Besponsa (inotuzumab ozogamicin)
(Intravenous)

Document Number: IC-0317

Last Review Date: 10/30/2018
Date of Origin: 09/19/2017
Dates Reviewed: 09/2017, 11/2018

I. Length of Authorization

Coverage will be provided for 6 months (for up to a maximum of 6 cycles) and may not be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Besponsa 0.9 mg powder for injection: 7 vials per 21 days

B. Max Units (per dose and over time) [Medical Benefit]:

Cycle 1

- 27 billable units on Day 1, 18 billable units on Days 8 and 15 of a 21 to 28-day cycle

Subsequent Cycles (maximum of 5 cycles)

- 27 billable units (2.7 mg) on Day 1, 18 billable units on Days 8 and 15 of a 28-day cycle for up to 2 cycles
- 18 billable units (1.8 mg) on Day 1, Day 8, and Day 15 of a 28-day cycle for up to 3 cycles

III. Initial Approval Criteria

Coverage is provided in the following conditions:

B-Cell Precursor Acute Lymphoblastic Leukemia (ALL) †

- Baseline electrocardiogram (ECG) is within normal limits; AND
- Patient has not previously received inotuzumab ozogamicin; AND
- Patient aged 18 years or older; AND
- Patient has CD22-positive disease; AND
- Used as single agent therapy; AND
- Patient has relapsed or refractory disease; AND
    - Patient is Philadelphia chromosome (Ph)-negative; OR

- Patient is Philadelphia chromosome (Ph)-positive and failed previous therapy with a tyrosine kinase inhibitor (e.g., imatinib, dasatinib, ponatinib, etc.)

† FDA Approved Indication(s); ‡ Compendium Recommended Indication(s)

IV. Renewal Criteria

Coverage cannot be renewed.

V. Dosage/Administration

Indication	Dose
B-Cell Precursor ALL	Cycle 1: • 1.8 mg/m^2 total per cycle, administered as 3 divided doses on Day 1 (0.8 mg/m^2), Day 8 (0.5 mg/m^2), and Day 15 (0.5 mg/m^2) • Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves CR or CRi, and/or to allow recovery from toxicity Subsequent Cycles (cycles are 4 weeks in duration): <u>CR or CRi achieved</u> • 1.5 mg/m^2 total per cycle, administered as 3 divided doses on Day 1 (0.5 mg/m^2), Day 8 (0.5 mg/m^2), and Day 15 (0.5 mg/m^2) <u>Did not achieve CR or CRi</u> • 1.8 mg/m^2 total per cycle, administered as 3 divided doses on Day 1 (0.8 mg/m^2), Day 8 (0.5 mg/m^2), and Day 15 (0.5 mg/m^2) • Patients who do not achieve a CR or CRi within 3 cycles should discontinue treatment. Patients proceeding to HSCT: • Recommended duration of treatment is 2 cycles • A third cycle may be considered for those patients who do not achieve CR or CRi and MRD negativity after 2 cycles Patients not proceeding to HSCT: • Additional cycles of treatment, up to a maximum of 6 cycles, may be administered
CR (complete remission); CRi (complete remission with incomplete hematologic recovery); HSCT (hematopoietic stem cell transplant); MRD (minimal residual disease) ● Refrigerate (2-8°C; 36-46°F) and store in the original carton to protect from light. Do not freeze.	

VI. Billing Code/Availability Information

<u>Jcode:</u>

- J9229 – Injection, inotuzumab ozogamicin, 0.1 mg (effective 1/1/19)
- J9999 – Not otherwise classified, antineoplastic drugs
- C9028 – Injection, inotuzumab ozogamicin, 0.1 mg: 1 billable units = 0.1 mg (inactive after 1/1/19)

<u>NDC:</u>

- Besponsa 0.9 mg lyophilized powder in single-dose vial: 00008-0100-xx

VII. References

1. Besponsa [package insert]. Philadelphia, PA; Pfizer Inc., March 2018. Accessed October 2018.
2. Kantarjian HM, DeAngelo DJ, Stelljes M, et al. Inotuzumab Ozogamicin versus Standard Therapy for Acute Lymphoblastic Leukemia. N Engl J Med. 2016 Aug 25;375(8):740-53.
3. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) inotuzumab ozogamicin. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed October 2018.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C91.00	Acute lymphoblastic leukemia not having achieved remission
C91.01	Acute lymphoblastic leukemia, in remission
C91.02	Acute lymphoblastic leukemia, in relapse

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto Government Benefit Administrators, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC