TX CLINICAL CRITERIA & PROCEDURE

CRITERIA NAME: Allogeneic processed thymus tissue-agdc (Rethymic)	**CRITERIA ID:** TX.CC.PHAR.59
BUSINESS UNIT: Superior HealthPlan	**FUNCTIONAL AREA:** Pharmacy
EFFECTIVE DATE: 07/01/2026	**PRODUCT(S):** STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate
REVIEWED/REVISED DATE: N/A	**REGULATOR MOST RECENT APPROVAL DATE(S):** N/A

CRITERIA STATEMENT:
The purpose of this clinical criteria is to provide a guide to medical necessity reviews for allogeneic processed thymus tissue-agdc (Rethymic).

PURPOSE:
Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

This medication is a non-risk based (NRB) payment drug and should follow state guidance for medical necessity review for Medicaid/CHIP due to the manner in which it is reimbursed. All determinations will be performed by a Medical Director. A pharmacy clinician will review the prior authorization request and make a recommendation to the Medical Director but will not make the ultimate determination on any case.

The procedure code J3590 (used for Rethymic) will be limited to one approval per lifetime, by any provider. If the code is updated in the future it will still be limited to once per lifetime.

This medication is also designated by HHSC as a high-cost clinician-administered drug (HCCAD), allowing separate reimbursement for inpatient use. When inpatient use is required, the drug may be billed on a separate outpatient claim or through specialty pharmacy billing, when available.

SCOPE:
This criteria applies to all directors, officers, and employees of Centene Corporation, its affiliates, health plans, and subsidiary companies (collectively, the "Company").

DEFINITIONS:
CPS = Centene Pharmacy Services

NRB = Non-Risk Based
SHP = Superior HealthPlan
UM = Utilization Management

POLICY:
It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of allogeneic processed thymus tissue-agdc (Rethymic); procedure code: 3590.

Description/Mechanism of Action:
Allogeneic processed thymus tissue-agdc (Rethymic) is used to reconstitute immunity in patients who are athymic. The mechanism of action is thought to involve the migration of recipient T cell progenitors from the bone marrow to the implanted allogeneic processed thymus tissue slices, which allows for the development of naive immunocompetent recipient T cells

FDA Approved Indications:
Rethymic is indicated for immune reconstitution in pediatric patients with congenital athymia.

PROCEDURE:
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

I. Initial Approval Criteria:

A. Congenital Athymia:

1. A Medical Director is required to review and approve or deny all requests. A pharmacy clinician will make a recommendation on the prior authorization, but ultimate determination will be made by the Medical Director only.
2. The client is 18 years of age or younger.
3. The client has a diagnosis of congenital athymia which is confirmed by flow cytometry (diagnosis code: D82.1).
4. Documentation that severe combined immunodeficiency (SCID) has been conclusively ruled out.
5. Provider attestation that the anti-Human Leukocyte Antigen (HLA) antibodies test conducted before treatment. If positive for anti-HLA antibodies, the client must receive Rethymic from a donor who does not express HLA alleles.
6. Prescriber attestation that the benefits and risks of treatment have been evaluated for clients with preexisting cytomegalovirus (CMV) infection or renal impairment.
7. The client has not previously received thymus tissue transplantation.
8. Provider attestation to monitor the following:
   a. After the surgical implantation of Rethymic, monitor the client for the following:
      i. The risk of developing of graft versus host disease (GVHD).
      ii. The possibility of developing autoimmune or lymphoproliferative disorders. Therefore, monitor complete blood counts (CBC) with differential, liver enzymes, serum creatinine, urinalysis, and thyroid function.
      iii. Renal impairment or failure.
   b. Monitor for infectious disease occurrence as these may develop due to Rethymic being derived from human tissue.

Approval duration: 12 months (Only 1 dose per lifetime will be provided on this drug regardless of Provider).

REFERENCES:
Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

ATTACHMENTS:

REVISION LOG

REVISION TYPE	REVISION SUMMARY	DATE APPROVED & PUBLISHED
New Policy	N/A	07/01/2026