Rethymic (allogeneic processed thymus tissue–agdc)

Humana

Medicaid Medical Coverage Policy

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Line of Business: Medicaid
State: VA

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Description

The complete absence of a thymus or severely reduced thymus function at birth is the extremely rare genetic or idiopathic (cause unknown) condition known as congenital athymia.[1] The thymus is the organ essential for the development and selection of T cells (type of white blood cells). Individuals with congenital athymia suffer from profound immunodeficiency, increased susceptibility to infections, and frequently, autologous graft-versus-host disease (GVHD). Congenital athymia is related to several hereditary and syndromic disorders and complete DiGeorge syndrome.[3]

This disorder can be recognized when babies are evaluated for severe combined immunodeficiency (SCID) and is now routinely detected in the United States (US) through newborn screening. Flow cytometry and testing for SCID-causing genes are used to confirm the diagnosis and very low naive T cell counts are present.[5] Pediatric individuals with this disease usually die within the first 2 years of life and may have repeated, life-threatening infections due to the lack of adequately working T cells.[2] Establishing a functional thymic environment is essential to achieving full immune reconstitution in individuals with congenital athymia.[3]

Cultured thymus tissue (CTT) implantation, historically described as thymus transplantation, has been shown in clinical trials to restore a functional T cell compartment via the migration of the recipient's bone marrow derived stem cells to the implanted CTT, followed by subsequent development of immunocompetent naive T cells.[3] Individuals who receive allogeneic (donor) processed thymus tissue and

survive past the first year generally survive long-term. Additionally, allogeneic processed thymus tissue also reduces the frequency and severity of infections over time.[2]

Rethymic (allogeneic processed thymus tissue–agdc) is the only US Food and Drug Administration (FDA)-approved curative treatment for congenital athymia in pediatric individuals. A single treatment of donor derived cultured tissue has the potential to reconstitute up to 10% normal immune function, which can extend an individual's life past the historical 3-year maximum lifespan without a thymus or adequate thymus function. Rethymic is administered by a surgical procedure and is indicated for immune reconstitution in pediatric individuals with congenital athymia.[1]

Requests for Rethymic *require review by a medical director.*

Coverage Determination

Refer all requests or questions regarding Rethymic to the Corporate Transplant Department.

Phone	Fax	Email
1-866-421-5663	502-508-9300	transplant@humana.com

Humana members may be eligible under the Plan for **Rethymic** when the following criteria are met:

- Absence of contraindications; **AND**
- Individual is 17 years of age or younger[9]; **AND**
- Individual has diagnosis of congenital athymia[7] and either of the following[5]:
  - Circulating CD3+ T cell count by flow cytometry less than (<) 50/mm3; **OR**
  - Circulating CD3+ T cells that were also positive for cluster of differentiation 45RA (CD45RA)+ CD62L+ and were less than (<) 50/mm3 or less than 5% of total T cells; **AND**
- Individual is a surgical candidate for thymus transplantation[5]; **AND**
- Individual will receive 1 dose per lifetime[9]

Coverage Limitations

Humana members may **NOT** be eligible under the Plan for **Rethymic** for any indications other than those listed above including, but may not be limited to[9]:

- Evidence of SCID; **OR**
- Presence of cytomegalovirus (CMV) OR human immunodeficiency virus (HIV) infection; **OR**
- History of previous thymus transplantation; **OR**

- Individual is pregnant or breastfeeding; **OR**
- Individual has desire to become pregnant/reproduce OR unwilling to use effective contraception

These are considered experimental/investigational as they are not identified as widely used and generally accepted for any other proposed uses as reported in nationally recognized peer-reviewed medical literature published in the English language.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT® Code(s)	Description	Comments
60699	Unlisted procedure, endocrine system	
CPT® Category III Code(s)	**Description**	**Comments**
No code(s) identified		
HCPCS Code(s)	**Description**	**Comments**
J3590	Unclassified biologics	

References

1. American Academy of Allergy Asthma & Immunology. Practice Parameter. Practice parameter for the diagnosis and management of primary immunodeficiency. https://www.aaaai.org. Published September 12, 2015.

2. ClinicalKey. Drug Monograph. Allogeneic processed thymus tissue. https://www.clinicalkey.com. Updated September 28, 2023.

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.

4. Hayes, Inc. Evolving Evidence Review. Rethymic (Enzyvant Therapeutics Inc.) for congenital athymia. https://evidence.hayesinc.com. Published April 1, 2022. Updated June 30, 2023.

5. Markert ML, Gupton SE, McCarthy EA. Experience with cultured thymus tissue in 105 children. *J Allergy Clin Immunol*. 2022;149(2):747-757.

6. UpToDate, Inc. DiGeorge (22q11.2 deletion) syndrome: clinical features and diagnosis. https://www.uptodate.com. Updated June 2024.

7. UpToDate, Inc. DiGeorge (22q11.2 deletion) syndrome: management and prognosis. https://www.uptodate.com. Updated June 2024.

8. UpToDate, Inc. Hematopoietic cell transplantation for non-SCID inborn errors of immunity. https://www.uptodate.com. Updated June 2024.

9. US Food & Drug Administration (FDA). Full prescribing information: Rethymic (allogeneic processed thymus tissue–agdc). https://www.fda.gov. Published July 2023.

Appendix

Table 1
Diagnostic Criteria for DiGeorge syndrome[6]

Definitive diagnosis*
Male or female with reduced numbers of CD3+ T cells (less than 500/mm^3) and 2 of the following characteristics: • Conotruncal cardiac defect (truncus arteriosus, tetralogy of Fallot, interrupted aortic arch, or aberrant right subclavian) • Hypocalcemia of greater than 3 weeks' duration that requires therapy • Deletion of chromosome 22q11.2
Probable diagnosis*
Male or female with reduced numbers of CD3+ T cells (less than 1500/mm^3) and a deletion of chromosome 22q11.2.
Possible diagnosis*
Male or female with reduced numbers of CD3+ T cells (less than 1500/mm3) and at least one of the following: • Cardiac defect • Hypocalcemia of greater than 3 weeks duration that requires therapy • Dysmorphic facies or palatal abnormalities
*Individuals with a definitive or probable diagnosis are assumed to have a greater than 98% and 85% probability, respectively, that in 20 years they will still have the same diagnosis. Individuals with a possible diagnosis are those that have some but not all of the characteristic clinical or laboratory findings of a particular disorder.

Change Summary

01/01/2025 New Policy.