Tremfya® (guselkumab)
(Intravenous/Subcutaneous)

Document Number: EOCCO-0310

Last Review Date: 04/07/2025
Date of Origin: 08/29/2017
Dates Reviewed: 08/2017, 04/2018, 08/2018, 08/2019, 08/2020, 08/2021, 08/2022, 08/2023, 10/2024, 03/2025, 04/2025

I. Length of Authorization

Ulcerative Colitis:

Initial coverage will be provided for 11 weeks (for 3 intravenous doses) as induction therapy and may be renewed annually thereafter for subcutaneous maintenance.

Crohn's Disease:

Initial coverage will be provided for 11 weeks (for 3 intravenous or subcutaneous doses) as induction therapy and may be renewed annually thereafter for subcutaneous maintenance.

All other indications:

Initial coverage will be provided for 6 months and may be renewed annually thereafter.

II. Dosing Limits

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

- **Plaque Psoriasis & Psoriatic Arthritis**
  - 100 billable units at weeks 0 & 4, then every 56 days
- **Ulcerative Colitis**
  - 200 billable units every 28 days
- **Crohn's Disease**
  - 400 billable units at weeks 0, 4, and 8, then 200 billable units every 28 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**
- Physician has assessed baseline disease severity utilizing an objective measure/tool; **AND**
- Patient is up to date with all age-appropriate vaccinations, in accordance with current vaccination guidelines, prior to initiating therapy; **AND**

Universal Criteria [1]

- 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**
- Patient does not have an active infection, including clinically important localized infections; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient is not on concurrent treatment with another biologic therapy or targeted synthetic therapy; **AND**

Plaque Psoriasis (PsO) † [1,11,21,22,28-30,32]

- 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) † [1,16,24,26,31,33]

- 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.)

Ulcerative Colitis (UC) † [1,37,38,44]

- Documented moderate to severe active disease; **AND**
  - 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**
  - 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**
  - Patient is already established on a biologic or targeted synthetic therapy for the treatment of UC

Crohn's Disease (CD) † [1,47-49]

- 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

***Examples of contraindications to phototherapy (PUVA or UVB) include the following: [12,13,30]**
– 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*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: clinically important infections, severe hypersensitivity reactions, etc.; **AND**

Plaque Psoriasis (PsO) [10,21,32,34]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as redness, thickness, scaliness, and/or the amount of surface area involvement (a total BSA involvement ≤ 1%), and/or an improvement on a disease activity scoring tool [e.g., Psoriasis Area and Severity Index (PASI) score ≤ 3, physician's global assessment (PGA) score ≤ 1, etc.].

Psoriatic Arthritis (PsA) [18,33,46]

- Disease response as indicated by improvement in signs and symptoms compared to baseline such as the number of tender and swollen joint counts, reduction of C-reactive protein, improvement of patient global assessment, improvement on imaging (X-ray, ultrasound, or MRI) and/or an improvement on a disease activity scoring tool.

Ulcerative Colitis (UC) [39-41,43,45]

- Patient is to start maintenance therapy and has received three 200 mg intravenous induction doses at weeks 0, 4 and 8.; **AND**
  - Patient has shown a beneficial disease response and/or no worsening of disease with an absence of unacceptable toxicity to the intravenous doses; **OR**
- Patient requires continuation of maintenance therapy; **AND**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as stool frequency, rectal bleeding, endoscopic activity, tapering or discontinuation of corticosteroid therapy, normalization of C-reactive protein (CRP) or fecal calprotectin (FC), and/or an improvement on a disease activity scoring tool.

Crohn's Disease (CD) [50,51]

- Patient is to start maintenance therapy and has received three 200 mg intravenous OR 400 mg subcutaneous induction doses at weeks 0, 4 and 8; **AND**
  - Patient has shown a beneficial disease response and/or no worsening of disease with an absence of unacceptable toxicity to the induction doses; **OR**
- Patient requires continuation of maintenance therapy; **AND**
  - Disease response as indicated by improvement in signs and symptoms compared to baseline such as endoscopic activity, number of liquid stools, presence and severity of abdominal pain, presence of abdominal mass, body weight regain, hematocrit, presence of extra-intestinal complications, use of anti-diarrheal drugs, tapering or discontinuation of corticosteroid therapy, improvement in biomarker levels [i.e., fecal calprotectin or serum C-reactive protein (CRP)], and/or an improvement on a disease activity scoring tool [e.g. an improvement on the Harvey-Bradshaw Index score, etc.].

V. Dosage/Administration [1]

Indication	Dose
Plaque Psoriasis & Psoriatic Arthritis	Administer 100 mg subcutaneously at Week 0, Week 4, and every 8 weeks thereafter.
Ulcerative Colitis	**Induction**: Administer 200 mg intravenously at Week 0, Week 4, and Week 8. **Maintenance:** • Administer 100 mg subcutaneously at Week 16, and every 8 weeks thereafter; **OR** • Administer 200 mg subcutaneously at Week 12, and every 4 weeks thereafter ***NOTE**: Use the lowest effective recommended dosage to maintain therapeutic response.*
Crohn's Disease	**Induction**: • Administer 200 mg intravenously at Week 0, Week 4, and Week 8; **OR** • Administer 400 mg (given as two consecutive injections of 200 mg each) subcutaneously at Week 0, Week 4, and Week 8 **Maintenance:** • Administer 100 mg subcutaneously at Week 16, and every 8 weeks thereafter; **OR** • Administer 200 mg subcutaneously at Week 12, and every 4 weeks thereafter ***NOTE**: Use the lowest effective recommended dosage to maintain therapeutic response.*

VI. Billing Code/Availability Information

HCPCS Code(s):

- J1628 – Injection, guselkumab, 1 mg; 1 billable unit = 1 mg

*(**Note**: CMS generally creates codes for products themselves, without specifying a route of administration in the code descriptor, as there might be multiple routes of administration for the same product. Drugs that fall under this category should be billed with either the JA modifier for the intravenous infusion of the drug or billed with the JB modifier for subcutaneous injection of the drug.)*

NDC(s):

- Subcutaneous
  - Tremfya 100 mg/mL single-dose prefilled syringe, prefilled pen, or One-Press injector: 57894-0640-xx
  - Tremfya 200 mg/2 mL single-dose prefilled pen or prefilled syringe: 57894-0651-xx
- Intravenous
  - Tremfya 200 mg/20 mL (10 mg/mL) single-dose vial: 57894-0650-xx

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 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

ICD-10	ICD-10 Description
K50.919	Crohn's disease, unspecified, with unspecified complications
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

ICD-10	ICD-10 Description
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

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC