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5.99.024

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Miscellaneous Products	**Original Policy Date:**	January 1, 2022
Subject:	Zortress	**Page:**	1 of 3

Last Review Date: March 7, 2025

Zortress

Description

Zortress (**everolimus**)

Preferred product: generic everolimus

This policy does not apply to generic everolimus

Background
Zortress (everolimus) inhibits antigenic and interleukin (IL-2 and IL-5) stimulated activation and proliferation of T and B lymphocytes. It is also an mTOR inhibitor. In models, Zortress effectively reduced kidney allograft rejection resulting in prolonged graft survival (1).

Regulatory Status
FDA-approved indication: Zortress is indicated for the prophylaxis of organ rejection in adult patients receiving a kidney or liver transplant (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Zortress may be considered **medically necessary** if the conditions indicated below are met.

Zortress may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Prophylaxis of organ rejection
   a. Post kidney **OR** liver transplant
   b. Patient **MUST** have tried the preferred product (generic Zortress: everolimus) unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary
Zortress (everolimus) is an mTOR inhibitor immunosuppressant used for the prophylaxis of organ rejection in patients who received a kidney or liver transplant (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Zortress while maintaining optimal therapeutic outcomes.

References

1. Zortress [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2024.

Policy History

Date	Action
December 2021	Addition to PA
December 2022	Annual review. Changed policy number to 5.99.024
December 2023	Annual review and reference update
March 2024	Annual review
September 2024	Annual review and reference update
March 2025	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.