Reauthorizations

RYTELO® (imetelstat) for Injection 47 mg 188 mg

Reauthorizations are typically required for patients continuing RYTELO after the initial authorization period has elapsed, typically around 6 months.

Requirements vary by health plan but generally include updated documentation from the initial prior authorization and demonstration of efficacy measures, such as proof of clinically meaningful reduction in amount of red blood cell (RBC) transfusions needed.

Consider following the steps below, keeping in mind the patient's coverage duration and next scheduled dose.

STEP 1

Contact the health plan to find out the specific requirements for reauthorization, such as required forms. Reference the health plan's current medical policy for RYTELO.

STEP 2

Determine the supporting documentation that may be required, such as patient history, tolerability, and transfusion dependence. Please note that RBC transfusion history may be found in the patient chart notes.

STEP 3

Submit documentation according to the health plan's policy.

Best Practice

Timing is crucial: consider planning ahead before reauthorization is needed and setting a reauthorization target date.

This educational resource is informational only and not intended as reimbursement advice, legal advice, medical advice, or a substitute for a provider's independent professional judgment.

Geron and its agents make no guarantee regarding reimbursement for any service or item. It is the provider's sole responsibility to determine details specific to individual patients' insurance plans and should contact third-party payers for more specific information.

INDICATION

RYTELO® (imetelstat) is indicated for the treatment of adult patients with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring 4 or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESA).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Thrombocytopenia

RYTELO® can cause thrombocytopenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased platelets occurred in 65% of patients with MDS treated with RYTELO.

Please see additional Important Safety Information on reverse and full Prescribing Information, including Medication Guide.

For more information regarding patient access, call REACH4RYTELO at **1-844-4RYTELO (1-844-479-8356)**, Monday through Friday, from 8:00 AM to 8:00 PM ET or email support@REACH4RYTELO.com.[a]

[a]All programs provided through REACH4RYTELO are subject to eligibility requirements. REACH4RYTELO and its agents make no guarantee regarding coverage and reimbursement for RYTELO. Geron reserves the right to modify or discontinue REACH4RYTELO at any time without notice.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Thrombocytopenia (cont'd)

Monitor patients with thrombocytopenia for bleeding. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer platelet transfusions as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Neutropenia

RYTELO can cause neutropenia based on laboratory values. In the clinical trial, new or worsening Grade 3 or 4 decreased neutrophils occurred in 72% of patients with MDS treated with RYTELO.

Monitor patients with Grade 3 or 4 neutropenia for infections, including sepsis. Monitor complete blood cell counts prior to initiation of RYTELO, weekly for the first two cycles, prior to each cycle thereafter, and as clinically indicated. Administer growth factors and anti-infective therapies for treatment or prophylaxis as appropriate. Delay the next cycle and resume at the same or reduced dose, or discontinue as recommended.

Infusion-Related Reactions

RYTELO can cause infusion-related reactions. In the clinical trial, infusion-related reactions occurred in 8% of patients with MDS treated with RYTELO; Grade 3 or 4 infusion-related reactions occurred in 1.7%, including hypertensive crisis (0.8%). The most common infusion-related reaction was headache (4.2%). Infusion-related reactions usually occur during or shortly after the end of the infusion.

Premedicate patients at least 30 minutes prior to infusion with diphenhydramine and hydrocortisone as recommended and monitor patients for at least one hour following the infusion as recommended. Manage symptoms of infusion-related reactions with supportive care and infusion interruptions, decrease infusion rate, or permanently discontinue as recommended.

Embryo-Fetal Toxicity

Based on animal findings, RYTELO can cause embryo-fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with RYTELO and for 1 week after the last dose.

ADVERSE REACTIONS

Serious adverse reactions occurred in 32% of patients who received RYTELO. Serious adverse reactions in >2% of patients included sepsis (4.2%), fracture (3.4%), cardiac failure (2.5%), and hemorrhage (2.5%). Fatal adverse reactions occurred in 0.8% of patients who received RYTELO, including sepsis (0.8%).

Most common adverse reactions (≥10% with a difference between arms of >5% compared to placebo), including laboratory abnormalities, were decreased platelets, decreased white blood cells, decreased neutrophils, increased AST, increased alkaline phosphatase, increased ALT, fatigue, prolonged partial thromboplastin time, arthralgia/myalgia, COVID-19 infections, and headache.

Please see full Prescribing Information, including Medication Guide.

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