Rethymic (allogeneic processed thymus tissue–agdc)

DRAFT

Humana

Medicaid Medical Coverage Policy

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Line of Business: Medicaid
State(s): LA

Table of Contents

Description

The thymus organ is essential for the development and selection of T cells (a type of white blood cell). 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 and is related to complete DiGeorge syndrome and several hereditary and syndromic disorders. An individual~~s~~ with congenital athymia experiences extreme immunodeficiency, higher susceptibility to infections, and often, autologous graft-versus-host disease (GVHD).[3]

Congenital athymia is routinely detected in the United States through newborn screening for severe combined immunodeficiency (SCID). Flow cytometry and testing for causing genes are used to confirm the diagnosis when very low naive T cell counts are present.[5] A pediatric individual~~s~~ diagnosed with congenital athymia may experience recurrent, life-threatening infections because of the lack of adequately working T cells and death typically occurs within the first 2 years of life.[Error! Reference source not found.]

Establishing a functional thymic environment is essential to achieving full immune reconstitution in an individual with congenital athymia. Rethymic (allogeneic [donor] processed thymus tissue–agdc) is the only FDA-approved curative treatment for congenital athymia. Rethymic (allogeneic processed thymus

tissue–agdc is indicated for immune reconstitution and is administered via surgery. An individual who receives allogenic processed thymus tissue and survives past the first year commonly survives long-term. Additionally, allogeneic processed thymus tissue eventually decreases the rate and severity of infections. Error! Reference source not found.

Requests for Rethymic *(allogeneic processed thymus tissue–agdc) require review by a medical director.*

Coverage Determination

Refer all requests or questions regarding Rethymic (allogeneic processed thymus tissue–agdc) 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 (allogeneic processed thymus tissue–agdc when the following criteria are met[9]:

- **Absence of contraindications; AND**
- **Individual is 17 years of age or younger; AND**
- **Individual has diagnosis of congenital athymia[7]; AND**
- **Individual will receive 1 dose per lifetime**

Coverage Limitations

Humana members may NOT be eligible under the Plan for Rethymic (allogeneic processed thymus tissue–agdc) for any indications other than those listed above including, but may not be limited to[9]:

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

A review of the current medical literature shows that there is no evidence to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

Humana members may NOT be eligible under the Plan for Rethymic (allogeneic processed thymus tissue–agdc) for any indications other than those listed above including, but may not be limited to[9]:

- **Evidence of SCID; OR**

- Renal impairment (eg, elevated serum creatinine at baseline)

A review of the current medical literature shows that the evidence is insufficient to determine that this service is standard medical treatment. There is an absence of current, widely-used treatment guidelines or acceptable clinical literature examining benefit and long-term clinical outcomes establishing the value of this service in clinical management.

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	-
ICD-10-PCS Code(s)	Description	Comments
XW020D8	Introduction of Engineered Allogeneic Thymus Tissue into Muscle, Open Approach, New Technology Group 8	

References

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

2. ClinicalKey. Drug Monograph. Allogeneic processed thymus tissue. https://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://uptodate.com. Updated June 2025.

7. UpToDate, Inc. DiGeorge (22q11.2 deletion) syndrome: management and prognosis. https://uptodate.com. Updated June 11, 2025.

8. UpToDate, Inc. Hematopoietic cell transplantation for non-SCID inborn errors of immunity. https://uptodate.com. Updated June 14, 2025.

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

Appendix

Appendix A

Diagnostic Criteria for DiGeorge syndrome Error! Reference source not found.

Diagnosis type	Diagnosis criteria
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) • 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.
09/02/2025 Annual Review, Coverage Change. Updated Coding Information