TREMFYA® Prior Authorization Checklist

Reminders and Tips When Completing Prior Authorizations for Your Patients

Each health plan may have its own unique prior authorization (PA) form with varying requirements. It is important to gather necessary information during the patient's first appointment to ensure an effective process with minimal delays.

4 Essentials for Approval

1 | **Diagnosis must match FDA Indication for TREMFYA®**
- Diagnosis must be moderate to severe plaque psoriasis and/or active psoriatic arthritis
- For moderate to severe plaque psoriasis, the patient must be a candidate for phototherapy or systemic therapy even if not on treatment

2 | **TB test results must be included**

3 | **Notes of previously used medications**, response to therapy (patient has tried and failed topicals, phototherapy, and DMARDs), and other medical record documentation must be included

4 | **Always indicate the starter dose** (100 mg/mL SC at Week 0 and Week 4) and **maintenance therapy** dosing (100 mg/mL every 8 weeks after)

Consider gathering the following information to assist when completing PA forms:

Patient Information

- ☐ **Patient Insurance Information**
  - Copy of the patient's prescription card (front and back)
  - Copy of the patient's health insurance card (front and back)
- ☐ **Patient Contact Information (phone and email preferred)**

Patient Diagnosis/Clinical Information

- ☐ **ICD-10 Code**
  - L40.0 (Plaque Psoriasis)
  - L40.50 (Psoriatic Arthritis)
- ☐ **Supporting Clinical Information**
  - Lab Results and Dates
  - Diagnostic Images and/or Photographs of Affected Areas
- ☐ **Labs, Lab Dates, and Risk of Chronic Disease, Including:**
  - Tuberculosis (TB)
  - Hepatitis B (HBV)
- ☐ **Patient Medication History (including treatments from previous healthcare providers):**
  - Duration of Therapy (including conventional therapy)
  - Clinical Response
  - Allergy
  - Strength
  - Schedule
- ☐ **Supporting Clinical Information for Moderate to Severe Plaque Psoriasis**
  - Psoriasis Area and Severity Index (PASI)/Investigator's Global Assessment (IGA) Score
  - % Body Surface Area Coverage
  - Disease Severity
- ☐ **Supporting Clinical Information for Active Psoriatic Arthritis**
  - PASI/IGA Score
  - % Body Surface Area Coverage
  - Disease Severity
  - Number of Swollen and/or Tender Joints
  - Number of Tender Areas Other Than Joints
  - Number of Entire Fingers or Toes Swollen
  - Patient Comorbidities That Could Serve as Contraindications to Certain Other Treatments (if applicable)

Codes are supplied for informational purposes only and represent no statement, promise, or guarantee that reimbursement will be made. Information provided is not intended to increase or maximize reimbursement.

SELECTED IMPORTANT SAFETY INFORMATION

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, may occur. TREMFYA® may increase the risk of infection. Do not initiate treatment in patients with clinically important active infection until the infection resolves or is adequately treated. If such an infection develops, discontinue TREMFYA® until infection resolves. Evaluate for tuberculosis (TB) before treating with TREMFYA®. Monitor patients for signs and symptoms of active TB during and after treatment with TREMFYA®. Drug-induced liver injury has been reported. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Avoid use of live vaccines in patients treated with TREMFYA®. Please see related and other Important Safety Information on the next page.

Tremfya® (guselkumab)

Other Resources

- [ ] **Letter of Medical Necessity**
  - Visit JNJwithMe.com/hcp/Tremfya and look under the Forms and Documents drop-down for a sample letter
  - For expedited requests, adequate information should be provided to support the urgent nature of the request
- [ ] **Patient Authorization and Notice of Release of Information**
- [ ] **Product Full Prescribing Information, Peer-Reviewed Journal Articles, or Clinical Guidelines**

Tremfya withMe — A Dedicated Support Program for patients prescribed TREMFYA®

Once a decision has been made to prescribe TREMFYA®, TREMFYA withMe provides a range of dedicated support and services to help make it easier for patients as they begin, and continue, their TREMFYA® treatment journey. TREMFYA withMe can help verify insurance coverage for your patients, provide reimbursement information, find financial assistance options for eligible patients, and provide ongoing support to help patients start and stay on TREMFYA®.

Call 1-844-4-withMe (494-8463), Monday-Friday, 8:00 AM to 8:00 PM ET.

Visit JNJwithMe.com/hcp/Tremfya.

The patient support and resources provided by TREMFYA withMe are not intended to provide medical advice, replace a treatment plan from the patient's doctor or nurse, provide case management services, or serve as a reason to prescribe TREMFYA®.

INDICATIONS

TREMFYA® (guselkumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

TREMFYA® is indicated for the treatment of adult patients with active psoriatic arthritis.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TREMFYA® is contraindicated in patients with a history of serious hypersensitivity reaction to guselkumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Serious hypersensitivity reactions, including anaphylaxis, have been reported with postmarket use of TREMFYA®. Some cases required hospitalization. If a serious hypersensitivity reaction occurs, discontinue TREMFYA® and initiate appropriate therapy.

Infections

TREMFYA® may increase the risk of infection. Treatment with TREMFYA® should not be initiated in patients with any clinically important active infection until the infection resolves or is adequately treated.

Consider the risks and benefits of treatment prior to prescribing TREMFYA® in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving TREMFYA® to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue TREMFYA® until the infection resolves.

Tuberculosis (TB)

Evaluate patients for TB infection prior to initiating TREMFYA® treatment. Do not administer TREMFYA® to patients with active TB infection. Initiate treatment of latent TB prior to administering TREMFYA®. Consider anti-TB therapy prior to initiating TREMFYA® in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor all patients for signs and symptoms of active TB during and after TREMFYA® treatment.

Hepatotoxicity

A serious adverse reaction of drug-induced liver injury was reported in a clinical trial subject with Crohn's disease following three doses of a higher than recommended induction regimen.

Consider other treatment options in patients with evidence of acute liver disease or cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations

Prior to initiating TREMFYA®, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid use of live vaccines in patients treated with TREMFYA®.

ADVERSE REACTIONS

Most common adverse reactions associated with TREMFYA® include: plaque psoriasis and psoriatic arthritis adverse reactions (≥1%): upper respiratory infections, headache, injection site reactions, arthralgia, bronchitis, diarrhea, gastroenteritis, tinea infections, and herpes simplex infections.

The overall safety profile observed in patients with psoriatic arthritis is generally consistent with the safety profile in patients with plaque psoriasis, with the addition of bronchitis and neutrophil count decreased.

Please read the full Prescribing Information and Medication Guide for TREMFYA®.
Provide the Medication Guide to your patients and encourage discussion.

TREMFYA® is available as a 100 mg/mL subcutaneous injection.

cp-510975v1

Johnson&Johnson

Tremfya® (guselkumab)