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 Pharmacy Scope (SC): Medicaid Medical Scope (IV): Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

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)

Tremfya IV:

- Treatment of adults with moderately to severely active ulcerative colitis (UC)

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

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

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

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IV. 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 (adalimumab), Enbrel (etanercept), Remicade (infliximab), etc.) and IL-inhibitors (e.g., Cosentyx (secukinumab), ustekinumab (e.g., Stelara, Wezlana, etc.), Ilumya (tildrakizumab), Skyrizi (risankizumab), Bimzelx (bimekizumab), etc.) or other oral non-biologic agent (e.g., Otezla (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.];* AND
- Member does not have an active infection, including clinically important localized infections; AND
- Member will not receive live vaccines during therapy; AND
- Only one formulation of Tremfya (guselkumab) will be used (intravenous or subcutaneous)

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 at maximum tolerated doses.

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 and documentation that the member meets either of the following criteria:
    a. If member has predominantly axial disease or active enthesitis and/or dactylitis, member has experienced an inadequate response or intolerance to at least two non-steroidal anti-inflammatory drugs (NSAIDs), unless use is contraindicated
    b. If member has peripheral arthritis, member has experienced an inadequate response to a ≥ 3 consecutive month trial a trial of one oral disease-modifying anti-rheumatic agent (DMARD) such as methotrexate, azathioprine, sulfasalazine, or hydroxychloroquine, unless intolerance experienced
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 at maximum tolerated doses.

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. Documentation that the 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. Documentation that the member has had an inadequate response, intolerance, or contraindication to at least a 6-month trial of ustekinumab

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 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 4 weeks

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

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)

B. Dosing for Tremfya SC and IV

Indication	Dose	Max units (1 unit = 1mg)
Plaque Psoriasis & Psoriatic Arthritis	• 100mg SC at week 0, week 4, and then every 8 weeks thereafter	100 billable units at weeks 0 & 4, then every 56 days
Ulcerative Colitis	Induction:	Induction (IV): 200 billable units week 0, week 4, and week 8

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	• 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.	Maintenance (SC): 100 units at week 16, then every 56 days OR 200 units at week 12, and every 4 weeks thereafter

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.; November 2024.
2. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 4: Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. *J Am Acad Dermatol.* 2009;61:451-485.
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.
5. Blauvelt A, Papp KA, Griffiths, CEM, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *Am J Clin Dermatol.* 2017;76(3):405-417.

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