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	
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 precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in relapse. (See Appendix A for definition of refractory or relapsed disease).
3. Age ≥ 18 years
4. The prescriber agrees to monitor the member for signs and symptoms of hepatic veno-occlusive disease (VOD) during treatment of Besponsa.
    a. 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 precursor B-cell acute lymphoblastic leukemia (ALL) that is refractory or in relapse. (See Appendix A for definition of refractory or relapsed disease).
4. Age ≥ 18 years;
5. The prescriber agrees to monitor the Member for signs and symptoms of hepatic veno-occlusive disease during treatment of Besponsa.
    a) Besponsa is not a benefit for Members who have hepatic veno-occlusive disease.
6. Member has not received ≥ 6 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

POLICY AND PROCEDURE APPROVAL

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