Drug Coverage Policy

Effective Date.....7/1/2024
Coverage Policy Number.....IP0408
Policy Title....Everolimus Products for Non-Oncology Uses

Everolimus Products for Non-Oncology Uses

- **Afinitor® (everolimus tablets – Novartis, generic)**
- **Afinitor Disperz® (everolimus tablets for oral suspension – Novartis)**

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW

Afinitor, a kinase inhibitor, is indicated for the following uses:[1]

- **Tuberous sclerosis complex (TSC)-associated renal angiomyolipoma,** treatment of adults not requiring immediate surgery.

Afinitor Disperz, a kinase inhibitor, is indicated for the following uses:[1]

- **TSC-associated partial-onset seizures**, adjunctive treatment of patients ≥ 2 years of age.

Of note, Zortress® (everolimus tablets) is indicated in combination with other drugs for prophylaxis of organ rejection in adults undergoing kidney or liver transplant.[2] The tablet strengths and dosing are different for Zortress and Afinitor. Zortress is not targeted in this policy.

Guidelines
The National Comprehensive Cancer Network (NCCN) Compendium recommends use of everolimus for the indications listed in the FDA-Approved Indications and Other Uses with Supportive Evidence sections.[3]

Medical Necessity Criteria

Everolimus products are considered medically necessary when ONE of the following are met:

FDA-Approved Indications

1. **Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma.** Approve for 1 year if the patient meets the following (A):
   A.) Preferred product criteria are met for the product(s) as listed in the below table(s).

2. **Tuberous Sclerosis Complex-Associated Partial Onset Seizures.** Approve for 1 year if the patient meets the following (A):
   A.) Preferred product criteria are met for the product(s) as listed in the below table(s).

Employer Plans:

Product	Criteria
Afinitor tablets (everolimus)	The following: 1. Trial of **everolimus tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction
Afinitor Disperz (everolimus tablets for oral suspension)	The following: 1. Trial of **everolimus tablets for oral suspension** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

Individual and Family Plans:

Product	Criteria
Afinitor tablets (everolimus)	The following: 1. Trial of **everolimus tablets** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

Product	Criteria
Afinitor Disperz (everolimus tablets for oral suspension)	The following: 1. Trial of **everolimus tablets for oral suspension** (the bioequivalent generic product) AND cannot take due to a formulation difference in the inactive ingredient(s) which would result in a significant allergy or serious adverse reaction

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Afinitor® tablets, Afinitor Disperz® tablets for oral suspension [prescribing information]. East Hanover, NJ: Novartis; February 2022.
2. Zortress® tablets [prescribing information]. East Hanover, NJ: Novartis; January 2021.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on March 5, 2024. Search term: everolimus.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** coverage policy title. **Tuberous Sclerosis Complex-Associated Renal Angiomyolipoma.** • **Removed** criterion screening for age. • **Removed** criterion requiring confirmation of angiomyolipoma greater than or equal to 3 cm diagnosed on radiographic imaging. **Tuberous Sclerosis Complex-Associated Partial Onset Seizures.** • **Removed** criterion screening for age. • **Removed** criteria requiring failure, contraindication, or intolerance to two antiepileptic drugs. • **Removed** criterion requiring use as adjunctive therapy to other antiepileptic drugs.	6/15/2024

	• **Removed** criterion requiring consultation with specialist.	

The policy effective date is in force until updated or retired.

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