POLICY AND PROCEDURE

POLICY NAME: Inotuzumab Ozogamicin (Besponsa)	**POLICY ID:** TX.PHAR.47
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 4/6/18	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: 2/12/19, 2/04/20, 2/16/21, 2/2022, 8/1/22, 07/12/23	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

POLICY STATEMENT:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of inotuzumab ozogamicin (Besponsa).

PURPOSE:
This medication is a pass through drug (non-risk based payment drug) and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Superior Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

SCOPE:
Superior HealthPlan Pharmacy Department, Medical Directors

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan to follow state guidance for medical necessity review of inotuzumab ozogamicin (Besponsa).

Description/Mechanism of Action:
Inotuzumab ozogamicin (Besponsa) is a CD22-directed antibody-drug conjugate.

Formulations:
Single-dose vial, powder for reconstitution: 0.9 mg

FDA Approved Indications:
Besponsa is indicated for the treatment of adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:
1. All prior authorization approvals or denials will be determined by a Superior HealthPlan Medical Director.
2. Member has a diagnosis of precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in relapse. (See *Appendix A* for definition of refractory or relapsed disease).
3. Member is 18 years of age or older.
4. The prescriber agrees to monitor the member for signs and symptoms of hepatic veno-occlusive disease (VOD) during treatment of Besponsa.
   Note: Besponsa is not a benefit for members who have hepatic veno-occlusive disease.
5. Dose does not exceed 0.8 mg/m² IV on day 1 and 0.5 mg/m² IV on days 8 and 15.

Approval duration: Up to 6 cycles total

II. Continued Therapy:
1. Currently receiving medication via the company benefit or member has previously met initial approval criteria or had received the drug from a previous Medicaid MCO (continuity of coverage).
2. All approvals or denials for continued therapy will be reviewed by a Superior Medical Director to continue coverage.

3. Member has a diagnosis of precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in relapse. (See *Appendix A* for definition of refractory or relapsed disease).
4. Member is 18 years of age or older.
5. The prescriber agrees to monitor the member for signs and symptoms of hepatic veno-occlusive disease during treatment of Besponsa.
   Note: Besponsa is not a benefit for members who have hepatic veno-occlusive disease.
6. Member has not received 6 or more cycles of Besponsa.
7. Dose does not exceed 0.8 mg/m² IV on day 1 and 0.5 mg/m² IV on days 8 and 15.

Approval duration: Up to 6 cycles total

Appendix A:
Definition of relapse or refractory precursor B-cell acute lymphoblastic leukemia (ALL):
Superior considers inotuzumab ozogamicin (Besponsa) medically necessary for the treatment of adults (18 years of age or older) with relapsed or refractory CD22 positive (i.e., ≥ 5% blasts CD22-positive) B-cell precursor acute lymphoblastic leukemia (B-ALL) when either of the following criteria are met:

- Member has Philadelphia chromosome-positive (Ph+) disease and has failed treatment with at least one tyrosine kinase inhibitor (e.g., imatinib (Gleevec), dasatinib (Sprycel), nilotinib (Tasygna), bosutinib (Bosulif), ponatinib (Iclusig)) and standard chemotherapy; *or*
- Member has Ph- disease and has failed treatment with at least one induction chemotherapy regimen for ALL.

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook.

ATTACHMENTS: N/A

ROLES & RESPONSIBILITIES: N/A

REGULATORY REPORTING REQUIREMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
Ad Hoc Review	Changed “Justin M. Weiss, Sr. V.P., Pharmacy Operations” to “Karen Tadlock, V.P., Pharmacy Operations ” Formatting	2/12/19
Ad Hoc Review	Added exclusion criteria per the Texas Medicaid Provider Procedures Manual	2/4/20
Annual Review	Formatting changes, removed requirement to be single agent therapy to align with state criteria, clarified max dose. Updated spelling from CHIP Prenate to Perinate for Product Type	2/16/21
Ad Hoc Review	Changed to new P&P template Removed specialist requirement	8/1/22
Annual Review	Formatting changes; removed “≥” symbol in criteria steps.	07/12/23

POLICY AND PROCEDURE APPROVAL

The electronic approval retained in RSA Archer, the Company’s P&P management software, is considered equivalent to a signature.