Oncology Medication Clinical Coverage (for Indiana Only)

Policy Number: CSIND0030.11
Effective Date: August 1, 2024

Ü Instructions for Use

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Related Clinical Guideline

. Chimeric Antigen Receptor T-Cell Therapy

Application

This Medical Benefit Drug Policy only applies to the state of Indiana.

Coverage Rationale

Ü See Benefit Considerations

Description

This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, denosumab (Prolia® & Xgeva®), erythropoiesis-stimulating agents, gonadotropin releasing hormone analogs, leucovorin, levoleucovorin, rituximab, somatostatin analogs, and white blood cell colony stimulating factors), including therapeutic radiopharmaceuticals, 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 Chimeric Antigen Receptor T-cell Therapy.

Coverage Rationale

The Oncology Products table below lists the UnitedHealthcare preferred oncology products and respective non-preferred products. Coverage will be provided for the UnitedHealthcare preferred oncology product contingent on the coverage criteria in the Diagnosis-Specific Criteria section.

Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the Preferred Product Criteria and the Diagnosis-Specific Criteria sections.

Preferred Product Criteria

Treatment with the respective non-preferred product specified in the Oncology Products table below is medically necessary for oncology indications when both of the following are met:

- History of intolerance or contraindication to one of UnitedHealthcare's preferred oncology products; **and**
- Physician attests that, in their clinical opinion, the same intolerance, contraindication, or adverse event would not be expected to occur with the respective non-preferred product

Oncology Products

Below are UnitedHealthcare preferred oncology products with therapeutically equivalent and/or biosimilar* non-preferred products as determined by the UnitedHealthcare Pharmacy & Therapeutic Committee:

Preferred Oncology Product	Non-Preferred Oncology Product
Gemcitabine	Infugem™ (gemcitabine in sodium chloride injection)
Leucovorin	Levoleucovorin

*Biosimilar means that the biological product is FDA-approved based on data demonstrating that it is highly similar to an already FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product.

Diagnosis-Specific Criteria

Injectable Oncology Medications

UnitedHealthcare recognizes indications and uses of injectable oncology medications, including therapeutic radiopharmaceuticals, in the NCCN Drugs and Biologics Compendium with Categories of Evidence and Consensus of 1, 2A, and 2B as **proven** and Categories of Evidence and Consensus of 3 as **unproven and not medically necessary**. (However, refer to the 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.

Refer to Preferred Product Criteria for the UnitedHealthcare preferred oncology products that have therapeutically equivalent and/or biosimilar products available.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS Code	Description
J0640	Injection, leucovorin calcium, per 50 mg
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
J9198	Injection, gemcitabine hydrochloride, (infugem), 100 mg
J9199	Injection, gemcitabine hydrochloride (infugem), 200 mg
J9201	Injection, gemcitabine hydrochloride, not otherwise specified, 200 mg

Background

The NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) are comprehensive guidelines documenting management decisions and interventions that apply to 97% of cancers affecting U.S. patients.

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 exists. 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.

Therapeutic radiopharmaceuticals [e.g., Azedra® (iobenguane I 131), Lutathera® (lutetium Lu 177 dotatate), Xofigo® (radium-223)] used to treat cancer are medications that contain radioactive material. The radioactive agent selectively accumulates within the tumor, releasing radiation which then kills cancer cells.

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 Chimeric Antigen Receptor T-cell Therapy.

References

1. NCCN Drugs and Biologics Compendium (NCCN Compendium®). https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia.
2. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) https://www.nccn.org/professionals/physician_gls/default.aspx.
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.
5. Center for Drug Evaluation and Research. Biosimilars. Refer to: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.

Policy History/Revision Information

Date	Summary of Changes
08/01/2024	**Related Policies** • Added reference link to the Optum Clinical Guideline titled *Chimeric Antigen Receptor T-cell Therapy* • Removed reference link to the Medical Benefit Drug Policy titled: o *Erythropoiesis-Stimulating Agents (for Indiana Only)*

Date	Summary of Changes
	o *Rituximab (Riabni™, Rituxan®, Ruxience™, & Truxima®) (for Indiana Only)* o *White Blood Cell Colony Stimulating Factors (for Indiana Only)* **Coverage Rationale** • Updated list of examples of injectable oncology medications: o Added: § Denosumab (Prolia® & Xgeva®) § Erythropoiesis-stimulating agents § Gonadotropin releasing hormone analogs § Rituximab § Somatostatin analogs § White blood cell colony stimulating factors o Removed: § Octreotide acetate • Revised list of applicable oncology products: ***Preferred*** o Removed: § Kanjinti® (trastuzumab-anns) § Mvasi® (bevacizumab-awwb) § Somatuline Depot (Lanreotide; HCPCS code J1930) ***Non-Preferred*** o Removed: § Alymsys (bevacizumab-maly) § Avastin® (bevacizumab) § Herceptin Hylecta™ (trastuzumab and hyaluronidase-oysk) § Herceptin® (trastuzumab) § Herzuma® (trastuzumab-pkrb) § Lanreotide (HCPCS J1932) § Ogivri® (trastuzumab-dkst) § Ontruzant® (trastuzumab-dttb) § Trazimera™ (trastuzumab-qyyp) § Vegzelma (bevacizumab-adcd) § Zirabev® (bevacizumab-bvzr) **Applicable Codes** • Removed HCPCS codes A9513, A9590, A9606, A9607, A9699, J1930, J1932, J9035, J9310, J9312, J9355, J9356, Q5107, Q5112, Q5113, Q5114, Q5115, Q5116, Q5117, Q5118, Q5119, Q5126, and Q5129 **Supporting Information** • Archived previous policy version CSIND0030.10

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 InterQual® criteria, 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.