ONCOLOGY MEDICATION CLINICAL COVERAGE

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Related Commercial Policies
- Denosumab (Prolia® & Xgeva®)
- Erythropoiesis-Stimulating Agents
- Lemtrada (Alemtuzumab)
- Rituxan® (Rituximab)
- White Blood Cell Colony Stimulating Factors

Related Clinical Guideline
- Transplant Review Guidelines: Hematopoietic Stem Cell Transplantation

Coverage Rationale

Injectable Oncology, Ancillary, and Supportive Care Medications

UnitedHealthcare recognizes indications and uses of injectable oncology medications listed in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as proven and medically necessary, and Categories of Evidence and Consensus of 3 as unproven and not medically necessary.

UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years for oncology indications. The majority of pediatric patients receive treatments on national pediatric protocols that are quite similar in concept to the NCCN patient care guidelines.

Select ancillary and supportive care medications for oncology conditions have therapeutically equivalent products available. When a therapeutically equivalent alternative is available, as determined by the United Healthcare Pharmacy and Therapeutics (P&T) Committee, certain medications may be excluded and/or not medically necessary. For purposes of the United Healthcare P&T Committee review, therapeutic equivalence refers to medications that can be expected to produce essentially the same therapeutic outcome and adverse events.

Below are ancillary and supportive care medications for oncology conditions with therapeutically equivalent alternatives as determined by the United Healthcare P&T Committee:

<table>
<thead>
<tr>
<th>Preferred</th>
<th>Non-Preferred</th>
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<tbody>
<tr>
<td>Leucovorin</td>
<td>Levoleucovorin</td>
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Additional Information

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are a comprehensive set of 71 guidelines documenting sequential management decisions and interventions and interventions that apply to malignancies which apply to more than 97% of cancers affecting U.S. patients. They also address supportive care issues. The guidelines are developed and updated by 54 volunteer panels, composed of more than 1,275 clinicians and oncology researchers representing the 27 NCCN Member Institutions and their affiliates.

NCCN Categories of Evidence and Consensus

- **Category 1**: The recommendation is based on high-level evidence (i.e., high-powered randomized clinical trials or meta-analyses), and the panel has reached uniform consensus that the recommendation is indicated. In this context, uniform means near unanimous positive support with some possible neutral positions.

- **Category 2A**: The recommendation is based on lower level evidence, but despite the absence of higher level studies, there is uniform consensus that the recommendation is appropriate. Lower level evidence is interpreted broadly, and runs the gamut from phase II to large cohort studies to case series to individual practitioner experience. Importantly, in many instances, the retrospective studies are derived from clinical experience of treating large numbers of patients at a member institution, so panel members have first-hand knowledge of the data. Inevitably, some recommendations must address clinical situations for which limited or no data exist. In these instances the congruence of experience-based opinions provides an informed if not confirmed direction for optimizing patient care. These recommendations carry the implicit recognition that they may be superseded as higher level evidence becomes available or as outcomes-based information becomes more prevalent.

- **Category 2B**: The recommendation is based on lower level evidence, and there is nonuniform consensus that the recommendation should be made. In these instances, because the evidence is not conclusive, institutions take different approaches to the management of a particular clinical scenario. This nonuniform consensus does not represent a major disagreement, rather it recognizes that given imperfect information, institutions may adopt different approaches. A Category 2B designation should signal to the user that more than one approach can be inferred from the existing data.

- **Category 3**: The recommendation has engendered a major disagreement among the panel members. Several circumstances can cause major disagreements. For example, if substantial data exists about two interventions but they have never been directly compared in a randomized trial, adherents to one set of data may not accept the interpretation of the other side's results. Another situation resulting in a Category 3 designation is when experts disagree about how trial data can be generalized. A Category 3 designation alerts users to a major interpretation issue in the data and directs them to the manuscript for an explanation of the controversy.

BENEFIT CONSIDERATIONS

If the coverage review using the NCCN Compendium determines that the drug is unproven, then further review is indicated. Some Certificates of Coverage allow for coverage of experimental/investigational/unproven treatments for life-threatening illnesses when certain conditions are met. The member specific benefit plan document must be consulted to make coverage decisions for this service. Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the member specific benefit plan document or in this policy.

Chimeric Antigen Receptor (CAR)-T Cell Therapy may be eligible for coverage as an autologous stem cell therapy under a member’s Transplantation Services benefit. Coverage determinations are based on the OptumHealth Transplant Solutions criteria for covered transplants; refer to the Clinical Guideline titled Transplant Review Guidelines: Hematopoietic Stem Cell Transplantation.

Benefit coverage for an otherwise unproven service for the treatment of serious rare diseases may occur when certain conditions are met. See the Policy and Procedure addressing the treatment of serious rare diseases.

REFERENCES

1. The NCCN Drugs and Biologics Compendium (NCCN Compendium®).
   http://www.nccn.org/professionals/drug_compendium/content/contents.asp.
2. The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®).
INSTRUCTIONS FOR USE

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Benefit Drug Policy may also be applied to Medicare Advantage plans in certain instances. 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).

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.