TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Imetelstat (Rytelo®)	**CRITERIA ID:** TX.CC.PHAR.46
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy, Medical Directors, Claims
EFFECTIVE DATE: 02/01/2025	**PRODUCT(S):** STAR, STAR PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE:	
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 imetelstat (Rytelo®).

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:
ESA = Erythropoiesis-stimulating agents

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of imetelstat (Rytelo®); procedure code: J0870.

Description/Mechanism of Action:
Imetelstat (Rytelo®) is an oligonucleotide telomerase inhibitor.

FDA Approved Indications:
Imetelstat (Rytelo®) is indicated for the treatment of adult clients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell (RBC) units over eight weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESA).

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. Myelodysplastic Syndrome (MDS) (must meet all):

1. The client is 18 years of age or older.
2. The client has a confirmed diagnosis of low- to intermediate-1 risk MDS (diagnosis codes: D460, D461, D464, D469, D46A, D46B, D46C, or D46Z).
3. The client has transfusion-dependent anemia requiring RBC transfusions, defined as more than four RBC units over eight weeks.

4. Documentation to support the prescriber has ruled out or addressed other causes of anemia (such as abnormal bleeding, hemolysis, nutritional deficiency, or renal disease).
5. Prescriber attestation that the client has not responded to, has lost response to, or is ineligible for ESAs.
6. The client does not have deletion 5q cytogenic abnormalities.
7. Rytelo will not be prescribed concomitantly with other erythropoiesis-stimulating agents.
8. Documentation of prescriber attestation that female clients of childbearing age will be counseled regarding the use of an effective method of contraception to prevent pregnancy during treatment with Rytelo.
9. Prescriber attestation to monitoring of the following parameters for clients receiving Rytelo:
    a. Liver function tests must be monitored before Rytelo administration, then weekly for the first cycle, and before each cycle thereafter;
    b. Thrombocytopenia and neutropenia must be monitored after Rytelo infusion.

Approval Duration: 6 months

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

ATTACHMENTS: N/A

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Criteria Document		02/01/2025