Drug and Biologic Coverage Policy

Effective Date **2/15/2024**
Coverage Policy Number **1403**

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 drug or biologic 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)	**Cigna Pathwell Specialty Drug List Plans** **Abraxane are considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: a. For **Breast Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) b. For **Cervical Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) c. For **Endometrial Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) d. For **Melanoma**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine)

	e. For **Non-Small Cell Lung Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) iv. Abraxane is being used as subsequent therapy for advanced or metastatic disease f. For **Ovarian Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine)
Afinitor tablets (everolimus)	**Employer Group and Individual and Family Plans:** **Afinitor (everolimus) tablets is considered medically necessary when BOTH of the following are met:** 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)	**Employer Group Plans:** **Akeega is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. For **BRCA-mutated Prostate Cancer**, documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **Lynparza (olaparib), with or without, generic abiraterone** [may require prior authorization] B. Currently receiving **Akeega**
Alymsys (bevacizumab-maly)	**Employer Group and Individual and Family Plans:** **Alymsys (bevacizumab-maly) is considered medically necessary when BOTH of the follow are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: i. **Mvasi (bevacizumab-awwb)** [may require prior authorization] ii. **Zirabev (bevacizumab-bvzr)** [may require prior authorization] B. Currently receiving Alymsys
Avastin® (bevacizumab)	**Employer Group and Individual and Family Plans:** **Avastin (bevacizumab) is considered medically necessary when BOTH of the follow are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: i. **Mvasi (bevacizumab-awwb)** [may require prior authorization]

	ii. **Zirabev (bevacizumab-bvzr)** [may require prior authorization] B. Currently receiving Avastin
Besremi (ropeginterferon-alfa-2b-njft)	**Employer Group Plans and Individual and Family Plans:** **Besremi (ropeginterferon-alfa-2b-njft) is considered medically when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **Only for Polycythemia Vera**, documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **BOTH** of the following: i. **Hydroxyurea** ii. **Pegasys (peginterferon alfa-2a)** [may require prior authorization] B. Has low-risk polycythemia vera C. Currently receiving Besremi
Bosulif (bosutinib tablets)	**Employer Group Plans and 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, Philadelphia Chromosome Positive,** documentation of **ONE** the following: A. Trial of contraindication, or intolerance to **ONE** of the following: i. **Imatinib (Gleevec)** [may require prior authorization] ii. **Sprycel** [may require prior authorization] B. Has intermediate- to high-risk disease AND **ONE** of the following: i. A history of a serious, chronic lung disease (for example, pulmonary arterial hypertension, interstitial pneumonitis) or has had or is at risk of pleural effusion ii. At risk of bleeding (for example, thrombocytopenia, taking a medication that inhibits platelet function or anticoagulants) iii. Has a prolonged QT interval or is at risk of developing QT interval prolongation C. Has a mutation in which imatinib or Sprycel should not be used D. Currently receiving therapy with Bosulif
Cyclophosphamide tablets *This applies to oncology and non-oncology uses of cyclophosphamide.*	**Employer Group Plans and Individual and Family Plans:** **Cyclophosphamide tablets is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documented trial of, contraindication, or intolerance to cyclophosphamide capsules
Fusilev® (levoleucovorin)	**Employer Group Plans and Individual and Family Plans:** **Fusilev (levoleucovorin) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. 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)
Gleevec® (imatinib)	**Employer Group Plans and Individual and Family Plans:**

	Gleevec (imatinib) is considered medically necessary when BOTH of the following are met: 1. When the Oncology Medications criteria above the table are met 2. Trial of **imatinib** (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
Herceptin® (trastuzumab)	**Employer Group Plans and Individual and Family Plans:** **Herceptin (trastuzumab) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: 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)	**Employer Group Plans and Individual and Family Plans:** **Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: 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)	**Employer Group Plans and Individual and Family Plans:** **Herzuma (trastuzumab-pkrb) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: 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)	**Employer Group Plans:**

	Ibrance (palbociclib) is considered medically necessary when BOTH of the following are met: 1. When the Oncology Medications criteria above the table are met 2. **For Breast Cancer**, documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **ONE** of the following: i. **Kisqali (ribociclib)** [may require prior authorization] ii. **Verzenio (abemaciclib)** [may require prior authorization] B. Currently receiving Ibrance
Iclusig (ponatinib tablets)	**Employer Group Plans and Individual and Family Plans:** **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. **ONLY for Chronic Myeloid Leukemia, Philadelphia Chromosome Positive,** documentation of **ONE** of the following: A. Trial of, contraindication, intolerance to **ONE** of the following: i. **Imatinib (Gleevec)** ii. **Sprycel** [may require prior authorization] B. Has the *T315I* mutation C. Has intermediate- to high-risk disease AND has a history of serious, chronic lung disease (for example, pulmonary arterial hypertension and interstitial pneumonitis), or has had or is at risk of pleural effusion D. Has a mutation in which imatinib or Sprycel should not be used E. Currently receiving Iclusig
Infugem™ (gemcitabine)	**Employer Group Plans and Individual and Family Plans:** **Infugem (gemcitabine) is considered medically necessary when BOTH of the following is met:** 1. When the Oncology Medications criteria above the table are met 2. Documented trial of, contraindication, or intolerance to generic gemcitabine
Jemperli™ (dostarlimab)	**Employer Group Plans and Individual and Family Plans:** **Jemperli (dostarlimab) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONE of the following:** A. For **Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Endometrial Cancer - Monotherapy,** documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to Keytruda (pembrolizumab) [may require prior authorization] ii. Currently receiving Jemperli B. For **Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors – Monotherapy**, documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to Keytruda (pembrolizumab) [may require prior authorization] ii. Currently receiving Jemperli
Khapzory™ (levoleucovorin)	**Employer Group Plans and Individual and Family Plans:**

	Khapzory (levoleucovorin) is considered medically necessary when BOTH of the following are met: 1. When the Oncology Medications criteria above the table are met 2. 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)
Krazati (adagrasib)	**Employer Group Plans and Individual and Family Plans:** **Krazati (adagrasib) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **sotorasib (Lumakras)** [may require prior authorization] B. Currently receiving Krazati
lanreotide acetate (Cipla)	**Employer Group Plans and Individual and Family Plans:** **Lanreotide acetate [Cipla] is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for 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,** documented trial of, contraindication, or intolerance to **Somatuline Depot (lanreotide) injection** [may require prior authorization]
Nexavar (sorafenib)	**Employer Group Plans:** **Nexavar (sorafenib) is considered medically necessary when BOTH of the following are met:** 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 **Individual and Family Plans: (Effective 1/1/2024)** **Nexavar (sorafenib) is considered medically necessary when BOTH of the following are met:** 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
Nilandron® (nilutamide)	**Employer Group Plans and Individual and Family Plans:** **Nilandron (nilutamide) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **BOTH** of the following: 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

	B. Trial of, contraindication, or intolerance to **ONE** of the following: i. Bicalutamide ii. Flutamide
Ontruzant® (trastuzumab-dttb)	**<u>Employer Group Plans and Individual and Family Plans</u>:** **Ontruzant (trastuzumab-dttb) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: 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
Orgovyx® (relugolix)	**<u>Individual and Family Plans</u>:** **Orgovyx (relugolix) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **ONE** of the following: 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
Paclitaxel albumin-bound intravenous infusion	**<u>Cigna Pathwell Specialty Drug List Plans</u>** **Abraxane are considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: a. For **<u>Breast Cancer</u>**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) b. For **<u>Cervical Cancer</u>**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) c. For **<u>Endometrial Cancer</u>**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) d. For **<u>Melanoma</u>**, **ONE** of the following:

	i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) e. For **Non-Small Cell Lung Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine) iv. Abraxane is being used as subsequent therapy for advanced or metastatic disease f. For **Ovarian Cancer**, **ONE** of the following: i. Currently receiving abraxane ii. Intolerance to paclitaxel intravenous infusion or docetaxel iii. Contraindication to the standard pre-medications (for example, dexamethasone, ranitidine, famotidine, diphenhydramine)
Pomalyst® (pomalidomide)	**Cigna Total Savings:** **Pomalyst (pomalidomide) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for Multiple Myeloma,** documentation of **ONE** of the following: A. Trial of, contraindication, or intolerance to **Revlimid (lenalidomide)** [may require prior authorization] B. Currently receiving Pomalyst
Provenge® (sipuleucel-T)	**Cigna Pathwell Specialty Drug List Plans** **Sipuleucel-T (Provenge) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for Metastatic Castration-Resistant Prostate Cancer (mCRPC),** documentation of **ONE** of the following: A. **BOTH** of the following: i. Tried **ONE** of **abiraterone acetate** or **Xtandi** ii. Meets **ONE** of the following: 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: i. Tried **docetaxel** ii. Meets **ONE** of the following: 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)	**Employer Group Plans and Individual and Family Plans:** **Rituxan (rituximab) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: 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)	**Employer Group Plans and Individual and Family Plans:** **Rituxan Hycela (rituximab and hyaluronidase human) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: A. **BOTH** of the following: 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: 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)	**Employer Group Plans and Individual and Family Plans:** **Sandostatin LAR Depot (octreotide injectable suspension) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for Neuroendocrine Tumor(s) [NETs] of the Gastrointestinal Tract, Lung, Thymus (Carcinoid Tumors), and Pancreas (including glucagonomas, gastrinomas, vasoactive intestinal peptides-secreting tumors [VIPomas], insulinomas), Meningioma and for Pheochromocytoma and Paraganglioma,** documentation of **ONE** of the following: 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

Scemblix (asciminib tablets)	**<u>Employer Group Plans and Individual and Family Plans</u>:** **Scemblix (asciminib tablets) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for Chronic Myeloid Leukemia, Philadelphia Chromosome Positive,** documentation of **ONE** of the following: A. Trial of, contraindication, intolerance to **ONE** of the following: i. **Imatinib (Gleevec)** ii. **Sprycel** [may require prior authorization] B. Has the *T315I* mutation C. Has intermediate- to high-risk disease and **ONE** of the following: i. A history of serious, chronic lung disease or has had or is at risk of pleural effusion (for example, pulmonary arterial hypertension and interstitial pneumonitis) ii. Is at risk of bleeding (for example, if a patient has thrombocytopenia or is receiving a medication that inhibits platelet function or anticoagulants) D. Has a mutation in which imatinib or Sprycel should not be used E. Currently receiving Scemblix
Sutent (sunitinib)	**<u>Employer Group Plans and Individual and Family Plans</u>:** **Sutent (sunitinib) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documented trial of **<u>sunitinib</u>** (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)	**<u>Employer Group Plans</u>** **Talzenna (talazoparib) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following: A. For ***BRCA*-mutated, recurrent or metastatic Breast Cancer**, **ONE** of the following: i. Documented trial of, contraindication, intolerance to **Lynparza (olaparib)** [may require prior authorization] ii. Currently receiving Talzenna B. For ***BRCA*-mutated Prostate Cancer**, **ONE** of the following: i. Documented trial of, contraindication, intolerance to **Lynparza (olaparib)** [may require prior authorization] ii. Currently receiving Talzenna
Tarceva® (erlotinib)	**<u>Employer Group Plans and Individual and Family Plans</u>:** **Tarceva (erlotinib) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documented trial of **<u>erlotinib</u>** (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)	**Employer Group Plans and Individual and Family Plans:** **Targretin (bexarotene) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. 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 capsules)	**Employer Group Plans and Individual and Family Plans:** **Tasigna (nilotinib capsules) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONLY for Chronic Myeloid Leukemia, Philadelphia Chromosome Positive,** documentation of **ONE** of the following: A. Trial of, contraindication, intolerance to **ONE** of the following: i. Imatinib (Gleevec) ii. **Sprycel** [may require prior authorization] B. Has intermediate- to high-risk disease AND **ONE** of the following: i. A history of serious, chronic lung disease (for example, pulmonary arterial hypertension, interstitial pneumonitis) or has had or is at risk of pleural effusion ii. Is at risk of bleeding (for example, thrombocytopenia, taking a medication that inhibits platelet function or anticoagulants)- C. Has a mutation in which imatinib or Sprycel should not be used D. Currently receiving Tasigna
Tecentriq® (atezolizumab)	**Employer Group Plans and Individual and Family Plans:** **Tecentriq (atezolizumab) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. **For Non-Small Cell Lung Cancer – Advanced** or **Metastatic Squamous or Non-Squamous Cell Disease Monotherapy,** documentation of **ONE** of the following: A. Currently receiving Tecentriq B. For use as Initial therapy, **BOTH** of the following: i. **ONE** of the following: a. PD-L1 stained greater than or equal to 50% of tumor cells (TC greater or equal to 50%) b. PD-L1 stained tumor-infiltrating immune cells cover greater than or equal to 10% of the tumor area (IC greater than or equal to 10%) ii. Documented trial of, contraindication, or intolerance to **Keytruda (pembrolizumab)** [may require prior authorization] C. For use as Subsequent therapy, **ONE** of the following: i. Programmed death-ligand 1 (PD-L1) stained less than 1% of tumor cells (tumor proportion score [TPS] less than 1%) ii. Documented trial of, contraindication, or intolerance to **Keytruda (pembrolizumab)** [may require prior authorization]
Temodar® (temozolomide)	**Employer Group Plans and Individual and Family Plans:** **Temodar (temozolomide) is considered medically necessary when BOTH of the following are met:**

	1. When the Oncology Medications criteria above the table are met 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
Tykerb® (lapatinib)	**Employer Group Plans and Individual and Family Plans:** **Tykerb (lapatinib) is considered medically necessary when BOTH of the following are met:** 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
Vegzelma (bevacizumab-adcd)	**Employer Group Plans and Individual and Family Plans:** **Vegzelma (bevacizumab-adcd) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation of **ONE** of the following: 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: i. **Mvasi (bevacizumab-awwb)** [may require prior authorization] ii. **Zirabev (bevacizumab-bvzr)** [may require prior authorization] B. Currently receiving Vegzelma
Xeloda® (capecitabine)	**Employer Group Plans and Individual and Family Plans:** **Xeloda (capecitabine) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. 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
Yonsa® (abiraterone)	**Employer Group Plans and Individual and Family Plans:** **Yonsa (abiraterone) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documented trial of, contraindication, or intolerance to generic abiraterone
Zytiga® (abiraterone)	**Employer Group Plans and Individual and Family Plans:** **Zytiga (abiraterone) is considered medically necessary when BOTH of the following are met:** 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:

- 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. (NCCN, 2020)

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.

Chronic Myeloid Leukemia (CML)

Tyrosine kinase inhibitor (TKI) have various indications for patients with chronic myeloid leukemia (CML).[1-7] Selected agents have additional indications, which are not detailed.

- **Bosulif** is indicated for: 1) newly diagnosed adults with Philadelphia chromosome-positive (Ph+) CML in chronic phase; and 2) chronic phase, accelerated phase or blast phase Ph+ CML with resistance or intolerance to prior therapy.
- **Imatinib** is indicated for: 1) newly diagnosed adult and pediatric patients with Ph+ CML in chronic phase and 2) Ph+ CML in blast crisis, accelerated phase, and chronic phase after interferon therapy.
- **Iclusig** is indicated for: 1) adults with chronic phase CML with resistance or intolerance to at least two prior TKIs, 2) adults with T315I-positive CML (chronic phase, accelerated phase, or blast phase), and 3) adults with accelerated phase or blast phase CML for whom no other TKI therapy is indicated.
- **Scemblix** is indicated for the treatment of adults with: 1): Ph+ AML in chronic phase, previously treated with two or more TKIs, and 2) Ph+ CML in chronic phase with the T315I mutation.
- **Sprycel** is indicated for: 1) newly diagnosed adults and pediatric patients ≥ 1 year of age with Ph+ CML in chronic phase, 2) Ph+ CML (adults) in chronic phase, accelerated phase, or blast phase with resistance or intolerance to prior therapy including imatinib, and 3) Ph+ CML in chronic phase in pediatric patients ≥ 1 year of age.
- **Tasigna** is indicated for: 1) newly diagnosed adult and pediatric patients (≥ 1 year of age) with Ph+ CML in chronic phase, 2) chronic phase and accelerated phase Ph+ CML in adults with resistance to or intolerance to prior therapy that included imatinib, and 3) pediatric patients ≥ 1 year of age with Ph+ CML in chronic phase and accelerated phase resistant or intolerant to prior TKI therapy.

Guidelines

The National Comprehensive Cancer Network (NCCN) CML guidelines (version 2.2022 – November 15, 2021) make many recommendations regarding TKI inhibitors. Therapy choice may be toxicity driven. For example, imatinib may be preferred for older patients with comorbidities (e.g., cardiovascular disease).[8]

- For patients with chronic phase CML with a low-risk score, the primary treatment recommended includes a first-generation TKI (imatinib 400 mg QD [category 1]), or a second-generation TKI (Bosulif 400 mg QD [category 1], Sprycel 100 mg QD [category 1], or Tasigna 300 mg BID [category 1]).
- For patients with chronic phase CML with an intermediate- or high-risk score, a second-generation TKI is preferred (Bosulif 400 mg QD [category 1], Sprycel 100 mg QD [category 1], or Tasigna 300 mg BID [category 1]). A first-generation TKI (imatinib 400 mg QD) is an alternative (category 2A).
- Second generation TKIs are preferred for patients with an intermediate- or high-risk score (Sprycel, Tasigna, and Bosulif). These agents associated with quicker, deeper and higher rates of major molecular response, as well as less disease progression, compared with imatinib. This applies to particular subgroups such as young patients who are interested in potentially discontinuing therapy or for female patients whose goal is to achieve deep and rapid molecular response with possible medication discontinuation of TKIs for purposes of family planning.
- Scemblix is a treatment option for chronic phase CML in patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs.
- Iclusig is an option for patients with the T315I mutation and/or chronic phase CML with resistance or intolerance to at least two prior TKIs or for patients with accelerated or blast phase CML for whom no other TKI is indicated. Iclusig has several serious toxicities such as a Boxed Warning regarding arterial occlusive events, venous thromboembolic events, heart failure, and hepatotoxicity.
- Regarding safety profiles, imatinib may be preferred for older patients with toxicities, such as cardiovascular disease. Tasigna or Bosulif may be preferred for patients with a history of lung disease or

at risk of developing pleural effusions. Sprycel may be more commonly associated with pleural effusion. Sprycel may be associated with significant but reversible inhibition of platelet aggregation that may contribute to bleeding in some patients, especially if a patient also has thrombocytopenia. Sprycel or Bosulif can be preferred for patients with a history of arrhythmias, heart disease, pancreatitis, or hyperglycemia. Tasigna prolongs the QT interval and has a Boxed Warning in its prescribing information regarding this risk.

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.