TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Inotuzumab ozogamicin (Besponsa®)	**CRITERIA ID:** TX.CC.PHAR.02
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, 2/27/2024	
REGULATOR MOST RECENT APPROVAL DATE(S): N/A	

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for inotuzumab ozogamicin (Besponsa®).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) 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 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:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS: NRB = non-risk based

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of inotuzumab ozogamicin (Besponsa®); procedure code:J9229.

Exclusion: Besponsa is not a benefit for clients who have hepatic veno-occlusive disease.

Description/Mechanism of Action:
Inotuzumab ozogamicin (Besponsa®) is a CD22-directed antibody-drug conjugate (ADC) that has 3 components: the antibody inotuzumab, N-acetyl-gamma-calicheamicin dimethylhydrazide (a cytotoxic agent) and an acid cleavable linker.

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

Formulations:
Inotuzumab ozogamicin (Besponsa®) is available as a single-dose vial, powder for reconstitution: 0.9 mg.

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. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. The client is 18 years of age or older.
3. The client has a confirmed 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. Prescriber attestation that client will be monitored for signs and symptoms of hepatic veno-occlusive disease (VOD) for duration of Besponsa therapy.
   Note: Besponsa is not a benefit for clients who have hepatic veno-occlusive disease.

Approval duration: Up to 6 cycles total

II. Continued Therapy:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization but ultimate determination will be made by the Medical Director only.
2. 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).
3. The client is 18 years of age or older.
4. The client has a confirmed 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).
5. Prescriber attestation that client will be monitored for signs and symptoms of hepatic veno-occlusive disease (VOD) for duration of Besponsa therapy.
   Note: Besponsa is not a benefit for clients who have hepatic veno-occlusive disease.
6. The client has not received 6 or more cycles of Besponsa.

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:

- Client 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*
- Client has Philadelphia chromosome-negative (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

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
Ad Hoc Review	Updated to TX.CC.PHAR format template Added Centene copyright statement Removed criteria step from initial and continuation: Dose does not exceed 0.8 mg/m² IV on day 1 and 0.5 mg/m² IV on days 8 and 15 as dosing is not listed in TMHP CAD Manual	2/27/24