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

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

Initial 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 – Avsola (infliximab-axxq), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast)] unless the following criteria is met:
   1. The individual has been receiving and is maintained on a stable dose of Ilumya (tildrakizumab-asmn).

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

Continuation requests for Ilumya (tildrakizumab-asmn) 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 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, other IL-23 inhibitors, or other biologic drugs (such as TNF antagonists or ustekinumab) or phototherapy; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. Prior to 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 therapy from another targeted immune modulator and no risk factors).

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. 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 15, 2020.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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.