TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Treosulfan (Grafapex®)	**CRITERIA ID:** TX.CC.PHAR.49
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 7/1/2025	**PRODUCT(S):** STAR, STAR Kids, STAR Health, STAR Plus, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):**

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for Treosulfan (Grafapex®)

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.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
SHP = Superior HealthPlan
CPS = Centene Pharmacy Service
HSCT = Hematopoietic stem cell transplantation
AML = Acute Myeloid Leukemia
MDS = Myelodysplastic Syndrome

POLICY:
It is the policy of Superior HealthPlan (SHP) and Centene Pharmacy Services (CPS) to follow state guidance for medical necessity review of Treosulfan (Grafapex®); procedure code: C9175.

Description/Mechanism of Action:
Treosulfan (Grafapex®) is an alkylating agent. Alkylating agents act by cross-linking strands of DNA and are nonspecific for cell cycle phase. DNA alkylation is thought to be responsible for the cytotoxic activities of treosulfan.

FDA Approved Indications:

Treosulfan (Grafapex®) is indicated for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (HSCT) in adult and pediatric clients 1 year or older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

Formulations:
Treosulfan (Grafapex®) is available as a lyophilized powder in a single-dose vial as 1 g/vial and 5 g/vial.

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

A. Acute myeloid leukemia

1. The client is 1 year or older.
2. The client has a diagnosis of acute myeloid leukemia (diagnosis code: C92.00).
3. Client is undergoing allogeneic hematopoietic stem cell transplantation.
4. Documentation fludarabine will be administered in conjunction with Grafapex as a preparative regimen or allogeneic HSCT.
5. Documentation the prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment and up to six months after the last dose of therapy. Male clients with female partners of reproductive potential should also be counseled.
6. Prescriber attestation they will monitor all of the following parameters following Grafapex administration:
    a) Hematologic laboratory parameters;
    b) Signs of neurological adverse reactions (e.g., seizures);
    c) Signs of extravasation and tissue necrosis;
    d) Signs of infections, anemia, thrombocytopenia, and secondary malignancies.

Duration of approval: 3 months (3 total doses)

B. Myelodysplastic syndrome

1. The client is 1 year or older.
2. The client has a diagnosis of myelodysplastic syndrome (diagnosis code D46.9).
3. Client is undergoing allogeneic hematopoietic stem cell transplantation.
4. Documentation fludarabine will be administered in conjunction with Grafapex as a preparative regimen or allogeneic HSCT.
5. Documentation the prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment and up to six months after the last dose of therapy. Male clients with female partners of reproductive potential should also be counseled.
6. Prescriber attestation they will monitor all of the following parameters following Grafapex administration:
    a) Hematologic laboratory parameters;
    b) Signs of neurological adverse reactions (e.g., seizures);
    c) Signs of extravasation and tissue necrosis;
    d) Signs of Infections, anemia, thrombocytopenia, and secondary malignancies.

Duration of approval: 3 months (3 total doses)

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

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy Document	N/A	6/26/2025