

Clinical Criteria

Subject:	Monoclonal Antibodies to Interleukin-17		
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Overview

This document addresses the use of monoclonal antibodies which bind to the interleukin-17A (IL-17) cytokine and disrupt its interaction with the IL-17 receptor thereby inhibiting the release of proinflammatory cytokines and chemokines. Indications are drug-specific but IL-17 inhibitors are approved for the treatment of plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis. Agents addressed in this clinical guideline include:

- Cosentyx (secukinumab)
- Siliq (brodalumab)
- Taltz (ixekizumab)

Plaque Psoriasis (otherwise known as psoriasis vulgaris): The American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) published joint guidelines on the management and treatment of psoriasis with biologics. The guidelines do not include a treatment algorithm or compare biologics to each other or conventional therapy. The guideline notes that patients with mild-moderate disease may be adequately controlled with topical therapy and/or phototherapy while moderate to severe disease may necessitate treatment with a biologic. Moderate to severe disease is defined as involvement in > 3% of body surface area (BSA) or involvement in sensitive areas that significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia). TNFi biologics, ustekinumab, IL17 inhibitors, and IL23 inhibitors are all recommended as monotherapy treatment options for adult patients with moderate to severe plaque psoriasis.

Psoriatic Arthritis: The American College of Rheumatology (ACR) guidelines recommend that initial treatment of patients with active severe PsA or concomitant psoriasis should include a TNFi biologic over an oral small molecule (OSM; including methotrexate, sulfasalazine, cyclosporine, leflunomide, and apremilast). For initial therapy, OSMs are preferred over IL-17 and ustekinumab; and may be considered over TNFi biologics in mild to moderate disease without comorbid conditions or in those who prefer oral therapy. Recommendations involving biologics over OSMs as first line therapy are conditional and based on low quality evidence. Evidence cited includes indirect comparisons of placebo-controlled trials, studies with open-label design, and extrapolation from studies in plaque psoriasis. Furthermore, most pivotal trials for TNFi biologics included a study population that were DMARD experienced. Overall, there is a lack of definitive evidence for the safety and efficacy of biologic drugs over conventional therapy for the initial treatment of most patients with psoriatic arthritis. The ACR guidelines also include recommendations for patients whose disease remains active despite treatment with an OSM. Here, TNFi biologics are recommended over other therapies including IL-17 inhibitors, ustekinumab, tofacitinib, and abatacept. When TNFi biologics are not used, IL-17 inhibitors are preferred over ustekinumab; both of which are preferred over tofacitinib and abatacept. For disease that remains active despite TNFi monotherapy, switching to a different TNFi is recommended over other therapies.

Axial Spondyloarthritis: Spondyloarthritis with predominantly axial involvement includes both ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA), based upon the presence or absence, respectively, of abnormalities of the sacroiliac joints on plain radiography. The American College of Rheumatology (ACR) and Spondylitis Association of America guidance recommend NSAIDs as initial treatment for AS and nr-axSpA. In adults with active AS despite treatment with NSAIDs, DMARDs [including sulfasalazine or MTX], TNF inhibitors, and IL-17 inhibitors [secukinumab or ixekizumab] are recommended. TNFi treatment is recommended over IL-17 inhibitors. IL-17 inhibitors are recommended over a different TNFi in patients with primary nonresponse to TNFi (no initial response). An alternative TNFi is recommended in patients with secondary nonresponse to the first TNFi used (relapse after initial response). Recommendations for nr-axSpA are largely extrapolated from evidence in AS; only certolizumab, ixekizumab and secukinumab have been approved for this indication.

Siliq (brodalumab) has a black box warning for suicidal ideation and behavior. Suicidal ideation and behavior, including completed suicides have occurred in individuals treated with Siliq. Potential risks and benefits should be weighed in individuals with a history of depression and/or suicidal ideation and behavior prior to initiation of therapy with Siliq. Due to the observed suicidal ideation and behavior in subjects treated with Siliq, discontinuation of therapy should be considered in individuals who do not achieve an adequate response within the first 12 to 16 weeks of therapy. The FDA has required the manufacturer to develop a comprehensive risk management program that includes the enrollment of prescribers in the Siliq REMS Program. Additional information and forms for individuals, prescribers, and pharmacists may be found on the manufacturer's website: <http://www.siliqrems.com>.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Cosentyx (secukinumab)

Initial 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 DMARDs (such as sulfasalazine)] or a tumor necrosis factor (TNF) antagonist;
- 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)] or a tumor necrosis factor (TNF) antagonist (ACR 2019);
- OR**
- III. Plaque psoriasis (Ps) 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 involving greater than three percent (3%) body surface area (BSA); **OR**
 2. Plaque Ps 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**
- 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 DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] or a TNF antagonist (ACR 2019).

Continuation requests for Cosentyx (secukinumab) may be approved if the following criterion is met:

- I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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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. Prior to imitation therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating secukinumab (unless switching therapy from another targeted immune modulator and no risk factors).

Siliq (brodalumab)

Initial Requests for Siliq (brodalumab) may be approved for the following:

- I. Plaque psoriasis (Ps) 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 involving greater than three percent (3%) body surface area (BSA); **OR**
 2. Plaque Ps 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).

Continuation requests for Siliq (brodalumab) may be approved if the following criterion is met:
 I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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Requests for Siliq (brodalumab) 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. Prior to initiation therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating brodalumab(unless switching therapy from another targeted immune modulator and no risk factors); **OR**
- VI. Individual has Crohn's disease.

Taltz (ixekizumab)

Initial Requests for Taltz (ixekizumab) 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 DMARDs (such as sulfasalazine)] or a tumor necrosis factor (TNF) antagonist;
- 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) 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 with either of the following (AAD 2019):
 - 1. Plaque Ps involving greater than three percent (3%) body surface area (BSA); **OR**
 - 2. Plaque Ps 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**
- 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 DMARDs (such as methotrexate, sulfasalazine, or leflunomide)] or a tumor necrosis factor (TNF) antagonist (ACR 2019).

Continuation requests for Taltz (ixekizumab) may be approved if the following criterion is met:
 I. There is confirmation of clinically significant improvement or stabilization in clinical signs and symptoms of disease.

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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**
- V. Prior to initiation therapy, individual has not had a tuberculin skin test (TST) or a Centers for Disease Control (CDC-) and Prevention -recommended equivalent to evaluate for latent tuberculosis prior to initiating ixekizumab(unless switching therapy from another targeted immune modulator and no risk factors).

Quantity Limits

Cosentyx (secukinumab) Quantity Limits

Drug	Limit
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Cosentyx (secukinumab) 150 mg/mL Sensoready® Pen ^Δ *	21 pens per 28 days
Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe ^Δ *	21 syringes per 28 days
Cosentyx (secukinumab) 150 mg/mL Sensoready® Pen 2-Pack*	1 pack (2 x 150 mg/mL pens) per 28 days
Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe 2-Pack*	1 pack (2 x 150 mg/mL syringes) per 28 days

Override Criteria

*Initiation of therapy for Psoriatic Arthritis (PsA) without coexistent plaque psoriasis, or Ankylosing Spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA): 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 (Ps) or Psoriatic Arthritis (PsA) with coexistent Ps: 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 pens (150 mg/mL), or 8 (eight) single syringes (150 mg/mL) in the first month (28 days) of treatment.

*Initiation of therapy:

May approve a total of 5 (five) single pens (150 mg/mL) or 5 (five) single syringes (150 mg/mL) in the first 35 days of treatment **OR** May approve a total of 5 (five) 2-pack pens (2 x 150 mg/mL) or 5 (five) 2-pack syringes (2 x 150 mg/mL) in the first 35 days of treatment

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*FDA recommended dosing for Psoriatic Arthritis (PsA) without coexistent plaque psoriasis, Ankylosing Spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA): Optional loading doses of 150 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg every 4 weeks; continued active PsA/AS maintenance dose of 300 mg every 4 weeks

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*FDA recommended dosing Plaque Psoriasis (Ps) with or without coexisting Psoriatic Arthritis (PsA): Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; maintenance dose of 150 mg every 4 weeks may be acceptable

Siliq (brodalumab) Quantity Limit

Drug	Limit
Siliq (brodalumab) 210 mg/1.5 mL*	2 prefilled syringes per 28 days
Override Criteria	
*Initiation of therapy for adult Plaque Psoriasis (Ps): May approve up to 2 (two) additional syringes (210 mg) in the first 28 days (4 weeks) of treatment.	

Taltz (ixekizumab) Quantity Limit

Drug	Limit
Taltz (ixekizumab) 80 mg/mL prefilled autoinjector*, prefilled syringe*	1 autoinjector/syringe per 28 days
Override Criteria	
*Initiation of therapy for adults with Plaque Psoriasis (Ps) 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 Psoriatic Arthritis (PsA) without concomitant Plaque Psoriasis (Ps) 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.	

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals (Hospital Outpatient Use ONLY) [when specified as brodalumab (Siliq), ixekizumab (Taltz), or secukinumab (Cosentyx)]
J3490	Unclassified drugs [when specified as brodalumab (Siliq), ixekizumab (Taltz), or secukinumab (Cosentyx)]
J3590	Unclassified biologics [when specified as brodalumab (Siliq), ixekizumab (Taltz), or secukinumab (Cosentyx)]

ICD-10 Diagnosis

L40.0	Psoriasis vulgaris (plaque psoriasis)
L40.50-L40.59	Arthropathic psoriasis [secukinumab (Cosentyx) or ixekizumab (Taltz) only]
L40.8-L40.9	Other, unspecified psoriasis
M45.0-M45.9	Ankylosing spondylitis [secukinumab (Cosentyx) or ixekizumab (Taltz) only]
M46.50-M46.59	Other infective spondylopathies

Document History

Revised: 11/20/2020

Document History:

- 11/20/2020 – Annual Review: Add continuation of use sections; update secukinumab quantity limit to adjust to monthly dose per package size; update override criteria for clarity and to allow adequate time for loading dose; update tuberculosis testing language. Coding Reviewed: No changes.
- 08/21/2020 – Select Review: Add new indication for secukinumab in non-radiographic axial Spondyloarthritis and include in quantity limit override. Administrative update to add drug specific quantity limit. Coding reviewed: Add ICD-10-CM M46.50-M46.59. 9/21/2020-Added ICD-10-CM L40.50-L40.59.
- 06/08/2020 – Select Review: Add new indication for Taltz in non-radiographic axial spondyloarthritis. Coding reviewed: Added Taltz to M45.0-M45.9
- 05/15/2020 – Select Review: Add new pediatric indication for Taltz in Psoriasis. Coding Reviewed: No changes
- 11/15/2019 – Annual Review: Add new ankylosing spondylitis indication to ixekizumab criteria; update definition of moderate psoriasis using BSA based on guidelines; update combination therapy criteria for consistency with other agents; wording and formatting changes. Coding reviewed: No Changes.
- 11/16/2018 – Annual Review: Initial P&T review of Monoclonal Antibodies to Interleukin-17 Clinical Guideline. Update clinical criteria to delete “active” disease wording. Update criteria to delete requirement agent is being used “to reduce signs and symptoms, maintain clinical response” etc. Add examples of conventional therapy to approval criteria for clarity. Wording and formatting changes to criteria for consistency. Add Crohn’s disease to non-approval criteria for brodalumab per label. HCPCS and ICD-10 Coding Review. Added C9399.

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