Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

Ilumya (tildrakizumab-asmn)

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 (Ps) (Psoriasis vulgaris): May approve 1 additional syringe (100 mg/mL) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Requests for Ilumya (tildrakizumab-asmn) 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 preferred biologic agents. [Current preferred biologics include – Cosentyx (secukinumab), 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 acceptable due to concomitant clinical conditions, including but not limited to any of the following:

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

a. Known hypersensitivity to any active or inactive component which is not also associated with Ilumya (tildrakizumab-asmn); **OR**
b. Pregnant or planning on becoming pregnant; **OR**
c. Serious infections or concurrent sepsis.

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

I. All other indications not included above; **OR**
II. In combination with JAK inhibitors, apremilast, or other biologic drugs or phototherapy; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. 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 tildrakizumab-asmn.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2019. 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: March 21, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; 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.

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.