WellMed Doctors helping patients for more than 25 years	**Effective Date: 01/03/2024**	**Revision Date(s):**
Department: PHARMACY	**MMC Review/ Approval Date(s):** 12/27/23	**Page(s):** 17
Policy Number: 071.000 **Title: Coverage Determination Policy for Cosentyx (secukinumab) intravenous solution**		

Regions: ☒ **Texas** ☒ **New Mexico**

Impacted Areas:

☒ Network Management/Provider Services	☒ Utilization Management
☐ Member services	☐ Case management
☐ Quality Management	☐ Disease management
☐ Credentialing	☒ Claims
☐ IT	☐ Human resources
☐ Administration	☐ Finance
☐ Compliance/delegation	☒ Pharmacy
	☐ ALL

Approved by: Vincent Huerta, MD, CHCQM Senior Medical Director		**Date:** 01/03/2024
Reviewed by: Pathik Tripathi, Pharm.D, MS Director, Clinical Pharmacy	Pathik Tripathi Digitally signed by Pathik Tripathi Date: 2024.01.03 13:00:00 -06'00'	**Date:** 01/03/2024

Available LCD/NCD/LCA: None

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Title: Coverage Determination Policy for: Cosentyx (secukinumab) intravenous solution

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Coverage Policy Number: 071.000

Line of Business: Medicare Part B

Policy Type: Prior Authorization

Coverage Determination:

This policy refers to Cosentyx® (secukinumab) injection for intravenous (IV) infusion only. Cosentyx for self-administered subcutaneous injection is obtained under the pharmacy benefit. Subcutaneously administered drugs listed on the Usually Self-Administered list will be denied as a benefit exclusion.

Cosentyx is listed on the self-administered drug exclusion list. (LCA A53127)[1].

PLEASE NOTE: **All requests for IV Cosentyx must include justification as to why IV route is medically reasonable and necessary**. Medicare rules expect that if a patient is clinically able to self-administer a drug and there is no clear medical justification to do otherwise, then the patient must either self-administer that drug or self-pay for the alternative. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-administer any injectable drug. Medicare considers the following factors to be unrelated to medical decision making: 1. Patient convenience, 2. Patient co-pays and financial liability. See the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

Documentation to support member has been screened for TB is recommended.[2]
Members should have age-appropriate vaccinations as recommended by current immunization guidelines prior to initiating treatment.[2]

Initial/New Requests

WellMed Medical Management will cover **Cosentyx (secukinumab)** Intravenous as medically necessary when **ALL** of the following are met for each indication:

1. Psoriatic Arthritis (PsA)

A. Diagnosis of active psoriatic arthritis

B. **ONE** of the following:

i. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of psoriatic arthritis [e.g., Humira (adalimumab), Simponi (golimumab), Cimzia (certolizumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz (tofacitinib), Otezla (apremilast), Rinvoq (upadacitinib)]

ii. Patient has contraindications to TNFi (tumor necrosis factor inhibitors) biologics, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease.

C. Cosentyx is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for psoriatic arthritis

D. Patient is NOT receiving Cosentyx with any of the following:

i. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)

ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

iii. Phosphodiesterase 4 (PDE4) inhibitor [e.g., Otezla (apremilast)]

2. Ankylosing Spondylitis (AS)

A. Diagnosis of active ankylosing spondylitis

B. **ONE** of the following:

   i. History of failure to NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

   ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of ankylosing spondylitis [e.g., Cimzia (certolizumab), Simponi (golimumab), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz/Xeljanz XR (tofacitinib), Enbrel (etanercept)]

C. Cosentyx is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for ankylosing spondylitis

D. Patient is NOT receiving Cosentyx in combination with **EITHER** of the following:

   i. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]

   ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

3. Non-radiographic Axial Spondyloarthritis (nr-axSpA)

A. Diagnosis of active non-radiographic axial spondyloarthritis

B. **ONE** of the following:

   i. History of failure to NSAIDs (e.g., ibuprofen, naproxen) at the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced

   ii. Patient has been previously treated with a biologic or targeted synthetic DMARD FDA-approved for the treatment of nr-axSpA [e.g., Cimzia (certolizumab), Rinvoq (upadacitinib)]

C. Cosentyx is initiated and titrated according to US Food and Drug Administration (FDA) labeled dosing for nr-axSpA

D. Patient is NOT receiving Cosentyx in combination with **EITHER** of the following:

   i. Biologic DMARD [e.g., Enbrel (etanercept), Humira (adalimumab), Cimzia (certolizumab), Orencia (abatacept)]

   ii. Janus kinase inhibitor [e.g., Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

Renewal/Continuation of Therapy Requests

WellMed Medical Management will cover **Cosentyx (secukinumab)** Intravenous as medically necessary for continuation of therapy when **ALL** of the following are met for the above indications:

A. Physician documentation showing positive clinical response to therapy (e.g. reduction in member's signs and symptoms)
B. Patient is currently on Cosentyx intravenous solution
C. The patient still meets indication specific criteria above with the exception of diagnosis of moderate-to-severe/active disease.
D. Cosentyx is dosed according to US Food and Drug Administration (FDA) labeled dosing for the requested indication.

Warning:

Inflammatory Bowel Disease (IBD): Cases of IBD were observed in clinical trials. Caution should be exercised when prescribing Cosentyx to patients with IBD

FDA Approved Dose and Indication

Approved Indication	Approved Dosing
Psoriatic Arthritis	• With a loading dosage: 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter **(max. maintenance dose 300 mg per infusion)** • Without a loading dosage: 1.75 mg/kg every 4 weeks **(max. maintenance dose 300 mg per infusion)**
Ankylosing Spondylitis	• With a loading dosage: 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter **(max. maintenance dose 300 mg per infusion)** • Without a loading dosage: 1.75 mg/kg every 4 weeks **(max. maintenance dose 300 mg per infusion)**
Non-Radiographic Axial Spondyloarthritis	• With a loading dosage: 6 mg/kg given at Week 0 as a loading dose, followed by 1.75 mg/kg every 4 weeks thereafter **(max. maintenance dose 300 mg per infusion)** • Without a loading dosage: 1.75 mg/kg every 4 weeks **(max. maintenance dose 300 mg per infusion)**

General Background

Cosentyx (secukinumab) is a human IgG1 monoclonal antibody that selectively binds to the interleukin-17A (IL-17A) cytokine, inhibiting its interaction with the IL-17 receptor. A naturally occurring cytokine, IL-17A is involved in normal inflammatory and immune responses. IL-17A stimulates keratinocytes to secrete chemokines and other proinflammatory cells. Elevated concentrations of IL-17A are found in psoriatic plaques. Treatment with secukinumab inhibits the release of proinflammatory cytokines and chemokines and may reduce epidermal neutrophils and IL-17A concentrations in psoriatic plaques.

Cosentyx (secukinumab) intravenous solution is indicated for the treatment of adults with moderate to severe psoriatic arthritis, adults with ankylosing spondylitis, and adults with non-radiographic axial spondyloarthritis with signs of inflammation.

*The effectiveness of intravenous Cosentyx in the treatment of adult patients with active AS, active nr-axSpA, and active PsA was extrapolated from the established effectiveness of subcutaneous Cosentyx in adult patients based on pharmacokinetic exposure[2].

Clinical Evidence

Adult Psoriatic Arthritis

The safety and efficacy of COSENTYX were assessed in 1,999 patients, in 3 randomized, double-blind, placebo controlled trials (PsA1, PsA2, and PsA3) in adult patients, age 18 years and older with active PsA (greater than or equal to 3 swollen and greater than or equal to 3 tender joints) despite non-steroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy. Patients in these trials had a diagnosis of PsA of at least 5 years across all trials.

- PsA1 Study (NCT 01752634) evaluated 397 patients, who were treated with 75 mg, 150 mg or 300 mg of COSENTYX (administered as two subcutaneous injections of 150 mg) at Weeks 0, 1, 2, 3, and 4, followed by the same subcutaneous dose every 4 weeks. Patients who received placebo were re-randomized to receive subcutaneous COSENTYX (either 150 mg or 300 mg every 4 weeks) at Week 16 or Week 24 based on responder status. The primary endpoint was the percentage of patients achieving an ACR20 response at Week 24.
- PsA2 Study (NCT 01392326) evaluated 606 patients, who were treated with intravenous secukinumab 10 mg/kg, or placebo at Weeks 0, 2, and 4, followed by either 75 mg or 150 mg of subcutaneous COSENTYX treatment (or placebo) every 4 weeks. Patients who received placebo were re-randomized to receive subcutaneous COSENTYX (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.
- PsA3 Study (NCT 02404350) evaluated 996 patients, who were treated with 150 mg or 300 mg of COSENTYX (administered as two subcutaneous injections of 150 mg) at Weeks 0, 1, 2, 3, and 4 followed by the same subcutaneous dose every 4 weeks, or once every 4 weeks of COSENTYX 150 mg. Patients treated with placebo received subcutaneous COSENTYX, either 150 mg or 300 mg, per baseline randomization, at Week 16 or Week 24 based upon responder status. The primary endpoint was ACR20 response at Week 16 with the key secondary endpoint the change from baseline in modified Total Sharp Score (mTSS) at Week 24.

Baseline Disease Characteristics

At baseline, over 61% and 42% of the patients had enthesitis and dactylitis, respectively. Overall, 31% of patients discontinued previous treatment with anti-TNFα agents due to either lack of efficacy or intolerance. In addition, approximately 53% of patients from both studies had concomitant methotrexate (MTX) use. Patients with different subtypes of PsA were enrolled, including polyarticular arthritis with no evidence of rheumatoid nodules (80%), asymmetric peripheral arthritis (63%), distal interphalangeal involvement (58%), spondylitis with peripheral arthritis (20%), and arthritis mutilans (7%).

Clinical Response

In PsA1, patients treated with 150 mg or 300 mg COSENTYX demonstrated a greater clinical response, including ACR20, ACR50, and ACR70 compared to patients treated with placebo at Week 24. Responses were similar in patients regardless of concomitant MTX treatment. Responses were seen regardless of prior anti-TNFα exposure.

In patients with coexistent PsO receiving COSENTYX (n = 99), the skin lesions of psoriasis improved with treatment, relative to placebo, as measured by the Psoriasis Area Severity Index (PASI).Improvements in enthesitis and dactylitis scores were observed in each COSENTYX group compared to placebo at Week 24.

Radiographic Response

In PsA3 Study, inhibition of progression of structural damage was assessed radiographically and expressed by the modified mTSS and its components, the Erosion Score (ES) and Joint Space Narrowing Score (JSN), at Week 24 compared to baseline. Radiographs of hands, wrists, and feet were obtained at baseline, Week 16 and/or Week 24 and scored independently by at least two readers who were blinded to treatment group and visit number. Treatment with subcutaneous COSENTYX 150 mg without a loading dose, 150 mg with a loading dose and 300 mg with a loading dose significantly inhibited progression of peripheral joint damage compared with treatment with placebo as measured by change from baseline in mTSS at Week 24. The percentage of patients with no disease progression (defined as a change from baseline in mTSS of less than or equal to 0.0) from randomization to Week 24 was 75.7%, 70.9%, and 76.5% for COSENTYX 150 mg without a loading dose, 150 mg, 300 mg, respectively versus 68.2% for placebo.

Physical Function

Improvement in physical function as assessed by Health Assessment Questionnaire-Disability Index (HAQ-DI) demonstrated that the proportion of patients who achieved at least -0.3 improvement in HAQ-DI score from baseline was greater in the subcutaneous COSENTYX 150 mg and 300 mg groups compared to the placebo group at Weeks 16 and 24. At Week 16 in PsA1 study, estimated mean change from baseline was -0.23 in the placebo group compared with -0.45 in the COSENTYX 150 mg group and -0.55 in the COSENTYX 300 mg group.

Treatment of Adult Patients with Active Psoriatic Arthritis with Intravenous COSENTYX

The effectiveness of intravenous COSENTYX in the treatment of adult patients with active PsA was extrapolated from the established effectiveness of subcutaneous COSENTYX in adult patients with active PsA based on pharmacokinetic exposure.

Ankylosing Spondylitis

The safety and efficacy of subcutaneous COSENTYX were assessed in 816 adult patients (18 years of age and older) with active AS in three randomized, double-blind, placebo-controlled trials (AS1, AS2, and AS3). Patients had active disease as defined by the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater or equal to 4 despite nonsteroidal anti-inflammatory drug (NSAID), corticosteroid or disease modifying anti-rheumatic drug (DMARD) therapy.

- AS1 Study (NCT01649375) evaluated 219 patients, who were treated with 75 mg or 150 mg of subcutaneous COSENTYX treatment at Weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks. At Week 16, patients who received placebo were re-randomized to either 75 mg or 150 mg of subcutaneous COSENTYX every 4 weeks. The primary endpoint was the percentage of patients who achieved an ASAS20 response at Week 16.

- AS2 Study (NCT01358175) evaluated 371 patients, who were treated with intravenous secukinumab 10 mg/kg at Weeks 0, 2, and 4 (for both treatment arms) or placebo, followed by either 75 mg or 150 mg subcutaneous COSENTYX treatment every 4 weeks or placebo. Patients who received placebo

were re-randomized to receive subcutaneous COSENTYX (either 75 mg or 150 mg every 4 weeks) at Week 16 or Week 24 based on responder status.

- AS3 Study (NCT02008916) evaluated 226 patients, who were treated with intravenous secukinumab 10 mg/kg at Weeks 0, 2, and 4 (for both treatment arms) or placebo, followed by either 150 mg or 300 mg subcutaneous COSENTYX treatment every 4 weeks or placebo. Patients who received placebo were re-randomized to receive subcutaneous COSENTYX (either 150 mg or 300 mg every 4 weeks) at Week 16. The primary endpoint was the percentage of patients who achieved an ASAS20 response at Week 16. Patients were blinded to the treatment regimen up to Week 52, and the trial continued to Week 156. In this study, each 300 mg dose was administered as two injections of 150 mg.

Baseline Disease Characteristics

At baseline, approximately 13% and 25% used concomitant MTX or sulfasalazine, respectively. Overall, 29% of patients discontinued previous treatment with anti-TNFα agents due to either lack of efficacy or intolerance.

Clinical Response

In AS1, patients treated with 150 mg COSENTYX demonstrated greater improvements in ASAS20 and ASAS40 responses compared to patients treated with placebo at Week 16 (Table 10). Responses were similar in patients regardless of concomitant therapies.

In AS3 Study, patients treated with subcutaneous COSENTYX (150 mg and 300 mg) demonstrated improved signs and symptoms, and had comparable efficacy responses, regardless of dose, that were superior to placebo at Week 16 for the primary and most secondary endpoints. At Week 16, the ASAS20 and ASAS40 responses were 58.1% and 40.5% for 150 mg and 60.5% and 42.1% for 300 mg, respectively.

Treatment of Adult Patients with Active Ankylosing Spondylitis with Intravenous COSENTYX

The effectiveness of intravenous COSENTYX in the treatment of adult patients with active AS was extrapolated from the established effectiveness of subcutaneous COSENTYX in adult patients with active AS based on pharmacokinetic exposure.

Non-Radiographic Axial Spondyloarthritis

The safety and efficacy of COSENTYX were assessed in 555 adult patients (18 years of age and older) with active nraxSpA in one randomized, double-blind, placebo-controlled Phase 3 study (nr-axSpA1, NCT02696031). Patients met ASAS criteria for axSpA with objective signs of inflammation and had active disease as defined by a BASDAI greater or equal to 4, a Visual Analogue Scale (VAS) for total back pain greater or equal to 40 (on a scale of 0-100 mm) despite NSAID therapy and no evidence of radiographic changes in the sacroiliac joints that would meet the modified New York criteria for AS. Patients also had to have objective signs of inflammation with a C-reactive protein (CRP) level above the upper limit of normal and/or evidence of sacroiliitis on Magnetic Resonance Imaging (MRI).

Patients were treated with 150 mg of subcutaneous COSENTYX treatment with a loading dosage (Weeks 0, 1, 2, 3, and 4) or without a loading dosage (Weeks 0 and 4) followed by the same dose every 4 weeks or placebo. In the double-blind period, patients (n = 555) received either placebo or COSENTYX for 52 weeks. Starting Week 16, dosage adjustment or addition of concomitant NSAIDs and DMARDs was permitted. Starting at Week 20, patients were allowed to switch to open-label 150 mg of subcutaneous COSENTYX monthly or other biologic at the discretion of the investigator and patient. The primary endpoint was at least 40% improvement in Assessment of Spondyloarthritis International Society (ASAS40) at Week 52.

Baseline Disease Characteristics

Approximately 10% and 15% of patients used concomitant MTX or sulfasalazine, respectively. Overall, 10% of patients had received previous treatment with anti-TNFα agents and discontinued these due to either lack of efficacy or intolerance.

Clinical Response

In nr-axSpA1 Study, treatment with COSENTYX 150 mg resulted in significant improvements in the measure of disease activity compared to treatment with placebo at Week 16 and Week 52.

Health-Related Quality of Life

COSENTYX treated patients showed improvement in both loading and without loading dosage arms compared to placebo-treated patients at Week 16 in health-related quality of life as measured by ASQoL (LS mean change: Week 16: -3.5 and -3.6 versus -1.8, respectively).

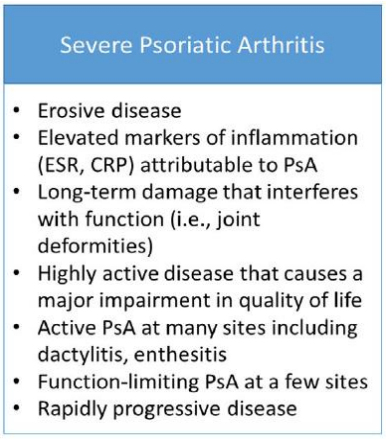
Treatment of Adult Patients with Active Non-radiographic Axial Spondyloarthritis with Intravenous COSENTYX

The effectiveness of intravenous COSENTYX in the treatment of adult patients with active nr-axSpA was extrapolated from the established effectiveness of subcutaneous COSENTYX in adult patients with active nr-axSpA based on pharmacokinetic exposure.

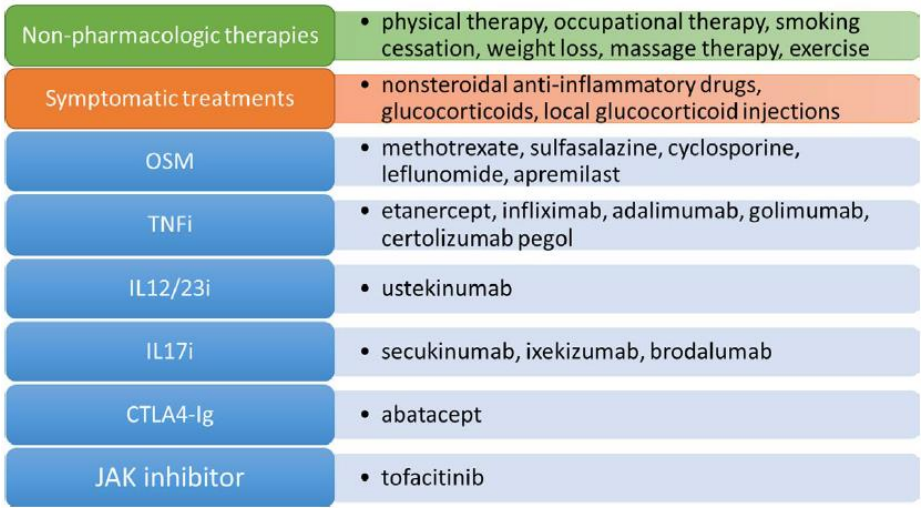
Professional Societies

Psoriatic Arthritis

In 2018, the American College of Rheumatology and the National Psoriasis Foundation published treatment guideline for the treatment of psoriatic arthritis. The guideline covers the management of active PsA in patients who are treatment-naive and those who continue to have active PsA despite treatment, and addresses the use of oral small molecules, tumor necrosis factor inhibitors, interleukin-12/23 inhibitors (IL-12/23i), IL-17 inhibitors, CTLA4-Ig (abatacept), and a JAK inhibitor (tofacitinib). In treatment-naïve patients with active PsA, a TNFi biologic agent is recommended over an OSM as a first-line option. OSMs may be used instead of a TNFi biologic in patients without severe PsA and without severe psoriasis those who prefer an oral drug instead of parenteral therapy, or those with contraindications to TNFi treatment, including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease. . Final determination of severity to be made by the patient and the health care provider.



Examples of "severe" psoriatic arthritis (PsA). The guideline development group defined severe PsA as the presence of 1 or more of the items listed[3].



Pharmacological, nonpharmacologic, and symptomatic therapies for psoriatic arthritis[3].

Ankylosing Spondylitis

In 2019, the American College of Rheumatology, Spondylitis Association of America and Spondyloarthritis Research and Treatment Network published updated recommendations for the treatment of patients with ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (SpA) which addressed the use of Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), tumor necrosis factor inhibitor (TNFi) biosimilars, and biologic tapering/discontinuation. Recommendations for AS and non-radiographic axial SpA are similar.

- TNFi are recommended over Cosentyx (secukinumab) or Taltz (ixekizumab) as the first biologic to be used.
- Cosentyx (secukinumab) or Taltz (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi.
- TNFi, Cosentyx (secukinumab), and Taltz (ixekizumab) are favored over Xeljanz (tofacitinib).
- Co-administration of low-dose methotrexate with TNFi is not recommended, nor is a strict treat-to-target strategy or discontinuation or tapering of biologics in patients with stable disease.
- Sulfasalazine is recommended only for persistent peripheral arthritis when TNFi are contraindicated.
- For patients with unclear disease activity, spine or pelvis magnetic resonance imaging could aid assessment.
- Routine monitoring of radiographic changes with serial spine radiographs is not recommended.

HCPCS Code

HCPCS Code	J3490, J3590, C9399
Dosage Form and Strength	125 mg/5 mL (25 mg/mL) single-dose vial for dilution
Route of Administration	Intravenous injection

Acronyms

American College of Rheumatology = (ACR)
Assessment of Spondylo Arthritis international Society = (ASAS)

American College of Rheumatology 20% response criteria = (ACR20)

Ankylosing Spondylitis = (AS)

Disease modifying anti-rheumatic drug = (DMARD)

Erosion Score = (ES)

Health Assessment Questionnaire-Disability Index = (HAQ-DI)

Interleukin-17A = (IL-17A)

Joint Space Narrowing Score = (JSN)

Methotrexate = (MTX)

modified Total Sharp Score = (mTSS)

Non-radiographic Axial Spondyloarthritis = (nr-axSpA)

Non-steroidal anti-inflammatory drug = (NSAID)

Oral small molecules = (OSMs)

Phosphodiesterase 4 = (PDE4)

Psoriasis Area Severity Index = (PASI)

Psoriatic arthritis = (PsA)

Tumor necrosis factor inhibitor = (TNFi)

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Policy History/Revision Information

Date Revised	Type of Changes (Major or Minor)	List Significant Changes and/or Status of policy
12/19/23	Major	New criteria creation. Mira Dawood, PharmD