the following: <ul style="list-style-type: none"> A. BOTH of the following: <ul style="list-style-type: none"> i. Tried ONE of abiraterone acetate or Xtandi ii. Meets ONE of the following: <ul style="list-style-type: none"> a. Tried docetaxel and experienced intolerance or other exceptional clinical circumstance b. According to the prescriber, is not a candidate for a systemic regimen (i.e., an elderly patient who is frail) c. Has hepatic impairment (elevated bilirubin or liver enzyme levels) d. Has cystoid macular edema e. Is at increased risk for developing gastrointestinal complications such as enterocolitis f. Is at increased risk of severe fluid retention B. BOTH of the following: <ul style="list-style-type: none"> i. Tried docetaxel

	<ul style="list-style-type: none"> ii. Meets ONE of the following: <ul style="list-style-type: none"> a. Tried ONE of abiraterone or Xtandi and experienced intolerance or other exceptional clinical circumstance b. Has diabetes mellitus and concomitant use with prednisone and abiraterone acetate may be contraindicated c. Is at increased risk for developing seizures d. Is at increased risk for falls and fractures e. Is taking concomitant medication that is either a strong CYP2C8 inhibitor or a strong CYP3A4 inducer f. Is at increased risk for hepatotoxicity g. Is at increased risk for fluid retention and cardiovascular morbidity (e.g., diagnosis of recent myocardial infarction, chronic heart failure)
Rituxan® (rituximab)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Rituxan (rituximab) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction for ALL of the following: <ol style="list-style-type: none"> i. Riabni (rituximab-arrx) [may require prior authorization] ii. Ruxience (rituximab-pvvr) [may require prior authorization] iii. Truxima (rituximab-abbs) [may require prior authorization] B. Currently receiving Rituxan
Rituxan Hycela™ (rituximab and hyaluronidase human)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Rituxan Hycela (rituximab and hyaluronidase human) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. BOTH of the following: <ol style="list-style-type: none"> i. Has received at least one dose of intravenous rituximab ii. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction for ALL of the following: <ol style="list-style-type: none"> a. Riabni (rituximab-arrx) [may require prior authorization] b. Ruxience (rituximab-pvvr) [may require prior authorization] c. Truxima (rituximab-abbs) [may require prior authorization] B. Currently receiving Rituxan Hycela
Sandostatin LAR Depot (octreotide injectable suspension)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Sandostatin LAR Depot (octreotide injectable suspension) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas],</u>

	<p><u>insulinomas), Meningioma and for Pheochromocytoma and Paraganlioma,</u> documentation of ONE of the following:</p> <ul style="list-style-type: none"> A. Trial of, contraindication, or intolerance to Somatuline Depot (lanreotide) injection [may require prior authorization] B. Has either Meningioma or Thymoma/Thymic Carcinoma C. Undergoing treatment with Lutathera D. Currently receiving Sandostatin LAR Depot
<p>Scemblix (asciminib tablets)</p>	<p><u>Individual and Family Plans</u></p> <p>Scemblix (asciminib tablets) is considered medically necessary when BOTH of the following are met:</p> <ul style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive,</u> documentation of ONE of the following: <ul style="list-style-type: none"> A. Patient meets BOTH of the following: <ul style="list-style-type: none"> i. Patient meets ONE of the following: <ul style="list-style-type: none"> a. Trial of, contraindication, significant intolerance to generic imatinib <u>Note:</u> Prior use of brand Gleevec (imatinib) counts. b. Patient has intermediate- to high-risk chronic phase CML, accelerated CML or blast phase CML c. Patient has tried at least one other tyrosine kinase inhibitor for CML <u>Note:</u> Examples of tyrosine inhibitors include: Sprycel, Phyrago, Bosulif, Tasigna and Iclusig. d. Patient has a resistance mutation in which imatinib should not be used ii. Patient meets ONE of the following: <ul style="list-style-type: none"> a. Trial of, contraindication, significant intolerance to Sprycel <u>Note:</u> Prior use of Phyrago (dasatinib tablets) also counts. b. Patient has tried at least two other tyrosine kinase inhibitors for CML <u>Note:</u> Examples of tyrosine kinase inhibitors include: Sprycel, Phyrago, Bosulif, Tasigna, and Iclusig. c. Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion <u>Note:</u> Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis. d. Patient is at risk of bleeding <u>Note:</u> Examples of increased risk of bleeding are if a patient has thrombocytopenia or is receiving a medication that inhibits platelet function or anticoagulants. e. Patient has a resistance mutation in which a dasatinib product should not be used <u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago. B. Patient is currently receiving Scemblix

	C. Patient has the <i>T315I</i> mutation
Sutent (sunitinib)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Sutent (sunitinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Documented trial of sunitinib (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Talzenna [®] (talazoparib)	<p><u>Employer Plans</u></p> <p>Talzenna (talazoparib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met ONE of the following: <ol style="list-style-type: none"> For <u>BRCA-mutated, recurrent or metastatic Breast Cancer</u>, ONE of the following: <ol style="list-style-type: none"> Documented trial of, contraindication, intolerance to Lynparza (olaparib) [may require prior authorization] Currently receiving Talzenna For <u>BRCA-mutated Prostate Cancer</u>, ONE of the following: <ol style="list-style-type: none"> Documented trial of, contraindication, intolerance to Lynparza (olaparib) [may require prior authorization] Currently receiving Talzenna
Tarceva [®] (erlotinib)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Tarceva (erlotinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Documented trial of erlotinib (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Targretin [®] (bexarotene)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Targretin (bexarotene) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met Documented trial of bexarotene (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Tasigna (nilotinib)	<p><u>Employer Group Plans and Individual and Family Plans:</u></p> <p>Tasigna (nilotinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> When the Oncology Medications criteria above the table are met For <u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, documentation of ONE of the following: <ol style="list-style-type: none"> Trial of, contraindication, significant intolerance to ONE of the following: <ol style="list-style-type: none"> Generic imatinib Sprycel [may require prior authorization] <p>Note: Prior use of Gleevec (imatinib) or Phyrago (dasatinib) also counts.</p>

	<p>B. Patient is currently receiving Tasigna</p> <p>C. Patient is less than 18 years of age with accelerated phase CML</p> <p>D. Patient meets BOTH of the following:</p> <ul style="list-style-type: none"> i. Patient meets ONE of the following: <ul style="list-style-type: none"> a. Patient has intermediate- to high-risk disease chronic phase CML b. Patient has accelerated phase CML or blast phase CML ii. Patient meets ONE of the following: <ul style="list-style-type: none"> a. Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion <u>Note:</u> Examples of lung disease, pulmonary arterial hypertension, and interstitial pneumonitis. b. Patient is at risk of bleeding <u>Note:</u> An example of a patient with an increased risk of bleeding is a patient with thrombocytopenia or with a medication that inhibits platelet function or anticoagulants. <p>E. Patient has a resistance mutation in which imatinib and a dasatinib product should not be used <u>Note:</u> Examples of dasatinib products include Sprycel and Phyrago.</p>
<p>Tecentriq® (atezolizumab)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Tecentriq (atezolizumab) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Non-Small Cell Lung Cancer – Advanced or Metastatic, Squamous or Non-Squamous Cell Disease - Monotherapy</u>, documentation of ONE of the following: <ol style="list-style-type: none"> A. Patient is currently receiving Tecentriq B. The medication is used for <u>First-line</u> therapy, patient meets ONE of the following: <ol style="list-style-type: none"> i. BOTH of the following: <ol style="list-style-type: none"> 1) ONE of the following: <ul style="list-style-type: none"> a. Tumor expresses programmed death-ligand (PD-L1) \geq 50% of tumor cells (tumor proportion score [TPS] \geq 50%) b. PD-L1 stained tumor-infiltrating immune cells cover \geq 10% of the tumor area (IC \geq 10%) 2) According to the prescriber, the patient has had a trial of, contraindication, or significant intolerance to Keytruda (pembrolizumab) [may require prior authorization] ii. Patient has a performance status of 3 C. The medication is used for <u>Subsequent</u> therapy, patient meets ONE of the following: <ol style="list-style-type: none"> i. Programmed death-ligand 1 (PD-L1) stained $<$ 1% of tumor cells (tumor proportion score [TPS] $<$ 1%) ii. According to the prescriber, the patient has had a trial of, contraindication, or significant intolerance to Keytruda (pembrolizumab) [may require prior authorization]
<p>Temodar® (temozolomide)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Temodar (temozolomide) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met

	<p>2. Documented trial of temozolomide (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction</p>
<p>Tykerb® (lapatinib)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Tykerb (lapatinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of lapatinib (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
<p>Vegzelma (bevacizumab-adcd)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Vegzelma (bevacizumab-adcd) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of AND cannot continue to use the alternative(s) due to a formulation difference in the inactive ingredient(s) which, according to the prescriber, would result in a significant allergy or serious adverse reaction to BOTH of the following: <ol style="list-style-type: none"> i. Mvasi (bevacizumab-awwb) [may require prior authorization] ii. Zirabev (bevacizumab-bvzr) [may require prior authorization] B. Currently receiving Vegzelma
<p>Votrient® (pazopanib)</p>	<p><u>Employer Plans</u></p> <p>Votrient (pazopanib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. The patient has tried the bioequivalent generic product, pazopanib [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the bioequivalent generic product which would result, per the prescriber, in a significant allergy or serious adverse reaction
<p>Xeloda® (capecitabine)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Xeloda (capecitabine) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 3. When the Oncology Medications criteria above the table are met 4. Documented trial of capecitabine (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
<p>Yonsa® (abiraterone)</p>	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Yonsa (abiraterone) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of, contraindication, or intolerance to generic abiraterone
<p>Zykadia</p>	<p><u>Employer Group Plans and Individual and Family Plans:</u></p>

(ceritinib)	<p>Zykadia (ceritinib) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. For <u>Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (ALK)-positive</u>, documentation of ONE of the following: <ol style="list-style-type: none"> A. Trial of, contraindication, intolerance to Alecensa (alectinib) [may require prior authorization] B. Patient is currently receiving Zykadia
Zytiga® (abiraterone)	<p><u>Employer Plans and Individual and Family Plans</u></p> <p>Zytiga (abiraterone) is considered medically necessary when BOTH of the following are met:</p> <ol style="list-style-type: none"> 1. When the Oncology Medications criteria above the table are met 2. Documented trial of abiraterone (the bioequivalent generic product) [may require prior authorization] AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Authorization Duration

Initial approval duration: up to 12 months, unless otherwise stated

Reauthorization approval duration: up to 12 months, unless otherwise stated

Conditions Not Covered

Any other oncology use is considered experimental, investigational or unproven.

Oncology Medications for uses that are an NCCN category 3 recommendation (unless the use is approved by the FDA) are not covered because they are considered not medically necessary.

Background

FDA Approved Indication

- **Drugs**
Drugs@FDA.
<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>
- **Biologics**
Licensed Biological Products with Supporting Documents.
<http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm>

Professional Societies/Organizations

- National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
[Available with free subscription]
http://www.nccn.org/professionals/physician_gls/f_guidelines.asp

- The NCCN Drugs & Biologics Compendium (NCCN Compendium®) [available with paid subscription] http://www.nccn.org/professionals/drug_compendium/content/contents.asp

The National Comprehensive Cancer Network® (NCCN®) is an organization of cancer centers, developing treatment guidelines for most cancers. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) present evidenced-based recommendations for the diagnosis and treatment of cancer and cancer care supportive therapies. NCCN provides the following definitions for their categories of recommendations:²

- Category 1: Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate;
- Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate;
- Category 2B: Based upon lower-level evidence, there is NCCN consensus that the intervention is appropriate;
- Category 3: Based upon any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

For the ‘uniform NCCN consensus’ defined in Category 1 and Category 2A, a majority Panel vote of at least 85% is required. For the ‘NCCN consensus’ defined in Category 2B, a Panel vote of at least 50% (but less than 85%) is required. Lastly, for recommendations where there is strong Panel disagreement regardless of the quality of the evidence, NCCN requires a vote from at least three Panel Members (representing at least three different Member Institutions) to include and designate a recommendation as Category 3. The large majority of the recommendations put forth in the Guidelines are Category 2A. Where categories are not specified within the Guidelines, the default designation for the recommendation is Category 2A.²

The NCCN Drugs & Biologics Compendium (NCCN Compendium®) includes FDA Approved Indications of cancer and cancer support medications and recommended non-FDA approved uses based upon the recommendations contained within the NCCN Guidelines.

References

1. U.S. Food and Drug Administration. Drugs@FDA. U.S. Department of Health & Human Services: <http://www.accessdata.fda.gov/scripts/cder/drugsatfda/>.
2. National Comprehensive Cancer Network. Retrieved from <https://www.nccn.org>. Accessed March 27, 2023.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology (version 2.2023 – March 13, 2023). © 2023 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on March 27, 2023.
4. U.S. Food and Drug Administration. Licensed Biological Products with Supporting Documents. U.S. Department of Health & Human Services: <http://www.fda.gov/BiologicsBloodVaccines/ucm133705.htm>.

Revision Details

Type of Revision	Summary of Changes	Date
Selected Revision	<p>Fruzaqla Appendiceal, Colon or Rectal Cancer: Added preferred product step requirement through Lonsurf for Employer Plans</p> <p>Krazati Added <i>has brain metastases</i> exception to the sotorasib (Lumakras) preferred product step requirement</p>	5/15/2024

Selected Revision	<p>Augtyro ROS1-positive non-small cell lung cancer: Added preferred product step requirement through Rozlytrek for Employer Plans</p> <p>Abraxane and Paclitaxel albumin-bound Updated Abraxane and Paclitaxel albumin-bound preferred product requirement criteria on Cigna Pathwell Specialty Drug List Plans</p>	6/1/2024
Selected Revision	<p>Alunbrig/Zykadia Non-Small Cell Lung Cancer – anaplastic lymphoma kinase (ALK)-positive: Added preferred product step requirement through Alecensa for Employer and Individual and Family Plans</p> <p>Votrient Added preferred product step requirement through generic pazopanib for Employer Plans</p> <p>Braftovi Melanoma, unresectable or metastatic, treatment of <i>BRAF</i> V600 mutation-positive: Added preferred product step requirement through Tafinlar or Zelboraf on Employer plans</p> <p>Mektovi Melanoma, unresectable or metastatic, treatment of <i>BRAF</i> V600 mutation-positive: Added preferred product step requirement through Cotellic or Mekinist for Employer plans</p> <p>Bosulif Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: Updated preferred product criteria to add Scemblix and Tasigna as step requirement options, Updated preferred product step requirement exceptions</p> <p>Gleevec Updated preferred product step through generic imatinib requirement criteria</p> <p>Iclusig Chronic Myeloid Leukemia, Philadelphia Chromosome Positive: Updated preferred product criteria to add Scemblix and Tasigna as step requirement options, Updated step requirement from requiring “ONE” to requiring “TWO” preferred products for Employer and Individual and Plans, Updated exceptions to the step requirement for Employer plans and Individual and Family Plans Acute Lymphoblastic Leukemia, Philadelphia Chromosome Positive: Added preferred product step requirement through generic imatinib or Sprycel for Iclusig</p> <p>Scemblix Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: Removed Scemblix preferred product step requirement on Employer Plans, Updated</p>	7/1/2024

	<p>step requirement from requiring “ONE” to requiring “TWO” preferred products for Individual and Plans, Updated exceptions to the step requirement for Individual and Family Plans</p> <p>Tasigna Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: Updated exceptions to the step requirement for Employer and Individual and Family Plans</p>	
Selected Revision	<p>Tecentriq Non-Small Cell Lung Cancer – Advanced or Metastatic, Squamous or Non-Squamous Cell Disease: Updated Tecentriq preferred product criteria: changed “initial therapy” to “first-line therapy”; added “patient has a performance status of 3” as an exception to the preferred product Keytruda step requirement</p>	8/1/2024
Selected Revision	<p>Pomalyst Removed Pomalyst preferred product criteria requirement.</p>	9/1/2024

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