BlueCross BlueShield of North Carolina

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Corporate Medical Policy

Inotuzumab (Besponsa®)

File Name:	inotuzumab_besponsa
Origination:	9/2017
Last CAP Review:	11/2020
Next CAP Review:	11/2021
Last Review:	11/2020

Description of Procedure or Service

Besponsa® is a CD22-directed antibody drug conjugate (ADC) indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

******Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.***

Policy

BCBSNC will provide coverage for Inotuzumab (Besponsa) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Inotuzumab (Besponsa) is covered

Inotuzumab (Besponsa) is considered medically necessary for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

Use of Inotuzumab (Besponsa) may be considered medically necessary for clinical indications not listed above when the drug is prescribed for the treatment of cancer either:

- In accordance with FDA label (when clinical benefit has been established, see Policy Guidelines); **OR**
- In accordance with specific strong endorsement or support by nationally recognized compendia, when such recommendation is based on strong/high levels of evidence, and/or uniform consensus of clinical appropriateness has been reached.

When Inotuzumab (Besponsa) is not covered

Inotuzumab (Besponsa) is considered not medically necessary and therefore not covered when above criteria are not met.

Inotuzumab (Besponsa®)

Inotuzumab (Besponsa) is considered investigational when used for:

1. Non-cancer indications; **OR**

2. When criteria are not met regarding FDA labeling **OR** strong endorsement/support by nationally recognized compendia, as stated under "When Inotuzumab (Besponsa) is covered."

Policy Guidelines

Drugs prescribed for treatment of cancer in accordance with FDA label may be considered medically necessary when clinical benefit has been established, and should not be determined to be investigational as defined in Corporate Medical Policy (CMP), "Investigational (Experimental) Services."

Please refer to CMP "Investigational (Experimental) Services" for a summary of evidence standards from nationally recognized compendia.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: J3490, J3590, J9229, J9999, S0353, S0354

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

U. S. Food and Drug Administration (FDA). Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/761040s000lbl.pdf

Senior Medical Director review 9/2017

Specialty Matched Consultant Advisory Panel 11/2018

Specialty Matched Consultant Advisory Panel 11/2019

Specialty Matched Consultant Advisory Panel 11/2020

Policy Implementation/Update Information

9/29/17	New policy developed. Inotuzumab (Besponsa) is considered medically necessary for the treatment of patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). Reference added. Senior Medical Director review 9/2017. (lpr)
12/29/17	Added HCPCS code C9028 to Billing/Coding section. No change to policy statement. (lpr)

12/14/18 Specialty Matched Consultant Advisory Panel review 11/28/2018. (krc)

12/31/18 Added HCPCS code J9229 to Billing/Coding section and deleted code C9028 effective 1/1/19. (krc)

12/10/19 Specialty Matched Consultant Advisory Panel review 11/20/2019. No change to policy intent. (krc)

1/12/21 Specialty Matched Consultant Advisory Panel review 11/18/2020. No change to policy intent. (krc)