Drug Coverage Policy

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Coverage Policy Number..... 1403
Policy Title.....Oncology Medications

Oncology Medications

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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.

Cigna Healthcare Coverage Policy

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.

For a list of medications included in the oncology medications coverage policy, refer to the **Cigna - Oncology Medication and Code List** document.

All products are approved for a duration of up to 12 months unless otherwise noted.

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

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.

Medical Necessity Criteria

Oncology Medications are considered medically necessary when BOTH of the following are met:

1. **ONE** of the following criteria are met:
    a. Use is an approved indication by the Food and Drug Administration (FDA)
    b. Use 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®)
    c. For **Pediatric Oncology** use, **ALL** of the following criteria are met:
        i. The drug is FDA approved for at least one indication
        ii. The drug has not been contraindicated or not recommended by the FDA for the off-label use
        iii. Supported by **ONE** of the following:
            1. Compendia recognized by federal Centers for Medicare and Medicare Services (CMS) as part of an anticancer chemotherapeutic regimen (AHFS, Clinical Pharmacology, DrugDex, etc.)
            2. 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
            3. Established as standard of care as analyzed in clinical practice guidelines from professional or medical specialty societies, national government supported evidence assessments or guidelines
2. If required, preferred product criteria are met as listed in the below table

Product	Criteria
Abraxane intravenous infusion (paclitaxel albumin-bound)	**Cigna Pathwell Specialty Drug List Plans** **Abraxane 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. For **Breast Cancer**, **ONE** of the following: 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 **Cervical Cancer**, **ONE** of the following: 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 **Endometrial Cancer**, **ONE** of the following: 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 **Melanoma**, **ONE** of the following: 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: 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: 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) g. **All Other Conditions**. Approve Abraxane intravenous infusion if the patient meets the Oncology Medications criteria above the table
Akeega (niraparib and abiraterone)	**Employer 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. **ONE** of the following: A. For **BRCA-mutated Prostate Cancer**, documentation of **ONE** of the following: 1. Trial of, contraindication, or intolerance to **Lynparza (olaparib), with or without, generic abiraterone** [may require prior authorization]

	2. Currently receiving **Akeega** B. **All Other Conditions**. Approve Akeega if the patient meets the Oncology Medications criteria above the table
Alunbrig (brigatinib)	**<u>Employer Plans and Individual and Family Plans</u>:** **Alunbrig (brigatinib) 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 **<u>Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (*ALK*)-positive</u>**, documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to **Alecensa (alectinib)** [may require prior authorization] ii. Patient has already been started on therapy with Alunbrig B. **All Other Conditions**. Approve Alunbrig if the patient meets the Oncology Medications criteria above the table
Alymsys (bevacizumab-maly)	**<u>Employer Plans and Individual and Family Plans</u>** **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 <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: i. **Mvasi (bevacizumab-awwb)** [may require prior authorization] ii. **Zirabev (bevacizumab-bvzr)** [may require prior authorization] B. Currently receiving Alymsys
Anktiva (nogapendekin alfa inbakicept-pmln)	**<u>Employer Plans and Individual and Family Plans</u>** **Anktiva (nogapendekin alfa inbakicept-pmln) 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 **<u>Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer</u>**, documentation of **ONE** of the following: i. Patient meets **TWO** of the following: a. Patient meets **ONE** of the following: b. Patient has tried intravesical chemotherapy <u>Note</u>: Intravesical chemotherapy includes gemcitabine, mitomycin c. Patient has a contraindication to intravesical chemotherapy OR according to the prescriber, intravesical chemotherapy is not clinically appropriate for the patient d. Patient meets **ONE** of the following:

	a. Patient has tried **Keytruda** [may require prior authorization] b. Patient has a contraindication to Keytruda OR according to the prescriber, Keytruda is not clinically appropriate for the patient e. Patient meets **ONE** of the following: i. Patient has tried **Adstiladrin** [may require prior authorization] ii. Patient has a contraindication to Adstiladrin OR according to the prescriber, Adstiladrin is not clinically appropriate for the patient ii. Patient has already been started on therapy with Anktiva. B. **All Other Conditions**. Approve Anktiva if the patient meets the Oncology Medications criteria above the table
Augtyro (repotrectinib)	**<u>Employer Plans</u>** **Augtyro (repotrectinib) is considered medically necessary when BOTH of the follow are met:** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following: A. **For <u>ROS1-positive non-small cell lung cancer</u>**, documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to **Rozlytrek** (entrectinib) ii. 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) iii. Patient has congestive heart failure or, according to the prescriber, the patient has a risk of QT prolongation iv. Patient is currently receiving therapy with Augtyro B. **All Other Conditions**. Approve Augtyro if the patient meets the Oncology Medications criteria above the table
Avastin® (bevacizumab)	**<u>Employer Plans and Individual and Family Plans</u>** **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 Plans and Individual and Family Plans** **Besremi (ropeginterferon-alfa-2b-njft) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met AND 2. **ONE** of the following: **A. For Polycythemia Vera, ONE** of the following (A, B, C, or D): i. Patient has high risk polycythemia vera and documentation provided that the patient has **ONE** of the following: (i or ii) 1. Documentation provided that the patient has tried hydroxyurea 2. Documentation provided that the patient is NOT a candidate for hydroxyurea therapy ii. Documentation provided that the patient has low-risk polycythemia vera iii. Documentation provided that the patient is currently receiving Besremi B. **All Other Conditions**. Approve Besremi if the patient meets the Oncology Medications criteria above the table
Boruzu (bortezomib injection)	**Employer Plans and Individual and Family Plans** **Boruzu (bortezomib injection) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met AND 2. Patient has tried bortezomib injection (Velcade, generics)
Bosulif (bosutinib tablets)	**Employer Plans:** **Bosulif (bosutinib tablets) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following (A or B): A. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE** the following: i. Trial of, contraindication, or significant intolerance to **ONE** of the following (1,2,3,4,5, or 6): 1. **dasatinib** 2. **imatinib** 3. **Danziten** [may require prior authorization] 4. **Imkeldi** [may require prior authorization] 5. **Scemblix** [may require prior authorization] 6. **Tasigna** [may require prior authorization] Note: Prior use of brand Gleevec, Phyrago, or Sprycel counts. ii. Patient is currently receiving therapy with Bosulif iii. Patient meets **BOTH** of the following:

1. 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
2. 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; OR
    Note: Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis.
    b. Patient is at risk of bleeding; OR
    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.
    c. Patient has a prolonged QT interval or is at risk of developing QT interval prolongation

iv. Patient has a resistance mutation in which imatinib, dasatinib, Danziten, Imkeldi, Scemblix, , or Tasigna should not be used

B. **All Other Conditions**. Approve Bosulif if the patient meets the Oncology Medications criteria above the table

Individual and Family Plans

Bosulif (bosutinib tablets) is considered medically necessary when BOTH of the following are met (1 and 2):

1. When the Oncology Medications criteria above the table are met
2. **ONE** of the following (A or B):
    A. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE** the following:
        i. Trial of, contraindication, or significant intolerance to **ONE** of the following (1 or 2):
            1. **imatinib** [may require prior authorization]
            2. **dasatinib or Sprycel** [may require prior authorization]
            Note: Prior use of brand Gleevec, Imkeldi, or Phyrago also counts.
        ii. Patient is currently receiving therapy with Bosulif
        iii. Patient meets **BOTH** of the following:
            1. 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
            2. 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. c. Patient has a prolonged QT interval or is at risk of developing QT interval prolongation iv. Patient has a resistance mutation in which one of imatinib and dasatinib should not be used B. **All Other Conditions**. Approve Bosulif if the patient meets the Oncology Medications criteria above the table
Braftovi® (encorafenib)	**Employer Plans:** **Braftovi 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 **Melanoma, Unresectable or Metastatic, Treatment of *BRAF* V600 Mutation-Positive Disease**, documentation of **ONE** of the following: i. Trial of, contraindication, significant intolerance, or other exceptional clinical circumstance to **ONE** of the following: 1. **Tafinlar** 2. **Zelboraf** ii. Patient is currently receiving Braftovi B. **All Other Conditions**. Approve Braftovi if the patient meets the Oncology Medications criteria above the table
Cyclophosphamide tablets *This applies to oncology and non-oncology uses of cyclophosphamide.*	**Employer 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
Danziten (nilotinib tablets)	**Employer Plans:** **Danziten (nilotinib tablets) is considered medically necessary when BOTH of the following are met (A and B):** A. When the Oncology Medications criteria above the table are met B. **ONE** of the following (a or b): a. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE** the following: A. Trial of, contraindication, or significant intolerance to **ONE** of the following: 1. dasatinib

2. imatinib

Note: Prior use of brand Gleevec, Imkeldi, Phyrago, or Sprycel also counts

B. Patient is currently receiving therapy with Danziten
C. Patient meets **BOTH** of the following:
1. 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
2. Patient meets **ONE** of the following:
a. Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion; OR

Note: Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis.

b. Patient is at risk of bleeding; OR

Note: An example of a patient with an increased risk of bleeding is a patient with thrombocytopenia or with medication use that inhibits platelet function or anticoagulants.

D. Patient has a resistance mutation in which imatinib and dasatinib should not be used

b. **All Other Conditions**. Approve Danziten if the patient meets the Oncology Medications criteria above the table

Individual and Family Plans

Danziten (nilotinib tablets) is considered medically necessary when BOTH of the following are met (A and B):

A. When the Oncology Medications criteria above the table are met
B. **ONE** of the following (a or b):
a. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE** the following:
A. Trial of, contraindication, or significant intolerance to **ONE** of the following:
1. dasatinib
2. imatinib

Note: Prior use of brand Gleevec, Imkeldi, Phyrago, or Sprycel also counts

B. Patient is currently receiving therapy with Danziten
C. Patient meets **BOTH** of the following:
1. 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
2. Patient meets **ONE** of the following:
a. Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion; OR

	Note: Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis. b. Patient is at risk of bleeding; OR Note: An example of a patient with an increased risk of bleeding is a patient with thrombocytopenia or with medication use that inhibits platelet function or anticoagulants. D. Patient has a resistance mutation in which imatinib and dasatinib should not be used b. **All Other Conditions**. Approve Danziten if the patient meets the Oncology Medications criteria above the table
Docivyx (docetaxel)	**Employer Plans and Individual and Family Plans** **Docivyx is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Patient has tried generic docetaxel
Fruzaqla™ (fruquintinib)	**Employer Plans** **Fruzaqla (fruquintinib) 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 **Appendiceal, Colon** or **Rectal Cancer in an individual 18 years of age or older**, **ONE** of the following: i. Trial of, contraindication, or intolerance to **Lonsurf (trifluridine-tipiracil) tablets** ii. According to the prescriber, the patient has or is at risk of myelosuppression iii. Patient has already been started on therapy with Fruzaqla B. **All Other Conditions**. Approve Fruzaqla if the patient meets the Oncology Medications criteria above the table
Gleevec® (imatinib)	**Employer 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. 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)	**Employer 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]
Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk)	**<u>Employer Plans and Individual and Family Plans</u>** **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. Patient has trial of, contraindication, or intolerance 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. Patient is unable to obtain or maintain intravenous access C. Currently receiving Herceptin Hylecta
Hercessi (Trastuzumab-strf)	**<u>Employer Plans and Individual and Family Plans</u>** **Hercessi (trastuzumab-strf) is considered medically necessary when BOTH of the following are met (1 and 2):** 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]
Herzuma® (trastuzumab-pkrb)	**<u>Employer Plans and Individual and Family Plans</u>** **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]
Ibrance® (palbociclib)	**Employer 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. **ONE** of the following: A. **For Breast Cancer**, documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to **ONE** of the following: a. **Kisqali (ribociclib)** [may require prior authorization] b. **Verzenio (abemaciclib)** [may require prior authorization] ii. For premenopausal patients using in combination with fulvestrant as subsequent therapy (not initial therapy), approve if the patient has tried Verzenio iii. Patient will be using Ibrance in combination with Itovebi iv. Currently receiving Ibrance B. **All Other Conditions**. Approve Ibrance if the patient meets the Oncology Medications criteria above the table
Iclusig (ponatinib tablets)	**Employer Plans** **Iclusig (ponatinib tablets) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. Meets **ONE** of the following (A, B, C, or D): A. Patient is currently receiving Iclusig B. **For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE** of the following: i. Trial of, contraindication, significant intolerance to **TWO** of the following: 1) **dasatinib** 2) **imatinib** 3) **Danziten** [may require prior authorization] 4) **Imkeldi** [may require prior authorization] 5) **Scemblix** [may require prior authorization] 6) **Tasigna** [may require prior authorization] Note: Prior use of brand Gleevec, Phyrago, or Sprycel also counts. ii. Patient meets **BOTH** of the following: 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 Note: Examples of tyrosine kinase inhibitors include: dasatinib products (e.g. Sprycel, Phyrago), Bosulif, Tasigna, Danziten and Scemblix. iii. Patient has a resistance mutation in which imatinib, dasatinib, Danziten, Imkeldi, Scemblix, or Tasigna should not be used iv. Patient has the *T315I* mutation C. For **Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive**, **ONE** of the following: i. Trial of, contraindication, significant intolerance to **ONE** of the following: 1) **dasatinib** 2) **imatinib** Note: Prior use of Gleevec , Imkeldi, Phyrago, or Sprycel also counts. ii. 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. iii. Patient has a resistance mutation in which imatinib or dasatinib should not be used iv. Patient is currently receiving therapy with Iclusig D. **All Other Conditions**. Approve Iclusig if the patient meets the Oncology Medications criteria above the table **Individual and Family Plans** **Iclusig (ponatinib tablets) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. Meets **ONE** of the following (A, B, or C): A. For **Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, 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 **imatinib** [may require prior authorization] Note: Prior use of brand Gleevec or Imkeldi 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: dasatinib, Phyrago, Bosulif, Tasigna, Danziten, 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 **dasatinib** or **Sprycel** [may require prior authorization] Note: Prior use of Phyrago (dasatinib) 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, Danziten, 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 has a resistance mutation in which dasatinib should not be used ii. Patient has the *T315I* mutation iii. Patient is currently receiving Iclusig B. For **Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive**, **ONE** of the following: i. According to the prescriber, patient has had a trial of, contraindication, significant intolerance to **ONE** of the following: 1) **imatinib** [may require prior authorization] 2) **dasatinib or Sprycel** [may require prior authorization] Note: Prior use of Gleevec, Imkeldo, or Phyrago also counts. ii. 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. iii. Patient has a resistance mutation in which imatinib or dasatinib should not be used iv. Patient is currently receiving Iclusig C. **All Other Conditions**. Approve Iclusig if the patient meets the Oncology Medications criteria above the table
Imkeldi (imatinib oral solution)	**Employer Plans** **Imkeldi (imatinib oral solution) is considered medically necessary when BOTH of the following is met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. Meets **ONE** of the following (A or B):

	A. For **<u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, patient meets BOTH** of the following: i. Patient is ≥ 18 years old; AND ii. Patient meets ONE of the following: 1. Patient meets BOTH of the following: a. Patient has tried imatinib tablets; AND <u>Note</u>: Prior use of Gleevec also counts. b. Patient cannot take generic imatinib 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; OR 2. Patient is unable to swallow or has difficulty swallow tablets. B. **All Other Conditions**. Approve Imkeldi if the patient meets the Oncology Medications criteria above the table **<u>Individual and Family Plans</u>** **Imkeldi (imatinib oral solution) is considered medically necessary when BOTH of the following is met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. Patients meets ONE of the following (A or B): A. Patient meets BOTH of the following: i. Patient has tried imatinib tablets; AND <u>Note</u>: Prior use of Gleevec also counts. ii. Patient cannot take generic imatinib 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; OR B. Patient is unable to swallow or has difficulty swallowing tablets.
Infugem™ (gemcitabine)	**<u>Employer Plans and Individual and Family Plans</u>** **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)	**<u>Employer Plans and Individual and Family Plans</u>** **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: Note: Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, and ovarian cancer. i. Trial of, contraindication, or intolerance to Keytruda (pembrolizumab) [may require prior authorization] ii. Currently receiving Jemperli C. **All Other Conditions** (e.g., rectal cancer). Approve Jemperli if the patient meets the Oncology Medications criteria above the table
Keytruda (pembrolizumab)	**Employer Plans and Individual and Family Plans** **Keytruda (pembrolizumab) 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, **Nasopharyngeal Carcinoma**, documentation of **ONE** of the following: i. Patient has been started on Keytruda ii. Patient meets **ALL** of the following: a. Patient has recurrent, unresectable, oligometastatic, or metastatic disease b. The medication is used in combination with cisplatin and gemcitabine c. According to the prescriber, the patient has inadequate efficacy, contraindication, or significant intolerance to **Loqtorzi (toripalimab intravenous infusion)** [may require prior authorization] iii. Patient meets **ALL** of the following: a. Patient has recurrent, unresectable, oligometastatic, or metastatic disease b. Tumor is tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase] c. Medication is used for subsequent therapy iv. Patient meets **ALL** of the following: a. Patient has recurrent or metastatic disease; AND b. Tumor is programmed death-ligand 1 positive (combined positive score [CPS] ≥ 1); AND c. Medication is used for subsequent therapy. B. **All Other Conditions**. Approve Keytruda if the patient meets the Oncology Medications criteria above the table
Khapzory™ (levoleucovorin)	**Employer 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. Meets **ONE** of the following: A. Patient has tried one generic levoleucovorin calcium injection or generic leucovorin injection B. If the patient has already been started on therapy with Khapzory, patient has tried generic levoleucovorin calcium injection
Krazati (adagrasib)	**Employer 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. **ONE** of the following: A. For ***KRAS* G12C-mutated Non-Small Cell Lung Cancer,** documentation of **ONE** of the following: i. Trial of, contraindication, or intolerance to **sotorasib (Lumakras)** [may require prior authorization] ii. Patient has brain metastases iii. Patient has already been started on therapy with Krazati B. **All Other Conditions**. Approve Krazati if the patient meets the Oncology Medications criteria above the table
Mektovi® (binimetinib)	**Employer Plans:** **Mektovi 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 **Melanoma, Unresectable or Metastatic, Treatment of *BRAF* V600 Mutation-Positive Disease**, documentation of **ONE** of the following: i. Trial of, contraindication, significant intolerance, or other exceptional clinical circumstance to **ONE** of the following: 1. **Cotellic** 2. **Mekinist** ii. Patient is currently receiving Mektovi B. **All Other Conditions**. Approve Mektovi if the patient meets the Oncology Medications criteria above the table
Nexavar (sorafenib)	**Employer 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**

	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 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. Documented trial of **nilutamide** (the bioequivalent generic product) AND cannot take due to formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Onivyde (irinotecan liposomal intravenous infusion)	**Employer Plans and Individual and Family Plans** **Onivyde (irinotecan liposomal intravenous infusion) 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 **Pancreatic Adenocarcinoma**, documentation of **ONE** of the following: i. According to the prescriber, the patient has experienced an inadequate response or significant intolerance, has a contraindication for irinotecan intravenous infusion ii. Patient has been started on Onivyde iii. Patient meets **BOTH** of the following: a. Medication will be used for subsequent therapy b. Patient meets **ONE** of the following: 1. According to the prescriber, patient is Eastern Cooperative Oncology Group performance status of 2 2. Patient has been previously treated with fluoropyrimidine-based therapy without irinotecan. B. **All Other Conditions**. Approve Onivyde if the patient meets the Oncology Medications criteria above the table
Ontruzant® (trastuzumab-dttb)	**Employer Plans and Individual and Family Plans** **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]
Opdivo (nivolumab)	**<u>Employer Plans and Individual and Family Plans</u>** **Opdivo (nivolumab) 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, **<u>Nasopharyngeal Carcinoma</u>**, documentation of **ONE** of the following: i. Patient has been started on Opdivo ii. Patient meets **ALL** of the following: a. Patient has recurrent, unresectable, oligometastatic, or metastatic disease b. The medication is used in combination with cisplatin and gemcitabine c. According to the prescriber, the patient has inadequate efficacy, contraindication, or significant intolerance to **Loqtorzi (toripalimab intravenous infusion)** [may require prior authorization] iii. Patient meets **BOTH** of the following: a. Patient has recurrent or metastatic non-keratinizing disease; AND b. Medication is used for subsequent therapy. B. **All Other Conditions**. Approve Opdivo if the patient meets the Oncology Medications criteria above the table
Opdivo Qvantig (nivolumab and hyaluronidase-nvhy)	**<u>Employer Plans and Individual and Family Plans</u>** **Opdivo Qvantig (nivolumab and hyaluronidase-nvhy) is considered medically necessary when BOTH of the following are met:** 1. When the Oncology Medications criteria above the table are met 2. Documentation provided that the patient has **ONE** of the following: A. Patient has tried and cannot take Opdivo intravenous (IV) [may require prior authorization] B. Patient is unable to obtain IV access.
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. **ONE** of the following: A. For, **<u>Prostate Cancer</u>**, documentation of **ONE** of the following: i. Patient has tried **ONE** of the following: a. **Eligard** [may require prior authorization] b. **Firmagon** [may require prior authorization] c. **Trelstar** [may require prior authorization]

	ii. According to the prescriber, is at risk of cardiovascular disease iii. Using for intermittent androgen deprivation therapy iv. Currently receiving Orgovyx B. **All Other Conditions**. Approve Orgovyx if the patient meets the Oncology Medications criteria above the table
Paclitaxel albumin-bound intravenous infusion	**<u>Cigna Pathwell Specialty Drug List Plans</u>** **Paclitaxel albumin-bound intravenous infusion 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. For **<u>Breast Cancer</u>**, **ONE** of the following: 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 **<u>Cervical Cancer</u>**, **ONE** of the following: 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) C. For **<u>Endometrial Cancer</u>**, **ONE** of the following: 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 **<u>Melanoma</u>**, **ONE** of the following: 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 **<u>Non-Small Cell Lung Cancer</u>**, **ONE** of the following: 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: 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) G. **All Other Conditions**. Approve paclitaxel albumin-bound intravenous infusion if the patient meets the Oncology Medications criteria above the table
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. **ONE** of the following: A. **For Metastatic Castration-Resistant Prostate Cancer (mCRPC),** documentation of **ONE** of the following: i. **BOTH** of the following: a. Tried **ONE** of **abiraterone acetate** or **Xtandi** b. Meets **ONE** of the following: 1) Tried **docetaxel** and experienced intolerance or other exceptional clinical circumstance 2) According to the prescriber, is not a candidate for a systemic regimen (i.e., an elderly patient who is frail) 3) Has hepatic impairment (elevated bilirubin or liver enzyme levels) 4) Has cystoid macular edema 5) Is at increased risk for developing gastrointestinal complications such as enterocolitis 6) Is at increased risk of severe fluid retention ii. **BOTH** of the following: a. Tried **docetaxel** b. Meets **ONE** of the following: 1) Tried **ONE** of **abiraterone** or **Xtandi** and experienced intolerance or other exceptional clinical circumstance 2) Has diabetes mellitus and concomitant use with prednisone and abiraterone acetate may be contraindicated 3) Is at increased risk for developing seizures 4) Is at increased risk for falls and fractures 5) Is taking concomitant medication that is either a strong CYP2C8 inhibitor or a strong CYP3A4 inducer

	6) Is at increased risk for hepatotoxicity 7) Is at increased risk for fluid retention and cardiovascular morbidity (e.g., diagnosis of recent myocardial infarction, chronic heart failure) B. **All Other Conditions.** Approve Provenge if the patient meets the Oncology Medications criteria above the table
Rituxan® (rituximab)	**<u>Employer Plans and Individual and Family Plans</u>** **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 provided that the patient has 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]
Rituxan Hycela™ (rituximab and hyaluronidase human)	**<u>Employer Plans and Individual and Family Plans</u>** **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
Scemblix (asciminib tablets)	**<u>Individual and Family Plans</u>** **Scemblix (asciminib tablets) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following (a or b):

	a. For **<u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, ONE** of the following: A. Patient meets **BOTH** of the following: i. Patient meets **ONE** of the following: a. Trial of, contraindication, significant intolerance to **imatinib** <u>Note</u>: Prior use of brand Gleevec and Imkeldi also counts. b. Patient has newly diagnosed disease c. Patient has intermediate- to high-risk chronic phase CML, accelerated CML or blast phase CML d. Patient has tried at least one other tyrosine kinase inhibitor for CML <u>Note</u>: Examples of tyrosine inhibitors include: dasatinib, Phyrago, Bosulif, Tasigna, Danziten and Iclusig. e. Patient has a resistance mutation in which imatinib should not be used ii. Patient meets **ONE** of the following: a. Trial of, contraindication, significant intolerance to **dasatinib or Sprycel** <u>Note</u>: Prior use of Phyrago (dasatinib tablets) also counts. b. Patient has tried at least one other tyrosine kinase inhibitors for CML <u>Note</u>: Examples of tyrosine kinase inhibitors include: dasatinib, Phyrago, Bosulif, Tasigna, Danziten, 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 dasatinib should not be used B. Patient is currently receiving Scemblix C. Patient has the *T315I* mutation b. **All Other Conditions**. Approve Scemblix if the patient meets the Oncology Medications criteria above the table
Sprycel (dasatinib)	**<u>Employer Plans</u>** **Sprycel (dasatinib) 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>dasatinib</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

Sutent (sunitinib)	**<u>Employer 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 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 ***<u>BRCA</u>*<u>-mutated, recurrent or metastatic Breast Cancer</u>**, **ONE** of the following: i. Documented trial of, contraindication, intolerance to **Lynparza (olaparib)** [may require prior authorization] ii. Currently receiving Talzenna B. For **<u>Prostate Cancer</u>**, **ONE** of the following: i. For BRCA-mutated prostate cancer, documented trial of, contraindication, intolerance to **Lynparza (Olaparib)** [may require prior authorization] ii. Patient has a homologous recombination repair (HHR) mutation OTHER THAN a BRCA-mutation (i.e., patient does not have a BRCA mutation) iii. Currently receiving Talzenna C. **All Other Conditions**. Approve Talzenna if the patient meets the Oncology Medications criteria above the table
Tarceva® (erlotinib)	**<u>Employer 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)	**<u>Employer Plans and Individual and Family Plans</u>** **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 **<u>bexarotene</u>** (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)	**<u>Employer Group Plans</u>** **Tasigna (nilotinib) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following (A or B): A. For **<u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, ONE** of the following: i. Trial of, contraindication, significant intolerance to **ONE** of the following: **a. dasatinib** **b. imatinib** <u>Note</u>: Prior use of brand Gleevec, Phyrago, or Sprycel also counts. ii. Patient is currently receiving Tasigna iii. Patient is less than18 years of age with accelerated phase CML iv. Patient meets **BOTH** of the following: a. Patient meets **ONE** of the following: i. Patient has intermediate- to high-risk disease chronic phase CML ii. Patient has accelerated phase CML or blast phase CML b. Patient meets **ONE** of the following: i. 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. ii. 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. v. Patient has a resistance mutation in which imatinib and dasatinib should not be used B. **All Other Conditions**. Approve Tasigna if the patient meets the Oncology Medications criteria above the table **<u>Individual and Family Plans</u>:** **Tasigna (nilotinib) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following (A or B): A. For **<u>Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive</u>, ONE** of the following: i. Trial of, contraindication, significant intolerance to **ONE** of the following: a. **imatinib** [may require prior authorization]

	b. dasatinib or Sprycel [may require prior authorization] Note: Prior use of brand Gleevec, Imkeldi or Phyrago counts. ii. Patient is currently receiving Tasigna iii. Patient is less than 18 years of age with accelerated phase CML iv. Patient meets **BOTH** of the following: a. Patient meets **ONE** of the following: i. Patient has intermediate- to high-risk disease chronic phase CML ii. Patient has accelerated phase CML or blast phase CML b. Patient meets **ONE** of the following: i. Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion Note: Examples of lung disease, pulmonary arterial hypertension, and interstitial pneumonitis. ii. Patient is at risk of bleeding Note: 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. v. Patient has a resistance mutation in which imatinib and dasatinib should not be used B. **All Other Conditions**. Approve Tasigna if the patient meets the Oncology Medications criteria above the table
Temodar® (temozolomide)	**Employer 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 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
Vectibix	**Cigna Pathwell Specialty Drug List Plans**

(panitumumab intravenous infusion)	**Vectibix (panitumumab intravenous infusion) 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 **Colon or Rectal Cancer**, documentation of **ONE** of the following: i. According to the prescriber, the patient has experienced an inadequate response or significant intolerance, has a contraindication for Erbitux (cetuximab intravenous infusion); OR ii. Patient has been started on Vectibix; OR iii. Patient had a serious infusion reaction to Erbitux; OR iv. **ONE** of the following (i or ii): a. According to the prescriber, patient lives in high endemic rates of alpha-gal; OR b. Patient has known alpha-gal positivity B. **All Other Conditions**. Approve Vectibix if the patient meets the Oncology Medications criteria above the table
Vegzelma (bevacizumab-adcd)	**Employer 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
Votrient® (pazopanib)	**Employer Plans and Individual and Family Plan** **Votrient (pazopanib)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 **pazopanib** (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
Xeloda® (capecitabine)	**Employer 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 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. **ONE** of the following: A. For **Prostate Cancer – Metastatic, Castration-Resistant,** documentation of **ONE** of the following: i. Documented trial of, contraindication, or intolerance to **generic abiraterone** ii. Patient has been started on therapy with Yonsa B. **All Other Conditions**. Approve Yonsa if the patient meets the Oncology Medications criteria above the table
Ziihera (zanidatamab-hrii)	**Employer Plans and Individual and Family Plans:** **Ziihera (zanidatamab-hrii) is considered medically necessary when BOTH of the following are met (1 and 2):** 1. When the Oncology Medications criteria above the table are met 2. **ONE** of the following (A or B): A. For **Biliary Tract Cancer in which the tumor is human epidermal growth factor receptor 2 (HER2) positive with immunohistochemistry score of 3+ (IHC3+) as determined by an approved test in a patient ≥ 18 years of age,** ONE of the following: 1. Patient has tried one of the following regimens or, according to the prescriber, all the regimens are contraindicated (A, B, or C): A. Enhertu; OR B. Trastuzumab plus Perjeta [may require prior authorization]; OR C. Trastuzumab plus Tukysa [may require prior authorization] 2. Patient has already been started on therapy with Ziihera. B. **All Other Conditions**. Approve Ziihera if the patient meets the Oncology Medications criteria above the table
Zykadia (ceritinib)	**Employer Plans and Individual and Family Plans:** **Zykadia (ceritinib) 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 **Non-Small Cell Lung Cancer – Anaplastic Lymphoma Kinase (*ALK*)-positive**, documentation of **ONE** of the following: 1. Trial of, contraindication, intolerance to **Alecensa (alectinib)** [may require prior authorization] 2. Patient is currently receiving Zykadia

	B. **All Other Conditions**. Approve Zykadia if the patient meets the Oncology Medications criteria above the table
Zytiga® (abiraterone)	**Employer 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.

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

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.
3. The NCCN Chronic Myeloid Leukemia Clinical Practice Guidelines in Oncology. © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org.
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	**Fruzaqla** Appendiceal, Colon or Rectal Cancer: **Added** preferred product step requirement through Lonsurf for Employer Plans **Krazati** **Added** *has brain metastases* exception to the sotorasib (Lumakras) preferred product step requirement	5/15/2024
Selected Revision	**Augtyro** ROS1-positive non-small cell lung cancer: **Added** preferred product step requirement through Rozlytrek for Employer Plans **Abraxane and Paclitaxel albumin-bound** **Updated** Abraxane and Paclitaxel albumin-bound preferred product requirement criteria on Cigna Pathwell Specialty Drug List Plans	6/1/2024
Selected Revision	**Alunbrig/Zykadia**	7/1/2024

	Non-Small Cell Lung Cancer – anaplastic lymphoma kinase (*ALK*)-positive: **Added** preferred product step requirement through Alecensa for Employer and Individual and Family Plans **Votrient** **Added** preferred product step requirement through generic pazopanib for Employer Plans **Braftovi** Melanoma, unresectable or metastatic, treatment of *BRAF* V600 mutation-positive: **Added** preferred product step requirement through Tafinlar or Zelboraf on Employer plans **Mektovi** Melanoma, unresectable or metastatic, treatment of *BRAF* V600 mutation-positive: **Added** preferred product step requirement through Cotellic or Mekinist for Employer plans **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 **Gleevec** **Updated** preferred product step through generic imatinib requirement criteria **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 **Scemblix** Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: **Removed** Scemblix preferred product step requirement on Employer Plans, **Updated** 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 **Tasigna** Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive: **Updated** exceptions to the step requirement for Employer and Individual and Family Plans	
Selected Revision	**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	8/1/2024
Selected Revision	**Pomalyst** **Removed** Pomalyst preferred product criteria requirement.	9/1/2024
Selected Revision	**Anktiva** **Added** Anktiva preferred product criteria requirement for Employer Plans and Individual and Family Plans **Besremi** **Updated from** "Employer Plans and" **to** "Employer Plans and Individual and Family Plans" **Docivyx** **Added** Docivyx preferred product criteria requirement for Employer Plans and Individual and Family Plans **Yonsa** **Added** "**Prostate Cancer – Metastatic, Castration-Resistant"** to the preferred product criteria for Employer Plans and Individual and Family Plans **Sandostatin LAR Depot.** **Removed** criteria for Sandostatin LAR Depot for Employer Plans and Individual and Family Plan Effective 1/1/2025: **Keytruda** **Added** Keytruda preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. **Lupron Depot**	10/15/2024

	Added Lupron Depot preferred product criteria for Employer Plans and Individual and Family Plans. **Onivyde** **Added** Onivyde preferred product criteria for Employer Plans and Individual and Family Plans. **Opdivo** **Added** Opdivo preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. **Orgovyx** **Updated from "**Trial of, contraindication, or intolerance to ONE of the following: Eligard [may require prior authorization], Firmagon [may require prior authorization], Lupron Depot [may require prior authorization], Trelstar [may require prior authorization]" to "Patient has tried ONE of the following: Eligard [may require prior authorization], Firmagon [may require prior authorization], Trelstar [may require prior authorization" for Individual and Family Plans. **Vectibix** **Added** Vectibix preferred product criteria requirement for Cigna Pathwell Specialty Drug List Plans. **Votrient** **Added** Votrient preferred product criteria for Individual and Family Plans.	
Selected Revision	**Ibrance.** **Added "**Patient will be using Ibrance in combination with Itovebi" **<u>Effective 1/15/2025</u>** **Scemblix.** Added "Patient has newly diagnosed disease" option under generic imatinib criteria	12/5/2024
Selected Revision	**Bosulif** **Employer Plans:** **Updated from** 'Sprycel [may require prior authorization]' **to '**generic dasatinib' **Updated from** '<u>Note</u>: Prior use of Gleevec or Phyrago (dasatinib) counts.' **to** '<u>Note</u>: Prior use of Gleevec (imatinib), Phyrago (dasatinib), or Sprycel (dasatinib) counts.' **Individual and Family Plans:** **Added** 'generic dasatinib or' **to** 'Sprycel [may require prior authorization]'	1/1/2025

	Keytruda **Updated** preferred product criteria **from** "Cigna Pathwell Specialty Drug List Plans" **to** "Employer Plans and Individual and Family Plans" **Updated from** "Tumor is tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase]" **to** "Tumor is tumor mutational burden-high (TMB-H) [≥ 10 mutations/megabase] " **Added** patient has recurrent or metastatic disease, tumor is programmed death-ligand 1 positive (combined positive score [CPS] ≥ 1), and medication is used as subsequent therapy as new option for approval. **Iclusig** **Employer Plans:** **Updated from** 'Sprycel [may require prior authorization]' **to '**generic dasatinib' **Updated from** 'Note: Prior use of Gleevec or Phyrago (dasatinib) counts.' **to** 'Note: Prior use of Gleevec (imatinib), Phyrago (dasatinib), or Sprycel (dasatinib) counts.' **Individual and Family Plans: Added** 'generic dasatinib' or' **to** 'Sprycel [may require prior authorization]' **Lanreotide acetate (by Cipla)** Added "Effective 1/1/2025 through 2/15/2025" to criteria **Opdivo** **Updated** preferred product criteria **from** "Cigna Pathwell Specialty Drug List Plans" **to** "Employer Plans and Individual and Family Plans" **Added** patient has recurrent or metastatic non-keratinizing disease and medication is used for subsequent therapy as new option for approval **Scemblix** **Individual and Family Plans: Updated from** Trial of, contraindication, significant intolerance to **Sprycel' to '**Trial of, contraindication, significant intolerance to **generic dasatinib or Sprycel'** **Sprycel** **Added** preferred product preferencing criteria for Employer Plans **Tasigna** **Employer Plans:** **Updated from** 'Sprycel [may require prior authorization]' **to '**generic dasatinib'	

	Updated from 'Note: Prior use of Gleevec or Phyrago (dasatinib) counts.' **to** 'Note: Prior use of Gleevec (imatinib), Phyrago (dasatinib), or Sprycel (dasatinib) counts.' **Individual and Family Plans: Added** 'generic dasatinib or' **to** 'Sprycel [may require prior authorization]' **Vectibix** **Added** "According to the prescriber, patient lives in high endemic rates of alpha-gal" or "patient has known alpha-gal positivity"	
Selected Revision	**Abraxane intravenous infusion**. **Added** "**All Other Conditions.** Approve Abraxane intravenous infusion if the patient meets the Oncology Medications criteria above the table" **Akeega.** **Added** "**All Other Conditions**. Approve Akeega if the patient meets the Oncology Medications criteria above the table" **Alunbrig.** **Added** "**All Other Conditions**. Approve Alunbrig if the patient meets the Oncology Medications criteria above the table" **Anktiva.** **Added** "**All Other Conditions**. Approve Anktiva if the patient meets the Oncology Medications criteria above the table" **Augtyro.** **Added** "**All Other Conditions**. Approve Augtyro if the patient meets the Oncology Medications criteria above the table" **Besremi.** **Removed,** for polycythemia vera, Pegasys as an alternative option **Added** "Documentation provided that the patient has:" to polycythemia vera criteria **Added** "**All Other Conditions**. Approve Besremi if the patient meets the Oncology Medications criteria above the table" **Bosulif.** **Added** "**All Other Conditions**. Approve Bosulif if the patient meets the Oncology Medications criteria above the table" **Braftovi.**	4/15/2025

	Added "**All Other Conditions**. Approve Braftovi if the patient meets the Oncology Medications criteria above the table" **Fruzaqla** **Added** "**All Other Conditions**. Approve Fruzaqla if the patient meets the Oncology Medications criteria above the table" **Fusilev.** **Removed** criteria for Fusilev. **Herceptin.** **Removed** "Currently receiving Herceptin" **Herceptin Hylecta.** **Updated from** "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:Kanjinti (trastuzumab-anns) [may require prior authorization], Ogivri (trastuzumab-dkst) [may require prior authorization], Trazimera (trastuzumab-qyyp) [may require prior authorization]" **to** "Trial of, contraindication, or intolerance to ONE of the following: Kanjinti (trastuzumab-anns) [may require prior authorization], Ogivri (trastuzumab-dkst) [may require prior authorization], Trazimera (trastuzumab-qyyp) [may require prior authorization]" **Updated from** "Unable to obtain or maintain intravenoud access" **to** "Patient is unable to obtain or maintain intravenous access" **Herzuma.** **Removed** "Currently receiving Herzuma" **Ibrance.** **Added** "For premenopausal patients using in combination with fulvestrant as subsequent therapy (not initial therapy), approve if the patient has tried Verzenio" **Added** "**All Other Conditions**. Approve Ibrance if the patient meets the Oncology Medications criteria above the table" **Iclusig.** **Added** "**All Other Conditions**. Approve Iclusig if the patient meets the Oncology Medications criteria above the table"	

	Jemperli. **Added,** for Mismatch Repair Deficient (dMMR) or Microsatellite Instability-High (MSI-H) Solid Tumors – Monotherapy, "Note: Examples of solid tumors include ampullary adenocarcinoma, biliary tract cancer, breast cancer, esophageal and esophagogastric junction cancer, gastric cancer, hepatocellular cancer, and ovarian cancer." **Added** "All Other Conditions (e.g., rectal cancer). Approve Jemperli if the patient meets the Oncology Medications criteria above the table" **Keytruda.** **Added** "**All Other Conditions**. Approve Keytruda if the patient meets the Oncology Medications criteria above the table" **Khapzory.** **Updated from** "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" **to** "Meets ONE of the following: Patient has tried one generic levoleucovorin calcium injection or generic leucovorin injection; If the patient has already started on therapy with Khapzory, patient has tried generic levoleucovorin calcium injection." **Krazati.** **Added** "**All Other Conditions**. Approve Krazati if the patient meets the Oncology Medications criteria above the table" **Lanreotide acetate (by Cipla).** **Removed** criteria for lanreotide acetate (by Cipla) **Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg.** **All Other Conditions**. Approve Lupron Depot 7.5 mg, 22.5 mg, 30 mg, 45 mg if the patient meets the Oncology Medications criteria above the table **Mektovi.** **Added** "**All Other Conditions**. Approve Mektovi if the patient meets the Oncology Medications criteria above the table" **Nilandron.** **Removed** "trial of, contraindication, or intolerance to ONE of the following: Bicalutamide, Flutamide" **Orgovyx.** **Added** to criteria "For Prostate Cancer"	

	Onivyde. **Added** "**All Other Conditions**. Approve Onivyde if the patient meets the Oncology Medications criteria above the table" **Ontruzant.** **Removed** "Currently receiving Ontruzant" **Opdivo.** **Added** "**All Other Conditions**. Approve Opdivo if the patient meets the Oncology Medications criteria above the table" **Orgovyx.** **Added** "**All Other Conditions**. Approve Orgovyx if the patient meets the Oncology Medications criteria above the table" **Paclitaxel albumin-bound intravenous infusion.** **Added** "**All Other Conditions**. Approve paclitaxel albumin-bound intravenous infusion if the patient meets the Oncology Medications criteria above the table" **Provenge.** **Added "<u>All Other Conditions.</u>** <u>Approve</u> Provenge <u>if the patient meets the Oncology Medications criteria above the table"</u> **Scemblix.** For the exception to the requirement of a trial of Sprycel, the requirement that the patient has tried at least "two" other tyrosine kinase inhibitors for CML was changed to at least "one" other tyrosine kinase inhibitor for CML. **Added** "**All Other Conditions**. Approve Scemblix if the patient meets the Oncology Medications criteria above the table" **Talzenna.** **Updated from** "For <u>*BRCA*-mutated Prostate Cancer</u>, ONE of the following: Documented trial of, contraindication, intolerance to Lynparza (olaparib) [may require prior authorization], Currently receiving Talzenna" **to** "For BRCA-mutated prostate cancer, documented trial of, contraindication, intolerance to Lynparza (Olaparib) [may require prior authorization], Patient has a homologous recombination repair (HHR) mutation OTHER THAN a BRCA-mutation (i.e., patient does not have a BRCA mutation), Currently receiving Talzenna"	

	Added "**All Other Conditions**. Approve Talzenna if the patient meets the Oncology Medications criteria above the table" **Tasigna.** **Added** "**All Other Conditions**. Approve Tasigna if the patient meets the Oncology Medications criteria above the table" **Tecentriq.** **Added** "**All Other Conditions**. Approve Tecentriq if the patient meets the Oncology Medications criteria above the table" **Vectibix** **Added** "**All Other Conditions**. Approve Vectibix if the patient meets the Oncology Medications criteria above the table" **Yonsa** **Added** "**All Other Conditions**. Approve Yonsa if the patient meets the Oncology Medications criteria above the table"	
Selected Revision	**Alunbrig.** **Updated** from "Patient is currently receiving Alunbrig" **to** "Patient has already been started on therapy with Alunbrig" **Boruzu.** **Added** criteria for Boruzu **Lupron Depot.** **Removed** criteria for Lupron Depot. **Tecentriq.** **Removed** criteria for Tecentriq (Effective 4/15/2025)	5/15/2025
Selected Revision	**Afinitor.** **Removed** Afinitor criteria **Bosulif.** **Employer Plans** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE the following:Trial of, contraindication, or significant intolerance to ONE of the following: Generic dasatinib, Generic imatinib, Scemblix [may require prior authorization], Tasigna [may require prior authorization] Note: Prior use of Gleevec (imatinib), Phyrago (dasatinib),	6/15/2025

	or Sprycel (dasatinib) counts" **to** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE the following: Trial of, contraindication, or significant intolerance to ONE of the following: dasatinib, imatinib, Danziten [may require prior authorization], Imkeldi [may require prior authorization], Scemblix [may require prior authorization], Tasigna [may require prior authorization]Note: Prior use of brand Gleevec, Phyrago, or Sprycel counts." **Added "**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." **Added** Danziten, Imkeldi to "Patient has a resistant mutation" criteria **Bosulif** **Individual and Family Plans** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE the following: Trial of, contraindication, or significant intolerance to ONE of the following: generic imatinib [may require prior authorization], generic dasatinib or Sprycel [may require prior authorization] Note: Prior use of Gleevec (imatinib), Imkeldi, or Phyrago (dasatinib) counts" **to** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE the following: Trial of, contraindication, or significant intolerance to ONE of the following: imatinib [may require prior authorization], dasatinib or Sprycel [may require prior authorization] Note: Prior use of brand Gleevec, Imkeldi, or Phyrago also counts" **Danziten.** **Added** Danziten criteria. **Hercessi.** **Added** Hercessi criteria **Iclusig.** **Employer Plans** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE of the following:Trial of, contraindication, significant intolerance to TWO of the following: Generic Dasatinib, generic imatinib, Scemblix [may require prior authorization], Tasigna [may require	

	prior authorization] Note: Prior use of Gleevec (imatinib), Phyrago (dasatinib), or Sprycel (dasatinib) counts." **To** " For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE of the following:Trial of, contraindication, significant intolerance to TWO of the following: dasatinib, imatinib, Danziten [may require prior authorization], Imkeldi [may require prior authorization], Scemblix [may require prior authorization], Tasigna [may require prior authorization] Note: Prior use of brand Gleevec, Phyrago, or Sprycel also counts." **Added** Danziten to tyrosine kinase inhibitor examples **Added** Danziten, Imkeldi to "Patient has a resistant mutation" criteria **Updated from** "For Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive, documentation of ONE of the following: Trial of, contraindication, significant intolerance to ONE of the following: generic dasatinib, generic imatinib Note: Prior use of Gleevec (Imatiib), Phyrago (dasatinib), or Sprycel (dasatinib) counts." **To** "Trial of, contraindication, significant intolerance to ONE of the following: dasatinib, imatinib Note: Prior use of Gleevec , Imkeldi, Phyrago, or Sprycel also counts." **Removed** examples of dasatinib products **Added** "Patient is currently receiving therapy with Iclusig **Iclusig** **Individual and Family Plans.** **Updated form** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE of the following: Patient meets BOTH of the following:Patient meets ONE of the following:Trial of, contraindication, significant intolerance to generic imatinib [may require prior authorization] Note: Prior use of Gleevec (Imatinib) also counts." **To** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE of the following: Patient meets BOTH of the following:Patient meets ONE of the following: Trial of, contraindication, significant intolerance to imatinib [may require prior authorization] Note: Prior use of brand Gleevec or Imkeldi also counts. **Added** Danziten to examples of tyrosine kinase inhibitors **Removed** "Patient is at risk of bleeding" with note	

	Updated from "For Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive, documentation of ONE of the following:According to the prescriber, patient has had a trial of, contraindication, significant intolerance to ONE of the following: generic imatinib [may require prior authorization], generic dasatinib or Sprycel [may require prior authorization] Note: Prior use of Gleevec (imatinib), or Phyrago (dasatiib) counts." **To** "For Acute Lymphoblastic Leukemia (ALL), Philadelphia Chromosome-Positive, ONE of the following: According to the prescriber, patient has had a trial of, contraindication, significant intolerance to ONE of the following: imatinib [may require prior authorization], dasatinib or Sprycel [may require prior authorization] Note: Prior use of Gleevec, Imkeldo, or Phyrago also counts." **Imkeldi.** **Added** Imkeldi criteria **Scemblix.** **Individual and Family Plan.** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE of the following: Patient meets BOTH of the following: Patient meets ONE of the following:Trial of, contraindication, significant intolerance to generic imatinib Note: Prior use of Gleevec (imatinib) counts." **To** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE of the following: Patient meets BOTH of the following:Patient meets ONE of the following: Trial of, contraindication, significant intolerance to imatinib Note: Prior use of brand Gleevec and Imkeldi also counts." **Added** Danziten to tyrosine kinase examples **Tasigna** **Employer Group Plans** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE of the following:Trial of, contraindication, significant intolerance to ONE of the following: generic dasatinib, generic imatinib Note: Prior use of Gleevec (imatinib), Phyrago (dasatinib), or Sprycel (dasatinib) counts." **To** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE of the following: Trial of, contraindication, significant intolerance to ONE of the following: dasatinib, imatinib Note: Prior use of brand Gleevec, Phyrago, or Sprycel also counts."	

	Tasigna **Individual and Family Plans** **Updated from** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, documentation of ONE of the following: Trial of, contraindication, significant intolerance to ONE of the following: generic imatinib [may require prior authorization], generic dasatinib or Sprycel [may require prior authorization] Note: Prior use of Gleevec (imatinib), or Phyrago (dasatinib) counts." **To** "For Chronic Myeloid Leukemia (CML), Philadelphia Chromosome Positive, ONE of the following: Trial of, contraindication, significant intolerance to ONE of the following: imatinib [may require prior authorization], dasatinib or Sprycel [may require prior authorization] Note: Prior use of brand Gleevec, Imkeldi or Phyrago counts." **Ziihera.** **Added** Ziihera criteria	
Selected Revision	**Danziten.** **Updated from** "Patient meets **ONE** of the following: 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; Patient has a prolonged QT interval or is at risk of developing QT interval prolongation**" to "**Patient meets ONE of the following: Patient has a history of serious, chronic lung disease or has had or is at risk of pleural effusion; OR Note: Examples of lung disease are pulmonary arterial hypertension and interstitial pneumonitis; Patient is at risk of bleeding; OR Note: An example of a patient with an increased risk of bleeding is a patient with thrombocytopenia or with medication use that inhibits platelet function or anticoagulants." **Opdivo Qvantig.** **Added** Opdivo Qvantig criteria **Rituxan.** **Removed** "Currently receiving Rituxan" **Ziihera.** **Added** 'may require prior authorization' to: trastuzumab plus Perjeta, trastuzumab plus Tukysa	7/1/2025

The policy effective date is in force until updated or retired.