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

Otezla (apremilast)

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

Medications	Quantity Limit
Otezla (apremilast)	14 Day Starter Pack – 1 pack (14 day supply, one time fill) 28 Day Starter Pack – 1 pack (28 day supply, one time fill) 30 mg – 2 tablets per day

APPROVAL CRITERIA

Requests for Otezla (apremilast) 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 22019):
      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 of TWO (2) preferred biologic agents [Current preferred biologics include - Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Otezla (apremilast); **OR**
      2. The preferred agents are not acceptable due to concomitant clinical conditions, including but not limited to any of the following:

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

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

3. Individual is unable to take biologic agent due to product warning contraindication for any of the following:
   a. Serious infection or sepsis; **OR**
   b. Chronic or recurrent infection; **OR**
   c. Tuberculosis infection; **OR**
   d. Malignancy; **OR**

OR

II. Psoriatic arthritis (PsA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe PsA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [nonbiologic disease modifying anti-rheumatic drugs (DMARDs) (such as methotrexate, sulfasalazine, leflunomide)];

   AND

   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance of TWO (2) preferred biologic agents [Current preferred biologics include - Enbrel (etanercept), Humira (adalimumab)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Otezla (apremilast); **OR**
      2. The preferred agents are not acceptable due to concomitant clinical conditions, including but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Otezla (apremilast); **OR**
         b. Pregnant or planning on becoming pregnant; **OR**
         c. Serious infections or concurrent sepsis; **OR**
      3. Individual is unable to take biologic agent due to product warning or contraindication for any of the following:
         a. Serious infection or sepsis; **OR**
         b. Chronic or recurrent infection; **OR**
         c. Tuberculosis infection; **OR**
         d. Malignancy; **OR**

OR

III. Oral Ulcers associated with Behcet's Disease when each of the following criteria are met:
   A. Individual is 18 years of age or older with a diagnosis of Behcet's Disease; **AND**
   B. Individual has recurrent oral ulcers as a result of Behcet's Disease; **AND**
   C. Individual has had an inadequate response to, is intolerant of, or has a

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

contraindication to conventional therapy [such as topical or systemic corticosteroids, immunosuppressants, colchicine, or NSAIDs].

Otezla (apremilast) may **not** be approved for the following:

I. In combination with a biologic drug (such as TNF antagonists).

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: October 18, 2018
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.

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