Allogeneic Processed Thymus Tissue-agdc (Rethymic®)

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

DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:

- Flow cytometry confirming ONE of the following:
  - Fewer than 50 naïve T-cells/mm^3 in the peripheral blood
  - Less than 5% of total T-cells being naïve in phenotype

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has congenital athymia confirmed by flow cytometry; **AND**
- The request is for immune reconstitution in a pediatric patient; **AND**
- The request is NOT for the treatment of severe combined immunodeficiency (SCID); **AND**
- The patient has NOT previously received Rethymic
- The patient does not have any comorbidities that are likely to result in severe complications including death from administration of allogenic processed thymus tissue (for example, pre-existing renal impairment, or cytomegalovirus or Epstein-Barr virus infection)

~~Supporting documentation must also be submitted for clinical review.~~

APPLICABLE TENNESSEE STATE MANDATE REQUIREMENTS

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. Rethymic [package insert]. Marlborough, MA; Sumitomo Pharma America, Inc.; 2024. Accessed July 2025.
2. Allogeneic Processed Thymus Tissue. In: Clinical Pharmacology. Tampa (FL): Elsevier. Revised October 2021. Accessed July 2025.
3. Collins C, Sharpe E, Silber A, Kulke S, Hsieh EWY. Congenital Athymia: Genetic Etiologies, Clinical Manifestations, Diagnosis, and Treatment. J Clin Immunol. 2021;41(5):881-895. doi:10.1007/s10875-021-01059-7

EFFECTIVE DATE

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