

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	X

\*FHK- Florida Healthy Kids

## Tremfya (guselkumab)

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

Medications	Quantity Limit
Tremfya (guselkumab)	1 injection per 56 days (8 weeks)*

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

### **APPROVAL CRITERIA**

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:
    1. Plaque Ps (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); **OR**
    2. Plaque Ps (psoriasis vulgaris) involving less than or equal to five percent (5%) 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 – Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
    1. Individual has been receiving and is maintained on a stable dose of Tremfya (guselkumab); **OR**
    2. The preferred agents are not FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Tremfya (guselkumab) does; **OR**

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
  - a. Known hypersensitivity to any active or inactive component which is not also associated with the Tremfya (guselkumab); **OR**
  - b. Individual's age; **OR**
  - c. Pregnant or planning on becoming pregnant; **OR**
  - d. Serious infections or concurrent sepsis; **OR**
4. The individual has either concomitant clinical condition:
  - a. Demyelinating disease; **OR**
  - b. Heart failure with documented left ventricular dysfunction; **OR**
5. The preferred agent(s) do not have activity against a concomitant clinical condition and Tremfya (guselkumab) does. Examples include but may not be limited to the following:
  - a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
  - b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

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

- I. In combination with other biologic drugs or phototherapy; **OR**
- II. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
- III. 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 prior to initiating guselkumab.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

**Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018.  
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: September 14, 2018.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

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4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.
5. Menter A, Korman NJ, Elmets CA et al for the American Academy of Dermatology. Guidelines of care for the management of psoriasis and psoriatic arthritis. *J Am Acad Dermatol.* 2011; 65: 137-174.

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