Effective Date: 2/2020
Reviewed: 12/2019, 7/2020, 12/2020, 5/2021, 4/2022, 7/2022, 12/2022, 8/2023, 2/2024, 12/2024, 1/2025, 5/2025, 8/2026 Pharmacy Scope (SC): Medicaid Medical Scope (IV): Medicaid, Commercial, Medicare

TREMFYA (guselkumab)
(Intravenous/Subcutaneous)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tremfya SC:

- Treatment of moderate-to-severe plaque psoriasis in adult and pediatric patients 6 years of age and older who weigh 40 kg or greater and are candidates for systemic therapy or phototherapy
- Treatment of active psoriatic arthritis in adult and pediatric patients 6 years of age and older who weigh 40 kg or greater
- Treatment of moderately to severely active ulcerative colitis (UC) in adults
- Treatment of moderately to severely active Crohn's disease (CD) in adults

Tremfya IV:

- Treatment of moderately to severely active ulcerative colitis (UC) in adults
- Treatment of moderately to severely active Crohn's disease (CD) in adults

All other indications are considered experimental/investigational and are not a covered benefit.

II. LENGTH OF AUTHORIZATION

a. **Tremfya SC**
   i. Initial and renewal requests are approved for 12 months for moderate-to-severe plaque psoriasis and active psoriatic arthritis
   ii. Initial and renewal requests are approved for up to 12 months for maintenance dosing of UC and CD

b. **Tremfya IV**
   i. Coverage will be provided once (one time induction doses) for Tremfya for 8 weeks for UC and CD

**** For members that meet criteria, Tremfya 100mg (subcutaneous dose) will be approved for week 16, and then every 8 weeks for 10 months for Medicaid and Commercial ONLY****

Neighborhood Health Plan OF RHODE ISLAND™

Effective Date: 2/2020
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III. SUMMARY OF EVIDENCE

Tremfya is an interleukin-23 antagonist 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 moderate to severe Crohn's disease. Four randomized, double-blind, multicenter trials (PsO1, PsO2, PsO3, PsO4) assessed the efficacy of Tremfya in moderate-to-severe plaque psoriasis. PsO1 and PsO2 enrolled 1443 subjects, comparing Tremfya (100 mg at Weeks 0, 4, then every 8 weeks) to placebo and adalimumab. Co-primary endpoints included achieving an IGA score of 0 or 1 and PASI 90 response at Week 16. Secondary endpoints included comparisons between Tremfya and adalimumab at Week 16, 24, and 48. At Week 16, Tremfya demonstrated superior efficacy, including significant improvements in psoriasis symptoms and scalp involvement. PsO3 (268 subjects) evaluated Tremfya in patients with inadequate response to ustekinumab, showing greater improvements in IGA scores compared to continued ustekinumab. PsO4 (78 subjects) showed that Tremfya administered with a One-Press injector was more effective than placebo, with 56% achieving IGA 0 and 50% achieving PASI 100 at Week 16. In psoriatic arthritis (PsA1, PsA2), 1120 adults were randomized to receive TR Tremfya or placebo, with the primary endpoint being ACR20 response at Week 24. Tremfya showed significant improvement in both clinical and physical function outcomes, including improvements in skin manifestations and enthesitis. For ulcerative colitis, the UC1 induction trial (701 subjects) showed that Tremfya 200 mg induced greater clinical remission and endoscopic improvement compared to placebo, with significant reductions in rectal bleeding and stool frequency. The UC2 maintenance trial (568 subjects) evaluated the efficacy of Tremfya 100 mg every 8 weeks or 200 mg every 4 weeks, showing sustained clinical remission at Week 44. Tremfya was assessed in three randomized, double-blind, placebo-controlled trials that enrolled adult subjects with moderately to severely active Crohn's disease who had a history of inadequate response, loss of response, or intolerance to oral corticosteroids, immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and/or biologic therapy (TNF blockers or vedolizumab). In CD1 & CD2 721 subjects were randomized to receive intravenous Tremfya 200 mg at Weeks 0, 4, and or placebo. In CD1 & CD2 clinical remission was reached in 47% of patients treated with Tremfya in both studies by week 12. Tremfya Common adverse reactions include gastroenteritis, bronchitis, arthralgia and upper respiratory tract infections.

IV. CRITERIA FOR INITIAL APPROVAL

For all Indications:

- Submission of the member's chart or medical record is required, documenting medical necessity based on the criteria corresponding to the applicable indication; AND
- Physician has assessed baseline disease severity utilizing an objective measure/tool; AND
- Member is free of any clinically important active infection, including clinically important, localized infections; AND
- Member 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
- Member will not receive live vaccines during therapy; AND
- Tremfya will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., adalimumab (e.g., Hadlima), Enbrel (etanercept), infliximab (e.g., Inflectra), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Otulfi, Selarsdi, Steqeyma, Yesintek, etc.), Icotyde (icotrokinra), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-

biologic agent (e.g., Otezla (apremilast), tofacitinib (Xeljanz), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.) ; AND

- Only one formulation of Tremfya (guselkumab) will be used (intravenous or subcutaneous); AND
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

A. Moderate to severe plaque psoriasis

Authorization of 12 months may be granted for treatment of moderate to severe plaque psoriasis when all of the following criteria are met:

1. Member is 6 years of age or older and weighs at least 40 kg; AND
2. Prescribed by, or in consultation with, a specialist in dermatology; AND
3. Documentation has been submitted of one or more of the following:
    a. BSA affected is at least 10%; OR
    b. Crucial body areas affected (e.g., face, hands, feet, genitals, scalp); OR
    c. Inadequate treatment response to topical therapy (corticosteroids, calcineurin inhibitors (e.g. tacrolimus), vitamin D analogs (e.g. calcipotriene), retinoids (e.g. tazarotene); AND
4. Documentation has been submitted that member meets any of the following criteria:
    a. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of a conventional oral agent for PsO (e.g., methotrexate, cyclosporine or acitretin); OR
    b. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of phototherapy (e.g., UVB, PUVA); OR
    c. Clinical rationale has been provided indicating member's disease severity warrants a biologic DMARD as first-line therapy; AND
5. Documentation has been submitted that the member meets either of the following criteria:
    a. If member is 18 years of age or older, member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; OR
    b. If member is 6 years of age or older but under 18, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of moderate to severe psoriatic arthritis when all of the following criteria are met:

1. Member is 6 years of age or older and weighs at least 40 kg; AND
2. Prescribed by, or in consultation with, a specialist in dermatology or rheumatology; AND
3. Documentation has been submitted indicating one of the following:
    a. Member has mild to moderate disease and meets one of the following criteria:
        i. Member has had an inadequate response, intolerance, or contraindication to methotrexate or another conventional synthetic DMARD (e.g., leflunomide, sulfasalazine, etc.); OR
        ii. Member has enthesitis or predominantly axial disease; OR
    b. Member has severe disease; AND
4. If member is 18 years of age or older, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 3-month trial of adalimumab at

maximum tolerated doses AND a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

5. If member is 6 years of age or older but under 18, documentation has been submitted that the member has had an inadequate response, intolerance or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses.

C. Moderately to Severely Active Ulcerative Colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by or in consultation with a gastroenterologist; AND
3. Member has documented moderate to severe UC; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; AND
5. If the member is requesting therapy with Tremfya SC for induction doses the provider must submit medical rationale for the patient not being able to receive Tremfya IV

D. Moderately to severely active Crohn's disease (CD)

Authorization of 12 months may be granted for treatment of moderate to severe active Crohn's disease when all of the following criteria are met:

1. Member is 18 years of age or older; AND
2. Prescribed by, or in consultation with, a specialist in gastroenterology; AND
3. Member has documented moderate to severe disease; AND
4. Documentation has been submitted that the member has had an inadequate response, intolerance, or contraindication to at least 3-month trial of infliximab IV or adalimumab AND at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses; AND
5. If the member is requesting therapy with Tremfya SC for induction doses the provider must submit medical rationale for the patient not being able to receive Tremfya IV

V. CONTINUATION OF THERAPY

A. Moderate to severe plaque psoriasis (PsO)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderate to severe plaque psoriasis and who achieve or maintain positive clinical response as evidenced by low disease activity (e.g., reduction in BSA from baseline), or improvement in signs and symptoms of the condition (e.g., itching, redness, flaking scaling, burning, cracking, pain)

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for active psoriatic arthritis and who achieve or maintain positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:

1. Number of swollen joints
2. Number of tender joints
3. Dactylitis
4. Enthesitis
5. Axial disease
6. Skin and/or nail involvement
7. Functional status
8. C-reactive protein (CRP)

C. Moderate to Severely Active Ulcerative Colitis (UC)

Tremfya 100mg every 56 days

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and chart notes or medical record documentation is provided supporting achievement or maintenance of remission or a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Stool frequency
    b. Rectal bleeding
    c. Urgency of defecation
    d. C-reactive protein (CRP)
    e. Fecal calprotectin (FC)
    f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)

Tremfya 200mg every 28 days

1. Authorization of 6 months may be granted on a case-by-case basis for all members (including new members) who are using the requested medication for moderately to severely active ulcerative colitis and chart notes or medical record documentation is provided supporting achievement or maintenance of remission or a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Stool frequency
    b. Rectal bleeding
    c. Urgency of defecation
    d. C-reactive protein (CRP)
    e. Fecal calprotectin (FC)
    f. Appearance of the mucosa on endoscopy, computed tomography enterography (CTE), magnetic resonance enterography (MRE), or intestinal ultrasound
    g. Improvement on a disease activity scoring tool (e.g., Ulcerative Colitis Endoscopic Index of Severity [UCEIS], Mayo score)
2. If the request is for Tremfya 200mg/2ml every 4 weeks, the provider has submitted medical rationale / documentation of inadequate clinical response for increased dose and frequency after at least 24 weeks of starting therapy; OR

3. If the request is to continue higher dose of Tremfya 200mg/2ml every 4 weeks, the provider has submitted documentation of a clinically meaningful incremental benefit from the previous lower dose 100mg every 8 weeks

D. Moderately to severely active Crohn's disease (CD)

Tremfya 100mg every 56 days

1. Authorization of 12 months may be granted for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and chart notes or medical record documentation is provided supporting achievement or maintenance of remission or a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Abdominal pain or tenderness
    b. Diarrhea
    c. Body weight
    d. Abdominal mass
    e. Hematocrit
    f. Endoscopic appearance of the mucosa
    g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)

Tremfya 200mg every 28 days

1. Authorization of 6 months may be granted on a case-by-case basis for all members (including new members) who are using the requested medication for moderately to severely active Crohn's disease and chart notes or medical record documentation is provided supporting achievement or maintenance of remission or a positive clinical response as evidenced by low disease activity or improvement in signs and symptoms of the condition when there is improvement in any of the following from baseline:
    a. Abdominal pain or tenderness
    b. Diarrhea
    c. Body weight
    d. Abdominal mass
    e. Hematocrit
    f. Endoscopic appearance of the mucosa
    g. Improvement on a disease activity scoring tool (e.g., Crohn's Disease Activity Index [CDAI] score)
2. If the request is for Tremfya 200mg/2ml every 4 weeks, the provider has submitted medical rationale / documentation of inadequate clinical response for increased dose and frequency after at least 24 weeks of starting therapy; OR
3. If the request is to continue higher dose of Tremfya 200mg/2ml every 4 weeks, the provider has submitted documentation of a clinically meaningful incremental benefit from the previous lower dose 100mg every 8 weeks

VI. DOSING/ QUANTITY LIMIT

A. Pharmacy Quantity Limit for Tremfya SC

- Tremfya 100mg/ml has a quantity limit of 1 prefilled syringe/pen per 56 days (daily dose of 0.02)
    - For plaque psoriasis and psoriatic arthritis, a quantity limit exception will be provided for the initial 2 loading doses of 200mg (2ml) per month.

- Tremfya 200mg/2ml has a quantity limit of 1 prefilled syringe/ pen per 28 days (daily dose of 0.072)
    - For Crohn's disease and ulcerative colitis, a quantity limit exception may be provided on a case-by-case basis for the initial 3 loading doses (2 doses of 400mg the first month [daily dose of 0.29], and 1 dose of 400mg the 2*nd* month [daily dose of 0.143] only if the provider has submitted medical rationale for not being able to receive IV induction.

B. Dosing for Tremfya SC and IV

Indication	Dose	Max units (1 unit = 1mg)
Plaque Psoriasis & Psoriatic Arthritis	Induction: • 100mg SC at week 0, week 4, and then every 8 weeks thereafter Maintenance: • 100mg every 56 days	Induction: 100 billable units at weeks 0 & 4, then 100 billable units every 56 days Maintenance: 100 billable units every 56 days
Ulcerative Colitis	Induction: • 200mg administered by intravenous infusion at week 0, week 4, and week 8 OR • 400 mg administered by subcutaneous injection (given as two consecutive injections of 200 mg each) at Week 0, Week 4, and Week 8. • Maintenance: • 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, OR • 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. • Use the lowest effective recommended dosage to maintain therapeutic response.	Induction (IV): 200 billable units week 0, week 4, and week 8 (SC): 400 billable units week 0, week 4, and week 8 Maintenance (SC): 100 units at week 16, then every 56 days OR 200 units at week 12, and every 4 weeks thereafter
Crohn's disease	Induction:	Induction

	• 200mg administered by intravenous infusion at week 0, week 4, and week 8 OR • 400mg administered by subcutaneous injection at week 0, week 4, and week 8 Maintenance: • 100 mg administered by subcutaneous injection at Week 16, and every 8 weeks thereafter, OR • 200 mg administered by subcutaneous injection at Week 12, and every 4 weeks thereafter. • Use the lowest effective recommended dosage to maintain therapeutic response.	IV: 200 billable units week 0, week 4, and week 8 OR SC: 400 billable units week 0, week 4, and week 8 Maintenance (SC): 100 units at week 16, then every 56 days OR 200 units at week 12, and every 4 weeks thereafter

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

Policy Rationale: Tremfya was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Tremfya according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

The following HCPCS/CPT codes are:

HCPCS/CPT codes	Description
J1628	Injection, guselkumab, 1mg

VII. REFERENCES

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; September 2025. Accessed May 2026.
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3. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 6: Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. *J Am Acad Dermatol.* 2011;65(1):137-174.
4. Reich K, Armstrong, AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator–controlled VOYAGE 2 trial. *Am J Clin Dermatol.* 2017;76(3):418-431.
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