Medical Policy:

Tremfya (guselkumab) intravenous infusion and subcutaneous injection

POLICY NUMBER	LAST REVIEW	ORIGIN DATE
MG.MM.PH.115	May 9, 2025	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, crohn's disease 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), Crohn's Disease (CD): Coverage will be provided for 11 weeks (for 3 intravenous doses) as induction therapy

Subcutaneous Maintenance- Ulcerative Colitis (UC), Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Crohn's Disease (CD): 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
Plaque Psoriasis & Psoriatic Arthritis
• 100 billable units at weeks 0 & 4, then every 56 days
Crohn's Disease
• 400mg at weeks 0, 4, and 8

Tremfya IV
Ulcerative Colitis
• 200 mg at weeks 0, 4, & 8
Crohn's Disease
• 200mg at weeks 0, 4, and 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

Plaque Psoriasis (PsO) †

A. Documented moderate to severe plaque psoriasis for at least 6 months with at least **ONE** of the following:
   i. Involvement of at least 3% of body surface area (BSA); **OR**
   ii. Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
   iii. Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, genitalia, etc.) or with intractable pruritus; **AND**
B. Patient meets ALL of the following ¥:
   i. Patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, tapinarof, roflumilast, retinoic acid derivatives, and/or vitamin D analogues); **AND**

ii. Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least **ONE** non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
iii. Patient did not respond adequately (or is not a candidate*) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol)

¥ Note: For patients already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.

Psoriatic Arthritis (PsA) †

A. Documented moderate to severe active disease; **AND**
   i. For patients with predominantly axial disease **OR** enthesitis, a failure of at least a 4-week trial of **ONE** non-steroidal anti-inflammatory drug (NSAID), unless use is contraindicated; **OR**
   ii. For patients with peripheral arthritis OR dactylitis, a failure of at least a 3-month trial of **ONE** conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, sulfasalazine, leflunomide, or hydroxychloroquine, etc.); **OR**
   iii. Patient is already established on biologic or targeted synthetic therapy for the treatment of PsA; **AND**

B. May be used as a single agent or in combination with csDMARD (e.g., methotrexate, etc.)

Crohn's Disease (CD) †

A. Documented moderate to severe active disease; **AND**
   i. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); **OR**
   ii. Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such (e.g., adalimumab, certolizumab, or infliximab); **OR**
   iii. Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; **OR**
   iv. Patient is already established on biologic or targeted synthetic therapy for the treatment of CD

***Examples of contraindications to phototherapy (PUVA or UVB) include the following:**
− Xeroderma pigmentosum − Other rare photosensitive genodermatoses (e.g., trichothiodystrophy, Cockayne syndrome, Bloom syndrome, Rothmund-Thomson syndrome) *(UVB only)* − Genetic disorders associated with increased risk of skin cancer (e.g., Gorlin syndrome, oculocutaneous albinism) *(UVB only)* − Pregnancy or lactation *(PUVA only)* − Lupus Erythematosus − History of one of the following: photosensitivity diseases (e.g., chronic actinic dermatitis, solar urticaria), melanoma, non-melanoma skin cancer, extensive solar damage *(PUVA only)*, or treatment with arsenic or ionizing radiation − Immunosuppression in an organ transplant patient *(UVB only)* − Photosensitizing medications *(PUVA only)* − Severe liver, renal, or cardiac disease *(PUVA only)* − Young age < 12 years old *(PUVA only)* − Anatomical location has been deemed ineligible for phototherapy (i.e., face, genital, scalp, or nail)
Note: Patients who do not have access to phototherapy will be reviewed on a case-by-case basis

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
57894-0651-04	Tremfya Pen Induction pack Two 200mg/2mL prefilled pens

ICD-10 Diagnoses

Code	Description
K50.00	Crohn's disease of small intestine without complications
K50.011	Crohn's disease of small intestine with rectal bleeding
K50.012	Crohn's disease of small intestine with intestinal obstruction
K50.013	Crohn's disease of small intestine with fistula
K50.014	Crohn's disease of small intestine with abscess
K50.018	Crohn's disease of small intestine with other complication
K50.019	Crohn's disease of small intestine with unspecified complications
K50.10	Crohn's disease of large intestine without complications
K50.111	Crohn's disease of large intestine with rectal bleeding
K50.112	Crohn's disease of large intestine with intestinal obstruction
K50.113	Crohn's disease of large intestine with fistula
K50.114	Crohn's disease of large intestine with abscess
K50.118	Crohn's disease of large intestine with other complication
K50.119	Crohn's disease of large intestine with unspecified complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.811	Crohn's disease of both small and large intestine with rectal bleeding
K50.812	Crohn's disease of both small and large intestine with intestinal obstruction
K50.813	Crohn's disease of both small and large intestine with fistula
K50.814	Crohn's disease of both small and large intestine with abscess
K50.818	Crohn's disease of both small and large intestine with other complication
K50.819	Crohn's disease of both small and large intestine with unspecified complications
K50.90	Crohn's disease, unspecified, without complications
K50.911	Crohn's disease, unspecified, with rectal bleeding
K50.912	Crohn's disease, unspecified, with intestinal obstruction
K50.913	Crohn's disease, unspecified, with fistula
K50.914	Crohn's disease, unspecified, with abscess
K50.918	Crohn's disease, unspecified, with other complication
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
K51.40	Inflammatory Polyps Of Colon Without 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
K51.812	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

L40.0	Psoriasis vulgaris
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.59	Other psoriatic arthropathy

Revision History

Company(ies)	DATE	REVISION
EmblemHealth & ConnectiCare	5/9/2025	Update: Updated length of authorization and dosing limits. Initial Criteria: Added: "Plaque Psoriasis (PsO) † Documented moderate to severe plaque psoriasis for at least 6 months with at least ONE of the following: Involvement of at least 3% of body surface area (BSA); OR Psoriasis Area and Severity Index (PASI) score of 10 or greater; OR Incapacitation or serious emotional consequences due to plaque location (e.g., hands, feet, head and neck, genitalia, etc.) or with intractable pruritus; AND Patient meets ALL of the following ¥: Patient did not respond adequately (or is not a candidate) to a 4-week minimum trial of topical agents (i.e., anthralin, coal tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, tapinarof, roflumilast, retinoic acid derivatives, and/or vitamin D analogues); AND Patient did not respond adequately (or is not a candidate) to a 3-month minimum trial of at least ONE non-biologic systemic agent (i.e., immunosuppressives, retinoic acid derivatives, and/or methotrexate); AND Patient did not respond adequately (or is not a candidate*) to a 3-month minimum trial of phototherapy (i.e., psoralens with UVA light [PUVA] or UVB with coal tar or dithranol) *¥ Note: For patients already established on biologic therapy, targeted synthetic therapy, or those with > 10% BSA involvement, trial and failure of topical agents, non-biologic systemic agents, and phototherapy is not required.* Psoriatic Arthritis (PsA) † Documented moderate to severe active disease; AND For patients with predominantly axial disease OR enthesitis, a failure of at least a 4-week trial of ONE non-steroidal anti-inflammatory drug (NSAID), unless use is contraindicated; OR For patients with peripheral arthritis OR dactylitis, a failure of at least a 3-month trial of ONE conventional synthetic disease-modifying anti-rheumatic drug (csDMARD) (e.g., methotrexate, azathioprine, sulfasalazine, leflunomide, or hydroxychloroquine, etc.); OR Patient is already established on biologic or targeted synthetic therapy for the treatment of PsA; AND May be used as a single agent or in combination with csDMARD (e.g., methotrexate, etc.) Crohn's Disease (CD) † Documented moderate to severe active disease; AND Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of corticosteroids or immunomodulators (e.g. azathioprine, 6-mercaptopurine, or methotrexate); OR Documented failure, contraindication, or ineffective response at maximum tolerated doses to a minimum 3-month trial of a TNF modifier such (e.g., adalimumab, certolizumab, or infliximab); OR Patient has evidence of high-risk disease for which corticosteroids or immunomodulators are inadequate and biologic therapy is necessary; OR Patient is already established on biologic or targeted synthetic therapy for the treatment of CD" Updated NDCs and ICD-10 codes.
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.