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5.99.024

Section:	Prescription Drugs	Effective Date:	April 1, 2024
Subsection:	Miscellaneous Products	Original Policy Date:	January 1, 2022
Subject:	Zortress	Page:	1 of 3

Last Review Date: March 8, 2024

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.

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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.

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References

1. Zortress [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2023.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.