

**Corporate Medical Policy:** Allogeneic Processed Thymus Tissue-agdc (Rethymic®) “Notification”

**Restricted Product(s):**

- allogeneic processed thymus tissue-agdc (Rethymic®) surgical implantation for administration by a healthcare professional

**FDA Approved Use:**

- For immune reconstitution in pediatric patients with congenital athymia
- Limitations of use: Not indicated for the treatment of patients with severe combined immunodeficiency (SCID)

**Criteria for Medical Necessity:**

**The restricted product(s) may be considered medically necessary when the following criteria are met:**

1. The patient is 3 years of age or younger; **AND**
2. The patient has a diagnosis of congenital athymia confirmed by flow cytometry demonstrating fewer than 50 naïve T-cells/mm<sup>3</sup> (CD45RA<sup>+</sup>, CD62L<sup>+</sup>) in the peripheral blood or less than 5% of total T-cells being naïve in phenotype **[medical record documentation required]; AND**
3. The patient has complete DiGeorge syndrome (cDGS) and at least one of the following **[medical record documentation required]**:
  - a. Congenital heart defect **[medical record documentation required]; OR**
  - b. Hypoparathyroidism or hypocalcemia requiring calcium replacement **[medical record documentation required]; OR**
  - c. 22q11.2 deletion syndrome **[medical record documentation required]; OR**
  - d. 10p13 hemizygosity **[medical record documentation required]; OR**
  - e. CHARGE (coloboma, heart defects, choanal atresia, growth and development retardation, genital hypoplasia, and ear anomalies including deafness) syndrome **[medical record documentation required]; OR**
  - f. CHD7 mutation **[medical record documentation required]; OR**
4. The patient has confirmed FOXP1 deficiency **[medical record documentation required]; AND**
5. The patient is NOT being treated for severe combined immunodeficiency (SCID) **[medical record documentation required]; AND**
6. The patient has been screened for anti-HLA antibodies prior to receiving treatment with the requested agent **[medical record documentation required]; AND**
7. For patients who received prior solid organ (e.g., thymus) or hematopoietic cell transplantation, the patient has undergone HLA matching of the requested agent to recipient alleles **[medical record documentation required]; AND**
8. The requested quantity does NOT exceed the maximum units allowed for the duration of approval (see table below).

**Duration of Approval:** 180 days (one treatment course per lifetime)

\*\* Please note, for certain identified gene and cellular therapies such as allogeneic Processed Thymus Tissue-agdc (Rethymic®), when coverage is available and the individual meets medically necessary criteria, distribution from a specialty pharmacy provider due to cost (distribution channel restriction) may be required in order for coverage to be provided. **Please contact Blue Cross NC** to coordinate this therapy.

FDA Label Reference				
Medication	Indication	Dosing	HCPCS	Maximum Units*
allogeneic processed thymus tissue-agdc (Rethymic®) surgical implantation	Immune reconstitution in pediatric patients with congenital athymia	5,000 to 22,000 mm <sup>2</sup> of Rethymic surface area/m <sup>2</sup> recipient body surface area (BSA) administered by surgical procedure	C9399** J3490** J3590**	22,000

\*Maximum units allowed for duration of approval

\*\*Non-specific assigned HCPCS codes, must submit requested product NDC

Other revenue codes that may be applicable to this policy: 0891, 0892

**References:** all information referenced is from FDA package insert unless otherwise noted below.

1. Collins C, Sharpe E, Silber A, et al. Congenital athymia: genetic etiologies, clinical manifestations, diagnosis, and treatment. *J Clin Immunol.* 2021;41(5): 881-895.
2. Markert ML, Gupton SE, McCarthy EA. Experience with cultured thymus tissue in 105 children. *J Allergy Clin Immunol.* 2021;S0091-6749(21):01056-3.

**Policy Implementation/Update Information:** Criteria and treatment protocols are reviewed annually by the Blue Cross NC P&T Committee, regardless of change. This policy is reviewed in Q1 annually.

April 2026: Coding change: Added the following applicable revenue codes associated with policy HCPCS code(s): 0891 (Special Processed Drugs – FDA Approved Cell Therapy) and 0892 (Special Processed Drugs – FDA Approved Gene Therapy). Added Gene/Cellular Therapy distribution channel management language according to benefit booklet for clarity. **Policy notification given 2/1/2026 for effective date 4/1/2026.**

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October 2025: Criteria update: Minor updates made to formatting throughout policy for clarity.  
January 2022: Original medical policy criteria issued.