MEDICAL MUTUAL®

Drug Policy

Policy:	**201731**	**Initial Effective Date: 07/24/2017**
Code(s):	**HCPCS J1628**	**Annual Review Date: 05/18/2023**
SUBJECT:	**Tremfya ® (guselkumab for subcutaneous injection)**	**Last Revised Date: 05/18/2023**

☒Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

Initial and renewal requests for the medication(s) listed in this policy are subject to site of care management. When billed under the medical benefit, administration of the medication will be restricted to a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) unless the member meets the site of care exception criteria. To view the exception criteria and a list of medications subject to site of care management please click here.

OVERVIEW

Tremfya is a fully human immunoglobulin (Ig)G monoclonal antibody that binds to interleukin (IL)-23, a pro-inflammatory cytokine. It binds to the p19 subunit of IL-23 and inhibits the intracellular and downstream signaling of IL-23 which is required for the terminal differentiation and survival of T helper (Th)17 cells. Tremfya is indicated for treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In plaque psoriasis, the recommended dose is 100 mg subcutaneously (SC) at Weeks 0 and 4 and then once every 8 weeks (Q8W) thereafter. Tremfya is intended for use under the guidance and supervision of a physician. Those trained in SC injection technique using the pen or prefilled syringe may self-inject when deemed appropriate.

POLICY STATEMENT

This policy involves the use of Tremfya. Prior authorization is recommended for medical benefit coverage of Tremfya. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tremfya as well as the monitoring required for AEs and long-term efficacy, initial approval requires Tremfya be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy

unless otherwise noted below. **Tremfya is subject to the Inflammatory Conditions Care Value Program under pharmacy benefits.**

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Tremfya is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1) **Plaque Psoriasis.**
   A. Initial Therapy. Approve if the patient meets the following criteria (i, ii, iii and iv):
      i. The patient is an adult ≥ 18 years of age; AND
      ii. The patient meets ONE of the following conditions (a, b or c):
         a) The patient has tried at least at least one traditional systemic agent for psoriasis (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.
         b) The patient has had a 3-month trial or previous intolerance to at least one biologic [See Appendix A for examples]; OR
         c) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND
      iii. Tremfya is prescribed by or in consultation with a dermatologist; AND
      iv. Site of care medical necessity is met.*

   B. Patient is Currently Receiving Tremfya. Approve for 1 year if the patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Tremfya. Site of care medical necessity is met.*

Dosing of plaque psoriasis: SubQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter

Initial Approval/ Extended Approval.
A) *Initial Approval:*3 months (90 days)
B) *Extended Approval:* 1 year (365 days)

2) **Psoriatic Arthritis**
   A. Initial Therapy. Approve if the patient meets the following criteria:
      i. Tremfya is prescribed by or in consultation with a rheumatologist or a dermatologist; AND
      ii. Site of care medical necessity is met.*

   B. Patient is Currently Receiving Tremfya. Approve for if the patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Tremfya. Site of care medical necessity is met.*

Dosing of Psoriatic Arthritis: SubQ: 100 mg at weeks 0, 4, and then every 8 weeks thereafter

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Initial Approval/ Extended Approval.
A) *Initial Approval:*6 months (180 days)
B) *Extended Approval:* 1 year (365 days)

Waste Management for All Indications.
Available as a Solution Prefilled Syringe, Subcutaneous [preservative free]:

Tremfya: 100 mg/mL (1 mL) [contains polysorbate 80]

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tremfya has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Tremfya should not be administered in combination with another biologics or with a targeted synthetic DMARD for an inflammatory condition. Combination therapy is generally not recommended due to a potential for a higher rate of adverse effects with combinations and lack of additive efficacy. Note: This does NOT exclude the use of MTX (a traditional systemic agent used to treat psoriasis) in combination with Tremfya.
2. **Concurrent use with Otezla.** There is no evidence to suggest Tremfya and Otezla in combination

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Tremfya™ injection [prescribing information]. Horsham, PA: Janssen Biotech; April 2019.
2. Blauvelt A, Papp KA, Griffiths CE, 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. *J Am Acad Dermatol*. 2017;76(3):405-417.
3. 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. *J Am Acad Dermatol*. 2017;76(3):418-431.
4. Hsu S, Papp KA, Lebwohl MG, et al. Consensus guidelines for the management of plaque psoriasis. *Arch Dermatol*. 2012;148(1):95-102.

5. Furst DE, Keystone EC, So AK, et al. Updated consensus statement on biological agents for the treatment of rheumatic diseases, 2012. *Ann Rheum Dis*. 2013;72 Suppl 2:ii2-34.
6. Otezla® tablets [prescribing information]. Summit, NJ: Celgene Corporation; December 2015.

Prior approval is required for HCPCS Codes C9029, J3590

†When *unclassified biologics* (J3590) is determined to be Tremfya

Edits and Denials:

Prior approval: Prior approval is required for Tremfya **(HCPCS Code J1628)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes Code J1628** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J1628	Injection, guselkumab, 1 mg (Tremfya) (Effective date 1/1/2019)

Appendix A

	Mechanism of Action	**Examples of Inflammatory Indications***
Biologics		
Adalimumab SC Products (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
Cimzia® (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
Etanercept SC Products (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
Infliximab IV Products (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
Simponi®, Simponi® Aria™ (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC
		IV formulation: AS, PJIA, PsA, RA
Actemra® (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA
		IV formulation: PJIA, RA, SJIA

Kevzara® (sarilumab SC injection)	Inhibition of IL-6	RA
Orencia® (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA
		IV formulation: JIA, PsA, RA
Rituximab IV Products (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
Kineret® (anakinra SC injection)	Inhibition of IL-1	JIA^, RA
Stelara® (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC
		IV formulation: CD, UC
Siliq™ (brodalumab SC injection)	Inhibition of IL-17	PsO
Cosentyx® (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
Taltz® (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
Ilumya™ (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
Skyrizi® (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO
		IV formulation: CD
Tremfya™ (guselkumab SC injection)	Inhibition of IL-23	PsO
Entyvio™ (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
Oral Therapies/Targeted Synthetic DMARDs		
Otezla® (apremilast tablets)	Inhibition of PDE4	PsO, PsA
Cibinqo™ (abrocitinib tablets)	Inhibition of JAK pathways	AD
Olumiant® (baricitinib tablets)	Inhibition of JAK pathways	RA
Rinvoq® (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
Xeljanz® (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
Xeljanz® XR (tofacitinib extended-release tablets)	Inhibition of JAK pathways	RA, PsA, UC

* Not an all-inclusive list of indications (e.g., oncology indications and rare inflammatory conditions are not listed). Refer to the prescribing information for the respective agent for FDA-approved indications; SC – Subcutaneous; TNF – Tumor necrosis factor; AS – Ankylosing spondylitis; CD – Crohn's disease; JIA – Juvenile idiopathic arthritis; PsO – Plaque psoriasis; PsA – Psoriatic arthritis; RA – Rheumatoid arthritis; UC – Ulcerative colitis; nr-axSpA – Non-radiographic axial spondyloarthritis; IV – Intravenous, PJIA – Polyarticular juvenile idiopathic arthritis; IL – Interleukin; SJIA – Systemic juvenile idiopathic arthritis; ^ Off-label use of Kineret in JIA supported in guidelines; ERA – Enthesitis-related arthritis; DMARD – Disease-modifying antirheumatic drug; PDE4 – Phosphodiesterase 4; JAK – Janus kinase; AD – Atopic dermatitis.