



## **RATIONALE FOR INCLUSION IN PA PROGRAM**

### **Background**

Tremfya (guselkumab) is a subcutaneous injectable treatment or intravenous infusion that helps regulate inflammation in plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. Tremfya is a monoclonal antibody that binds to interleukin 23 (IL-23), a protein involved in inflammation. Tremfya binds to IL-23 and prevents it from binding to its receptor, and it inhibits its ability to trigger an inflammatory response. Tremfya inhibits the release of proinflammatory cytokines and chemokines (1).

### **Regulatory Status**

FDA-approved indications: Tremfya is an interleukin-23 blocker indicated for the treatment of adult patients with: (1)

1. Moderate-to-severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy
2. Active psoriatic arthritis (PsA)
3. Moderately to severely active ulcerative colitis (UC)
4. Moderately to severely active Crohn's disease

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Tremfya. Do not administer to patients with active TB infection. Initiate treatment for latent TB prior to administering Tremfya. Consider anti-TB therapy prior to initiation of Tremfya in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients receiving Tremfya for signs and symptoms of active TB during and after treatment (1).

Tremfya affects the immune system, thus patients may be at greater risk for infection. If a patient develops a serious infection or is not responding to standard therapy for the infection, monitor the patient closely and discontinue Tremfya therapy until the infection resolves. Avoid use of live vaccines in patients treated with Tremfya. There is no data available on the ability of live or inactive vaccines to elicit an immune response in patients being treated with Tremfya (1).

The safety and effectiveness of Tremfya in pediatric patients less than 18 years of age have not been established (1).



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## **TREMFYA (guselkumab)**

### **Summary**

Tremfya (guselkumab) is a subcutaneous injectable or intravenous infusion treatment that helps regulate inflammation in plaque psoriasis, psoriatic arthritis, ulcerative colitis, and Crohn's disease. Tremfya is a monoclonal antibody that binds to interleukin 23 (IL-23) a protein involved in inflammation. Tremfya binds to IL-23 and prevents it from binding to its receptor, and it inhibits its ability to trigger an inflammatory response. Tremfya inhibits the release of proinflammatory cytokines and chemokines. The safety and effectiveness of Tremfya have not been evaluated in pediatric patients (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Tremfya while maintaining optimal therapeutic outcomes.

### **References**

1. Tremfya [package insert]. Horsham, PA: Janssen Biotech, Inc.; March 2025.