Inotuzumab ozogamicin (Besponsa®)	Place of Service Office Administration Infusion Center Administration Outpatient Facility Administration Home Infusion HCPCS: J9229 per 0.1 mg

Condition(s) listed in policy (*see criteria for details*)

- Acute lymphoblastic leukemia, B-cell precursor

AHFS therapeutic class: Antineoplastic agent
Mechanism of action: CD22-directed antibody-drug conjugate (ADC)

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Besponsa® (inotuzumab ozogamicin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Acute lymphoblastic leukemia

1. Diagnosis is B-cell precursor acute lymphoblastic leukemia, **AND**
2. Either of the following:
    a. Patient has relapsed or refractory Philadelphia chromosome-positive (Ph +) and one of the following:
        i. Being used as a single agent, OR
        ii. Patient is intolerant or refractory to a tyrosine-kinase inhibitor, and being used in combination with mini-hyperCVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine), OR
        iii. Being used in combination with a tyrosine-kinase inhibitor (TKI)

    OR

    b. Patient is Philadelphia chromosome-negative (Ph -) and ONE of the following:
        i. Being used for induction therapy in combination with mini-hyperCVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine), OR
        ii. Being used for relapsed or refractory disease as monotherapy or in combination with mini-hyperCVD (cyclophosphamide, dexamethasone, vincristine, methotrexate, cytarabine)

Covered Doses

Induction therapy (*PH negative only*):
Up to 1.8 mg/m^2 on day 3 of the first cycle, followed by up to 1.3 mg/m^2 on day 3 of cycles 2-4. A cycle is 28 days.

Relapsed or refractory disease:
Up to 0.8 mg/m^2 IV on day 1, followed by up to 0.5 mg/m^2 on days 8 and 15. A cycle is 21-days or 28-days.

Coverage Period

Induction therapy (*PH negative only*):
4 cycles

Relapsed or refractory disease:
Initial: up to 3 cycles
Reauthorization: up to 3 additional cycles for patients who have achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi) and are not proceeding to hematopoietic stem cell transplant (HSCT)

ICD-10:
C83.50-C83.59, C91.00-C91.02

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Besponsa® (inotuzumab ozogamicin) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:

- 0.9 mg (single-dose vial)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- Besponsa® (inotuzumab ozogamicin) [Prescribing information}. Philadelphia, PA: Pfizer. 3/2018.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- National Comprehensive Cancer Network Drugs and Compendium. Besponsa (2023). Available at: www.nccn.org
- National Comprehensive Cancer Network. Acute Lymphoblastic Leukemia (Version 1.2022). Available at: www.nccn.org
- National Comprehensive Cancer Network. Pediatric Acute Lymphoblastic Leukemia (Version 2.2023). Available at: www.nccn.org.

(7) Policy Update

Date of last review: 2Q2023
Date of next review: 2Q2024
Changes from previous policy version:

- No clinical change to policy following routine annual review.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee