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

Effective: March 16, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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

OVERVIEW

FDA-APPROVED INDICATIONS

Astagraf XL is a calcineurin-inhibitor immunosuppressant indicated for the prophylaxis of organ rejection in patients receiving a kidney transplant with mycophenolate mofetil (MMF) and corticosteroids, with or without basiliximab induction.

COVERAGE GUIDELINES

The plan may authorize coverage of Astagraf XL® (tacrolimus extended-release capsules) 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 Astagraf XL concurrently with a corticosteroid and mycophenolate

AND

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

LIMITATIONS

None

CODES

None

REFERENCES

1. Astagraf XL (tacrolimus extended-release capsules) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; June 2019.
2. Tacrolimus @ http://online.factsandcomparisons.com , accessed December 2013.

APPROVAL HISTORY

December 13, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. November 4, 2014: Changed approval duration to one year.
2. November 10, 2015: Approval duration modified to life of plan.
3. January 1, 2016: Administrative change to rebranded template.
4. November 15, 2016: No changes
5. December 19, 2016: Removed quantity limit.
6. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
7. December 12, 2017: No changes.
8. November 13, 2018: Administrative changes made to template.
9. April 9, 2019: No changes.

10. March 10, 2020: Effective March 16, 2020, removed the requirement that the member must be 16 years of age or older.

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.