Medical Policy

Healthcare Services Department

Policy Name	Policy Number	Scope	
Monoclonal Antibodies to Interleukin-17 Cosentyx® (secukinumab)	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** , approved by the Food and Drug Administration (FDA) for the treatment of plaque psoriasis, psoriatic arthritis, axial spondylitis, enthesitis-related arthritis, and hidradenitis suppurativa (HS).

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. Agents addressed in this document include:

- Cosentyx® (secukinumab)

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). 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

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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, secukinumab and bimekisumab 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).

Hidradenitis Suppurativa (HS)

Hidradenitis Suppurativa is a chronic inflammatory skin condition that causes painful nodules and abscesses primarily occurring in intertriginous areas. HS is typically classified according to severity based on the number of abscesses and extent of skin involvement. General management includes antiseptic washes, intralesional therapies (steroids or antibiotics), and non-steroidal anti-inflammatories for pain. According to the United States and Canadian HS clinical guidelines, medical management may include oral antibiotics such as tetracyclines (level C recommendation) or rifampin and clindamycin (level B recommendation) for all stages of disease. Moderate to severe disease management includes biologics such as anti-TNF agents (Level A recommendation for adalimumab). Prior to secukinumab and bimekizumab, adalimumab was the only biologic approved for HS. Guidelines were published prior to FDA approval of secukinumab.

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Approved indications

Secukinumab is FDA approved for the treatment of:

A. Plaque psoriasis (PsO)
B. Active Psoriatic arthritis (PsA)
C. Active ankylosing spondylitis (AS)
D. Enthesitis-related arthritis (ERA)
E. Non-radiographic axial spondyloarthritis (nr-axSpA)
F. Hidradenitis suppurativa (HS)

Other uses

i. N/A

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 secukinumab (Cosentyx)]
C9166	Injection, secukinumab, intravenous, 1 mg
J3490	Unclassified drugs [when specified as secukinumab (Cosentyx)]
J3590	Unclassified biologics [when specified as secukinumab (Cosentyx)]
J3247	Injection, secukinumab, IV, 1 mg

ICD-10	Description
L40.0	Psoriasis vulgaris (plaque psoriasis)
L40.50-L40.59	Arthropathic psoriasis
L40.8-L40.9	Other, unspecified psoriasis
L73.2	Hidradenitis suppurativa
M08.80-M08.89	Juvenile arthritis, unspecified [enthesitis-related arthritis]
M45.0-M45.9	Ankylosing spondylitis
M45.A0-M45.AB	Non-radiographic axial spondyloarthritis
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.

Clinical Criteria

Secukinumab (Cosentyx®)

A. Criteria For Initial Approval

Initial requests for Cosentyx (secukinumab) may be approved for the following:

i. *Active Ankylosing spondylitis (AS*) when each of the following criteria are met:
   A. Individual is 18 years of age or older; **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. *Active Non-radiographic axial spondyloarthritis (nr-axSpA)* when each of the following criteria are met:
   A. Individual is 18 years of age or older with objective signs of inflammation; **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:
(For this indication only the SC formulation is FDA approved)

   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. *Active Psoriatic* arthritis (PsA) when each of the following criteria are met:

A. Individual is 2 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. *Active Enthesitis-Related Arthritis (ERA)* when each of the following criteria are met:
(For this indication only the SC formulation is FDA approved)

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)];

OR

vi. *Hidradenitis* suppurativa (HS) when each of the following criteria are met:
(For this indication only the SC formulation is FDA approved)

A. Individual is 18 years of age or older; **AND**
B. Individual has moderate to severe HS; **AND**
C. Individual has had an inadequate response to or is intolerant of conventional therapy (such as oral antibiotics); **OR**
D. Individual has a contraindication to oral antibiotics.

B. Criteria For Continuation of Therapy

Continuation requests for Cosentyx (secukinumab) may be approved if the following criterion is met:
A. Individual has been receiving and is maintained on a stable dose of Cosentyx; **AND**
B. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease.

C. Conditions not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):
Requests for Cosentyx (secukinumab) may not be approved for the following:
i. In combination with phototherapy; **OR**
ii. In combination with topical or oral JAK inhibitors, ozanimod, etrasimod, 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 [repeat TB testing not required for ongoing therapy]; **OR**

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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.

D. Approval Duration

i. Initial Approval Duration: Up to 6 months

ii. Reauthorization Approval Duration: Up to 6 months

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Limits or Restrictions

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. 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.

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
Cosentyx (secukinumab) 300 mg/2 mL UnoReady Pen/Prefilled syringe*^	1 pen/syringe per 28 days
Cosentyx (secukinumab) 125 mg/5 mL single-dose vial*	1.75 mg/kg, up to a max limit of 300 mg [3 vials], every 4 weeks

Exceptions

*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; **OR**
- May approve a total of 5 (five) 300 mg pens or 5 (five) 300 mg syringes in the first 35 days of treatment; **OR**
- May approve enough single-dose vials for a single 6 mg/kg loading dose for initiating intravenous treatment in PsA, nr-axSpA, and AS.

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^Maintenance therapy:

- May approve up to two 2-pack pens (2 x 150 mg/mL); **OR**
- May approve up to two 2-pack syringes (2 x 150 mg/mL); **OR**
- May approve up to two 300 mg pen/syringes every 28 days for individuals with Hidradenitis Suppurativa who do not respond to standard dosing of 300 mg every 4 weeks.

*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; loading and 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.

*FDA recommended dosing for Hidradenitis Suppurativa: Loading doses of 300 mg at weeks 0, 1, 2, 3, 4; maintenance dose of 300 mg every 4 weeks; may increase to 300 mg every 2 weeks for inadequate response.
*FDA recommended intravenous dosing for adult PsA, AS, and nr-axSpA: Optional 6 mg/kg loading dose followed by maintenance dosing of 1.75 mg/kg [max 300 mg] every 4 weeks thereafter.

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Policy History

Revision Type	Summary of Changes	P&T Approval Date	MPCC Approval Date
Annual Review. 7/25/2025	Wording and formatting changes. Added to the section of Conditions not covered: etrasimod combination (JAK inhibitors). Added dosage form specifications based on FDA approved indication to the clinical criteria section: for PsO, ERA and HS only the SC formulation is FDA approved. Added "Active" to the indications based on FDA criteria (ERA, PsA, AS, nr-axSpA). Changed clinical criteria for *Active nr-axSpA* based on FDA approved indication: "with moderate to severe nr-axSpA" to "with objective signs of inflammation". Coding Reviewed: No change.	8/25/2025	9/8/2025
Annual Review. 8/16/2024	Wording and formatting changes. Added sections: Approved indications, Other uses, Approval duration, Therapeutic Alternatives, Quantity Limitations (table). Update entire policy to remove information related to Taltz and Siliq (Part D drugs). Coding Reviewed: added HCPCS J3247; ICD-10: CM M45.A0-M45.AB, L73.2, M08.80-M08.89. Add new IV dosage form for secukinumab; add new indication for secukinumab for hidradenitis suppurativa; update secukinumab quantity limit; add etrasimod to combination use exclusion for consistency; update contraindication to prior therapy language for clarity; clarify repeat TB testing requirements; add continuation of use language. Update references.	2/24/2025	3/6/2025
Policy Inception 8/13/2023	Elevance Health's Medical Policy adoption.	N/A	11/30/2023
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