VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Hematology – Rytelo Utilization Management Medical Policy
- Rytelo® (imetelstat intravenous infusion – Geron)

REVIEW DATE: 06/12/2024

OVERVIEW

Rytelo, an oligonucleotide telomerase inhibitor, is indicated for the treatment of **transfusion-dependent anemia** in adults with **low- to intermediate-1 risk myelodysplastic syndrome (MDS)** requiring ≥ 4 red blood cell units over 8 weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESAs).[1]

Rytelo was not studied in patients with deletion 5q [del(5q)] cytogenetic abnormalities.[1] Discontinue if a patient does not experience a decrease in red blood cell transfusion burden after 24 weeks of treatment (administration of 6 doses) or if unacceptable toxicity occurs at any time.

Dosing Information

The recommended dosage of Rytelo is 7.1 mg/kg given by a healthcare provider via intravenous infusion over 2 hours once every 4 weeks.[1]

Guidelines

Rytelo is not currently recommended in guidelines.[2] The National Comprehensive Cancer Network guidelines for MDS (version 2.2024 – May 22, 2024) recommend ESAs for the treatment of symptomatic anemia in patients with MDS. Revlimid® (lenalidomide capsules) is also recommended in a variety of clinical scenarios among patients with symptomatic anemia both with and without 5q deletion abnormalities (category 2A). Reblozyl® (luspatercept-aamt subcutaneous injection) is supported for lower-risk disease associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts ≥ 15% (or ring sideroblasts ≥ 5% with an SF3B1 mutation) as a single agent (category 1). Treatment with Reblozyl is also supported for lower-risk disease associated with symptomatic anemia with no del(5q), with or without other cytogenetic abnormalities with ring sideroblasts < 15% (or ring sideroblasts < 5% with an SF3B1 mutation) and serum erythropoietin levels ≤ 500 mU/L, as a single agent or following no response to an ESA (despite adequate iron stores) [category 2A]. Data from the Rytelo pivotal study (IMerge) are noted regarding treatment of MDS-related ESA-refractory anemia.

POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Rytelo. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indication. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Rytelo as well as the monitoring required for adverse events and long-term efficacy, approval requires Rytelo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Rytelo is recommended in those who meet the following:

FDA-Approved Indication

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1. **Myelodysplastic Syndrome.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve for 6 months if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** According to the prescriber, patient has low- to intermediate-1 risk myelodysplastic syndrome (MDS); AND
       Note: MDS risk category is determined using the International Prognostic Scoring System (IPSS).
     - **iii.** Patient has transfusion-dependent anemia, defined as requiring transfusion of ≥ 4 red blood cell units over an 8-week period; AND
     - **iv.** According to the prescriber, patient has not responded, lost response to, or is ineligible for erythropoiesis-stimulating agents; AND
       Note: Examples of erythropoiesis-stimulating agents include an epoetin alfa product (e.g., Epogen, Procrit, or Retacrit), a darbepoetin alfa product (e.g., Aranesp), or a methoxy polyethylene glycol-epoetin beta product (e.g., Mircera).
     - **v.** Patient does NOT have deletion 5q [del(5q)] cytogenic abnormalities; AND
     - **vi.** Rytelo will NOT be used in combination with an erythropoiesis stimulating agent; AND
     - **vii.** The medication is being prescribed by or in consultation with an oncologist or hematologist; OR
   - **B)** Patient is Currently Receiving Rytelo. Approve for 1 year if, according to the prescriber, the patient has experienced a clinically meaningful decrease in transfusion burden.
     Note: For a patient who has not received 6 months (24 weeks) of therapy or who is restarting therapy, refer to Initial Therapy criteria above.

   Dosing. Approve up to 7.1 mg/kg by intravenous infusion administered not more frequently than once every 4 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Rytelo is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Rytelo® intravenous infusion [prescribing information]. Foster City, CA: Geron; June 2024.
2. The NCCN Myelodysplastic Syndromes Clinical Practice Guidelines in Oncology (version 2.2024 – May 22, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 7, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	06/12/2024