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	X

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Taltz (ixekizumab)

DRUG.00077

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

Medications	Quantity Limit
Taltz 80 mg/mL prefilled autoinjector*	1 autoinjector per 28 days
Taltz 80 mg/mL prefilled syringe*	1 syringe per 28 days

*Initiation of therapy for Plaque Psoriasis (Psoriasis Vulgaris): May approve up to 3 (three) additional prefilled autoinjectors or syringes (80 mg/mL) in the first 28 days (4 weeks) of treatment and up to 2 (two) additional prefilled autoinjectors or syringes (80 mg/mL) during days 29-84 (4-12 weeks) of treatment.

*Initiation of therapy for Psoriatic Arthritis without concomitant Plaque Psoriasis: May approve up to 1 (one) additional prefilled autoinjector or syringe (80 mg/mL) in the first 28 days (4 weeks) of treatment.

APPROVAL CRITERIA

Requests for Taltz (ixekizumab) may be approved if the following criteria are met:

I. Plaque Psoriasis (Psoriasis Vulgaris) when the following criteria are met:
   A. Individual is 18 years of age or older with 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

      3. Agent is used for any of the following reasons:
         a. To reduce signs or symptoms; **OR**
         b. To induce or maintain clinical response;

      AND

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	X

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4. Individual has failed to respond to, is intolerant of, or has a medical contraindication to phototherapy or other systemic therapy (such as acitretin, cyclosporine, or methotrexate);

OR

II. Psoriatic Arthritis when the following are met:
   A. Individual is 18 years of age or older with active psoriatic arthritis; **AND**
      1. Agent is used for any of the following reasons:
         a. To reduce signs or symptoms; **OR**
         b. To induce or maintain clinical response;

AND

2. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional drug therapy including disease-modifying antirheumatic drugs or a tumor necrosis factor antagonist;

AND

III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab), unless the following criteria is met:
   A. Individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab); **OR**
   B. 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 Taltz (ixekizumab) does; **OR**
   C. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
      1. Known hypersensitivity to any active or inactive component which is not also associated with the Taltz (ixekizumab); **OR**
      2. Individual's age; **OR**
      3. Pregnant or planning on becoming pregnant; **OR**
      4. Serious infections or concurrent sepsis; **OR**
   D. The individual has either concomitant clinical condition:
      1. Demyelinating disease; **OR**
      2. Heart failure with documented left ventricular dysfunction; **OR**
   E. The preferred agent(s) do not have activity against a concomitant clinical condition and Taltz (ixekizumab) does. Examples include but may not be limited to the following:

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	X

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1. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
2. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred.

Taltz (ixekizumab) may **not** be approved for any of the following:

I. In combination with other immunosuppressive therapy or phototherapy; **OR**
II. In combination with a biologic DMARD [such as Cimzia (certolizumab pegol), Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), Siliq (brodalumab), or Stelara (ustekinumab)]; **OR**
III. Tuberculosis, invasive fungal 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 Taltz (ixekizumab).

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

Key References:

American Academy of Dermatology (AAD). American Academy of Dermatology Association (AADA). Guidelines of care for management of psoriasis and psoriatic arthritis. May 2008. Available at: http://www.aad.org/education-and-quality-care/clinical-guidelines. Accessed on December 7, 2017.

Centers for Disease Control (CDC) and Prevention. Updated guidelines for using interferon gamma release assays to detect Mycobacterium tuberculosis infection - United States, 2010; 59(No. RR 5):1-28. Available at: http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. Accessed on December 7, 2017.

Ixekizumab. In: DrugPoints System (electronic). Truven Health Analytics, Greenwood Village, CO. Updated December 5, 2017. Available at: https://www.micromedexsolutions.com. Accessed on December 7, 2017.

Taltz [Product Information]. Indianapolis, IN. Eli Lilly and Company; December 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125521s004lbl.pdf. Accessed on December 7, 2017.