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	NA

*FHK- Florida Healthy Kids

Tremfya (guselkumab)

DRUG.00111

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 (Psoriasis Vulgaris): May approve up to 1 additional injection (100 mg) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

I. Diagnosis of Plaque Psoriasis (Psoriasis Vulgaris)

A. Individual is 18 years of age or older with chronic moderate to severe plaque psoriasis (psoriasis vulgaris) with either of the following;
   1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% body surface area; **OR**
   2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% body surface area involving sensitive areas or areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia);

AND

B. Agent is used for either of the following reasons:
   1. To reduce signs or symptoms; **OR**
   2. To induce or maintain clinical response;

AND

C. 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

D. 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:

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	NA

*FHK- Florida Healthy Kids

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**
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.

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

I. When used in combination with other immunosuppressive therapy (such as other biologic drugs or phototherapy); **OR**
II. Individuals with tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
III. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention-recommended equivalent test to evaluate for latent tuberculosis prior to initiating Tremfya (guselkumab).

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

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	NA

*FHK- Florida Healthy Kids

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

Blauvelt A, Papp KA, Griffiths CE, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the continuous treatment of patients with moderate to severe psoriasis: Results from the phase III, double-blinded, placebo- and active comparator-controlled VOYAGE 1 trial. *J Am Acad Dermatol*. 2017; 76(3):405-417. Available from: http://www.jaad.org/article/S0190-9622(16)31157-4/pdf. Accessed on: April 27, 2017.

Reich K, Armstrong AW, Foley P, et al. Efficacy and safety of guselkumab, an anti-interleukin-23 monoclonal antibody, compared with adalimumab for the treatment of patients with moderate to severe psoriasis with randomized withdrawal and retreatment: Results from the phase III, double-blind, placebo- and active comparator-controlled VOYAGE 2 trial. *J Am Acad Dermatol*. 2017; 76(3):418-431. Available from: http://www.jaad.org/article/S0190-9622(16)31158-6/pdf. Accessed on: April 27, 2017.