ONCOLOGY MEDICATION CLINICAL COVERAGE

Guideline Number: MMG094.H **Effective Date**: March 1, 2019

Instructions for Use

Table of Contents **Page**

Related Clinical Guideline

- Transplant Review Guidelines: Hematopoietic Stem Cell Transplantation

COVERAGE RATIONALE

See Benefit Considerations

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 US Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each commendation 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 OptumHealth Transplant Solutions criteria for covered transplants, refer to 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**.

UnitedHealthcare will cover all chemotherapy agents for individuals under the age of 19 years. 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:

- 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 that apply to malignancies which apply to more than 97% 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

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 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 benefit document or in the drug 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.

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®) http://www.nccn.org/professionals/physician_gls/f_guidelines.asp
3. Pazdur R. Endpoints for assessing drug activity in clinical trials. Oncologist. 2008;13 Suppl 2:19-21.
4. Therasse P, Arbuck SG, Eisenhauer EA, et al. New guidelines to evaluate the response to treatment in solid tumors. European Organization for Research and Treatment of Cancer, National Cancer Institute of the United States, National Cancer Institute of Canada. J Natl Cancer Inst. 2000 Feb 2;92(3):205-16.

GUIDELINE HISTORY/REVISION INFORMATION

Date	Action/Description
03/01/2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Archived previous policy version MMG094.G

INSTRUCTIONS FOR USE

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard 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 guideline, 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 Management Guideline 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. UnitedHealthcare West Medical Management Guidelines 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.

Member benefit coverage and limitations may vary based on the member's benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.