Medical Policy:

Tremfya (guselkumab) intravenous infusion and subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.115	October 11, 2024	January 1, 2020

Definitions

Tremfya is indicated for the treatment of moderate-to-severe plaque psoriasis (in patients who are candidates for systemic therapy or phototherapy), active psoriatic arthritis and ulcerative colitis. Guselkumab is a human monoclonal IgG1λ antibody that selectively binds to the p19 subunit of interleukin 23 (IL-23) and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Guselkumab inhibits the release of proinflammatory cytokines and chemokines.

Length of Authorization

Intravenous Induction- Ulcerative Colitis (UC): Coverage will be provided for 11 weeks (for 3 intravenous doses) as induction therapy

Subcutaneous Maintenance- Ulcerative Colitis (UC): Coverage will be provided for 3 months and cannot be renewed. (All other indications are covered under the pharmacy benefit.)

Dosing Limits [Medical Benefit]

Max Units (per dose and over time) [HCPCS Unit]:

Tremfya SQ

Ulcerative Colitis
• 200 billable units every 28 days

Tremfya IV

Ulcerative Colitis
• 200 mg at weeks 0, 4, & 8

Guideline

I. INITIAL CRITERIA

Coverage is provided in the following conditions:

1. Patient is at least 18 years of age; **AND**
2. Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
3. Patient has been evaluated and screened for the presence of latent tuberculosis (TB) infection prior to initiating treatment and will receive ongoing monitoring for the presence of TB during treatment; **AND**
4. Patient does not have an active infection, including clinically important localized infections; **AND**
5. Patient will not receive live vaccines during therapy; **AND**
6. Patient is not on concurrent treatment with another biologic therapy (e.g., IL-inhibitor, TNF inhibitor, integrin receptor antagonist, T cell costimulation modulator, etc.) or targeted synthetic therapy (e.g., apremilast, abrocitinib, tofacitinib, baricitinib, upadacitinib, deucravacitinib, ritlecitinib, ruxolitinib, etrasimod, ozanimod, etc.); **AND**

Ulcerative Colitis (UC) †

A. Documented moderate to severe active disease; **AND**
   i. Documented failure or ineffective response to a minimum 3-month trial of conventional therapy [aminosalicylates, corticosteroids, or immunomodulators (e.g., azathioprine, 6-mercaptopurine, methotrexate, etc.)] at maximum tolerated doses, unless there is a contraindication or intolerance to use; **OR**
   ii. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such as adalimumab, golimumab, or infliximab; **OR**
   iii. Patient is already established on a biologic or targeted synthetic therapy for the treatment of UC

I. RENEWAL CRITERIA

Coverage cannot be renewed.

Applicable Procedure Codes

Code	Description
J1628	Injection, guselkumab, 1 mg
J3590	Unclassified biologics (IV formulation ONLY)

Applicable NDCs

Code	Description
57894-0640-xx	Tremfya 100 mg/mL single-dose prefilled syringe or One-Press injector
57894-0651-xx	Tremfya 200 mg/mL single-dose prefilled pen or prefilled syringe
57894-0650-xx	Tremfya 200 mg/mL (10 mg/mL) single-dose vial

ICD-10 Diagnoses

Code	Description
K51.00	Ulcerative (chronic) pancolitis without complications
K51.011	Ulcerative (chronic) pancolitis with rectal bleeding
K51.012	Ulcerative (chronic) pancolitis with intestinal obstruction
K51.013	Ulcerative (chronic) pancolitis with fistula
K51.014	Ulcerative (chronic) pancolitis with abscess
K51.018	Ulcerative (chronic) pancolitis with other complication
K51.019	Ulcerative (chronic) pancolitis with unspecified complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.211	Ulcerative (chronic) proctitis with rectal bleeding
K51.212	Ulcerative (chronic) proctitis with intestinal obstruction
K51.213	Ulcerative (chronic) proctitis with fistula
K51.214	Ulcerative (chronic) proctitis with abscess
K51.218	Ulcerative (chronic) proctitis with other complication
K51.219	Ulcerative (chronic) proctitis with unspecified complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.311	Ulcerative (chronic) rectosigmoiditis with rectal bleeding
K51.312	Ulcerative (chronic) rectosigmoiditis with intestinal obstruction
K51.313	Ulcerative (chronic) rectosigmoiditis with fistula
K51.314	Ulcerative (chronic) rectosigmoiditis with abscess
K51.318	Ulcerative (chronic) rectosigmoiditis with other complication
K51.319	Ulcerative (chronic) rectosigmoiditis with unspecified complications
K51.50	Left sided colitis without complications
K51.511	Left sided colitis with rectal bleeding
K51.512	Left sided colitis with intestinal obstruction
K51.513	Left sided colitis with fistula
K51.514	Left sided colitis with abscess
K51.518	Left sided colitis with other complication
K51.519	Left sided colitis with unspecified complications
K51.80	Other ulcerative colitis without complications
K51.811	Other ulcerative colitis with rectal bleeding
K51.812	Other ulcerative colitis with intestinal obstruction
K51.813	Other ulcerative colitis with fistula
K51.814	Other ulcerative colitis with abscess
K51.818	Other ulcerative colitis with other complication
K51.819	Other ulcerative colitis with unspecified complications
K51.90	Ulcerative colitis, unspecified, without complications
K51.911	Ulcerative colitis, unspecified with rectal bleeding
K51.912	Ulcerative colitis, unspecified with intestinal obstruction
K51.913	Ulcerative colitis, unspecified with fistula
K51.914	Ulcerative colitis, unspecified with abscess
K51.918	Ulcerative colitis, unspecified with other complication
K51.919	Ulcerative colitis, unspecified with unspecified complications

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	10/11/2024	Added IV Tremfya and criteria. Added Tremfya SQ coverage.
EmblemHealth & ConnectiCare	1/2/2024	Annual Review: updated indications and ICD-10 codes
EmblemHealth & ConnectiCare	5/02/2023	Annual Review: no changes
EmblemHealth & ConnectiCare	1/17/2023	Transfer to New Template
EmblemHealth & ConnectiCare	1/1/2020	New Policy

References

1. Product Information: TREMFYA® subcutaneous injection, guselkumab subcutaneous injection. Janssen Biotech, Inc (per FDA), Horsham, PA, 2019.