Oncology Medication Clinical Coverage

Policy Number: CS2025D0030AL
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➲ Instructions for Use

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Application

This Medical Benefit Drug Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Indiana	Oncology Medication Clinical Coverage (for Indiana Only)
Kansas	Refer to the state's Medicaid Clinical Policy
Louisiana	Oncology Medication Clinical Coverage (for Louisiana Only)
North Carolina	None
Ohio	Oncology Medication Clinical Coverage (for Ohio Only)
Pennsylvania	Oncology Medication Clinical Coverage (for Pennsylvania Only)

The Preferred Product Criteria for:

- **Bevacizumab, Trastuzumab, and Rituximab** do not apply to the states of Arizona, Washington, and Wisconsin.
- **Rituximab** does not apply to the state of Florida.
- **All products** included within this policy do not apply to the state of Michigan.

Coverage Rationale

➲ See Benefit Considerations

Description

This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide acetate, leuprolide acetate, leucovorin, and levoleucovorin), 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. Refer to the Medical Benefit Drug Policy titled White Blood Cell Colony Stimulating Factors or Erythropoiesis-Stimulating Agents, for information on those agents. This policy does not provide coverage criteria for chimeric antigen receptor (CAR) T-cell or tumor-infiltration lymphocyte (TIL) 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 (CAR T) Therapy or Tumor-Infiltrating Lymphocyte (TIL) 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 the UnitedHealthcare preferred oncology products:

Preferred Oncology Product	Non-Preferred Oncology Product	Indications
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab) Zirabev (bevacizumab-bvzr) Alymsys (bevacizumab-maly) Vegzelma (bevacizumab-adcd)	All oncology indications
Kanjinti (trastuzumab-anns) Ogivri (trastuzumab-dkst) Trazimera (trastuzumab-qyyp)	Herceptin (trastuzumab) Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) Herzuma (trastuzumab-pkrb) Hercessi (trastuzumab-strf) Ontruzant (trastuzumab-dttb)	All oncology indications
Ruxience (rituximab-pvvr) Truxima (rituximab-abbs)	Rituxan (rituximab) Rituxan Hycela (rituximab/hyaluronidase human, recombinant) Riabni (rituximab-arrx)	All oncology indications
Leucovorin	Levoleucovorin	All oncology indications
Eligard (leuprolide acetate), Lupron Depot 7.5 mg (leuprolide acetate for depot suspension - J9217, J1954)	Lupron Depot 3.75 mg (leuprolide acetate for depot suspension - J1950)	All oncology indications
Keytruda (pembrolizumab) Libtayo (cemiplimab-rwlc) Tecentriq (atezolizumab)	Opdivo (nivolumab) + Yervoy (ipilimumab)	Non-small cell lung cancer: advanced or metastatic, monotherapy, PD-L1 expression positive ≥ 50%
Loqtorzi (toripalimab-tpzi)	Keytruda (pembrolizumab) Opdivo (nivolumab)	Head and neck cancers: recurrent, unresectable, oligometastatic, or metastatic disease, nasopharyngeal

Preferred Oncology Product	Non-Preferred Oncology Product	Indications
Alimta, Pemetrexed (J9294, J9296, J9297, J9305, J9314)	Pemfexy (J9304), Pemrydi RTU (J9324), Axtle (J9292)	All oncology indications
Irinotecan	Onivyde (irinotecan liposome)	Pancreatic cancer
Tecvayli (teclistamab-cqyv)	Elerexfio (elranatamab-bcmm)	Multiple myeloma

Any U.S. Food and Drug Administration approved product that may belong to the UnitedHealthcare Preferred or Non-Preferred Oncology Product categories, but not listed by name in this policy will be considered non-preferred until reviewed by UnitedHealthcare P&T committee.

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 section.)

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 and indications.

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
A9513	Lutetium lu 177, dotatate, therapeutic, 1 millicurie
A9590	Iodine i-131, iobenguane, 1 millicurie
A9606	Radium Ra-223 dichloride, therapeutic, per microcurie
A9607	Lutetium Lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie
A9699	Radiopharmaceutical, therapeutic, not otherwise classified
J0640	Injection, leucovorin calcium, 50 mg
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J1950	Injection, leuprolide acetate (for depot suspension), 3.75 mg
J1954	Injection, leuprolide acetate for depot suspension (cipla), 7.5 mg
J3263	Injection, toripalimab-tpzi, 1 mg
J9022	Injection, atezolizumab, 10 mg
J9035	Injection, bevacizumab, 10 mg
J9119	Injection, cemiplimab-rwlc, 1 mg
J9205	Injection, irinotecan liposome, 1 mg
J9206	Injection, irinotecan, 20 mg
J9217	Leuprolide acetate (for depot suspension), 7.5 mg
J9228	Injection, ipilimumab, 1 mg

HCPCS Code	Description
J9271	Injection, pembrolizumab, 1 mg
J9292	Injection, pemetrexed (Axtle), 10 mg
J9294	Injection, pemetrexed (Hospira), not therapeutically equivalent to J9305, 10 mg
J9296	Injection, pemetrexed (Accord), not therapeutically equivalent to J9305, 10 mg
J9297	Injection, pemetrexed (sandoz) 10mg
J9299	Injection, nivolumab, 1 mg
J9304	Injection, pemetrexed, 10 mg
J9305	Injection, pemetrexed nos 10mg
J9310	Injection, rituximab, 100 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
J9314	Injection, pemetrexed (Teva), not therapeutically equivalent to J9305, 10 mg
J9324	Injection, pemetrexed (Pemrydi RTU), 10 mg
J9355	Injection, trastuzumab, 10 mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
J9380	Injection, teclistamab cqyv, 0.5 mg
Q5107	Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg
Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (truxima) 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg
Q5118	Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (ruxience), 10 mg
Q5123	Injection, rituximab-arrx, biosimilar, (Riabni), 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5129	Injection, bevacizumab-adcd, biosimilar, (vegzelma), 10 mg
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 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 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.

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 (CAR T) 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. Retrieved from: https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars.

Policy History/Revision Information

Date	Summary of Changes

04/01/2025	**Application**
	• Removed language indicating preferred product criteria does not apply to the states of Arizona, Mississippi, or Texas for Somatuline Depot
	• Replaced language indicating:
	  ○ "Preferred product criteria does not apply to the states of Arizona, Washington, and Wisconsin for *Mvasi, Kanjinti, Ruxience, and Truxima*" with "preferred product criteria does not apply to the states of Arizona, Washington, and Wisconsin for bevacizumab, trastuzumab, and rituximab"
	  ○ "Preferred product criteria does not apply to the state of Florida for *Ruxience and Truxima*" with "preferred product criteria does not apply to the state of Florida for *rituximab*"
	Coverage Rationale

Date	Summary of Changes

	• Revised list of UnitedHealthcare preferred and non-preferred oncology products for all oncology indications:
	  ○ Added Axtle (HCPCS code J9292) (non-preferred)
	  ○ Removed:
	  ▪ Somatuline Depot (Lanreotide) (HCPCS code J1930) (preferred)
	  ▪ Lanreotide (HCPCS code J1932) (non-preferred)
	Applicable Codes
	• Added HCPCS code J9292
	• Removed HCPCS codes J1930 and J1932
	Supporting Information
	• Archived previous policy version CS2025D0030AK

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.