

Cigna Medical Coverage Policies – Medical Oncology Medications Policy

Effective August 13th, 2021



Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit 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 policy. In the absence of federal or state coverage mandates, 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 and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

This evidence-based medical coverage policy has been developed by eviCore, Inc. Some information in this coverage policy may not apply to all benefit plans administered by Cigna.

These guidelines include procedures eviCore does not review for Cigna. Please refer to the [Cigna Drug List](#) for the current list of high-tech imaging procedures that eviCore reviews for Cigna.

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Oncology Medications Policy

Please click here for [Cigna specific Prescription Drug Lists](#)

Please click here for [Cigna specific Coverage Policies](#)

Scope of Policy

- All medications approved by the United States Food & Drug Administration (FDA) and used for the direct treatment of cancer are subject to governance within this document.
- All hematopoietic growth factors, myeloprotective agents, erythroid maturation agents, fibroblast growth factor 23 inhibitors, antiemetic agents, bone modifying agents, somatostatin analogues, and tryptophan hydroxylase inhibitors approved by the FDA and used for the supportive treatment of cancer are subject to governance within this document. Bevacizumab use for the management of radiation induced necrosis symptoms is also subject to governance within this document.
 - ◆ All other medication uses for the supportive treatment of cancer are outside the scope of this policy.
- When eviCore is delegated to perform clinical trial utilization management, routine oncology treatments recognized as standard of care for adult and pediatric members enrolled in a clinical trial are subject to governance within this document.
- When eviCore is not delegated for clinical trial utilization management, all oncology medications that will be utilized as part of the clinical trial (including supportive drugs) are outside the scope of this policy.
- All oncology medication uses related to hematopoietic stem cell transplantation (including but not limited to mobilization, harvest, transplant, supportive care, and graft vs. host disease) are outside the scope of this policy.
- All medication uses that are not associated with the direct treatment of cancer or cancer-related symptoms are outside the scope of this policy.

Section 1: Medications Used for Primary Treatment of Cancer

eviCore recognizes all injectable, oral, and topical oncology medications listed for a specific oncologic direct treatment indication in the National Comprehensive Cancer Network (NCCN[®]) Guidelines with Categories of Evidence and Consensus of 1, 2A, or 2B as evidence-based standards of care and medically necessary. The complete versions of the most recent NCCN Guidelines[®] are available free of charge to the general public at <http://www.nccn.org>. Detailed descriptions of the methodology for establishing NCCN[®] Categories of Evidence and Consensus can be found at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

All U.S Food and Drug Administration (FDA) approved medications used for direct cancer treatment not currently addressed in the NCCN Guidelines[®] will be recognized as medically necessary when used in accordance with the FDA indication. All drugs used

for direct treatment of cancer require prior authorization unless listed as exempted in the “Prior Authorization NOT Required” Section 1a below.

Section 1a: Exempted Cancer Treatment Medications - Prior Authorization NOT Required

| Drug Class | Exempted Drugs |
|-------------------|--|
| Hormonal agents | Anastrozole Ethinyl estradiol Exemestane Letrozole Levonorgestrel Medroxyprogesterone Tamoxifen Toremifene |
| Antimetabolites | 6-mercaptopurine (oral formulation) 6-thioguanine (oral formulation) Methotrexate (oral formulation) |
| Corticosteroids | Dexamethasone (oral and injectable formulations) Hydrocortisone (oral and injectable formulations) Methylprednisolone (injectable formulation) Prednisolone (oral formulation) Prednisone (oral formulation) |
| NSAIDs | Celecoxib Diclofenac sodium Sulindac |
| Antimicrobials | Doxycycline Ketoconazole |
| Antihypertensives | Doxazosin mesylate |

Section 1b: Exceptions to NCCN Guidelines® in Medications Used for Primary Treatment of Cancer

eviCore acknowledges that not all medically necessary treatments will conform to NCCN Guidelines® based on patient variability and unique clinical circumstances. Approximately 85% of primary treatment regimens authorized under the eviCore Medical Oncology solution have NCCN® consensus support. The remaining 15% of regimen approvals primarily encompass rare cancers or subtypes not addressed by NCCN® or clinically appropriate exceptions based on individual patient and/or disease factors. eviCore supports a highly efficient process to conduct thorough clinical review of all requested treatment regimens. A variety of additional standard references are used to determine medical necessity in these highly individualized cases. Common examples include peer-reviewed scientific articles, clinical practice guidelines from professional or medical specialty societies, coverage policies of government or commercial payers, FDA indications, and clinical expertise of experienced board-certified oncology practitioners provided through real-time peer consultation.

eviCore frequently performs utilization management as a delegate for commercial and government payers. For those delegated members, certain medications may have differing authorization requirements and specific health plan coverage policies that supersede this eviCore policy will be applied to determine medical necessity.

Section 2: Medications Used for Supportive Treatment of Cancer Patients

Medications approved by the United States Food & Drug Administration (FDA) that are used as supportive care in cancer treatment are subject to governance within this guideline document. Supportive care therapies can prevent and treat clinical symptoms that result from primary cancer treatment medications or from the disease itself. The supportive therapy classes included in this policy are hematopoietic growth factors, myeloprotective agents, erythroid maturation agents, fibroblast growth factor 23 inhibitors, antiemetic agents, bone modifying agents, somatostatin analogues, and tryptophan hydroxylase inhibitors. Bevacizumab use for the management of radiation induced necrosis symptoms is also subject to governance within this document. Uses that are not associated with treatment of cancer-related symptoms are outside of the scope of this policy.

eviCore recognizes all injectable, oral, and topical oncology medications listed for a specific oncologic supportive treatment indication in the National Comprehensive Cancer Network (NCCN[®]) Guidelines with Categories of Evidence and Consensus of 1, 2A, or 2B as evidence-based standards of care and medically necessary. The complete versions of the most recent NCCN Guidelines[®] are available free of charge to the general public at <http://www.nccn.org>. Detailed descriptions of the methodology for establishing NCCN[®] Categories of Evidence and Consensus can be found at: https://www.nccn.org/professionals/physician_gls/categories_of_consensus.aspx.

All FDA-approved hematopoietic growth factors, myeloprotective agents, erythroid maturation agents, fibroblast growth factor 23 inhibitors, antiemetic agents, bone modifying agents, somatostatin analogues, and tryptophan hydroxylase inhibitors used as supportive care in cancer treatment that are not currently addressed in the NCCN Guidelines[®] will be recognized as medically necessary when used in accordance with the FDA indication. All drugs in the above listed classes require prior authorization unless listed as exempted in the “Prior Authorization NOT Required” Section 2a below.

Section 2a: Exempted Supportive Medications - Prior Authorization NOT Required

| Supportive Medication Group | Exempted Drugs and/or Classes |
|------------------------------------|--|
| Antiemetic Therapies | Generic ondansetron (oral and injectable formulations) Generic granisetron (oral and injectable formulations) Generic aprepitant (oral formulation) Corticosteroids (all drugs in class) Benzodiazepines (all drugs in class) Phenothiazines (all drugs in class) Atypical and typical antipsychotics (all drugs in class) Cannabinoids (all drugs in class) Metoclopramide Anticholinergics (all drugs in class) |
| Bone Modifying agents | Alendronate Pamidronate |

Section 2b: Exceptions to NCCN Guidelines® for Medications Used for Supportive Treatment of Cancer

eviCore acknowledges that not all medically necessary and clinically appropriate treatments will conform to NCCN Guidelines® based on patient variability and unique clinical circumstances. Approximately 95% of supportive medications authorized under the eviCore Medical Oncology solution have NCCN® consensus support. The remaining 5% of regimen approvals primarily encompass clinically appropriate exceptions based on individual patient and disease factors. eviCore supports a highly efficient process to conduct thorough clinical review of all requested treatment regimens. A variety of additional standard references are used to determine medical necessity in these highly individualized cases. Common examples include peer-reviewed scientific articles, clinical practice guidelines from professional or medical specialty societies, coverage policies of government or commercial payers, FDA indications, and clinical expertise of experienced board-certified oncology practitioners provided through real-time peer consultation.

eviCore frequently performs utilization management as a delegate for commercial and government payers. For those delegated members, certain medications may have differing authorization requirements and specific health plan coverage policies that supersede this eviCore policy will be applied to determine medical necessity.

Section 3: eviCore Oncology Medication Guideline Methodology

eviCore's Oncology Medication Policy is developed by specialty-focused oncology pharmacists and board-certified oncologists and is then reviewed and approved by eviCore's Medical Advisory Committee on at least an annual basis. Additionally, eviCore's oncology pharmacists and board-certified oncologists collaboratively develop and maintain highly specific and up-to-date algorithms translated from the NCCN Guidelines®. All new and revised algorithms are critically reviewed and approved by NCCN® to ensure concordance with the Guidelines prior to implementation for medical necessity determination uses. By evaluating clinical, pathologic, radiologic, genetic, and molecular findings for an individual patient, NCCN®-recommended single and/or

multidrug regimen options are rapidly determined through an efficient decision support process that can be completed in as little as three minutes via web-based or telephonic tools.

eviCore conducts ongoing monitoring of the drug pipeline and incorporates new FDA-approved therapies or expanded indications into the Medical Oncology solution almost immediately after the approval date. The development of the NCCN Guidelines® is an ongoing and iterative process, which is based on a critical review of the best available evidence and derivation of recommendations by a multidisciplinary panel of experts in the field of cancer. In addition to scheduled annual updates, NCCN® frequently releases interim real-time guideline updates to incorporate recent critical advancements in the field of cancer research and management. eviCore collaborates closely with NCCN® to ensure that the eviCore Medical Oncology algorithms are updated rapidly following the release of an update to any NCCN Guideline®.

About NCCN®

The National Comprehensive Cancer Network® (NCCN®) is a not-for-profit alliance of 30 leading cancer centers devoted to patient care, research, and education. NCCN® is dedicated to improving and facilitating quality, effective, efficient, and accessible cancer care so patients can live better lives. Through the leadership and expertise of clinical professionals at NCCN® Member Institutions, NCCN® develops resources that present valuable information to the numerous stakeholders in the health care delivery system. By defining and advancing high-quality cancer care, NCCN® promotes the importance of continuous quality improvement and recognizes the significance of creating clinical practice guidelines appropriate for use by patients, clinicians, and other health care decision-makers around the world.

World-renowned experts from NCCN® Member Institutions diagnose and treat patients with a broad spectrum of cancers and are recognized for dealing with complex, aggressive, or rare cancers. NCCN® Member Institutions pioneered the concept of the multidisciplinary team approach to patient care and conduct innovative research that contributes significantly to understanding, diagnosing, and treating cancer. NCCN® programs offer access to expert physicians, superior treatment, and quality and safety initiatives that continuously improve the effectiveness and efficiency of cancer care globally.

Reference

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®)
https://www.nccn.org/professionals/physician_gls/default.aspx