

December 20, 2024

PRIOR AUTHORIZATION CRITERIA FOR RYTELO EFFECTIVE FEB. 1, 2025

BACKGROUND

On Jan. 1, 2025, Rytelo will become a benefit of Medicaid and CHIP. HHSC requires prior authorization for Rytelo (procedure code J0870) for Medicaid and CHIP, effective for dates of service on or after Feb. 1, 2025.

KEY DETAILS

Rytelo (Imetelstat) is an oligonucleotide telomerase inhibitor 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).

Rytelo (Imetelstat) is an intravenous infusion indicated for the treatment of clients who meet all of the following requirements:

- The client is 18 years or older.
- The client has a confirmed diagnosis of low- to intermediate-1 risk MDS (diagnosis code D460, D461, D464, D469, D46A, D46B, D46C, or D46Z).
- The client has transfusion-dependent anemia requiring regular RBC transfusions, defined as more than four RBC units over eight weeks.
- The prescriber has ruled out or addressed other causes of anemia (such as abnormal bleeding, hemolysis, nutritional deficiency, or renal disease).
- The prescriber attests that the client has not responded to, has lost response to, or is ineligible for ESAs.
- The client does not have deletion 5q cytogenetic abnormalities.
- Rytelo (Imetelstat) will not be prescribed concomitantly with other erythropoiesis-stimulating agents.
- The prescriber attests to counseling female clients of childbearing age regarding the use of an effective method of contraception to prevent pregnancy during treatment with Rytelo (Imetelstat).

Required Monitoring Parameters:

- Liver function tests must be monitored before Rytelo (Imetelstat) administration, then weekly for the first cycle, and before each cycle thereafter.
- Thrombocytopenia and neutropenia must be monitored after Rytelo (Imetelstat) infusion.

ADDITIONAL INFORMATION

Refer to the [Outpatient Drug Services Handbook Chapter](#) of the Texas Medicaid Provider Procedure Manual for more details on the clinical policy and prior authorization requirements.

HHSC approved this updated clinical prior authorization for use by MCOs and will implement criteria for fee-for-service Medicaid on Feb. 1, 2025. MCOs do not need to wait for publication in the TMPPM before implementation. MCOs may choose to implement the updated requirements but shall not make them more restrictive.