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

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tildrakizumab

Override(s)	Approval Duration
Prior Authorization	1 year

Washington Medicaid – See State Specific Mandates

Medications
tildrakizumab

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 TWO preferred biologic agents. [Current preferred biologics include – Enbrel (etanercept), Humira (adalimumab] unless the following criteria is met:
   1. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:

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

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a. Known hypersensitivity to any active or inactive component which is not also associated with tildrakizumab; **OR**
b. Individuals age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis;

OR

2. The individual has either concomitant clinical condition:
   a. Demyelinating disease; **OR**
   b. Heart failure with documented left ventricular dysfunction.

Tildrakizumab may not be approved for any of the following:

I. Use in combination with a biologic disease modifying anti-rheumatic drug (DMARD) [such as Cimzia (certolizumab) Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), or Stelara (ustekinumab)]; **OR**
II. Use in combination with other immunosuppressive therapy (such as methotrexate) or phototherapy; **OR**
III. Individual's with Tuberculosis, chronic infection, 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) -recommended equivalent test to evaluate for latent tuberculosis prior to initiating tildrakizumab.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
Washington	1/1/2018	Washington State PDL prefers Enbrel and Humira; all other clinical criteria apply

Key References:

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

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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.

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.

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.