Drug Policy:
Besponsa™ (inotuzumab ozogamicin)

I. PURPOSE
To define and describe the accepted indications for Besponsa (inotuzumab 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 Lymphoblastic Leukemia (ALL)

1. NOTE: Per NCH Policy & NCH Pathway, Blincyto (blinatumomab) is the preferred agent for relapsed/refractory B-ALL (Philadelphia chromosome positive or negative) and Besponsa (inotuzumab ozogamicin) is non-preferred.

2. Besponsa (inotuzumab ozogamicin) may be used as a single agent for relapsed/refractory, Philadelphia chromosome negative or positive, CD22-positive B cell ALL.

III. EXCLUSION CRITERIA

A. Besponsa (inotuzumab ozogamicin) use after disease progression with the same regimen.

B. Lack of documentation of CD-22 positivity on leukemia cells.

C. Dosing exceeds single dose limit of Besponsa (inotuzumab ozogamicin) 0.8 mg/m².

D. Treatment exceeds a total of 6 cycles (if HSCT not planned).

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

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


VIII. ADDENDUM

A. For Superior Texas Medicaid members: when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid coverage provisions for Besponsa clinical policy.