Draft New Policy: Do Not Implement

Remestemcel-L-rknd (Ryoncil®)

IMPORTANT REMINDER

We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

The proposal is to add text/statements in red and to delete text/statements with strikethrough:

POLICY

INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Acute Graft versus Host Disease
Ryoncil is indicated for the treatment of steroid-refractory acute graft versus host disease (SR-aGvHD) in pediatric patients 2 months of age and older.

All other indications are considered experimental/investigational and not medically necessary.

COVERAGE CRITERIA

Acute Graft versus Host Disease

Authorization of 2 months (maximum of 8 infusions) may be granted for treatment of acute graft versus host disease when all of the following criteria are met:

- The member is a pediatric patient
- The disease is steroid-refractory (progressed within 3 days or did not improve within 7 consecutive days of treatment with methylprednisolone 2 mg/kg/day or equivalent)

CONTINUATION OF THERAPY

Authorization of 2 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when either of the following criteria are met:

- Partial or mixed response - there is an improvement in symptoms and there is no evidence of unacceptable toxicity while on the current regimen. (Maximum of 4 infusions)
- Recurrence after complete response -all members (including new members) requesting authorization for continuation of therapy must meet all the requirements in the coverage criteria section. (Maximum of 8 infusions)

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

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BlueCross BlueShield of Tennessee's Medical Policy complies with Tennessee Code Annotated Section 56-7-2352 regarding coverage of off-label indications of Food and Drug Administration (FDA) approved drugs when the off-label use is recognized in one of the statutorily recognized standard reference compendia or in the published peer-reviewed medical literature.

ADDITIONAL INFORMATION

For appropriate chemotherapy regimens, dosage information, contraindications, precautions, warnings, and monitoring information, please refer to one of the standard reference compendia (e.g., the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) published by the National Comprehensive Cancer Network®, Drugdex Evaluations of Micromedex Solutions at Truven Health, or The American Hospital Formulary Service Drug Information).

REFERENCES

1. Ryoncil [package insert]. New York, NY: Mesoblast, Inc.; December 2024.

EFFECTIVE DATE

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