Pharmacy Medical Necessity Guidelines:
Astagraf XL® (tacrolimus extended-release)

Effective: July 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Astagraf XL (tacrolimus extended-release) is a calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant in combination with other immunosuppressants in adult and pediatric patients who can swallow capsules intact.

COVERAGE GUIDELINES

The plan may authorize coverage of tacrolimus extended-release capsules (Astagraf XL) for Members when **ALL** of the following criteria for a particular regimen are met and limitations do not apply:

1. The Member will be taking the requested medication concurrently with other immunosuppressants

AND

2. The provider indicated clinical inappropriateness of treatment with the immediate-release tacrolimus formulation

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Astagraf XL (tacrolimus extended-release capsules) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; August 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 11, 2023: No changes.
2. April 9, 2024: Effective May 1, 2024, updated RxUM fax number.
3. April 8, 2025: No changes
4. June 9, 2026: Effective July 1, 2026, updated criteria and limitation to reflect generic availability of Astagraf XL and brand name will be reviewed according to the Brand Name criteria.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services