Tremfya (guselkumab)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Tremfya (guselkumab)	1 prefilled syringe/autoinjector per 56 days (8 weeks)*

*Initiation of therapy for Plaque Psoriasis (Ps) (Psoriasis Vulgaris) or Psoriatic Arthritis (PsA): May approve up to 1 additional injection (100 mg) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Initial requests for Tremfya (guselkumab) may be approved for the following:

I. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque Ps (psoriasis vulgaris) with either of the following (AAD 2019):
      1. Plaque Ps (psoriasis vulgaris) involving greater than three percent (3%) body surface area (BSA); **OR**
      2. Plaque Ps (psoriasis vulgaris) involving less than or equal to three percent (3%) BSA involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia);

   AND

   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

   AND

   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents. [Current preferred biologics include – adalimumab-adbm, Cosentyx*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Stelara (ustekinumab)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Tremfya (guselkumab);

   *Note – Trial of Cosentyx (secukinumab) is not required in states where not covered (CA, CO)

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic DMARDs (such as methotrexate, sulfasalazine, cyclosporine or leflunomide)].

   AND
   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents. [Current preferred biologics include – adalimumab-adbm, Cosentyx*, Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast), Simponi (golimumab), Stelara (ustekinumab)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Tremfya (guselkumab)**.**

   *Note – Trial of Cosentyx (secukinumab) is not required in states where not covered (CA, CO)

Continuation requests for Tremfya (guselkumab) may be approved if the following criterion is met:

I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

Requests for Tremfya (guselkumab) may **not** be approved for the following:

I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, apremilast, deucravacitinib, ozanimod, or any of the following biologic immunomodulators: TNF antagonists, other IL-23 inhibitors, IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. If initiating therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent test to evaluate for latent tuberculosis (unless switching from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: October 5, 2022.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. 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: 1029-72.

6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
7. Centers for Disease Control and Prevention (CDC). Tuberculosis (TB). Available at: https://www.cdc.gov/tb/topic/basics/risk.htm. Last updated: March 18, 2016. Accessed October 5, 2022.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.