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 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 adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy
- Treatment of adult patients with active psoriatic arthritis
- Treatment of adults with moderately to severely active ulcerative colitis (UC)
- Treatment of adults with moderately to severely active Crohn's disease (CD)

Tremfya IV:

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

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****

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III. CRITERIA FOR INTIAL AND RENEWAL CRITERIA

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

IV. 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. Tremyfya 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.

V. CRITERIA FOR INITIAL APPROVAL

For all Indications:

- Tremfya will not be used concomitantly with an injectable biologic response modifier including TNF-inhibitors (e.g., Humira/Hadlima (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, , , Otulfi, Selarsdi, Steqeyma, Yesintek etc.), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla

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(apremilast), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), etc.) ; AND

- Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SPOT.TB). *[Note: Members who have received Tremfya or any other biologic DMARD or targeted synthetic DMARD (e.g., Xeljanz) are exempt from requirements related to TB screening in this Policy.]*
- Member does not have an active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy.
- Only one formulation of Tremfya (guselkumab) will be used (intravenous or subcutaneous)
- 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 for members who are 18 years of age or older when all of the following criteria are met:

1. Tremfya will be is prescribed by, or in consultation with, a specialist in dermatology
2. Documentation that the member has at least 10% of body surface area (BSA) is affected OR crucial body areas (e.g., hands, feet, face, neck, scalp, genitals/groin, intertriginous areas) are affected.
3. Documentation that the member meets either of the following criteria:
    a. Member has had an inadequate response to at least a 3-month trial of methotrexate, cyclosporine or acitretin, or experienced clinically significant adverse effects from methotrexate, cyclosporine or acitretin
    b. Member has had an inadequate response to at least a 3-month trial of phototherapy (e.g., UVB, PUVA), unless intolerance experienced
4. Documentation that the 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.

B. Active psoriatic arthritis (PsA)

Authorization of 12 months may be granted for treatment of moderate to severe psoriatic arthritis for members who are 18 years of age or older when all of the following criteria are met:

1. Tremfya is prescribed by, or in consultation with, a specialist in dermatology or rheumatology.
2. Documented moderate to severe active disease
3. Documentation that the 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.

C. Moderately to Severely Active Ulcerative Colitis (UC)

Authorization of 12 months may be granted for treatment of moderately to severely active ulcerative colitis for members who are 18 years of age or older when all of the following criteria are met:

1. This medication must be prescribed by or in consultation with a gastroenterologist.
2. Documented moderate to severe UC
3. Member has had an inadequate response, intolerance, or contraindication to at least 3-month trial of infliximab IV or adalimumab at maximum tolerated doses.
4. Member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar

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 in members who are 18 years of age or older when all of the following criteria are met:

1. Prescribed by, or in consultation with, a specialist in gastroenterology
2. Documented moderate to severe disease
3. Member has had an inadequate response, intolerance, or contraindication to at least a 3-month trial of infliximab IV or adalimumab at maximum tolerated doses
4. Member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab biosimilar at maximum tolerated doses
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

VI. 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 or improvement in signs and symptoms of the condition when any of the following is met:

1. Reduction in body surface area (BSA) affected from baseline
2. Improvement in signs and symptoms from baseline (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. Skin and/or nail involvement

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

VII. 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, 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 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 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: • 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.	Induction 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

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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

VIII. REFERENCES

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