

Chemotherapy and Associated Drugs and Treatments

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[Instructions for Use](#)

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Related Medicare Advantage Policy Guidelines
• Aprepitant for Chemotherapy-Induced Emesis (NCD 110.18)
• Autologous Cellular Immunotherapy Treatment (NCD 110.22)
• Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumor (NCD 110.20)
• Camptosar® (Irinotecan)
• Eloxatin® (Oxaliplatin)
• Erbix® (Cetuximab)
• Jevtana® (Cabazitaxel)
• Scalp Hypothermia During Chemotherapy to Prevent Hair Loss (NCD 110.6)

Coverage Guidelines

Chemotherapy, and associated drugs and treatments are covered when Medicare coverage criteria are met.

Chemotherapy, Immunotherapy and Hormonal Agents

Chemotherapy, immunotherapy, and hormonal agents are covered when medically indicated and used according to FDA approved indications or as a part of an anticancer chemotherapeutic regimen or cancer treatment regimen.

FDA approved drug or biological is one that has received final marketing approval by the Food and Drug Administration (FDA) and, as a part of its labeling, contains its recommended uses and dosages as well as adverse reactions and recommended precautions in using it.

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50.4.1 – Approved Use of Drug](#). (Accessed September 10, 2021)

Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen

Effective January 1, 1994, off-label, medically accepted indications of Food and Drug Administration (FDA) approved drugs and biologicals used in an anti-cancer chemotherapeutic regimen are identified under the conditions described below.

A regimen is a combination of anti-cancer agents clinically recognized for the treatment of a specific type of cancer.

Off-label, medically accepted indications are supported in either one or more of the compendia or in peer-reviewed medical literature. Compendia documentation or peer-reviewed literature supporting off-label use by the treating physician may also be requested.

Compendia List

Do not deny coverage based solely on the absence of FDA-approved labeling for the use, if the use is supported by any of the following compendia and the use is not listed as unsupported, not indicated, not recommended, or equivalent terms, in any of the following compendia:

- American Hospital Formulary Service-Drug Information (AHFS-DI) (Existing)
- National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium (Effective June 5, 2008). For NCCN access, [see below](#).
- Micromedex DrugDex (Effective June 10, 2008)
- Clinical Pharmacology (Effective July 2, 2008)
- Lexi-Drugs (Effective August 12, 2015)

The listed compendia employ various rating and recommendation systems that may not be readily cross-walked from compendium to compendium.

In general, a use is identified by a compendium as medically accepted if the:

- Indication is a category 1 or 2A in NCCN, or class I, class IIa, or class IIb in DrugDex; or
- Narrative text in AHFS-DI or clinical pharmacology is supportive, or
- Indication is listed in Lexi-Drugs as “Use: Off-Label” and rated as “Evidence Level A”.

A use is not medically accepted by a compendium if the:

- Indication is a category 3 in NCCN or a class III in DrugDex; or
- Narrative text in AHFS or clinical pharmacology is “not supportive,” or
- Indication is listed in Lexi-Drugs as “Use: Unsupported”.

The complete absence of narrative text on a use is considered neither supportive nor non-supportive.

Compendia Access for Providers (NCCN)

The NCCN Drugs and Biologics Compendium (NCCN Compendium®) is available at <https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia>. (Accessed September 10, 2021)

For convenience, participating providers can access the link to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium on the provider portal at uhcprovider.com [Menu>Resource Library> NCCN Drugs and Biologics Compendium]. (Accessed September 10, 2021)

For other compendia referenced in the coverage guidelines for [Off-label Use of Drugs and Biologics in an Anti-Cancer Chemotherapeutic Regimen](#), free access is not available at this time through uhcprovider.com.

Use Supported by Clinical Research that Appears in Peer-Reviewed Medical Literature

Peer-reviewed medical literature may appear in scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased, independent experts prior to publication. In-house publications of entities whose business relates to the manufacture, sale, or distribution of pharmaceutical products are excluded from consideration. Abstracts (including meeting abstracts) are excluded from consideration.

In determining whether an off-label use is supported, evaluate the evidence in published, peer-reviewed medical literature listed below. When evaluating this literature, consider (among other things) the following:

- Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence
- Whether the administered chemotherapy regimen is adequately represented in the published evidence
- Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients
- Whether the study is appropriate to address the clinical question, consider:
 - Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover.);

- That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
- That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Use peer-reviewed medical literature appearing in the regular editions of the following publications, not to include supplement editions privately funded by parties with a vested interest in the recommendations of the authors:

- American Journal of Medicine;
- Annals of Internal Medicine;
- Annals of Oncology;
- Annals of Surgical Oncology;
- Biology of Blood and Marrow Transplantation;
- Blood;
- Bone Marrow Transplantation;
- British Journal of Cancer;
- British Journal of Hematology;
- British Medical Journal;
- Cancer;
- Clinical Cancer Research;
- Drugs;
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology);
- Gynecologic Oncology;
- International Journal of Radiation, Oncology, Biology, and Physics;
- The Journal of the American Medical Association;
- Journal of Clinical Oncology;
- Journal of the National Cancer Institute;
- Journal of the National Comprehensive Cancer Network (NCCN);
- Journal of Urology;
- Lancet;
- Lancet Oncology;
- Leukemia;
- The New England Journal of Medicine; or
- Radiation Oncology.

Notes:

- FDA approved drugs and biologicals may also be considered for use in the determination of medically accepted indications for off-label use if to be reasonable and necessary.
- If a use is identified as not indicated by the Centers for Medicare and Medicaid Services (CMS) or the FDA, or if a use is specifically identified as not indicated in one or more of the compendia listed, or it's determined, based on peer-reviewed medical literature, that a particular use of a drug is not safe and effective, the off-label usage is not supported and, therefore, the drug is not covered. (This criteria does not apply for the determination of drug eligibility for Part D.)

Refer to the [Medicare Benefit Policy Manual, Chapter 15, §50.4.5 – Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen](#). (Accessed September 10, 2021)

National Cancer Institute (NCI) Designated "Group C" Drugs

Under its Cancer Therapy Evaluation, the Division of Cancer Treatment of the National Cancer Institute (NCI), in cooperation with the Food and Drug Administration, approves and distributes certain drugs for use in treating terminally ill cancer patients. One group of these drugs, designated as Group C drugs, unlike other drugs distributed by the NCI, are not limited to use in clinical trials for the purpose of testing their efficacy. Drugs are classified as Group C drugs only if there is sufficient evidence demonstrating their efficacy within a tumor type and that they can be safely administered.

National Cancer Institute (NCI) designated "Group C" drugs and the related hospital stay is covered if all other applicable coverage requirements are satisfied.

For coverage requirements, refer to the [NCD for Certain Drugs Distributed by the National Cancer Institute \(110.2\)](#). (Accessed September 10, 2021)

Examples of Not Reasonable and Necessary

Determinations as to whether medication is reasonable and necessary for an individual patient should be made on the same basis as all other such determinations (i.e., with the advice of medical consultants and with reference to accepted standards of medical practice and the medical circumstances of the individual case). The following guidelines identify three categories with specific examples of situations in which medications would not be reasonable and necessary according to accepted standards of medical practice:

- **Not for Particular Illness:** Medications given for a purpose other than the treatment of a particular condition, illness, or injury are not covered (except for certain immunizations). Charges for medications, e.g., vitamins, given simply for the general good and welfare of the patient and not as accepted therapies for a particular illness are excluded from coverage.
- **Injection Method Not Indicated:** Medication given by injection (parenterally) is not covered if standard medical practice indicates that the administration of the medication by mouth (orally) is effective and is an accepted or preferred method of administration. For example, the accepted standard of medical practice for the treatment of certain diseases is to initiate therapy with parenteral penicillin and to complete therapy with oral penicillin. UnitedHealthcare Medicare excludes the entire charge for penicillin injections given after the initiation of therapy if oral penicillin is indicated unless there are special medical circumstances that justify additional injections.
- **Excessive Medications:** Medications administered for treatment of a disease and which exceed the frequency or duration of injections indicated by accepted standards of medical practice are not covered. For example, the accepted standard of medical practice in the maintenance treatment of pernicious anemia is one vitamin B-12 injection per month. UnitedHealthcare excludes the entire charge for injections given in excess of this frequency unless there are special medical circumstances that justify additional injections.

Notes:

- UnitedHealthcare will supplement the guidelines as necessary with guidelines concerning appropriate use of specific injections in other situations. They will use the guidelines to screen out questionable cases for special review, further development, or denial when the injection billed for would not be reasonable and necessary. They will coordinate any type of drug treatment review with the Quality Improvement Organization (QIO).
- If a medication is determined not to be reasonable and necessary for diagnosis or treatment of an illness or injury according to these guidelines, UnitedHealthcare excludes the entire charge (i.e., for both the drug and its administration). Also, UnitedHealthcare excludes from payment any charges for other services (such as office visits) which were primarily for the purpose of administering a non-covered injection (i.e., an injection that is not reasonable and necessary for the diagnosis or treatment of an illness or injury).

Refer to the [Medical Benefit Policy Manual, Chapter 15, §50.4.3 – Examples of Not Reasonable and Necessary](#). (Accessed September 10, 2021)

Medicare Approved Clinical Trials: [Oxaliplatin (Eloxatin®), Irinotecan (Camptosar®), Cetuximab (Erbitux®), and Bevacizumab (Avastin®)]

Members may be eligible to participate in a Medicare approved clinical trial, including anti-cancer chemotherapy for colorectal cancer, when criteria are met.

Effective January 28, 2005, the off-label use of clinical items and services, including the use of the studied drugs oxaliplatin, irinotecan, cetuximab, or bevacizumab, are covered in specific clinical trials identified by the Centers for Medicare and Medicaid Services (CMS). The clinical trials identified by CMS for coverage of clinical items and services are sponsored by the National Cancer Institute (NCI) and study the use of one or more off-label uses of these four drugs in colorectal cancer and in other cancer types.

Refer to the [NCD for Anti-Cancer Chemotherapy for Colorectal Cancer \(110.17\)](#). (Accessed September 10, 2021)

The list of Medicare approved clinical trials is available at <https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/index.html>. (Accessed September 10, 2021)

For payment rules for NCDs requiring CED, refer to the Coverage Summary titled [Experimental Procedures and Items, Investigational Devices and Clinical Trials](#).

Examples of Chemotherapy Services

Examples of chemotherapy services include, but are not limited to:

Oral Anti-Cancer Drugs

Oral anticancer drugs prescribed as anticancer chemotherapeutic agents are covered when all of the following criteria are met:

- Approved by the Food and Drug Administration (FDA)
- Prescribed by a physician or other practitioner licensed under state law to prescribe such drugs as anticancer chemotherapeutic agents
- Contains or is metabolized (prodrug) into the same active ingredients as a non-self-administrated anticancer chemotherapeutic drug or biological that is covered when furnished incident to a physician's service
- Has the same chemical/generic name as non-self-administrated drug indicated by the FDA's approved drug products, Physician's Desk Reference (PDR), or an authoritative drug compendium
- Used for the same indications, including off-labeled uses, as the non-self-administrated version of the drug
- Considered reasonable and necessary for the individual member

Note: Members may have additional coverage for oral anti-cancer under the Part D. Prescription Drug Plan, which are not covered in this coverage summary. Refer to the member's pharmacy booklet or contact the Prescription Solutions customer service department to determine coverage eligibility for prescription drug plan benefit.

For detailed coverage requirements, refer to the [Medicare Benefit Policy Manual, Chapter 15, §50.5.3 Oral Anti-Cancer Drugs](#). (Accessed September 10, 2021)

For claims payment and coding information, refer to the [Medicare Claims Processing Manual, Chapter 17, §80.1 Oral Cancer Drugs](#). (Accessed September 10, 2021)

Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. These LCDs/LCAs are available at <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. (Accessed September 10, 2021)

Anti-Nausea (Anti-Emetic) Drugs

Oral anti-nausea (anti-emetic) drugs are covered when all of the following criteria are met:

- Approved by the FDA for use as anti-emetics
- Administered by the treating physician or in accordance with a written order from the physician as part of a cancer chemotherapy regimen
- Administered with a particular chemotherapy treatment and initiated within 2 hours of the administration of the chemotherapeutic agent and may be continued for a period not to exceed 48 hours from that time
- Used as a full therapeutic replacement for the intravenous anti-emetic drugs that would have otherwise been administered at the time of the chemotherapy treatment

Notes:

- Intravenous anti-emetics may be covered (subject to the rules of medical necessity) when furnished to the patients who fail on oral anti-emetics therapy.
- Members may have additional coverage for oral anti-emetic under the Part D Prescription Drug Plan, which are not covered in this Coverage Summary. Refer to the Member's Pharmacy Booklet or contact the Prescription Solutions Customer Service Department to determine coverage eligibility for prescription drug plan benefit.

For detailed coverage requirement, refer to the [Medicare Benefit Policy Manual, Chapter 15, §50.5.4 – Oral Anti-Nausea \(Anti-Emetic\) Drugs](#). (Accessed September 10, 2021)

For claims payment and coding information, refer to the [Medicare Claims Processing Manual, Chapter 17, §80.2 – Oral Anti-emetic Drugs Used as Full Replacement for Intravenous Anti-Emetic Drugs as Part of a Cancer Chemotherapeutic Regimen](#). (Accessed September 10, 2021)

Aprepitant

Aprepitant for chemotherapy-induced emesis is covered when Medicare criteria are met. For the list of approved agents and specific coverage information. Refer to the [NCD for Aprepitant for Chemotherapy-Induced Emesis \(110.18\)](#). (Accessed September 10, 2021)

Inpatient or Outpatient Oncology Services

Inpatient or outpatient oncology services (which includes infusion clinic services) are covered. Refer to the UnitedHealthcare Commercial Utilization Review Guideline (URG) titled [Chemotherapy Observation and Inpatient Hospitalization](#). Refer to the *Instruction for Use* within this URG document. URGs apply clinical guidelines to determine whether the health care services provided or planned for an individual member are the most appropriate and cost-effective services under the specific circumstances. (Accessed September 10, 2021)

Osmotic Blood Brain Barrier Disruption (BBBD)

Osmotic blood brain barrier disruption (BBBD) the treatment of brain tumors is not covered.

BBBD is the disruption of the tight junctions between the endothelial cells that line the capillaries in the brain accomplished by osmotic disruption, bradykinin or irradiation. Theoretically, disruption of the BBB may, in the treatment of brain tumors, increase the concentration of chemotherapy drugs delivered to the tumor and may prolong the drug-tumor contact time.

Osmotic disruption of the BBB is the most common technique used. Chemotherapeutic agents are given in conjunction with barrier disruption. The BBBD process includes all items and services necessary to perform the procedure, including hospitalization, monitoring, and repeated imaging procedures. Refer to the [NCD for Blood Brain Barrier Osmotic Disruption for Treatment of Brain Tumors \(110.20\)](#). (Accessed September 10, 2021)

Scalp Hypothermia During Chemotherapy

Scalp hypothermia during chemotherapy for prevention of hair loss (ice bag and cool bandages) may be used as supplies during chemotherapy but are not recognized for reimbursement. Refer to the [NCD for Scalp Hypothermia During Chemotherapy \(110.6\)](#). (Accessed September 10, 2020)

Local Hyperthermia

Local hyperthermia is not covered when used alone or in connection with chemotherapy. It is covered when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. Refer to the [NCD for Hyperthermia for Treatment of Cancer \(110.1\)](#). (Accessed September 10, 2021)

Also refer to the Coverage Summary titled [Radiologic Therapeutic Procedures](#).

Sipuleucel-T (PROVENGE®)

On-label Indication:

- Effective for services performed on or after June 30, 2011, the Centers for Medicare and Medicaid Services (CMS) proposed that the evidence is adequate to conclude that the use of autologous cellular immunotherapy treatment - sipuleucel-T; PROVENGE® improves health outcomes for Medicare beneficiaries with for asymptomatic or minimally symptomatic metastatic castrate-resistant (hormone refractory) prostate cancer, and thus is reasonable and necessary for this on-label indication under 1862(a)(1)(A) of the Social Security Act. Medicare will allow a maximum of three (3) infusions per lifetime. Refer to the [NCD for Autologous Cellular Immunotherapy Treatment \(110.22\)](#). (Accessed September 10, 2021)
- Local Coverage Articles(LCAs) for sipuleucel-T (PROVENGE®) exist and compliance with these articles is required where applicable. These LCAs are available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search.asp&>. (Accessed September 10, 2021)

- Additional PROVENGE® product information is available at the FDA website at <http://www.fda.gov/downloads/BiologicsBloodVaccines/CellularGeneTherapyProducts/ApprovedProducts/UCM210031.pdf>. (Accessed September 10, 2021)

Off-label Indications:

- Effective for services performed on or after June 30, 2011, coverage of all off-label uses of autologous cellular immunotherapy treatment – sipuleucel-T; PROVENGE® for the treatment of prostate cancer is left to the discretion of the local Medicare Administrative Contractors. Refer to the [NCD for Autologous Cellular Immunotherapy Treatment \(110.22\)](#). (Accessed September 10, 2021)
- Local Coverage Articles (LCAs) for sipuleucel-T (PROVENGE®) exist and compliance with these articles is required where applicable. These LCAs are available at <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search.asp&>. (Accessed September 10, 2021)
- For states/territories with no LCDs/LCAs, refer to the [Chemotherapy, Immunotherapy, and Hormonal](#) and [Off-Label Use](#) guidelines in this coverage summary for Medicare guidelines for covered chemotherapy services and the use of compendia and evidence-based medical literature in determining coverage for this medication.

Rituximab (Rituxan®)

Rituximab (Rituxan®) can be used for chemotherapeutic indications as well as for non-chemotherapeutic indications. For non-chemotherapeutic indications, refer to the Coverage Summary titled [Medications/Drugs \(Outpatient/Part B\)](#).

Medicare does not have a National Coverage Determination (NCD) for Rituximab (Rituxan®) for chemotherapeutic indications. Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs) exist and compliance with these policies is required where applicable. For specific LCD/LCA, refer to the table for [Rituximab \(Rituxan®\)](#).

For states/territories with no LCDs/LCAs, refer to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled [Oncology Medication Clinical Coverage](#).

Note: After checking the [Rituximab \(Rituxan®\)](#) table and searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the policy referenced above for coverage guidelines.

Erythropoietin

Refer to the Coverage Summary titled [Medications/Drugs \(Outpatient/Part B\)](#) for coverage guidelines.

Other Specific Chemotherapeutic Agents

For coverage guideline for specific chemotherapeutic agents:

- Check for available LCDs/LCAs at <https://www.cms.gov/medicare-coverage-database/new-search/search.aspx>. (Accessed September 10, 2021)
- If there are no applicable LCDs/LCAs found, refer to the [Chemotherapy, Immunotherapy, and Hormonal](#) and [Off-Label Use](#) guidelines in this coverage summary for Medicare guidelines for covered chemotherapy services and the use of compendia and evidence-based medical literature in determining coverage for specific medication.

Shortage of Leucovorin (J0640)

There is currently a nationwide shortage of injectable racemic leucovorin, available only as a generic drug and only from three manufacturers in the US (Fresenius Kabi USA, [Sagent Pharmaceuticals](#) and Teva Pharmaceuticals). According to the FDA, the shortages are due to manufacturing delays. Information on current availability of specific vial sizes and expected release dates for others can be found on the FDA website at <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>. (Accessed September 10, 2021)

For patients affected by this shortage, the UnitedHealthcare Medicare plan will consider levoleukovorin (J0641) as an alternative for leucovorin (J0640).

Supporting Information

Important Note: When searching the [Medicare Coverage Database](#), if no LCD/LCA is found, then use the applicable referenced default policy below for coverage guidelines.

Rituximab (Rituxan®)				
Accessed September 10, 2021				
LCD/LCA ID	LCD/LCA Title	Contractor Type	Contractor Name	Applicable States/Territories
L33394 (A52452)	Drugs and Biologicals, Coverage of, for Label and Off-Label Uses	Part A and B MAC	National Government Services, Inc.	CT, IL, ME, MA, MN, NH, NY, RI, WI, VT
L35026 (A56380)	Rituximab	Part A and B MAC	Palmetto GBA	AL, GA, NC, SC, TN, VA, WV
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Policy History/Revision Information

Date	Summary of Changes
09/21/2021	<p>Coverage Guidelines</p> <p><i>Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen</i></p> <p>Compendia Access for Providers (NCCN)</p> <ul style="list-style-type: none"> Removed language addressing member applicability for the oncology program described in the NCCN Drugs and Biologics Compendium (NCCN Compendium®) <p>Examples of Chemotherapy Services</p> <p>Rituximab (Rituxan®)</p> <ul style="list-style-type: none"> Updated language to clarify Medicare does not have a National Coverage Determination (NCD) for Rituximab (Rituxan®) <i>for chemotherapeutic indications</i> Revised default guidelines for states/territories with no Local Coverage Determinations (LCDs)/Local Coverage Articles (LCAs): <ul style="list-style-type: none"> Added reference link to the UnitedHealthcare Commercial Medical Benefit Drug Policy titled <i>Oncology Medication Clinical Coverage</i> Removed reference link to the National Government Services LCD for <i>Drugs and Biologicals, Coverage of, for Label and Off-Label Uses (L33394)</i> <p>Supporting Information</p> <ul style="list-style-type: none"> Archived previous policy version MCS017.01

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The benefit information in this Coverage Summary is based on existing national coverage policy; however, Local Coverage Determinations (LCDs) may exist and compliance with these policies are required where applicable.

There are instances where this document may direct readers to a UnitedHealthcare Commercial Medical Policy, Medical Benefit Drug Policy, and/or Coverage Determination Guideline (CDG). In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)).

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