

Oncology Medication Clinical Coverage (for Louisiana Only)

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☐ Instructions for Use

Table of Contents	Page
Application	
Coverage Rationale	1
Applicable Codes	3
Background	
Benefit Considerations	
References	
Policy History/Revision Information	
Instructions for Use	

Application

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

Refer to the Louisiana Medicaid Preferred Drug List/Non-Preferred Drug List (PDL/NPDL) for outpatient retail pharmacy coverage.

Coverage Rationale

See Benefit Considerations

Description

This policy provides parameters for coverage of injectable oncology medications (including, but not limited to, octreotide 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. Coverage of White Blood Cell Colony Stimulating Factors and Erythropoiesis-Stimulating Agents are addressed in separate policies. 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 Therapy* or *Tumor-Infiltrating Lymphocyte (TIL) Cell Therapy*.

Coverage Rationale

The <u>Oncology Products</u> 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 <u>Diagnosis-Specific Criteria</u> section.

Coverage for any respective non-preferred oncology product will be provided contingent on the criteria in the <u>Preferred Product Criteria</u> and the <u>Diagnosis-Specific Criteria</u> 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:

Preferred Oncology Product Non-Preferred Oncology Product		Indication(s)	
Mvasi (bevacizumab-awwb)	Avastin (bevacizumab)	All oncology indications	
	Zirabev (bevacizumab-bvzr)		
	Alymsys (bevacizumab-maly)		
	Vegzelma (bevacizumab-adcd)		
Kanjinti (trastuzumab-anns)	Herceptin (trastuzumab)	All oncology indications	
Ogivri (trastuzumab-dkst)	Herceptin Hylecta (trastuzumab and		
Trazimera (trastuzumab-qyyp)	hyaluronidase-oysk)		
	Herzuma (trastuzumab-pkrb)		
	Hercessi (trastuzumab-strf)		
	Ontruzant (trastuzumab-dttb)		
Ruxience (rituximab-pvvr)	Rituxan (rituximab)	All oncology indications	
Truxima (rituximab-abbs)	Rituxan Hycela (rituximab/hyaluronidase		
	human, recombinant) Riabni (rituximab-arrx)		
Leucovorin	Levoleucovorin	All an aslam, in disastions	
		All oncology indications	
Keytruda (pembrolizumab)	Opdivo (nivolumab) + Yervoy (ipilimumab)	Non-Small Cell Lung Cancer: Advanced or Metastatic, Monotherapy, PD-L1 expression	
Libtayo (cemiplimab-rwlc) Tecentriq (atezolizumab)		positive ≥50%	
Tecentriq Hybreza (atezolizumab		p = = = = = = = = = = = = = = = = = = =	
and hyaluronidase-tqjs)			
Loqtorzi (toripalimab-tpzi)	Keytruda (pembrolizumab)	Head and Neck Cancers: Cancer of the	
Edger 21 (torrpainting tp21)	Opdivo (nivolumab)	Nasopharynx, Recurrent, Unresectable,	
	Opdivo Qvantig (nivolumab and	Oligometastatic, or Metastatic Disease,	
	hyaluronidase-nvhy)	Nasopharyngeal Head and Neck Cancers:	
	Tevimbra (tislelizumab-jsgr)	Recurrent, Unresectable, Oligometastatic, or	
		Metastatic Disease, Nasopharyngeal	
Tecentriq (atezolizumab) + Mvasi	Tecentriq (atezolizumab) + any of the	Hepatocellular Carcinoma: combination	
(bevacizumab-awwb)	following: Avastin (bevacizumab), Zirabev (bevacizumab-bvzr), Alymsys (bevacizumab-	systemic therapy	
<u>Tecentriq Hybreza (atezolizumab</u> <u>and hyaluronidase-tqjs) + Mvasi</u>	maly), Vegzelma (bevacizumab-adcd)		
(bevacizumab-awwb)	mary, vegzenna (sevacizamas adea)		
Imjudo (tremelimumab-actl) +	Tecentrig Hybreza (atezolizumab and		
Imfinzi (durvalumab)	hyaluronidase-tqjs) + any of the following:		
	Avastin (bevacizumab), Zirabev		
	(bevacizumab-bvzr), Alymsys (bevacizumab-		
	maly), Vegzelma (bevacizumab-adcd)		
	Onding (nivelymph) + Verney (initiation - b)		
	Opdivo (nivolumab) + Yervoy (ipilimumab)		

Preferred Oncology Product	Non-Preferred Oncology Product	Indication(s)
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
Cyclophosphamide (J9071, J9073, J9075)	Cyclophosphamide (J9074, J9076), Frindovyx (J9072)	All oncology indications
Docetaxel (J9171)	Docivyx (J9172)	All oncology indications
Bortezomib (J9041, J9049)	Boruzu (J9051, J9054)	All oncology indications

Any U.S. Food and Drug Administration approved product that may belong to 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 medically necessary**, and Categories of Evidence and Consensus of 3 as **unproven and not medically necessary**. (However, refer to the <u>Benefit</u> 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, per 50 mg
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (Khapzory), 0.5 mg
J1323	Injection, elranatamab-bcmm, 1 mg
J9024	Injection, atezolizumab, 5 mg and hyaluronidase-tqjs
J9035	Injection, bevacizumab, 10 mg
J9041	Injection, bortezomib, 0.1mg
J9049	Injection, bortezomib, hospira, 0.1 mg

HCPCS Code	Description		
J9051	Injection, bortezomib, maia, 0.1 mg		
J9054	Injection, bortezomib (Boruzu), 0.1 mg		
J9071	Injection, cyclophosphamide, auromedic, 5 mg		
J9072	Injection, cyclophosphamide, (Frindovyx), 5mg		
J9073	Inj cyclophosphamide, dr reddys, 5 mg		
J9074	Inj, cyclophosphamide, sandoz, 5 mg		
J9075	Inj, cyclophosphamide, nos, 5 mg		
J9076	Inj, cyclophosphamide, baxter, 5 mg		
J3263	Inejction, toripalimab-tpzi, 1 mg		
J9022	Injection, atezolizumab, 10 mg		
J9119	Injection, cemiplimab-rwlc, 1 mg		
J9171	Injection, docetaxel, 1 mg		
J9172	Injection, docetaxel (Docivyx), 1 mg		
J9205	Injection, irinotecan liposome, 1 mg		
J9206	Injection, irinotecan, 20 mg		
J9228	Injection, ipilimumab, 1 mg		
J9271	Injection, pembrolizumab, 1 mg		
<u>J9289</u>	Injection, nivolumab, 2mg and hyaluronidase-nvhy		
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		
J9329	Injection, tislelizumab-jsgr, 1mg		
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		

HCPCS Code	Description	
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 Therapy*.

References

- 1. The NCCN Drugs and Biologics Compendium (NCCN Compendium*). https://www.nccn.org/compendia-templates/compendia/drugs-and-biologics-compendia.
- 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.
- 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
<u>TBD</u>	Added preferred and non-preferred immune checkpoint inhibitors combination systemic therapy for
	hepatocellular carcinoma. Added HCPCS codes J9289.

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 InterQual®, 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.

Archived Policy Versions

Effective Date	Policy Number	Policy Title
03/01/2023 - 03/31/2023	CSLA2023D0030V	Oncology Medication Clinical Coverage (for Louisiana Only)
01/01/2023 - 02/28/2023	CSLA2023D0030U	Oncology Medication Clinical Coverage (for Louisiana Only)
12/01/2022 – 12/31/2022	CSLA2022D0030T	Oncology Medication Clinical Coverage (for Louisiana Only)
10/01/2022 - 11/30/2022	CSLA2022D0030S	Oncology Medication Clinical Coverage (for Louisiana Only)
04/01/2022 - 09/30/2022	CSLA2021D0030R	Oncology Medication Clinical Coverage (for Louisiana Only)
01/01/2022 - 03/31/2022	CSLA2021D0030Q	Oncology Medication Clinical Coverage (for Louisiana Only)
09/01/2021 - 12/31/2021	CSLA2021D0030P	Oncology Medication Clinical Coverage (for Louisiana Only)
03/01/2019 - 08/31/2021	CSLA2019D0030O	Oncology Medication Clinical Coverage (for Louisiana Only)
07/01/2018 - 02/28/2019	CS2018D0030N	Oncology Medication Clinical Coverage
12/01/2017 - 06/30/2018	CS2017D0030M	Oncology Medication Clinical Coverage Policy
07/01/2017 – 11/30/2017	CS2017D0030L	Oncology Medication Clinical Coverage Policy
07/01/2016 – 06/30/2017	CS2016D0030K	Oncology Medication Clinical Coverage Policy