

<u>Targeted Immunomodulators</u> Tremfya (guselkumab) vial Effective 04/03/2025

Plan	 ☑ MassHealth UPPL □Commercial/Exchange 		☑ Prior Authorization
Benefit	 Pharmacy Benefit Medical Benefit 	Program Type	Quantity Limit Step Therapy
Specialty Limitations	N/A		
	Medical and Specialty Medications		
Contact Information	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
	Non-Specialty Medications		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029
Notes	 Tremfya vial is also available on the pharmacy benefit. Please see the <u>MassHealth Drug</u> <u>List</u> for coverage and criteria. Additional agents from this class are available through the pharmacy benefit. Please see the <u>MassHealth Drug List</u> for coverage and criteria. 		

Overview

Tremfya (guselkumab) <u>vial</u> is only indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (induction dosage).

Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization may be granted for members when all the following criteria are met:

Ulcerative Colitis

- 1. Diagnosis of moderate-to-severe ulcerative colitis
- 2. Appropriate dosing
- 3. Inadequate response, adverse reaction, or contraindication to ALL of the following:
 - a. Stelara (ustekinumab)
 - b. Skyrizi (risankizumab)
 - c. Omvoh (mirikizumab-mrkz)
- 4. Inadequate response or adverse reaction to ONE or contraindication to ALL anti-TNF agents that are FDA-approved for ulcerative colitis

Pityriasis rubra pilaris (PRP) – off label

Mass General Brigham Health Plan includes Mass General Brigham Health Plan, Inc. and Mass General Brigham Health Insurance Company.

- 1. Diagnosis of pityriasis rubra pilaris (PRP)
- 2. Inadequate response or adverse reaction to ONE topical corticosteroid or contraindication to ALL topical corticosteroids
- 3. Clinical rationale for use of the requested agent instead of Stelara and Taltz

More Frequent or Higher Doses

- 1. Severe disease
- 2. Inadequate response or adverse reaction to ONE or contraindication to ALL other injectable biologic which is FDA-approved for the requested indication
- 3. Partial response to FDA-approved dosing of current biologic therapy
- 4. Prescriber is a specialist or consult notes for the requested indication from a specialist are provided

Continuation of Therapy

Resubmission by prescriber will infer a positive response to therapy.

Limitations

- 1. Initial approvals will be granted for the following:
 - a. Off-label indications, frequent/high dosing: 3 months
 - b. Ulcerative Colitis: 6 months
- 2. Reauthorizations will be granted for 12 months

References

1. Tremfya[®] [package insert]. Horsham (PA): Janssen Biotech, Inc.; 2024 Sep.

Review History

03/12/25 – Created for P&T. Adopted MH criteria for vial formulation of Tremfya. This formulation will be available through both pharmacy and medical benefits. Effective 4/3/25