POLICY NUMBER UM ONC_1387	SUBJECT Unituxin™ (dinutuximab)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 02/12/20	APPROVAL DATE February 12, 2020	EFFECTIVE DATE March 01, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 02/12/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1		NCQA STANDARDS UM 2	ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS All	

I. PURPOSE

To define and describe the accepted indications for Unituxin (dinutuximab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

1. **PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:**
    a. When health plan Medicaid coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    b. When health plan Exchange coverage provisions- including any applicable PDLs (Preferred Drug Lists)- conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the **Preferred Drug Guidelines OR**
    c. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the **Preferred Drug Guidelines shall follow NCH L1 Pathways** when applicable, otherwise shall follow NCH drug policies: http://pathways.newcenturyhealth.com **AND**
    d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
    e. When available, generic alternatives are preferred over brand-name drugs.
2. **Neuroblastoma**
    a. The member has unresectable high-risk neuroblastoma **AND**
    b. High risk is defined as members who are older than 18 months year of age and have disseminated disease, or localized disease with unfavorable markers such as MYCN amplification (see Attachment A) **AND**
    c. The member had at least a partial response to induction chemotherapy followed by autologous stem cell transplant (ASCT) and radiotherapy **AND**

d. The member is in a hospital/acute care setting to mitigate potential risks of serious infusion reactions, capillary leak syndrome, and hypotension **AND**

e. Unituxin (dinutuximab) is being used in combination with 13-cis-retinoic acid (isotretinoin), granulocyte-macrophage colony-stimulating factor (sargramostim), and interleukin-2 (aldesleukin) **AND**

f. The member has contraindications, intolerance, or failure to cyclophosphamide, vincristine, and/or doxorubicin containing chemotherapy.

III. EXCLUSION CRITERIA

1. Unituxin (dinutuximab) is being used after disease progression with the same regimen or prior anti-disialoganglioside (GD2) antibody therapy.
2. The member has any of the following conditions:
   a. Active infection
   b. Neurological, pulmonary, or cardiovascular disorders.
3. Treatment related infusion reactions, neuropathic pain, peripheral neuropathy, hypokalemia, capillary leak syndrome and hypotension, or atypical hemolytic uremic syndrome.
4. Dosing exceeds single dose limit of Unituxin (dinutuximab) 17.5 mg/m^2.
5. Treatment exceeds the maximum months duration limit of 5 cycles.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

1. Attachment A: Children's Oncology Group neuroblastoma risk strata

VII. REFERENCES

1. Unituxin PI prescribing information. United Therapeutics Corp. Silver Spring, MD 2019,
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.
6. UpToDate accessed on February 5, 2020:

   https://www.uptodate.com/contents/treatment-and-prognosis-of-neuroblastoma?search=treatment%20of%20neuroblastoma&source=search_result&selectedTitle=1~121&usage_type=default&display_rank=1#H21

Attachment A: Children's Oncology Group neuroblastoma risk strata

Children's Oncology Group neuroblastoma risk strata

Risk	Stage	Age	MYCN status	DNA ploidy	INPC	Other
Low*	1	Any	Any	Any	Any	
	2a/2b	Any	Not amp	Any	Any	Resection ≥50 percent
	4s	<365 days	Not amp	DI >1	FH	Asymptomatic
Intermediate¶	2a/2b	0-12 years	Not amp	Any	Any	Biopsy or resection <50 percent
	3	<547 days	Not amp	Any	Any	
	3	≥547 days - 12 years	Not amp	Any	FH	
	4	<365 days	Not amp	Any	Any	
	4	365 - <547 days	Not amp	DI >1	FH	
	4s	<365 days	Not amp	Any	Any	Symptomatic
	4s	<365 days	Not amp	DI = 1	Any	Asymptomatic or symptomatic
	4s	<365 days	Not amp	Any	UH	Asymptomatic or symptomatic
	4s	<365 days	Missing	Missing	Missing	Too sick for biopsy
High△	2a/2b	Any	Amp	Any	Any	Any degree of resection
	3	Any	Amp	Any	Any	
	3	≥547 days	Not amp	Any	UH	
	4	<365 days	Amp	Any	Any	
	4	365 - <547 days	Amp	Any	Any	
	4	365 - <547 days	Any	DI = 1	Any	
	4	365 - <547 days	Any	Any	UH	
	4	≥547 days	Any	Any	Any	
	4s	<365 days	Amp	Any	Any	Asymptomatic or symptomatic

INPC: International Neuroblastoma Pathology Classification; FH: favorable histology; UH: unfavorable histology; Amp: amplified; DI: DNA Index.
* Low risk groups as defined in Children's Oncology Group trial ANBL00B1.
¶ Intermediate risk group as defined in Children's Oncology Group trial ANBL0531.
△ High risk group as defined in the Children's Oncology Group trial ANBL0532.

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