Drug Policy:

Mylotarg™ (gemtuzumab ozogamicin)

POLICY NUMBER UM ONC_1325	**SUBJECT** Mylotarg™ (gemtuzumab ozogamicin)	**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 2**
DATES COMMITTEE REVIEWED 09/13/17, 09/21/18, 08/14/19, 12/11/19, 08/12/20, 08/11/21	**APPROVAL DATE** August 11, 2021	**EFFECTIVE DATE** August 27, 2021	**COMMITTEE APPROVAL DATES** 09/13/17, 09/21/18, 08/14/19, 12/11/19, 08/12/20, 08/11/21
PRIMARY BUSINESS OWNER: UM		**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** Commercial, Exchange, Medicaid	

I. PURPOSE

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

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH 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

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. 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
2. 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

3. 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 AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs.

B. Acute Myeloid Leukemia (AML)

1. The member has CD33-positive AML and Mylotarg (gemtuzumab ozogamicin) is being used as a single agent OR in combination with chemotherapy for members with newly diagnosed/relapsed/refractory AML who have not received Mylotarg previously.

III. EXCLUSION CRITERIA

A. Disease progression on Mylotarg (gemtuzumab ozogamicin).

B. Dosing exceeds single dose limit of Mylotarg (gemtuzumab ozogamicin) combination therapy 3mg/m^2 (max dose is 4.5 mg) or 6 mg/m^2 as single agent.

C. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Mylotarg prescribing information. Pfizer Inc, Philadelphia, PA 2020.

B. Clinical Pharmacology Elsevier Gold Standard 2021.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.