ONCOLOGY MEDICATION CLINICAL COVERAGE

Policy Number: 2019D0030O **Effective Date**: March 1, 2019

Instructions for Use

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Related Clinical Guideline

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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 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; 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 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:

Preferred	Non-Preferred
Leucovorin	Levoleucovorin

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®). 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.

POLICY 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 2018D0030N.
07/01/2018	Annual review. Updated additional information. Updated references. Approved by the National Pharmacy & Therapeutics Committee 06/20/2018. Policy 2017D0030M archived.
11/01/2017	Annual review. Updated to address CAR-T Cell products. Updated references. Approved by the National Pharmacy & Therapeutics Committee 09/27/2017. Policy 2017D0030L archived.
06/01/2017	Off-cycle review. Moved policy to new template. Coverage rationale updated to include ancillary and supportive care medications (including leucovorin and levoleucovorin), as well as added additional verbiage and grid detailing therapeutic equivalence of preferred (leucovorin)/non-preferred (levoleucovorin) products. Approved by the National Pharmacy & Therapeutics Committee 03/22/2017. Policy 2016D0030K archived.
07/01/2016	Annual review with minor update to the coverage rationale. Approved by the National Pharmacy & Therapeutics Committee 05/20/2016. Policy 2015D0030J archived.
07/01/2015	Policy revised for annual review. Added additional language to Benefits Considerations. Approved by the National Pharmacy & Therapeutics Committee 04/14/2015. Policy 2014D0030I archived.
11/01/2014	Policy revised to include updated medical necessity clarification. Approved by the National Pharmacy & Therapeutics Committee 08/20/2014. Policy 2014D0030H archived.
01/01/2014	Annual review of drug policy. Updated policy to include coverage of leuprolide acetate and octreotide acetate for oncology indications per NCCN. Clarified indication for coverage of chemotherapy agents for individuals under the age of 19 applies to oncology indications only. Approved by the National Pharmacy & Therapeutics Committee 11/12/2013. Policy 2013D0030G archived.
04/01/2013	Policy revised for annual review. Approved by the National Pharmacy & Therapeutics Committee 02/19/2013. Policy 2012ED0030F archived.
03/01/2012	Policy revised for annual review. Approved by the National Pharmacy & Therapeutics Committee 01/10/2012. Policy 2011ED0030E archived.
02/01/2011	Policy revised for annual review. Approved by the National Pharmacy & Therapeutics Committee 01/11/2011. Policy 2010D0030D archived.
04/01/2010	Policy revised to include coverage of all chemotherapy for patients under 19 years old. Approved by the National Pharmacy & Therapeutics Committee 03/09/2010. Policy 2010D0030C archived.
02/10/2010	Policy updated for annual review. Approved by the National Pharmacy & Therapeutics Committee 01/12/2010. Policy 2009D0030B archived.
02/12/2009	Policy revised for annual review. Policy 2007D0030A archived.
11/28/2007	New policy. 2007D0030A.

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 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.