

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit		Medicare Part B	Reference #
	Standard Opt-out	✓	ACSF		MMT		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	3301-D
✓	VF	✓	Balanced		Medical Benefit: Managed Medicaid		Medical Benefit: Add-on		Medicare Part B: Add-on	

EXCEPTIONS CRITERIA TRANSPLANT

PREFERRED PRODUCTS: EVEROLIMUS, SIROLIMUS

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the transplant products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Transplant products

	Product(s)
Preferred	<ul style="list-style-type: none"> • everolimus • sirolimus
Targeted	<ul style="list-style-type: none"> • Rapamune (sirolimus) • Zortress (everolimus)

II. EXCEPTION CRITERIA

- Coverage for the targeted product, Rapamune, is provided when the member has had a documented intolerable adverse event to the preferred product, generic sirolimus, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Coverage for the targeted product, Zortress, is provided when the member has had a documented intolerable adverse event to the preferred drug, generic everolimus, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

REFERENCES

- Rapamune [package insert]. Philadelphia, PA: Pfizer; August 2019.
- Sirolimus [package insert]. Visakhapatnam, India: Dr. Reddy's Laboratories Limited; January 2020.
- Zortress [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2018.
- Everolimus [package insert]. Eatontown, NJ: Hikma Pharmaceuticals USA Inc.; August 2019.