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

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Cosentyx (secukinumab)

DRUG.00077

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

Medications	Quantity Limit*
Cosentyx 150 mg/mL Sensoready pen^*	2 pens per 28 days
Cosentyx 150 mg/mL Sensoready Pen 2-Pack^*	1 pack (2 x 150 mg/mL pens)
Cosentyx 150 mg/mL prefilled syringe^*	2 syringes per 28 days
Cosentyx 150 mg/mL prefilled Syringe 2-Pack^*	1 pack (2 x 150 mg/mL syringes)

^Initiation of therapy for Psoriatic Arthritis without coexistent Plaque Psoriasis (Psoriasis Vulgaris) or Ankylosing Spondylitis: May approve up to an additional 3 (three) single pens (150 mg/mL) or 3 (three) single syringes (150 mg/mL) in the first month (28 days) of treatment.

* Initiation of therapy for Plaque Psoriasis (Psoriasis Vulgaris) or Psoriatic Arthritis with coexistent Plaque Psoriasis (Psoriasis Vulgaris): May approve up to an additional 4 (four) 2-pack pens (2 x 150 mg/mL), 4 (four) 2-pack syringes (2 x 150 mg/mL), 8 (eight) single additional pens (150 mg/mL), or 8 (eight) single syringes (150 mg/mL) in the first month (28 days) of treatment.

APPROVAL CRITERIA

I. **Ankylosing spondylitis**
   A. Individual is 18 years of age or older with active ankylosing spondylitis ; **AND**
   B. The 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 failed to respond to, is intolerant of, or has a medical contraindication to conventional drug therapy including a tumor necrosis factor (TNF) antagonist;

   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	NA

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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. Individual has been receiving and is maintained on a stable dose of Cosentyx (secukinumab); **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 Cosentyx (secukinumab) 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 Cosentyx (secukinumab); **OR**
        b. Individual's age; **OR**
        c. Pregnant or planning on becoming pregnant; **OR**
        d. Serious infections or concurrent sepsis; **OR**
    4. The individual has either concomitant clinical condition:
        a. Demyelinating disease; **OR**
        b. Heart failure with documented left ventricular dysfunction;

OR

II. **Psoriatic Arthritis**

A. Individual is 18 years of age or older with active psoriatic arthritis; **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 failed to respond to, is intolerant of, **or** has a medical contraindication to conventional drug therapy including disease-modifying anti-rheumatic drugs (DMARDs) or TNF antagonists;

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. Individual has been receiving and is maintained on a stable dose of Cosentyx (secukinumab); **OR**

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

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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 Cosentyx (secukinumab) 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 Cosentyx (secukinumab); **OR**
    b. Individual's age; **OR**
    c. Pregnant or planning on becoming pregnant; **OR**
    d. Serious infections or concurrent sepsis; **OR**
4. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction; **OR**
5. The preferred agent(s) do not have activity against a concomitant clinical condition and Cosentyx (secukinumab) 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

III. **Plaque Psoriasis (Psoriasis Vulgaris)**

A. Individual is 18 years of age or older with chronic moderate to severe plaque psoriasis with either of the following;
    1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% body surface area; **OR**
    2. Plaque psoriasis (psoriasis vulgaris) involving less than or equal to 5% body surface area 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

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

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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. Individual has been receiving and is maintained on a stable dose of Cosentyx (secukinumab); **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 Cosentyx (secukinumab) 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 Cosentyx (secukinumab); **OR**
        b. Individual's age; **OR**
        c. Pregnant or planning on becoming pregnant; **OR**
        d. Serious infections or concurrent sepsis; **OR**
    4. The individual has either concomitant clinical condition:
        a. Demyelinating disease; **OR**
        b. Heart failure with documented left ventricular dysfunction; **OR**
    5. The preferred agent(s) do not have activity against a concomitant clinical condition and Cosentyx (secukinumab) 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.

Cosentyx (secukinumab) may **not** be approved for any of the following:

I. Use in combination with other immunosuppressive therapy or phototherapy; **OR**

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

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II. Use in combination with other biologic drugs [such as Cimzia (certolizumab), Enbrel (etanercept), Humira (adalimumab), Remicade (infliximab), Siliq (brodalumab), Stelara (ustekinumab), or Taltz (ixekizumab)]; **OR**

III. Individuals with 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 Cosentyx (secukinumab).

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.: 2018. 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.; 2018; Updated periodically.