

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

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 if the following criteria are met: Plaque

- I. Psoriasis (Psoriasis Vulgaris)
 - A. Individual is 18 years of age or older with chronic moderate to severe (that is, extensive or disabling) plaque psoriasis (psoriasis vulgaris) with either of the following (AAD 2009, 2011):
 1. Plaque psoriasis (psoriasis vulgaris) involving greater than five percent (5%) body surface area (BSA); **OR**
 2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to five percent (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 any 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 of TWO (2)

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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 FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Otezla (apremilast) 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 Otezla (apremilast); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
4. 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**
5. The preferred agent(s) do not have activity against a concomitant clinical condition and Otezla (apremilast) 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;

OR

II. Psoriatic Arthritis (PsA)

- A. Individual is 18 years of age or older with active PsA; **AND**
- B. Agent is used for any of the following reasons:
 1. To reduce signs or symptoms; **OR**
 2. To induce or maintain clinical response; **OR**
 3. To improve physical function; **AND**
- C. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy (such as methotrexate, sulfasalazine, leflunomide);

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AND

- D. 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 FDA-approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Otezla (apremilast) 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 Otezla (apremilast); **OR**
 - b. Individual's age; **OR**
 - c. Pregnant or planning on becoming pregnant; **OR**
 - d. Serious infections or concurrent sepsis; **OR**
 4. 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**
 5. The preferred agent(s) do not have activity against a concomitant clinical condition and Otezla (apremilast) 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.

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

- I. In combination with a biologic DMARD [such as Enbrel (etanercept), Humira (adalimumab), Simponi (golimumab), Cimzia (certolizumab pegol), Remicade (infliximab), Stelara (ustekinumab)].

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

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. 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/daily_med/about.cfm.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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