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

Taltz (ixekizumab)

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

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

*Initiation of therapy for adults with Plaque Psoriasis (Ps) (Psoriasis vulgaris) with or without concomitant Psoriatic Arthritis (PsA): 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 individuals age 6 to 17 weighing >50 kg with Plaque Psoriasis (Ps): May approve up to one additional prefilled autoinjector or syringe (80 mg/mL in the first 28 days (4 weeks) of treatment.

*Initiation of therapy for PsA without concomitant Plaque Ps (Psoriasis vulgaris) or Ankylosing Spondylitis (AS): 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 for the following:

I. Ankylosing spondylitis (AS) when 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 (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab), unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Taltz (ixekizumab); **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 the Taltz (ixekizumab); **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. Non-radiographic axial spondyloarthritis (nr-axSpA) when each of the following criteria are met:
   A. Individual is 18 years of age or older with moderate to severe nr-axSpA; **AND**
   B. Individual has had an inadequate response to, is intolerant of, or has a contraindication to conventional therapy [such as NSAIDs or nonbiologic DMARDs (such as sulfasalazine)] (ACR 2019, Deodhar 2020);

OR

III. Plaque psoriasis (Ps) (Psoriasis vulgaris) when each of the following criteria are met:
   A. Individual is 6 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 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);

   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 (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 Taltz (ixekizumab); **OR**
      2. The preferred agents are not acceptable due to concomitant clinical

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

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 the Taltz (ixekizumab); **OR**
b. Individual's age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis.

OR

IV. 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 tumor necrosis factor (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 (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 Taltz (ixekizumab); **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 the Taltz (ixekizumab); **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 Taltz (ixekizumab) 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**

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

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 ixekizumab.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: http://www.clinicalpharmacology.com. Updated periodically.
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3. Deodhar A, van der Heijde D, Gensler LS, et ak.; COAST-X Study Group. Ixekizumab for patients with non-radiographic axial spondyloarthritis (COAST-X): a randomised, placebo-controlled trial. Lancet. 2020; 395: 53-64.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
6. 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.
7. 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.
8. 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.

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.