Original Effective Date: 08/01/2018
Current Effective Date: 06/28/2025
Last P&T Approval/Version: 04/30/2025
Next Review Due By: 10/2025
Policy Number: C14612-A

Tremfya (guselkumab)

PRODUCTS AFFECTED

Tremfya (guselkumab)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Moderate to severe plaque psoriasis, Active psoriatic arthritis, Ulcerative Colitis, Crohn’s Disease

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:
1. Prescriber attests member does not have an active or latent untreated infection (e.g., Hepatitis B,

tuberculosis, etc.), including clinically important localized infections, according to the FDA label
AND

2. Member is not on concurrent treatment or will not be used in combination with TNF- inhibitor, biologic response modifier or other biologic DMARDs, Janus kinase Inhibitors, or Phosphodiesterase 4inhibitor (i.e., apremilast, tofacitinib, baricitinib) as verified by prescriber attestation, member medication fill history, or submitted documentation
AND
3. IF THIS IS A NON-FORMULARY/NON-PREFERRED PRODUCT: Documentation of trial/failure of or serious side effects to a majority (not more than 3) of the preferred formulary/PDL alternatives for the given diagnosis. Submit documentation including medication(s) tried, dates of trial(s) and reason for treatment failure(s).

B. CHRONIC PLAQUE PSORIASIS:

1. Documented diagnosis of moderate to severe psoriasis (BSA ≥ 3% OR < 3% body surface area with plaque psoriasis that involves sensitive areas of the body or areas that would significantly impact daily function (e.g., face, neck, hands, feet, genitals)
AND
2. (a) Documentation of treatment failure, serious side effects, or clinical contraindication to TWO of the following systemic therapies for ≥ 3 months: Methotrexate (oral or IM at a minimum dose of 15 mg/week), cyclosporine, acitretin, azathioprine, hydroxyurea, leflunomide, mycophenolate mofetil, or tacrolimus
OR
(b) Documentation of treatment failure to Phototherapy for ≥3 months with either psoralens with ultraviolet A (PUVA) or ultraviolet B (UVB) radiation (provider to submit documentation of duration of treatment, dates of treatment, and number of sessions; contraindications include type 1 or type 2 skin, history of photosensitivity, treatment of facial lesions, presence of premalignant lesions, history of melanoma or squamous cell carcinoma, or physical inability to stand for the required exposure time)
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

C. PSORIATIC ARTHRITIS (PsA):

1. Documentation of active psoriatic arthritis
AND
2. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]
AND
3. (a) Documented treatment failure serious side effects or clinical contraindication to a minimum 3-month trial of ONE of the following: Leflunomide, Methotrexate, Sulfasalazine, Cyclosporine
OR
(b) Documentation member has severe psoriatic arthritis [erosive disease, elevated markers of inflammation, long term damage that interferes with function, highly active disease that causes a major impairment in quality of life, active PsA at many sites including dactylitis, enthesitis, function-limiting PsA at a few sites or rapidly progressive disease]
OR
Documentation member has severe psoriasis [PASI ≥12, BSA of >5-10%, significant involvement in specific areas (e.g., face, hands or feet, nails, intertriginous areas, scalp), impairment of physical or mental functioning with lower amount of surface area of skin involved]
AND
4. Documentation of treatment failure, serious side effects or clinical contraindication to a trial (>3 months) of ONE FORMULARY OR PREFERRED TNF-inhibitor
NOTE: Contraindications to TNF treatment include congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease

D. ULCERATIVE COLITIS:
1. Documentation of ulcerative colitis diagnosis with evidence of moderate to severe disease activity
AND
2. (a) Documentation of treatment failure, serious side effects or clinical contraindication to a 2-month trial of one systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone, methylprednisolone) for ulcerative colitis or will continue to take concurrently
NOTE: A previous trial of a biologic (e.g., an adalimumab product [e.g., Humira], Simponi SC [golimumab SC injection], or Entyvio [vedolizumab IV infusion]) also counts as a trial of one systemic agent for UC.
OR
(b) Documentation the Member has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® (hydrocortisone enema, generics)], or topical mesalamine
AND
3. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

E. CROHN'S DISEASE:
1. Documentation of a diagnosis of Crohn's Disease
AND
2. Member has one or more high risk feature:
   i. Diagnosis at a younger age (<30 years old)
   ii. History of active or recent tobacco use
   iii. Elevated C-reactive protein and/or fecal calprotectin levels
   iv. Deep ulcers on colonoscopy
   v. Long segments of small and/or large bowel involvement
   vi. Perianal disease
   vii. Extra-intestinal manifestations
   viii. History of bowel resections
AND
3. (a) Documentation of treatment failure, serious side effects or clinical contraindication to an adequate trial (> 3 months) of ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine, methotrexate) up to maximally indicated doses
OR
(b) Prescriber provides documented medical justification that supports the inability to use immunomodulators
   i. Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
   ii. High-risk factors for intestinal complications may include: Initial extensive ileal, ileocolonic, or proximal GI involvement, Initial extensive perianal/severe rectal disease, Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas), Deep ulcerations, Penetrating, stricturing or stenosis disease and/or phenotype, Intestinal obstruction or abscess
   iii. High risk factors for postoperative recurrence may include: Less than 10 years duration between time of diagnosis and surgery, Disease location in the ileum and colon, Perianal fistula, Prior history of surgical resection, Use of corticosteroids prior to surgery
AND
4. Documentation of prescriber baseline disease activity evaluation and goals for treatment to be used to evaluate efficacy of therapy at renewal [DOCUMENTATION REQUIRED]

CONTINUATION OF THERAPY:

A. ALL INDICATIONS:
1. Adherence to therapy at least 85% of the time as verified by the prescriber or member medication

fill history OR adherence less than 85% of the time due to the need for surgery or treatment of an infection, causing temporary discontinuation
AND

2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
AND
3. Documentation of positive clinical response as demonstrated by low disease activity and/or improvements in the condition's signs and symptoms [DOCUMENTATION REQUIRED]
AND
4. Prescriber attests to ongoing monitoring for development of infection (e.g., tuberculosis, Hepatitis B reactivation, etc.) according to the FDA label

DURATION OF APPROVAL:
Initial authorization: 6 months, Continuation of Therapy: 12 months
MOLINA REVIEWER NOTE: For Texas Marketplace, please see Appendix.

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with a board-certified dermatologist, rheumatologist, gastroenterologist, or colorectal surgeon. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:
18 years of age and older

QUANTITY:
PLAQUE PSORIASIS, PSORIATIC ARTHRITIS: 100 mg via subcutaneous injection at week 0, week 4, and every 8 weeks thereafter. Max quantity allowed is one injection every 8 weeks during maintenance phase.
ULCERATIVE COLITIS: Induction: 200 mg via IV infusion at week 0, week 4, and week 8. Maintenance: 100 mg via subcutaneous injection at week 16 and every 8 weeks thereafter OR 200 mg via subcutaneous injection at week 12 and every 4 weeks thereafter.
CROHN'S DISEASE: Induction: 200 mg via IV infusion at week 0, week 4, and week 8 OR 400 mg via subcutaneous injection at week 0, week 4, and week 8. Maintenance: 100 mg via subcutaneous injection at week 16 and every 8 weeks thereafter OR 200 mg via subcutaneous injection at week 12 and every 4 weeks thereafter

PLACE OF ADMINISTRATION:
The recommendation is that injectable medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Subcutaneous, Intravenous

DRUG CLASS:
Antipsoriatics - Systemic

FDA-APPROVED USES:
Indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, active psoriatic arthritis,moderately to severely active ulcerative

colitis, and moderately to severely active Crohn's disease.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*

State Specific Information
State Marketplace
Texas (Source: Texas Statutes, Insurance Code)
"Sec. 1369.654. PROHIBITION ON MULTIPLE PRIOR AUTHORIZATIONS.
(a) A health benefit plan issuer that provides prescription drug benefits *may not require an enrollee to receive more than one prior authorization annually* of the prescription drug benefit for *a prescription drug prescribed to treat an autoimmune disease, hemophilia, or Von Willebrand disease*.
(b) This section does not apply to:
(1) opioids, benzodiazepines, barbiturates, or carisoprodol;
(2) prescription drugs that have a typical treatment period of less than 12 months;
(3) drugs that:
(A) have a boxed warning assigned by the United States Food and Drug Administration for use; and
(B) must have specific provider assessment; or
(4) the use of a drug approved for use by the United States Food and Drug Administration in a manner other than the approved use."

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tremfya (guselkumab) is a human monoclonal antibody that selectively targets interleukin-23 (IL-23), a key cytokine involved in the pathogenesis of several chronic inflammatory diseases. It was initially approved for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. It has also gained approval for psoriatic arthritis (PsA) and ulcerative colitis.

Guselkumab specifically binds to the p19 subunit of IL-23, inhibiting its interaction with the IL-23 receptor. This blockade downregulates the downstream signaling cascade responsible for Th17 cell differentiation and the subsequent production of pro-inflammatory cytokines like IL-17 and IL-22, which are critical in driving inflammation in psoriasis and psoriatic arthritis. Importantly, guselkumab does not affect IL-12, which shares the p40 subunit with IL-23, thus providing a more targeted approach compared to older biologics.

In clinical trials, Tremfya has demonstrated significant efficacy in achieving skin clearance in psoriasis patients, with a substantial proportion achieving Psoriasis Area and Severity Index (PASI) 90 and 100 responses. It has also shown favorable outcomes in PsA, with improvements in joint symptoms, physical function, and skin involvement. Tremfya has a generally well-tolerated safety profile. Common adverse events include upper respiratory infections, headache, and injection- site reactions. Serious infections and malignancies are infrequent but should be monitored, particularly in patients with a history of these conditions. Tremfya does not require laboratory monitoring.

Tremfya has been studied for safety and efficacy in the induction and maintenance of remission for ulcerative colitis and Crohn's disease. In the Phase 3 QUASAR Ulcerative Colitis Induction Study, 22.6% of patients receiving Tremfya achieved clinical remission at Week 12, compared to 7.9% in the placebo group ($p<0.001$). Additionally, 49.9% of Tremfya-treated patients achieved symptomatic remission by Week 12, versus 20.7% with placebo ($p<0.001$). The QUASAR Ulcerative colitis Maintenance Study

reported that 50.0% of patients receiving Tremfya 200 mg every four weeks and 45.2% receiving 100 mg every eight weeks achieved clinical remission at Week 44, compared to 18.9% with placebo (p<0.001). Furthermore, 33.7% and 34.6% of patients in the respective Tremfya groups achieved endoscopic remission, versus 15.3% with placebo (p<0.001). For Crohn's disease the Phase 3 GRAVITI study evaluated subcutaneous Tremfya induction therapy in patients with moderately to severely active CD. At Week 12, clinical remission rates were significantly higher in Tremfya-treated patients compared to placebo. Endoscopic response and remission rates were also notably improved with Tremfya. Adverse events were consistent with previous findings for Tremfya and the most common adverse events were COVID-19, anemia, and worsening UC.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Tremfya (guselkumab) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Tremfya (guselkumab) include: serious hypersensitivity reactions to guselkumab or to any of the excipients, avoid concurrent use of live vaccines.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all-inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
J1628	Injection, guselkumab, 1 mg

AVAILABLE DOSAGE FORMS:

Tremfya Crohns Induction SOAJ 200MG/2ML
Tremfya SOAJ 100MG/ML single-dose autoinjector
Tremfya SOAJ 200MG/2ML single-dose autoinjector
Tremfya SOLN 200MG/20ML single-dose vial
Tremfya SOSY 100MG/ML single-dose prefilled syringe
Tremfya SOSY 200MG/2ML single-dose prefilled syringe

REFERENCES

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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Required Medical Information Quantity FDA-Approved Uses Background References	Q2 2025
REVISION- Notable revisions: Coding/Billing Information Template Update Diagnosis Required Medical Information Continuation of Therapy Quantity Place of Administration Route of Administration FDA-Approved Uses Background Coding/Billing Information Available Dosage Forms References	Q4 2024

REVISION- Notable revisions: Required Medical Information Continuation of Therapy Available Dosage Forms	Q4 2023
REVISION- Notable revisions: Diagnosis Required Medical Information Continuation of Therapy FDA-Approved Uses Contraindications/Exclusions/Discontinuation References	Q4 2022
Q2 2022 Established tracking in new format	Historical changes on file