Billing and Coding Guide

Ryoncil® (remestemcel-L-rknd) Suspension for IV infusion

Mesoblast is pleased to provide this information to help you, and your staff navigate coverage and reimbursement for RYONCIL®. This information is not intended to supersede any individual payer guidance or processes. Please check directly with each patient's insurance for specific requirements needed to obtain coverage and reimbursement. This document is presented for informational purposes only and does not guarantee reimbursement.

ICD-10-CM Diagnosis Codes[1] for Acute Graft-Versus-Host Disease

D89.810	Acute graft-versus-host disease
D89.812	Acute or chronic graft-versus-host disease
D89.813	Graft-versus-host disease, unspecified
T86.09	Other complications of bone marrow transplant
T86.899	Unspecified complication of other transplanted tissue - primary diagnosis code

ICD-10-PCS Codes[2] for Drug Administration in the Inpatient Setting

3E033GC	Introduction of other therapeutic substance into peripheral vein, percutaneous approach
3E043GC	Introduction of other therapeutic substance into central vein, percutaneous approach

CPT Codes[3] for Drug Administration in the Outpatient Setting

96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour

Drug Codes for RYONCIL®

HCPCS Level II Codes[4,*]

J3490 (Unclassified drug)

J3590 (Unclassified biologics)

C9399 (Unclassified drugs or biologicals – hospital outpatient setting)

NDC Numbers[5,†,§,‖]

73648-111-01 (1-Vial Kit, <12.5 kg)
73648-112-02 (2-Vial Kit, 12.5-<25 kg)
73648-113-03 (3-Vial Kit, 25-<37.5 kg)
73648-114-01 (4-Vial Kit, 37.5-<50 kg)
73648-115-02 (5-Vial Kit, 50-<62.5 kg)
73648-116-03 (6-Vial Kit, 62.5-<75 kg)
73648-117-04 (7-Vial Kit, 75-<87.5 kg)
73648-118-02 (8-Vial Kit, 87.5-<100 kg)

Revenue Codes for RYONCIL®[6]

0636	Drugs requiring detailed coding
0260	IV therapy – general classification
0269	Other IV therapy[‡]

*Payer preference varies, both HCPCS level II codes can be used.
†Payer requirements regarding the use of the 10- or 11-digit NDC may vary.
‡Payer requirements regarding the use of 0260 or 0269 may vary.
§Each NDC listed corresponds to a specific package configuration, with the number of vials per box determined based on patient weight. Please select the appropriate NDC to align with the prescribed dosing requirements when placing an order.
‖ Specific ASD product numbers can vary by distributor; it's advisable to contact the authorized specialty distributors directly to obtain the precise product numbers.

CPT, Current Procedural Terminology; HCPCS, Healthcare Common Procedure Coding System; ICD-10, International Classification of Diseases, Tenth Revision; ICD-10-CM, ICD-10 Clinical Modification; ICD-10-PCS, ICD-10 Procedure Coding System; IV, intravenous; NDC, National Drug Code.

INDICATIONS AND USAGE

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.

IMPORTANT SAFETY INFORMATION

Contraindications

Do not use RYONCIL in patients with known hypersensitivity to dimethyl sulfoxide (DMSO) or porcine and bovine proteins.

Please see additional Important Safety Information on page 2. Click here for full Prescribing Information.

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IMPORTANT SAFETY INFORMATION (cont)

WARNINGS AND PRECAUTIONS

Hypersensitivity and Acute Infusion Reactions
Hypersensitivity reactions including acute infusion reactions have occurred with RYONCIL administration. Serious hypersensitivity reactions, including anaphylaxis, may occur due to DMSO and trace amounts of porcine or bovine proteins. Signs and symptoms may include fever, dyspnea, and hypotension during or after RYONCIL infusion.

Premedicate patients with antihistamine and corticosteroids and monitor closely for signs and symptoms of hypersensitivity or acute infusion reactions.

If a hypersensitivity or infusion reaction occurs, interrupt RYONCIL infusion. Do not administer RYONCIL in patients who experience serious or life-threatening reactions.

Transmission of Infectious Agents
Transmission of infectious disease or agents may occur with RYONCIL administration because it contains cells from human donors and is manufactured using human, porcine and bovine-derived reagents. Donors are screened and tested for Human Immune-deficiency Virus 1 (HIV-1); Human Immune-deficiency Virus 2 (HIV-2); Hepatitis B Virus (HBV); Hepatitis C Virus (HCV); Human T-cell Leukemia-lymphoma Virus 1 (HTLV-1); Human T-cell Leukemia-lymphoma Virus 2 (HTLV-2); West Nile Virus (WNV); Cytomegalovirus (CMV); Epstein-Barr Virus (EBV); and Syphilis (Treponema pallidum). Screening was performed for Creutzfeldt-Jakob disease (CJD) and communicable disease risks associated with xenotransplantation. RYONCIL cell banks are tested for human and animal viruses, retroviruses, bacteria, fungi, yeast, and mycoplasma. Human and animal-derived reagents are tested for human and animal viruses, bacteria, fungi, and mycoplasma before use. These measures do not eliminate the risk of transmitting these or other infectious diseases or agents.

Ectopic Tissue Formation
Ectopic tissue formation may occur following treatment with RYONCIL due to the ability of human mesenchymal stromal cells to differentiate into mesenchymal lineage cells such as bone, cartilage and fat cells.

ADVERSE REACTIONS

Clinical Trials Experience
Because clinical studies are conducted under widely varying conditions, adverse reaction rates observed in the clinical studies of a drug cannot be directly compared to rates in the clinical studies of another drug and may not reflect the rates observed in practice.

The safety data described in this section reflect exposure to RYONCIL in 54 patients in Study MSB-GVHD001 for the treatment of SR-aGvHD. Patients received intravenous infusion of RYONCIL at a dosage of 2 x 106 MSCs/kg twice a week for four consecutive weeks, for a total of eight infusions. Patients with partial or mixed response at Day 28 received additional infusions of RYONCIL 2 x 106 MSCs/kg once a week for an additional four weeks. The median number of doses administered were 10 (range 1 to 16), and the treatment was administered over a median of 43 days (range 1 to 104 days). Serious adverse reactions occurred in 35 patients (65%) including pyrexia (n=5;9%), respiratory failure (n=5;9%), pneumatosis intestinalis (n=4;7%) and staphylococcal bacteremia (n=2;<5%). Eight patients had discontinuation of RYONCIL treatment due to the following: acute infusion reactions (n=3), hypotension (n=1), gastroenteritis (n=1), and death (n=3).

Adverse reactions ≤ grade 3 occurring in ≥10% of patients in Study MSB-GVHD001 up to day 100 after RYONCIL treatment included viral infectious disorders, bacterial infectious disorders, infections – pathogen unspecified, pyrexia, hemorrhage, abdominal pain, hypertension, vomiting, arrhythmia, diarrhea, rash, arthralgia, fungal infectious disorders, hypotension, cough and respiratory failure. No grade 4 or 5 adverse reactions occurred in the study.

Grade 3 or 4 laboratory abnormalities that worsened from baseline in ≥ 10% of patients in Study MSB-GVHD001 included elevated Gamma-glutamyl transferase, thrombocytopenia, and elevated bilirubin.

USE IN SPECIFIC POPULATIONS

Pregnancy
There are no available data for RYONCIL use in pregnant women. No animal reproductive and developmental toxicity studies have been conducted with RYONCIL to assess whether it can cause fetal harm when administered to a pregnant woman. It is not known if RYONCIL has the potential to be transferred to the fetus. Therefore, RYONCIL is not recommended for women who are pregnant. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 10-20%, respectively.

Lactation
There is no information regarding the presence of RYONCIL in human milk, the effect on the breastfed infant, and the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for RYONCIL and any potential adverse effects on the breastfed infant from RYONCIL or from the underlying maternal condition.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Mesoblast at toll-free phone #1-844-889-MESO (6376)

Please see the RYONCIL full Prescribing Information for additional Important Safety Information.

Please see additional Important Safety Information on page 1. Click here for full Prescribing Information.

References
1. AAPC. Codify. Accessed January 22, 2025. https://www.aapc.com/codes/ **2.** ICD10Data. Accessed January 22, 2025. www.icd10data.com **3.** AAPC. Codify. Accessed January 22, 2025. https://www.aapc.com/codes/cpt-codes **4.** AAPC. Codify. Accessed January 22, 2025. https://www.aapc.com/codes/hcpcs-codes **5.** National Drug Codes List. Accessed January 22, 2025. https://ndclist.com/ **6.** Noridian Healthcare Solutions. Medicare Part A Revenue Codes. Accessed January 22, 2025. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes

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