

<b>POLICY NUMBER</b> UM ONC_1330	<b>SUBJECT</b> Besponsa™ (inotuzumab ozogamicin)	<b>DEPT/PROGRAM</b> UM Department	<b>PAGE 1 OF 2</b>
<b>DATES COMMITTEE REVIEWED</b> 12/14/17, 11/14/18, 11/13/19, 12/11/19, 04/08/20	<b>APPROVAL DATE</b> April 8, 2020	<b>EFFECTIVE DATE</b> April 24, 2020	<b>COMMITTEE APPROVAL DATES</b> (latest version listed last) 12/14/17, 11/14/18, 11/13/19, 12/11/19, 04/08/20
<b>PRIMARY BUSINESS OWNER: UM</b> <b>APPROVED BY:</b> Dr. Andrew Hertler		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee	
<b>URAC STANDARDS</b> HUM 1		<b>NCQA STANDARDS</b> UM 2	<b>ADDITIONAL AREAS OF IMPACT</b>
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>	<b>APPLICABLE LINES OF BUSINESS</b> All	

## 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 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:

- 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**
- 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**
- 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: **Error! Hyperlink reference not valid. AND**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic alternatives are preferred over brand-name drugs.

### 2. Acute Lymphoblastic Leukemia (ALL)

- As a single agent for relapsed/refractory, Philadelphia chromosome negative, CD22 positive B cell ALL **OR**
- As a single agent for relapsed/refractory, Philadelphia chromosome positive, CD22 positive B-ALL, in members who are intolerant to/have experienced disease progression on TKI-Tyrosine Kinase Inhibitor therapy ( e.g. Imatinib, Nilotinib, Dasatinib, Bosutinib).



### **III. EXCLUSION CRITERIA**

1. Besponsa (inotuzumab ozogamicin) use after disease progression with the same regimen.
2. Dosing exceeds single dose limit of Besponsa (inotuzumab ozogamicin) 0.8 mg/m<sup>2</sup>.
3. Treatment exceeds a total of 6 cycles (if HSCT not planned).
4. Indications not supported by CMS recognized compendia or acceptable peer reviewed.

### **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**

None

### **V. REFERENCES**

1. Besponsa PI prescribing information. Wyeth Pharmaceuticals Inc. Philadelphia, PA 2018.
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.