Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope	
Monoclonal Antibodies to Interleukin-17 [Cosentyx (secukinumab), Siliq (brodalumab), Taltz (ixekizumab)]	MP-RX-FP-60-23	☒ MMM MA	☒ MMM Multihealth

Service Category

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Part B DRUG

Service Description

This document addresses the use of Monoclonal Antibodies to Interleukin-17 , a drug approved by the Food and Drug Administration (FDA) for the treatment of plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and enthesitis-related arthritis.

Background Information

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 IL17 inhibitors are approved for the treatment of plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, and enthesitis-related arthritis.
Agents addressed in this document 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 mildmoderate 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). Tumor necrosis factor inhibitor (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: Sponyloarthritis with predominantly axial involvement includes both ankylosing spondylitis (AS) and nonradiographic 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], 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.

Enthesitis-related arthritis: The American College of Rheumatology and Arthritis Foundation published joint guidelines on the treatment of juvenile idiopathic arthritis (JIA) manifesting as non-systemic polyarthritis, sacroiliitis, and enthesitis. In children and adolescents with JIA and active enthesitis, NSAID treatment is strongly recommended. These guidelines for enthesitis-related arthritis (ERA) were published prior to secukinumab gaining approval for ERA; and it is the first biologic to be approved specifically for ERA. The pivotal trial resulting in this approval included a study population who had an inadequate response or intolerance to at least one NSAID and DMARD (NCT03031782).

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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.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

HCPCS	Description
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	Description
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

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Medical Necessity Guidelines

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.

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

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**
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**
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, cyclosporine or leflunomide)] (ACR 2019); **OR**
V. Enthesitis-Related Arthritis (ERA) when each of the following criteria are met:
A. Individual is 4 years of age or older with moderate to severe ERA; **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 methotrexate or sulfasalazine)].

Continuation requests for Cosentyx (secukinumab) may be approved if the following criterion is met:
I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Requests for Cosentyx (secukinumab) may not be approved for the following:
I. In combination with phototherapy; **OR**

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II. In combination with topical or oral JAK inhibitors, ozanimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. If initiating 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 (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

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 clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Requests for Siliq (brodalumab) may not be approved for the following:
I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections; **OR**
IV. If initiating 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 (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. Individual has Crohn's disease; **OR**
VI. When the above criteria are not met and for all other indications.

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**
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**

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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, cyclosporine or leflunomide)] (ACR 2019).

Continuation requests for Taltz (ixekizumab) may be approved if the following criterion is met:
I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.
Requests for Taltz (ixekizumab) may not be approved for the following:
I. In combination with phototherapy; **OR**
II. In combination with topical or oral JAK inhibitors, ozanimod, apremilast, deucravacitinib, or any of the following biologic immunomodulators: TNF antagonists, IL-23 inhibitors, other IL-17 inhibitors, vedolizumab, ustekinumab, abatacept, IL-1 inhibitors, IL-6 inhibitors, rituximab or natalizumab; **OR**
III. Tuberculosis, other active serious infections, or a history of recurrent infections;
IV. If initiating 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 (unless switching therapy from another targeted immune modulator and no new risk factors); **OR**
V. When the above criteria are not met and for all other indications.

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Limits or Restrictions

A. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Cosentyx (secukinumab) Quantity Limits

Drug	Limit
Cosentyx (secukinumab) 75 mg/0.5 mL Prefilled Syringe*	1 syringe per 28 days
Cosentyx (secukinumab) 150 mg/mL Sensoready® Pen*	1 pen per 28 days
Cosentyx (secukinumab) 150 mg/mL Prefilled Syringe*	1 syringe 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: May approve a total of 5 (five) single pens (150 mg/mL) or 5 (five) single syringes (150 mg/mL or 75 mg/mL/0.5 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	

*FDA recommended dosing for Adult Psoriatic Arthritis (PsA) without coexistent plaque psoriasis (Ps), 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.
*FDA recommended dosing for Enthesis-related arthritis (ERA) or Pediatric PsA without coexistent Ps: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.
*FDA recommended dosing Plaque Psoriasis (Ps) with or without coexisting Psoriatic Arthritis (PsA): Adults: 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. Pediatric: Loading doses of 150 mg or 75 mg (depending on weight) at weeks 0, 1, 2, 3, 4; maintenance dose of 150 mg or 75 mg (depending on weight) every 4 weeks.

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.	

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Policy Inception	Elevance Health's Medical Policy adoption.	N/A	11/30/2023

Revised: 03/13/2023