EXPRESS SCRIPTS®

PRIOR AUTHORIZATION POLICY

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

TAC APPROVAL DATE: 07/31/2019

OVERVIEW

Tremfya is a fully human immunoglobulin (Ig)G monoclonal antibody that binds to interleukin (IL)-23, a pro-inflammatory cytokine.[1] 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.

Disease Overview

Although the etiology of psoriasis is not fully established, abnormal keratin formation, epidermal proliferation, activation of the immune system, and hereditary factors appear to play roles in the pathogenesis of the disease. In psoriasis, levels of IL-23p40 and IL-12/23p40 messenger RNA are upregulated but decrease with treatment. By blocking the release of proinflammatory cytokines and chemokines, Ilumya has an inhibitory effect on the inflammatory process.

Guidelines

Joint guidelines from the American Academy of Dermatology (AAD) and National Psoriasis Medical Board (2019) have been published for management of psoriasis with biologics.[2] These guidelines list Skyrizi as a monotherapy treatment option for patients with moderate to severe plaque psoriasis. Guidelines from the European Dermatology Forum (EDF) [2015] recommend biologics (i.e., etanercept, adalimumab, infliximab, Stelara SC) as second-line therapy for induction and long-term treatment if phototherapy and conventional systemic agents have failed, are contraindicated, or are not tolerated.[3]

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

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

FDA-Approved Indications

1. **Plaque Psoriasis.**
   - **A)** Initial Therapy. Approve for 3 months if the patient meets ALL of the following (i, ii, and iii):
     - **i.** The patient is an adult ≥ 18 years of age; AND
     - **ii.** The patient meets ONE of the following conditions (a or b):
       - **a)** The patient has tried at least at least one traditional systemic agent for psoriasis for at least 3 months, unless intolerant.
         Note: Examples include methotrexate (MTX), cyclosporine, acitretin [Soriatane®, generics], 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 (e.g., an adalimumab product [e.g., Humira], an etanercept product [e.g., Enbrel®], a certolizumab pegol product [Cimzia], Cosentyx® [secukinumab SC injection], Ilumya [tildrakizumab SC injection], an infliximab product [e.g., Remicade®, Inflectra™, Renflexis], Siliq® [brodalumab SC injection], Skyrizi [risankizumab-rzaa SC injection], Stelara® [ustekinumab SC injection], or Taltz® [ixekizumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to "step back" and try a traditional systemic agent for psoriasis); OR
       - **b)** The patient has a contraindication to methotrexate (MTX), 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 3 years 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.

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).** 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 MTX (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™ injection [prescribing information]. Horsham, PA: Janssen Biotech; March 2016.
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 Feb 13. [Epub ahead of print].
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.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New Policy	NA	07/17/2017
Annual revision	Plaque Psoriasis: • Update the list of previous therapies to include Ilumya and Cimzia. • References to Humira and Enbrel were reworded as adalimumab and etanercept products, respectively, with the innovator names listed as examples of these products. Renflexis was added as an example of an infliximab product.	08/01/2018
Annual revision	**Plaque Psoriasis:** For the exception applying to patients with a contraindication to methotrexate, wording was updated to more generally allow this determination by the prescriber (criteria previously specified this was according to the prescribing physician). Skyrizi was added to the list of biologics that the patient may have tried prior to Tremfya.	07/31/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committee; NA – Not applicable.

APPENDIX

Brand (generic name)	Mechanism of Action
Cimzia® (certolizumab pegol for SC injection)	Inhibition of TNF
Enbrel® (etanercept for SC injection)	Inhibition of TNF
Erelzi™ (etanercept-szzs for SC injection)	Inhibition of TNF
Humira® (adalimumab for SC injection)	Inhibition of TNF
Amjevita® (adalimumab-atto for SC injection)	Inhibition of TNF
Cyltezo® (adalimumab-adbm SC injection)	Inhibition of TNF
Simponi® (golimumab for SC injection)	Inhibition of TNF
Simponi® Aria™ (golimumab for IV infusion)	Inhibition of TNF
Remicade® (infliximab for IV infusion)	Inhibition of TNF
Inflectra™ (infliximab-dyyb for IV infusion)	Inhibition of TNF
Renflexis® (infliximab-abda for IV infusion)	Inhibition of TNF
Actemra® (tocilizumab for IV infusion)	Inhibition of IL-6
Actemra® (tocilizumab for SC injection)	Inhibition of IL-6
Kevzara® (sarilumab for SC injection)	Inhibition of IL-6
Orencia® (abatacept for IV infusion)	T-cell costimulation modulator
Orencia® (abatacept for SC injection)	T-cell costimulation modulator
Rituxan® (rituximab for IV infusion)	CD20-directed cytolytic antibody
Truxima® (rituximab-abbs IV injection)	CD20-directed cytolytic antibody
Kineret® (anakinra for subcutaneous SC injection)	Inhibition of IL-1
Stelara® (ustekinumab for SC injection)	Inhibition of IL-12/23
Stelara® (ustekinumab for IV infusion)	Inhibition of IL-12/23
Siliq™ (brodalumab SC injection)	Inhibition of IL-17
Cosentyx™ (secukinumab for SC injection)	Inhibition of IL-17A
Taltz® (ixekizumab for SC injection)	Inhibition of IL-17A
Ilumya® (tildrakizumab SC injection)	Inhibition of IL-23
Skyrizi™ (risankizumab SC injection)	Inhibition of IL-23
Tremfya™ (guselkumab for SC injection)	Inhibition of IL-23
Otezla® (apremilast tablets)	Inhibition of PDE4
Olumiant® (baricitinib tablets)	Inhibition of the JAK pathways
Xeljanz®, Xeljanz XR (tofacitinib tablets, tofacitinib extended-release tablets)	Inhibition of the JAK pathways

SC – Subcutaneous; TNF – Tumor necrosis factor; IV – Intravenous, IL – Interleukin;PDE4 – Phosphodiesterase 4; JAK – Janus kinase.