### Overview

Tremfya is a monoclonal antibody against interleukin-23, FDA indicated for Plaque psoriasis and Psoriatic arthritis.

All other indications are considered experimental/investigational and are not a covered benefit.

### Coverage Guidelines

#### Moderate to severe plaque psoriasis

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Tremfya, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs.

**OR**

Authorization may be granted for treatment of moderate to severe plaque psoriasis when all the following criteria are met:

1. Member has had a documented inadequate response or intolerable adverse event with ALL the preferred products (Cosentyx, Enbrel, Humira, Otezla, Skyrizi and Stelara) unless there is a documented clinical reason to avoid these products.
2. At least 5% 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. Member meets any of the following criteria:
   a. Member has experienced an inadequate response or adverse reaction to TWO conventional therapies in any one of the following combinations:
      - 1 topical agent + 1 systemic agent (methotrexate, acitretin or cyclosporine)
      - 1 topical agent + 1 phototherapy (e.g., UVB, PUVA)
Active psoriatic arthritis (PsA)

Authorization may be granted for members new to AllWays Health Partners who are currently receiving treatment with Tremfya for treatment of PsA, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

OR

Authorization may be granted for treatment of active PsA when ONE the following criteria are met:

1. The member has had a documented inadequate response or intolerable adverse event with ALL the preferred products indicated for PsA (Cosentyx, Enbrel, Humira, Otezla and Stelara).
2. The member has a contraindication to all the preferred agents and BOTH of the following criteria is met:
   a. The member has had an intolerance to or inadequate response (after at least 3 months of treatment) with methotrexate OR leflunomide.
   b. The member has a contraindication to BOTH methotrexate and leflunomide AND has experienced an inadequate response, intolerance, or contraindication to sulfasalazine.

Continuation of Therapy

Reauthorization may be granted for all members (including new members) who meet all initial authorization criteria and achieve or maintain positive clinical response after at least 4 months of therapy with Tremfya as evidenced by low disease activity or improvement in signs and symptoms of the condition.

Limitations

1. Approvals will be granted for 24 months
2. For all indications: Member has a pretreatment tuberculosis (TB) screening with a TB skin test or an interferon gamma release assay (e.g., QFT-GIT, T-SOT.TB).
   a. 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.
3. The following quantity limits apply:

   | Tremfya 100mg/ml Loading Dose | 100mg at week 0 and week 4 |
   | Tremfya 100mg/ml Maintenance Dose | 100 mg (1 ml) every 8 weeks |

Appendix

Examples of Clinical Reasons to Avoid Pharmacologic Treatment with Methotrexate, Cyclosporine or Acitretin

1. Alcoholism, alcoholic liver disease or other chronic liver disease
2. Breastfeeding
3. Cannot be used due to risk of treatment-related toxicity
4. Drug interaction
5. Pregnancy or planning pregnancy (male or female)
6. Significant comorbidity prohibits use of systemic agents (examples include liver or kidney disease, blood dyscrasias, uncontrolled hypertension)

References

Review History
02/26/18 – Reviewed
06/01/18 – Implemented
02/20/19 – Updated
11/20/19 – Added Skyrizi as a preferred trial for PS
07/19/2021- Reviewed at July P&T; started and stabilized statement updated to include “new tot AllWays Health Partners”; Added criteria for PsA indication; overview updated; references updated; loading dose added to limitations. Effective 10/01/2021.

Disclaimer
AllWays Health Partners complies with applicable federal civil rights laws and does not discriminate or exclude people on the basis of race, color, national origin age, disability, or sex.