Pharmacy Medical Necessity Guidelines: Tremfya™ (guselkumab)

Effective: March 19, 2018

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

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans

☐ Tufts Health Plan Commercial Plans – large group plans
☐ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans

☐ Tufts Health Direct – Health Connector
☒ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products

☐ Tufts Health Freedom Plan - large group plans
☐ Tufts Health Freedom Plan - small group plans

Fax Numbers:

RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Tremfya (guselkumab) is an interleukin-23 blocker indicated for the treatment of:

- **Plaque Psoriasis**
  Tremyfa (guselkumab) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

COVERAGE GUIDELINES

The plan may authorize coverage of Tremfya (guselkumab) for Members when the following criteria are met:

1. The Member has a documented definitive diagnosis from a dermatologist of moderate to severe chronic plaque psoriasis

AND

2. The Member is 18 years of age or older

AND

3. The Member has tried and failed treatment with, or the Member has a contraindication to, at least 2 of the preferred therapies, such as PUVA or UVB phototherapy, acitretin, cyclosporine, or methotrexate

AND

4. The Member has tried and failed treatment with, has a contraindication to or the provider has indicated clinical inappropriateness of treatment with Enbrel (etanercept) and Humira (adalimumab)

LIMITATIONS

- Samples, free goods or similar offerings of Tremfya (guselkumab) do not qualify for an established clinical response and will not be considered for prior authorization.
- Members new to the plan and stable on Tremfya (guselkumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., cyclosporine, methotrexate) but are required to provide documentation of prerequisite trials with preferred biologic therapies as outlined in the above criteria.
- For the diagnosis of plaque psoriasis, inconvenience does not qualify as a contraindication to phototherapy.
- Documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.
- Coverage for Tremfya (guselkumab) for the diagnoses of plaque psoriasis will be limited to a 56-day supply as follows:
  - Tremfya 100 mg syringe – one 28-day supply of two 100 mg syringes, followed by one syringe per 56 days for maintenance dosing

CODES

Medical billing codes may not be used for these medications. These medications must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Boehncke WH, Schön MP. Psoriasis. *Lancet*. 2015; 386(9997): 983-94.
2. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. *J Am Acad Dermatol*. 2003; 49:897-9.
3. Krueger G, Ellis CN. Psoriasis-recent advances in understanding its pathogenesis and treatment. *J Am Acad Dermatol*. 2005; 53(1 Suppl 1): S94-100.
4. Langley RG, Ellis CN. Evaluating psoriasis with Psoriasis Area and Severity Index, Psoriasis Global Assessment, and Lattice System Physician's Global Assessment. *J Am Acad Dermatol*. 2004; 51: 563–69.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2008; 58(5): 826-50.
6. Menter A, Korman N, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: Case-based presentations and evidence-based conclusions. *J Am Acad Dermatol*. 2011; 65(1):137-74.
7. Pariser DM, Bagel J, Gelfand JM, Korman NJ, Ritchlin CT, Strober BE, Van Voorhees AS, Young M, Rittenberg S, Lebwohl MG, Horn EJ; National Psoriasis Foundation. National Psoriasis Foundation clinical consensus on disease severity. *Arch Dermatol*. 2007 Feb;143(2):239-42.
8. Tremfya (guselkumab) [package insert]. Horshma, PA: Janssen Biotech, Inc.; July 2017.

APPROVAL HISTORY

January 9, 2018: Reviewed by Pharmacy & Therapeutics Committee.
Subsequent endorsement date(s) and changes made:

- March 13, 2018: Added the following two limitations: Members new the plan and stable on Siliq (brodalumab) are not required to provide documentation of prerequisite trials with conventional (i.e., non-biologic) therapies (e.g., cyclosporine, methotrexate) AND documentation of a Member being a social drinker does not qualify as a medically acceptable contraindication or clinically inappropriateness to methotrexate therapy.

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. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink^{SM} Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.