SmartHealth Ascension

Guselkumab

(Tremfya®) J1628 (1mg)

Covered with prior authorization

Tremfya® (guselkumab) may be authorized when the following criteria are met:

Plaque Psoriasis

- Individual 18 years of age or older; **AND**
- Body Surface Area (BSA) of greater than 5% OR BSA less than 5% and there is involvement of the scalp, face, the palms and soles (e.g.., palmoplantar disease), or genitals; **AND**
- Medication is being prescribed by, or in consultation with, a dermatologist or a prescriber who specializes in plaque psoriasis; **AND**
- Documentation of **ONE** of the following:

  Individual has had an inadequate response to **ONE** of the following:
  - Topical therapy (e.g., coal tar, keratolytics, corticosteroids, anthralin, Dovonex, Tazorac)
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin)
  - Phototherapy [narrow or broad band ultraviolet B (UVB), or psoralen plus ultraviolet A (PUVA)]

  OR

  Individual has a contraindication per FDA label, significant intolerance, or is not a candidate for the **ALL** of the following:
  - Topical therapy (e.g., coal tar, keratolytics, corticosteroids, anthralin, Dovonex, Tazorac)]
  - Systemic therapy (e.g., methotrexate, cyclosporine, acitretin)
  - Phototherapy [narrow or broad band ultraviolet B (UVB), or psoralen plus ultraviolet (PUVA)]

  OR

  Individual has already tried a biologic or targeted synthetic DMARD.

Psoriatic Arthritis

- Individual 18 years of age or older; **AND**
- Medication is being prescribed by, or in consultation with a rheumatologist, dermatologist or a prescriber who specializes in psoriatic arthritis; **AND**
- Documentation of **ONE** of the following:
  - For Non-Axial disease, **ONE** of the following
    - Individual has had an inadequate response to **ONE** disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine); **OR**
    - Individual has a contraindication per FDA label, significant intolerance, or is otherwise not a candidate for ALL

disease-modifying anti-rheumatic drug (DMARD) therapy (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine)

NOTE: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation.

- For Axial disease, **ONE** of the following :
  - Individual has had an inadequate response to ONE disease-modifying anti-rheumatic drug (DMARD) (e.g., methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), OR a nonsteroidal anti-inflammatory drug (NSAID); **OR**
  - Individual has a contraindication per FDA label, significant intolerance, or is otherwise not a candidate for ALL disease-modifying anti-rheumatic drug (DMARD) therapy (for example, methotrexate, leflunomide, hydroxychloroquine, sulfasalazine), **AND** nonsteroidal anti-inflammatory drugs (NSAIDs).

    NOTE: Not a candidate due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], other attributes/conditions, or is unable to administer and requires this dosage formulation)
  - Individual has already tried a biologic or targeted synthetic DMARD.

*Not a candidate for conventional DMARD therapy is defined by the presence of a patient specific characteristic/factor, disease specific factor, or individual clinical factor that is subject to a warning per the FDA prescribing information (labeling)

Exclusion criteria:

- Concurrent Use with other Biologics or with Targeted Synthetic Disease-Modifying Antirheumatic Drugs (DMARDs) (***NOTE:*** *This does NOT exclude the use of methotrexate (a traditional systemic agent used to treat psoriasis) in combination with Tremfya.)*
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Not covered as a medical benefit if self-administered.

Initial authorization is up to 12 months.

Reauthorization approval duration is up to 12 months.

Tremfya® (guselkumab) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

FDA Recommended Dosage in Adults with Plaque Psoriasis or Psoriatic Arthritis
100 mg administered by subcutaneous injection at Week 0, Week 4 and every 8 weeks thereafter.
For treatment of Psoriatic Arthritis, TREMFYA can be used alone or in combination with a conventional DMARD (e.g. methotrexate)

Tremfya® (guselkumab) is an interleukin (IL)-23 blocker, is indicated for the following uses:

- **Plaque psoriasis**, in adults with moderate to severe disease who are candidates for systemic therapy or phototherapy.
- **Psoriatic arthritis**, in adults with active disease (given ± a conventional synthetic disease-modifying antirheumatic drug).

References:

1. 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;80(4):1029-1072.
2. 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.
3. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. Arthritis Rheumatol. 2019;71(1):5-32.
4. Tremfya® subcutaneous injection [prescribing information]. Horsham, PA: Janssen Biotech/Johnson & Johnson, 2020.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.