ATRIO HEALTH PLANS

Tremfya

Tremfya (Guselkumab) J1628

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

☐ **Plaque Psoriasis (PsO) – Moderate to Severe**

- ☐ Patient is 6 years of age or older and weighs at least 40 kg
- ☐ Diagnosis confirmed by dermatologist
- ☐ Disease severity meets at least ONE of the following:
  - ☐ Body Surface Area (BSA) involvement ≥10%
  - ☐ Involvement of critical areas (hands, feet, face, neck, scalp, genitals, intertriginous areas)
  - ☐ BSA ≥3% with inadequate response, intolerance, or contraindication to phototherapy, methotrexate, cyclosporine, or acitretin
- ☐ Tuberculosis screening (IGRA / TST) negative in 12 months prior to initiation (or latent TB treated prior to start)
- ☐ No concurrent use with other biologic or targeted synthetic drugs for same indication
- ☐ Prescribed by or in consultation with dermatologist

☐ **Psoriatic Arthritis (PsA) – Active**

- ☐ Patient is 6 years of age or older and weighs at least 40 kg
- ☐ Diagnosis confirmed by rheumatologist or dermatologist

☐ Patient meets at least ONE of the following:
- ☐ Inadequate response, intolerance, or contraindication to methotrexate, leflunomide, or sulfasalazine after adequate trial (typically ≥3 months at maximum tolerated dose)
- ☐ Presence of enthesitis
- ☐ Severe disease requiring biologic therapy

☐ Tuberculosis screening (IGRA / TST) negative in 12 months prior to initiation (or latent TB treated prior to start)
☐ No concurrent use with other biologic or targeted synthetic drugs for same indication
☐ Prescribed by or in consultation with rheumatologist or dermatologist

☐ **Ulcerative Colitis (UC) – Moderately to Severely Active**
☐ Patient is 18 years or older
☐ Diagnosis confirmed by gastroenterologist
☐ Documentation of moderately to severely active disease (endoscopic evidence, Mayo score, etc.)
☐ Tuberculosis screening (IGRA / TST) negative in 12 months prior to initiation (or latent TB treated prior to start)
☐ No concurrent use with other biologic or targeted synthetic drugs for same indication
☐ Prescribed by or in consultation with gastroenterologist

☐ **Crohn's Disease (CD) – Moderately to Severely Active**
☐ Patient is 18 years or older
☐ Diagnosis confirmed by gastroenterologist
☐ Documentation of moderately to severely active disease (CDAI score, endoscopic evidence, etc.)
☐ Tuberculosis screening (IGRA / TST) negative in 12 months prior to initiation (or latent TB treated prior to start)
☐ No concurrent use with other biologic or targeted synthetic drugs for same indication
☐ Prescribed by or in consultation with gastroenterologist

If not, please provide **clinical rationale** for formulary exception: _____
_____

☐ Continuation Requests: (Clinical documentation required for all requests)

☐ Patient continues to meet initial approval criteria
☐ Documentation of positive clinical response (e.g., reduction in BSA, PASI improvement, reduced joint counts, remission or improvement in signs/symptoms)
☐ No unacceptable toxicity requiring discontinuation
☐ No disease progression while on therapy
☐ TB screening updated if clinically indicated (typically annually) ☐ Medical record documentation of positive response is included

If not, please provide clinical rationale for continuing this medication: _____
_____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – Tremfya Prior Authorization

Drug Name(s):
TREMFYA **GUSELKUMAB**

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.
- Continuation Requests: Provider must verify continued clinical benefit in confirmatory trial(s).

Exclusion Criteria:
N/A

Prescriber Restrictions:
Gastroenterologist or other related specialist

Coverage Duration:
Approval will be for 6 months

FDA Indications:
Tremfya

- Crohn's disease (Moderate to Severe), Active
- Plaque psoriasis, Moderate to severe disease, in patient who are candidates for systemic therapy or phototherapy
- Psoriatic arthritis
- Ulcerative colitis (Moderate to Severe), Active

Off-Label Uses:
N/A

Age Restrictions:
Indicated for patients 6-years old and up.

Other Clinical Consideration:
N/A

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/63B7DF/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/E38C07/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.GoToDashboard?docId=932290&contentSetId=100&title=Guselkumab&servicesTitle=Guselkumab&brandName=Tremfya&UserMdxSearchTerm=Tremfya#