Washington State Health Care Authority

Cytokine and CAM Antagonists: IL-17 Inhibitors

Medical policy no. **.**.**-* Effective Date: Month, 1, Year

Related medical policies:

Policy Name
66.27.00.AA TNF inhibitors
66.27.00.AD IL-12, -23 inhibitors
66.27.00.AG T-Lymphocyte Inhibitor
66.27.00.AF Oral PDE inhibitors

Note: *New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.*

To see the list of the current Apple Health Preferred Drug List (AHPDL), please visit: https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx

Medical necessity

Drug	Medical Necessity
brodalumab (Siliq) ixekizumab (Taltz) secukinumab (Cosentyx)	**IL-17 Inhibitors** may be considered medically necessary in patients who meet the criteria described in the clinical policy below. If not all criteria are met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration. Clients new to Apple Health or new to an MCO who are requesting regimens for continuation of therapy are reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria

<table>
<tr>
<td>Ankylosing spondylitis

Non-radiographic axial spondyloarthritis
ixekizumab (Taltz)
secukinumab (Cosentyx)</td>
<td>Ixekizumab (Taltz) or secukinumab (Cosentyx) may be approved when all of the following documented criteria are met:
1. Patient is 18 years of age or older, AND
2. Prescribed by, or in consultation with a rheumatologist; AND
3. Not used in combination with another Cytokine and CAM medication; AND
4. Diagnosis of Ankylosing Spondylitis (AS); AND
5. High disease activity as indicated by a Bath Ankylosing Disease Activity Index (BASDAI) score of at least 4 or an Ankylosing Spondylitis Disease Activity Score (ASDAS) score of at least 2.1; AND
6. Treatment with at least two different NSAIDs (e.g., indomethacin, meloxicam, celecoxib, naproxen, nabumetone, etc.) has been ineffective, contraindicated, or not tolerated [minimum trial of four weeks]; AND
7. Disease manifested as either of the following:
a. Axial disease; OR
b. Peripheral arthritis; AND
i. Treatment with at least one non-Cytokine and CAM disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, sulfasalazine, leflunomide) has been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]; AND
8. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks].

If ALL criteria are met, the request will be authorized for 6 months.

Criteria (Reauthorization)
Ixekizumab (Taltz) or secukinumab (Cosentyx) may be approved when all of the following criteria are met:
1. Not used in combination with another Cytokine and CAM medication; AND
2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in BASDAI or ASDAS score).

If ALL criteria are met, the request will be authorized for 12 months.</td>
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<tr>
<td>Enthesitis-related arthritis
secukinumab (Cosentyx)</td>
<td>Secukinumab (Cosentyx) may be approved when all of the following criteria are met:
1. Patient is 4 to 17 years of age; AND
2. Prescribed by, or in consultation with, a rheumatologist; AND
3. Not used in combination with another Cytokine and CAM medication; AND</td>
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</table>

	4. Diagnosis of enthesitis-related arthritis; **AND** 5. Documentation of current weight is provided; **AND** 6. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, azathioprine, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. 7. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (PDL) medications has each been ineffective for at least 12 weeks, contraindicated, or not tolerated. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Secukinumab (Cosentyx) may be approved when all of the following criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Plaque psoriasis brodalumab (Siliq) ixekizumab (Taltz) secukinumab (Cosentyx)	Ixekizumab (Taltz), secukinumab (Cosentyx), or brodalumab (Siliq) may be approved when all of the following criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For ixekizumab and secukinumab, 6 years of age or older**; OR** b. For brodalumab, 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe plaque psoriasis; **AND** 5. For pediatric ixekizumab and secukinumab requests, documentation of current weight is provided; **AND** 6. Presence of ongoing disease for greater than 6 months; **AND** 7. The patient meets one of the following: a. Disease affects at least 10% body surface area; **OR** b. Disease affects the face, ears, hands, feet, or genitalia; **AND** 8. Baseline assessments are included (e.g., body surface area (BSA), Psoriasis Area and Severity Index (PSAI), Psoriasis Physician's Global Assessment (PGA), itch numeric rating scale, etc.); **AND**

	9. History of failure, contraindication, or intolerance to one of the following: a. Phototherapy (UVB or PUVA) [minimum trial of 12 weeks]; **OR** b. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, cyclosporine, acitretin, azathioprine, etc.) [minimum trial of 12 weeks]; **AND** 10. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Ixekizumab (Taltz), secukinumab (Cosentyx), or brodalumab (Siliq) may be approved when all of the following criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in BSA, PSAI, Psoriasis PGA, itch numeric rating scale). If ALL criteria are met, the request will be authorized for **12 months.**
Psoriatic arthritis ixekizumab (Taltz) secukinumab (Cosentyx)	Ixekizumab (Taltz) or secukinumab (Cosentyx) may be approved when all of the following criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For ixekizumab, 18 years of age or older; **OR** b. For secukinumab, 2 years of age or older, **AND** 2. Prescribed by, or in consultation with a rheumatologist or dermatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Psoriatic Arthritis (PsA); **AND** 5. For pediatric secukinumab and intravenous formulation requests, documentation of current weight is provided; **AND** 6. Patient meets one of the following: a. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]; **OR** b. Presence of active, severe disease as indicated by provider assessment and the presence of at least ONE of the following: i. Erosive disease

	ii. Elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) iii. Long-term damage interfering with function (e.g., joint deformities, vision loss) iv. Major impairment of quality of life due to high disease activity at many sites (including dactylitis, enthesitis) or functionally limiting arthritis at a few sites; **AND** 7. For adult requests, treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Ixekizumab (Taltz) or secukinumab (Cosentyx) may be approved when all of the following criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Drug	Indication	FDA Approved Dosing	Dosage Form and Quantity Limit
Siliq	Plaque psoriasis	210 mg subcutaneously at weeks 0, 1, and 2, followed by 210 mg once every 2 weeks	• 210mg/1.5mL PFS: 4 per 28 days for the first month followed by 2 per 28 days
Taltz	Ankylosing spondylitis	160 mg subcutaneously once, followed by 80 mg subcutaneously every 4 weeks	• 80mg/1mL autoinjector or PFS: 2 per 28 days for the first month followed by 1 per 28 days
	Non-radiographic axial spondyloarthritis	80 mg subcutaneously every 4 weeks	• 80mg/1mL autoinjector or PFS: 1 per 28 days
	Plaque psoriasis	Pediatrics (<18 years old) weight based: • <25 kg: 40 mg subcutaneously once followed by 20 mg every 4 weeks thereafter	• 6 – 17 years old AND > 50 kg: 80mg/1mL autoinjector or PFS; 2 per 28 days for the first month and 1 per 28 days thereafter • ≥ 18 years old: 80mg/1mL autoinjector or PFS; 3 per 28 days for the first month, 2 per 28 days for months 2-3, and 1 per 28 days thereafter

		• 25 to 50 kg: 80 mg subcutaneously once followed by 40 mg every 4 weeks thereafter • 50 kg and greater: 160 mg subcutaneously once followed by 80 mg every 4 weeks thereafter • Adults: 160 mg subcutaneously once, followed by 80 mg subcutaneously at weeks 2, 4, 6, 8, 10, and 12; then 80 mg subcutaneously every 4 weeks	
	Psoriatic arthritis	160 mg subcutaneously once, followed by 80 mg subcutaneously every 4 weeks	• 80mg/1mL autoinjector or PFS: 2 per 28 days for the first month followed by 1 per 28 days thereafter
Cosentyx	Ankylosing spondylitis Non-radiographic axial spondyloarthritis	Intravenous: With a loading dose: 6 mg/kg at week 0 followed by 1.75 mg/kg every 4 weeks Without a loading dose: 1.75 mg/kg every 4 weeks Subcutaneous: With a loading dose: 150 mg at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter Without a loading dose: 150 mg every 4 weeks For ankylosing spondylitis: May consider a dosage of 300 mg every 4 weeks if active disease persists	Intravenous: 125 mg/ 5mL vial • Loading dose: Up to 6 mg/kg • 1.75 mg/kg dose: Up to 300 mg per dose Subcutaneous: • Ankylosing spondylitis: ≥ 18 years old: 150mg/mL Sensoready pen or PFS; 5 for first 56 days followed by 1 per 28 days thereafter • Non-radiographic axial spondyloarthritis: ≥ 18 years old: 150mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter
	Plaque psoriasis	Adults (≥ 18 years old) 300 mg subcutaneously once weekly at weeks 0, 1, 2, 3, and 4; then 300 mg subcutaneously every 4 weeks	• Subcutaneous: • ≥ 18 years old: 150mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter

		Pediatrics (<18 years old) weight based: • < 50kg: 75 mg SUBQ once weekly at weeks 0, 1, 2, 3, and 4, followed by 75 mg every 4 weeks • ≥ 50 kg: 150 mg subcutaneously once weekly at weeks 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks	• ≥ 18 years old: 300mg/2mL autoinjector; 5 for the first 56 days followed by 1 per 28 days thereafter • <18 years old: ○ < 50kg: 75 mg/0.5 mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter ○ ≥ 50 kg: 150 mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter
	Psoriatic arthritis	Intravenous: Adults (≥ 18 years old): With a loading dose: 6 mg/kg at week 0 followed by 1.75 mg/kg every 4 weeks Adults (≥ 18 years old): Without a loading dose: 1.75 mg/kg every 4 weeks Subcutaneous: Adults (≥ 18 years old) 150 mg subcutaneously every 4 weeks Pediatrics (<18 years old) weight based: • 15 to <50 kg: 75 mg subcutaneously once weekly at weeks 0, 1, 2, 3, and 4, followed by 75 mg every 4 weeks • ≥ 50 kg: 150 mg subcutaneously once weekly at weeks 0, 1, 2, 3, and 4, followed by 150 mg every 4 weeks	Intravenous: 125 mg/ 5mL vial • Loading dose: Up to 6 mg/kg • 1.75 mg/kg dose: Up to 300 mg per dose Subcutaneous: • ≥ 18 years old: 150 mg/mL Sensoready pen or PFS; 5 for the 56 days followed by 1 per 28 days thereafter • ≥ 18 years old: 300 mg/2 mL autoinjector; 5 for the first 56 days followed by 1 per 28 days thereafter • <18 years old: ○ 15 to <50 kg: 75 mg/0.5 mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter ○ ≥ 50 kg: 150 mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter
	Coexistent plaque psoriasis and psoriatic arthritis	300 mg subcutaneously once weekly at weeks 0, 1, 2, 3, and 4; then, 300 mg subcutaneously every 4 weeks	• ≥ 18 years old: 150 mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter • ≥ 18 years old: 300 mg/2 mL autoinjector; 5 for the first 56 days followed by 1 per 28 days thereafter
	Enthesitis-related arthritis	Weight-based dose subcutaneously at weeks 0, 1, 2, 3, and 4 and every 4 weeks thereafter	• ≥ 15 kg and < 50 kg: 75 mg/0.5 mL PFS; 5 for the first 56 days followed by 1 per 28 days thereafter • ≥ 50 kg: 150 mg/mL Sensoready pen or PFS; 5 for the first 56 days followed by 1 per 28 days thereafter

Coding:

HCPCS Code	Description
J3247	Injection, secukinumab, intravenous, 1 mg

Background:

Ankylosing spondylitis and non-radiographic axial spondyloarthritis

The 2019 American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (ACR/SAA/SPARTAN) guidelines on the treatment of ankylosing spondylitis strongly recommend the use of NSAIDs as first-line treatment (with 70-80% responding). Recommendations against the use of non-biologic DMARDs are made for patients with active ankylosing spondylitis despite NSAID treatment. Some benefit has been seen in patients with peripheral arthritis, thus treatment with sulfasalazine or methotrexate may be considered in patients with predominantly peripheral disease; however, evidence is based on older RCTs with very low quality of evidence. For those patients with inadequate response despite continuous NSAID treatment, the ACR strongly recommends use of TNF inhibitors over no treatment with TNF inhibitors. In patients with secondary nonresponse to TNF inhibitors, the guidelines conditionally recommend treatment with a different TNF inhibitor over treatment with a non-TNF inhibitor biologic. The 2022 Assessment of SpondyloArthritis international Society (ASAS)-EULAR guidelines for the treatment of axial spondyloarthritis (axSpA) reference the use of JAK inhibitors in the treatment algorithm. The term axial spondyloarthritis (axSpA), encompasses both active ankylosing spondylitis (or radiographic AS) and nr-axSpA as one entity part of the same chronic inflammatory musculoskeletal spectrum with similar clinical presentations, comorbidities, disease burden, and treatment response. ASAS/EULAR recommends patients try and fail at least 2 NSAIDs over 4 weeks as first line therapy and treat local musculoskeletal inflammation with glucocorticoid injection; sulfasalazine may be considered in patients with peripheral symptoms, however use of conventional non-biologic DMARDS (e.g. sulfasalazine, leflunomide, methotrexate, etc.) is not recommended in axial disease. In contrast to ACR/SAA/SPARTAN, ASAS/EULAR guidelines highly recommend treatment with a TNF inhibitor, IL-17 inhibitor, or JAK inhibitor for patients with high disease activity, defined by a BASDAI of at least 4 or an ASDAS of at least 2.1, despite conventional treatment with NSAIDS. Starting with a TNF inhibitor or IL-17 inhibitor is preferred clinically, given long term data for use of JAK inhibitors in axSpA is still missing. There is no specific treatment algorithm after primary non-response to biologic (TNF inhibitor or IL-17 inhibitor) or JAK inhibitor therapy.

Enthesitis-related arthritis

Enthesitis-related arthritis (ERA) is a subset of juvenile idiopathic arthritis (JIA) and is characterized primarily by inflammation of the entheses, or connective tissue between tendon/ligament and bone, and commonly affects sacroiliac or lumbosacral joints. Other subsets of JIA include PJIA, oligoarthritis (less than five joints affected), systemic juvenile idiopathic arthritis (SJIA; fever, rash, hepatic/splenic/lymphatic involvement) and psoriatic arthritis (psoriasis and dactylitis). While these are distinct disease states, their pathogenesis and presentation are similar so there is significant overlap in effective treatments. The 2019 ACR JIA guidelines provide recommendations for enthesitis, which include ERA, psoriatic arthritis, and undifferentiated arthritis, all of which fall under the JIA umbrella. For patients with ERA, initial therapy with an NSAID is recommended. In the second-line setting, ACR provides a conditional recommendation for TNF inhibitors over DMARD, though this is based on low-quality evidence; this recommendation is rooted in retrospective cohort and phase 3 studies of etanercept and adalimumab for several different subtypes of JIA, including ERA, which provided mixed signals that biologics are more effective than placebo or no comparator, but the majority of included patients had previously been treated with at least one NSAID and DMARD. It has also been suggested that methotrexate is

not as effective at managing axial manifestations of ERA. However, DMARDs remain a viable first-line option for ERA patients given their well-established efficacy and safety profile, especially in those with mild disease or concomitant active polyarthritis. Age-appropriate biologics approved for ERA, PJIA or juvenile psoriatic arthritis should be reserved for subsequent therapy. While other biologics have been evaluated for use in ERA or other JIA subtypes, only secukinumab (Cosentyx) is FDA-approved for ERA.

Plaque psoriasis
Plaque psoriasis is a common chronic skin disorder typically characterized by erythematous papules and plaques with a silver scale. Joint American Academy of Dermatology–National Psoriasis Foundation guidelines for the management of psoriasis with systemic nonbiologic therapies and for the management and treatment of psoriasis with biologics indicate that the majority of patients are capable of adequately controlling disease solely with topical medications or phototherapy. Phototherapy is recognized as a beneficial therapy for controlled plaque psoriasis and is a cost-effective treatment strategy. Additionally, oral immunomodulatory medications (e.g., methotrexate, cyclosporine, acitretin) are cost-effective therapies with a well-known safety profile for the treatment of plaque psoriasis. For moderate-to-severe disease, where a JAK inhibitor or biologics are warranted, adalimumab (Humira) and etanercept (Enbrel) are one of many options. However, it would not be indicated for mild psoriasis given that patients are better managed from a safety perspective on well-established therapies (e.g., topical agents, phototherapy, conventional DMARDS, apremilast [Otezla]).

Psoriatic arthritis
Psoriatic arthritis is an inflammatory musculoskeletal disease associated with psoriasis that was initially considered a variant of rheumatoid arthritis but has emerged as a distinct clinical entity. The 2018 American College of Rheumatology/National Psoriasis Foundation Guideline (ACR) for psoriatic arthritis make a conditional recommendation for starting a TNF inhibitor over an oral small molecule (OSM) as a first-line option for patients who are treatment-naïve with active psoriatic arthritis. This recommendation is based on low- to very-low quality of evidence. Many of the studies in which greater benefit was seen in terms of disease severity or radiographic progression compared methotrexate to TNF inhibitors, however, most patients included in these groups were not truly treatment naïve to OSM medications. Guidelines note that OSM can be used first-line in naïve patients who do not have severe PsA, severe PsO, prefers oral therapy, or has contraindications to TNF inhibitors.

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Pending Approval (draft/unpublished version) -Updated clinical criteria for indication A to require Lab A. -Added indication for X. -Added new products in class which include Drug A and Drug B. -Updating dosing for Drug A. -Updating language at header note to include “If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.”
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by HCA. Updated dosing limits for expanded indication for drug X.
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by DUR Board.