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

Ilumya (tildrakizumab-asmn)

DRUG.00111

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

Medications	Quantity Limit
Ilumya (tildrakizumab-asmn) prefilled syringe 100mg/mL	1 prefilled syringe per 84 days (12 weeks)

*Initiation of therapy for Plaque Psoriasis (Psoriasis vulgaris): May approve 1 additional syringe (100 mg/mL) 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 (BSA); OR
   2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% BSA 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

Market Applicability														
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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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TWO preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab] unless the following criteria is met:

1. The individual has been receiving and is maintained on a stable dose of Ilumya (tildrakizumab-asmn); **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 Ilumya (tildrakizumab-asmn) 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 Ilumya (tildrakizumab-asmn); **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 Ilumya (tildrakizumab-asmn) 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.

Ilumya (tildrakizumab-asmn) may **not** be approved for any of the following:

I. Use 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 therapy.

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

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

Key References:

1. American Academy of Dermatology (AAD). American Academy of Dermatology Association (AADA). Guidelines of care for management of psoriasis and psoriatic arthritis. May 2008. Available at: http://www.aad.org/education-and-quality-care/clinical-guidelines. Accessed on April 4, 2018.
2. Tildrakizumab-asmn (Ilumya) [Product Information Label]. Merck & CO., Whitehouse Station, NJ. March 2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761067s000lbl.pdf. Accessed on April 4, 2018.
3. Sbidian E, Chaimani A, Garcia-Doval I, et al. Systemic pharmacological treatments for chronic plaque psoriasis: a network meta-analysis. Cochrane Database Syst Rev. 2017; 12:CD011535.