



## Utilization Review Policy 208

**POLICY:** Inflammatory Conditions – Tremfya™ (guselkumab for subcutaneous injection– Janssen Biotech/Johnson & Johnson)

**EFFECTIVE DATE:** 1/1/2020

**LAST REVISION DATE:** 08/03/2022

**COVERAGE CRITERIA FOR:** All UCare Plans

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### OVERVIEW

Tremfya, an interleukin (IL)-23 blocker, is indicated for the following uses:<sup>1</sup>

- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease (given ± a conventional synthetic disease-modifying antirheumatic drug).

### Guidelines

IL blockers are mentioned in guidelines for treatment of inflammatory conditions.

- **Plaque Psoriasis:** Joint guidelines from the American Academy of Dermatology and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.<sup>2</sup> These guidelines list Tremfya as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. It is recommended that a response to therapy be ascertained after 12 weeks of continuous therapy. Guidelines from the European Dermatology Forum (2015) recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara® [ustekinumab subcutaneous injection]) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.<sup>3</sup>
- **Psoriatic Arthritis:** Guidelines from the American College of Rheumatology/National Psoriasis Foundation (2018) were published prior to approval of Tremfya for psoriatic arthritis. However, these guidelines generally recommend tumor necrosis factor inhibitors as the first-line treatment strategy over other biologics (e.g., IL-17 blockers, IL-12/23 inhibitor) with differing mechanisms of action.<sup>4</sup>

### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tremfya. Because of the specialized skills required for evaluation and diagnosis of patients treated with Tremfya as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tremfya to be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals are for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

**Automation:** None.

### RECOMMENDED AUTHORIZATION CRITERIA

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Coverage of Tremfya is recommended in those who meet one of the following criteria:

### FDA-Approved Indications

1. **Plaque Psoriasis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) **Initial Therapy.** Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient is  $\geq$  18 years of age; AND
    - ii. Patient meets ONE of the following conditions (a or b):
      - a) Patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant; OR  
Note: Examples include methotrexate, cyclosporine, acitretin, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic other than the requested drug. A biosimilar of the requested biologic does not count. Refer to [Appendix](#) for examples of biologics used for psoriasis. A patient who has already tried a biologic for psoriasis is not required to “step back” and try a traditional systemic agent for psoriasis.
      - b) Patient has a contraindication to methotrexate, as determined by the prescriber; AND
    - iii. The requested agent is prescribed by or in consultation with a dermatologist.
  - B) **Patient is Currently Receiving Tremfya.** Approve for 1 year if the patient meets ALL of the following (i, ii, and iii):
    - i. Patient has been established on the requested drug for at least 90 days; AND  
Note: A patient who has received < 90 days of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
    - ii. Patient experienced a beneficial clinical response, defined as improvement from baseline (prior to initiating the requested drug) in at least one of the following: estimated body surface area, erythema, induration/thickness, and/or scale of areas affected by psoriasis; AND
    - iii. Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as decreased pain, itching, and/or burning.
2. **Psoriatic Arthritis.** Approve for the duration noted if the patient meets ONE of the following (A or B):
  - A) **Initial Therapy.** Approve for 6 months if Tremfya is prescribed by or in consultation with a rheumatologist or a dermatologist.
  - B) **Patient is Currently Receiving Tremfya.** Approve for 1 year if the patient meets BOTH of the following (i and ii):
    - i. Patient has been established on the requested drug for at least 6 months; AND  
Note: A patient who has received < 6 months of therapy or who is restarting therapy with the requested drug is reviewed under criterion A (Initial Therapy).
    - ii. Patient meets at least one of the following (a or b):
      - a) When assessed by at least one objective measure, patient experienced a beneficial clinical response from baseline (prior to initiating the requested drug); OR  
Note: Examples of objective measures of disease activity include Disease Activity Index for Psoriatic Arthritis (DAPSA), Composite Psoriatic Disease Activity Index (CPDAI), Psoriatic Arthritis Disease Activity Score (PsA DAS), Grace Index, Leeds Enthesitis Score (LEI), Spondyloarthritis Consortium of Canada (SPARCC) enthesitis score, Leeds Dactylitis Instrument Score, Minimal Disease Activity (MDA), Psoriatic Arthritis Impact of Disease (PsAID-12), and/or serum markers (e.g., C-reactive protein, erythrocyte sedimentation rate).

- b) Compared with baseline (prior to initiating the requested drug), patient experienced an improvement in at least one symptom, such as less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths.

**CONDITIONS NOT RECOMMENDED FOR APPROVAL**

Coverage of Tremfya is not recommended in the following situations:

1. **Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs).** Data are lacking evaluating concomitant use of Tremfya in combination with another biologic or with a targeted synthetic DMARD for an inflammatory condition (see [Appendix](#) for examples). Combination therapy with biologics and/or biologics + targeted synthetic DMARDs has a potential for a higher rate of adverse effects and lack controlled trial data in support of additive efficacy.  
Note: This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Tremfya.
2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**REFERENCES**

1. Tremfya® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson July 2020.
2. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. *J Am Acad Dermatol.* 2019;80(4):1029-1072.
3. Nast A, Gisondi P, Ormerod AD, et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris – Update 2015 – Short version – EDF in cooperation with EADV and IPC. *J Eur Acad Dermatol Venereol.* 2015;29(12):2277-2294.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol.* 2019;71(1):5-32.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	08/04/2021
Selected Revision	<b>Plaque Psoriasis:</b> Note was clarified to state that a previous trial of a biologic applies to one biologic other than the requested drug. For a patient currently receiving the requested drug, it was clarified that this applies to a patient who is taking the drug for ≥ 90 days. Requirements were added for a patient who is currently taking, that there is has at least one objective and at least one subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years. <b>Psoriatic Arthritis:</b> Initial approval duration was changed to 6 months (previously was 3 months). For a patient currently receiving this drug, it was clarified that this applies to a patient who is taking for ≥ 6 months. A requirement was added for a patient who is currently receiving to have at least one objective or subjective response to therapy. For continuation, approvals were changed to be 1 year in duration. Previously, response was more general and according to the prescriber, and approvals were for 3 years.	12/01/2021
Annual Revision	No criteria changes.	08/03/2022

**APPENDIX**

	<b>Mechanism of Action</b>	<b>Examples of Inflammatory Indications*</b>
<b>Biologics</b>		
<b>Adalimumab SC Products</b> (Humira®, biosimilars)	Inhibition of TNF	AS, CD, JIA, PsO, PsA, RA, UC
<b>Cimzia®</b> (certolizumab pegol SC injection)	Inhibition of TNF	AS, CD, nr-axSpA, PsO, PsA, RA
<b>Etanercept SC Products</b> (Enbrel®, biosimilars)	Inhibition of TNF	AS, JIA, PsO, PsA
<b>Infliximab IV Products</b> (Remicade®, biosimilars)	Inhibition of TNF	AS, CD, PsO, PsA, RA, UC
<b>Simponi®, Simponi® Aria™</b> (golimumab SC injection, golimumab IV infusion)	Inhibition of TNF	SC formulation: AS, PsA, RA, UC IV formulation: AS, PJIA, PsA, RA
<b>Actemra®</b> (tocilizumab IV infusion, tocilizumab SC injection)	Inhibition of IL-6	SC formulation: PJIA, RA, SJIA IV formulation: PJIA, RA, SJIA
<b>Kevzara®</b> (sarilumab SC injection)	Inhibition of IL-6	RA
<b>Orencia®</b> (abatacept IV infusion, abatacept SC injection)	T-cell costimulation modulator	SC formulation: JIA, PsA, RA IV formulation: JIA, PsA, RA
<b>Rituximab IV Products</b> (Rituxan®, biosimilars)	CD20-directed cytolytic antibody	RA
<b>Kineret®</b> (anakinra SC injection)	Inhibition of IL-1	JIA <sup>^</sup> , RA
<b>Stelara®</b> (ustekinumab SC injection, ustekinumab IV infusion)	Inhibition of IL-12/23	SC formulation: CD, PsO, PsA, UC IV formulation: CD, UC
<b>Siliq™</b> (brodalumab SC injection)	Inhibition of IL-17	PsO
<b>Cosentyx®</b> (secukinumab SC injection)	Inhibition of IL-17A	AS, ERA, nr-axSpA, PsO, PsA
<b>Taltz®</b> (ixekizumab SC injection)	Inhibition of IL-17A	AS, nr-axSpA, PsO, PsA
<b>Ilumya™</b> (tildrakizumab-asmn SC injection)	Inhibition of IL-23	PsO
<b>Skyrizi®</b> (risankizumab-rzaa SC injection, risankizumab-rzaa IV infusion)	Inhibition of IL-23	SC formulation: CD, PsA, PsO IV formulation: CD
<b>Tremfya™</b> (guselkumab SC injection)	Inhibition of IL-23	PsO
<b>Entyvio™</b> (vedolizumab IV infusion)	Integrin receptor antagonist	CD, UC
<b>Oral Therapies/Targeted Synthetic DMARDs</b>		
<b>Otezla®</b> (apremilast tablets)	Inhibition of PDE4	PsO, PsA
<b>Cibinco™</b> (abrocitinib tablets)	Inhibition of JAK pathways	AD
<b>Olumiant®</b> (baricitinib tablets)	Inhibition of JAK pathways	RA
<b>Rinvoq®</b> (upadacitinib extended-release tablets)	Inhibition of JAK pathways	AD, AS, RA, PsA, UC
<b>Xeljanz®</b> (tofacitinib tablets)	Inhibition of JAK pathways	RA, PJIA, PsA, UC
<b>Xeljanz® XR</b> (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; <sup>^</sup> 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.