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

Cosentyx (secukinumab)

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

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

^Initiation of therapy for Psoriatic Arthritis (PsA) without coexistent Plaque Psoriasis (Ps) (Psoriasis vulgaris) or Ankylosing Spondylitis (AS): 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 Ps (Psoriasis vulgaris) or PsA with coexistent Plaque Ps (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

Requests for Cosentyx (secukinumab) may be approved for the following:

I. Ankylosing spondylitis (AS) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe AS;
   AND
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic disease-modifying anti-rheumatic drugs (DMARDs) (such as sulfasalazine)] or a tumor necrosis factor (TNF) antagonist;
   AND
   C. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO

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

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 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 Cosentyx (secukinumab); **OR**
    b. Pregnant or planning on becoming pregnant; **OR**
    c. Serious infections or concurrent sepsis; **OR**
3. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction;

OR

II. 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 with either of the following: (AAD 2019):
    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);

OR

III. 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, or leflunomide)] or a TNF antagonist (ACR 2019).

AND

C. 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**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 Cosentyx (secukinumab); **OR**
    b. Pregnant or planning on becoming pregnant; **OR**
    c. Serious infections or concurrent sepsis; **OR**
3. The individual has either concomitant clinical condition:
    a. Demyelinating disease; **OR**
    b. Heart failure with documented left ventricular dysfunction.

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

I. All other indications not included above; **OR**
II. In combination with phototherapy; **OR**
III. In combination with JAK inhibitors, apremilast, other IL-17 inhibitors or biologic drugs (such as TNF antagonists or ustekinumab) ; **OR**
IV. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
V. Individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent test to evaluate for latent tuberculosis prior to initiating secukinumab.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018. 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: September 14, 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.; 2018; 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.
6. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheum. 2019; 71(1): 5-32.
7. Ward MM. Deodhar A, Gensler LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/ Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019; 71(10):1599-1613.

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

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.