ONCOLOGY MEDICATION CLINICAL COVERAGE

Policy Number: CS2019D00300

Effective Date: March 1, 2019

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**Description**

This policy provides parameters for coverage of injectable oncology medications (J9000–J9999) and select ancillary and supportive care medications for oncology conditions [including, but not limited to octreotide acetate (J2353 and J2354), leuprolide acetate (J1950), leucovorin (J0640) and levoleucovorin (J0641)] covered under the medical benefit based upon the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium® (NCCN Compendium®). The Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category. This policy does not provide coverage criteria for Chimeric Antigen Receptor (CAR)-T Cell products. Coverage determinations are based on the member’s benefits and the OptumHealth Transplant Solutions criteria for covered transplants in the Clinical Guideline titled 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**. (However, see Benefit Considerations.)

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 UnitedHealthcare Pharmacy and Therapeutics (P&T) Committee, certain medications may be excluded and/or not medically necessary. For purposes of the UnitedHealthcare 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 UnitedHealthcare P&T Committee:

- Leucovorin (Preferred)
- Levoleucovorin (Non-Preferred)
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 exist 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
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 in the Clinical Guideline titled Transplant Review Guidelines: Hematopoietic Stem Cell Transplantation.

STATE EXCEPTIONS

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<tr>
<th>State</th>
<th>Note</th>
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<tbody>
<tr>
<td>Kansas</td>
<td>Drug policy not approved for use in this market</td>
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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®).


**POLICY HISTORY/REVISION INFORMATION**

<table>
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<tr>
<td>04/01/2019</td>
<td>• Updated list of related policies to reflect title change for Rituximab (Rituxan® &amp; Truxima®) [previously titled Rituxan® (Rituximab)]</td>
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<tr>
<td>03/01/2019</td>
<td>• Reorganized policy template; simplified and relocated Instructions for Use and Benefit Considerations section</td>
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<td>• Archived previous policy version CS2018D0030N</td>
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**INSTRUCTIONS FOR USE**

This Medical Benefit Drug Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage.

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.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The 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.