secukinumab (Cosentyx™)

Policy # 00432
Original Effective Date: 05/20/2015
Current Effective Date: 09/11/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Plaque Psoriasis

Based on review of available data, the Company may consider secukinumab (Cosentyx™)‡ for the treatment of patients with plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for secukinumab (Cosentyx) will be considered when all of the following criteria are met:

- Patient has a diagnosis of moderate to severe plaque psoriasis; AND
- Patient is 6 years of age or older; AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as Humira®‡ or Enbrel®‡, OR other drugs, such as Otezla®‡ or Xeljanz/XR®‡; AND
- Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia); AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

- Patient has failed to respond to an adequate trial of one of the following treatment modalities unless there is clinical evidence or patient history that suggests the use of these treatments will be ineffective or cause an adverse reaction to the patient:
    - Ultraviolet B; OR
    - Psoralen positive Ultraviolet A; OR
    - Systemic therapy (i.e. methotrexate (MTX), cyclosporine, acitretin).
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Psoriatic Arthritis

Based on review of available data, the Company may consider secukinumab (Cosentyx) for the treatment of patients with active psoriatic arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for secukinumab (Cosentyx) will be considered when all of the following criteria are met:

- Patient has a diagnosis of active psoriatic arthritis; AND
- Patient is 2 years of age or older; AND
- Patient has a negative TB test (e.g. PPD, blood test) prior to treatment; AND
- Cosentyx is NOT used in combination with other biologic DMARDs, such as Humira or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has failed treatment with one or more traditional DMARDs, such as methotrexate, unless there is clinical evidence or patient history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Ankylosing Spondylitis

Based on review of available data, the Company may consider secukinumab (Cosentyx) for the treatment of patients with active ankylosing spondylitis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for secukinumab (Cosentyx) will be considered when all of the following criteria are met:

- Patient has a diagnosis of active ankylosing spondylitis; AND
- Patient is 18 years of age or older; AND
- Patient has a negative TB test (e.g. PPD, blood test) prior to treatment; AND
- Cosentyx is NOT used in combination with other biologic DMARDs, such as Humira or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs), such as naproxen, or has documented contraindications to NSAIDs usage.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

Non-Radiographic Axial Spondyloarthritis

Based on review of available data, the Company may consider the use of secukinumab (Cosentyx) for the treatment of patients with non-radiographic axial spondyloarthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for secukinumab (Cosentyx) will be considered when all of the following criteria are met:

- Patient has active non-radiographic axial spondyloarthritis as confirmed by the presence of sacroiliitis on magnetic resonance imaging (MRI); AND
- Patient has failed at least TWO months of current continuous therapy with at least TWO different oral NSAIDs (at prescription strength dosages) unless there is clinical evidence or patient history that suggests these products will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*
- Patient is 18 years of age or older; AND
- Cosentyx is NOT used in combination with other biologic DMARDs, such as Humira or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment.

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Enthesitis-Related Arthritis

Based on review of available data, the Company may consider the use of secukinumab (Cosentyx) for the treatment of patients with enthesitis-related arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for secukinumab (Cosentyx) will be considered when all of the following criteria are met:

- Patient has a diagnosis of active enthesitis-related arthritis; AND
- Patient is 4 years of age or older; AND
- Patient has a negative TB test (e.g. PPD, blood test) prior to treatment; AND
- Cosentyx is NOT used in combination with other biologic DMARDs, such as Humira or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has failed treatment with NSAIDs), such as naproxen, or has documented contraindications to NSAIDs usage.
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of secukinumab (Cosentyx) when any of the following criteria for their respective disease listed below (and denoted in the patient selection criteria above) are not met to be **not medically necessary**:**

- For plaque psoriasis:
  - Patient has greater than 10% of body surface area (BSA) OR less than or equal to 10% BSA with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
  - Patient has failed to respond to an adequate trial of one of the following treatment modalities:
    - Ultraviolet B; OR
    - Psoralen positive Ultraviolet A; OR
    - Systemic therapy (i.e. methotrexate, cyclosporine, acitretin)
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs

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- For ankylosing spondylitis:
  - Patient has failed treatment with NSAIDs
- For active non-radiographic axial spondyloarthritis:
  - Patient has failed at least TWO months of current continuous therapy with at least TWO different oral NSAIDs (at prescription strength dosages)
- For enthesitis-related arthritis:
  - Patient has failed treatment with NSAIDs

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of secukinumab (Cosentyx) when patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary**).**

Based on review of available data, the Company considers the use of secukinumab (Cosentyx) for indications other than those listed above to be **investigational.***

Background/Overview

Cosentyx is a human interleukin (IL)-17A antagonist indicated in patients 6 years and older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, patients 2 years of age and older with active psoriatic arthritis, adults with active ankylosing spondylitis, adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active enthesitis-related arthritis in patients 4 years of age and older. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Cosentyx inhibits the release of pro-inflammatory cytokines and chemokines. Cosentyx is available in 150 mg dosages supplied as vials, pens, and prefilled syringes for subcutaneous injection as well as 300 mg dosages supplied as pens and prefilled syringes for subcutaneous injection. For pediatric patients, there is a 75 mg prefilled syringe available. Dosing information can be found in the package insert.

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Plaque Psoriasis
Psoriasis is a common skin condition that is caused by an increase in production of skin cells. It is characterized by frequent episodes of redness, itching and thick, dry silvery scales on the skin. It is most commonly seen on the trunk, elbows, knees, scalp, skin folds and fingernails. This condition can appear suddenly or gradually and may affect people of any age; it most commonly begins between the ages of 15 and 35. Psoriasis is not contagious. It is an inherited disorder related to an inflammatory response in which the immune system produces too much TNF-alpha. It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. Treatment is focused on control of the symptoms and prevention of secondary infections. Lesions that cover all or most of the body may be acutely painful and require hospitalization. The body loses vast quantities of fluid and becomes susceptible to severe secondary infections that can involve internal organs and even progress to septic shock. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as methotrexate or cyclosporine. Newer biologic therapies are also approved for the treatment of plaque psoriasis.

Psoriatic Arthritis
Psoriatic arthritis is an arthritis that is often associated with psoriasis of the skin. Typically, first line treatments such as DMARDs (disease modifying anti-rheumatic drugs) are used to treat this condition. An example of a DMARD would include methotrexate.

Ankylosing Spondylitis
Ankylosing spondylitis is a chronic inflammatory disease that affects the joints between the vertebrae of the spine, and the joints between the spine and the pelvis. It eventually causes the affected vertebrae to fuse or grow together. Nonsteroidal anti-inflammatory drugs such as ibuprofen or naproxen are used to reduce inflammation and pain associated with the condition. Corticosteroid therapy or medications to suppress the immune system may be prescribed to control various symptoms.

Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
Disease-modifying anti-rheumatic drugs are typically used for the treatment of inflammatory conditions. These drugs slow the disease process by modifying the immune system.

- methotrexate
- cyclosporine
- sulfasalazine

- mercaptopurine
- gold compounds

Non-Radiographic Axial Spondyloarthritis.
Axial spondyloarthritis is an inflammatory arthritis of the spine. It often presents as chronic back pain, typically before the age of 45 and is often associated with one or more articular features (e.g., synovitis, enthesitis, and dactylitis) and/or non-articular features (e.g., uveitis, psoriasis, and inflammatory bowel diseases). Patients with this condition are classified as having one of two types of axial spondyloarthritis: either radiographic or non-radiographic. As supported by the name, the non-radiographic variety isn't evident on plain radiography and instead the diagnosis is supported by evidence of active inflammation of the sacroiliac joints via magnetic resonance imaging (MRI). Traditional pharmacologic therapy for the treatment of non-radiographic axial spondyloarthritis includes oral NSAIDs. Approximately 70-80% of patients with this condition report substantial relief with NSAID therapy. The effect of an NSAID is typically seen within two to four weeks and multiple NSAIDs need to be tried as patient response to a particular NSAID isn't predictable. Currently, Cimzia®‡ is the only TNF inhibitor product that is approved for non-radiographic axial spondyloarthritis. Most recently, Taltz®‡ and Cosentyx, both interleukin blockers, have gained approval for this indication. Rinvoq®‡, a janus kinase inhibitor, has this indication as well. If a response to two NSAIDs has not proven beneficial, a tumor necrosis factor (TNF) alpha inhibitor, such as Cimzia, or an interleukin blocker, such as Taltz or Cosentyx, would be the next treatment option. Rinvoq is typically used after failure of a TNF inhibitor.

Enthesitis-Related Arthritis
Enthesitis related arthritis is classified under the terms spondyloarthropathy or spondyloarthritis, which are a group of seronegative (rheumatoid factor negative) inflammatory diseases that involve the spine, large joints and the entheses. Enthesitis is the inflammation of the sites where tendons, ligaments, or joint capsule insert into the bone. The presence of Human Leukocyte Antigen (HLA B27) is often associated with enthesitis related arthritis. Enthesitis related arthritis most commonly occurs in the lower extremities, in particular the inferior pole of the patella and at the calcaneus. Typical treatment for enthesitis-related arthritis includes the use of NSAIDs. Cosentyx is the first biologic FDA approved medication for this condition.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Cosentyx was approved by the FDA in January of 2015 for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. In January of 2016, Cosentyx gained additional indications for active psoriatic arthritis and active ankylosing spondylitis. In June of 2020, Cosentyx was granted FDA approval for adults with active non-radiographic axial spondyloarthritis. In May of 2021, the plaque psoriasis indication was expanded from 18 years of age and older to 6 years of age and older. In December of 2021, the age for active psoriatic arthritis was changed from 18 years of age to 2 years of age and older. At the same time, Cosentyx was granted FDA approval for the treatment of active enthesitis-related arthritis in patients 4 years of age and older.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Adult Plaque Psoriasis Studies

The safety and efficacy of Cosentyx was assessed in four pivotal studies in adults with plaque psoriasis. Study 1 randomized subjects to Cosentyx 300 mg, Cosentyx 150 mg, or placebo. Treatment was provided at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks. Subjects in the placebo group that were non-responders at week 12 were then crossed over to receive either dose of Cosentyx. All subjects were then followed for up to 52 weeks from the first administration of treatment. The proportion of subjects achieving a reduction in the Psoriasis Area and Severity Index (PASI) score of at least 75% (PASI 75) from baseline to week 12 and treatment success on the investigator's global assessment (IGA) were the primary endpoints. The PASI 75 response in the Cosentyx 300 mg, 150 mg, and placebo groups was 82%, 71%, and 4%, respectively. The percentage of patients achieving an IGA of clear or almost clear for the Cosentyx 300 mg, 150 mg, and placebo groups was 65%, 51%, and 2%, respectively. In patients treated with Cosentyx 300 mg and 150 mg, 81% and 72%, respectively, maintained PASI 75 response through week 52. Subjects that were clear

or almost clear on the IGA also maintained their responses in 74% of subjects treated with Cosentyx 300 mg and in 59% of subjects treated with Cosentyx 150 mg.

Study 2 had a similar setup; however, it also included a biologic active control (Enbrel). The PASI 75 response in the Cosentyx 300 mg, 150 mg, and placebo groups was 76%, 67%, and 5%, respectively. The percentage of patients achieving an IGA of clear or almost clear for the Cosentyx 300 mg, 150 mg, and placebo groups was 62%, 51%, and 3%, respectively. Similar results to study 1 were seen with maintaining responses in both PASI 75 and IGA in study 2. In regard to the biologic active control, Cosentyx 300 mg and 150 mg were superior to Enbrel at week 12 based on the PASI 75 response (77%, 67%, and 44%, respectively) as well as for the IGA measurement (63%, 51%, and 27%, respectively; p=0.025 for all comparisons). Both doses of Cosentyx were superior to Enbrel for maintaining PASI 75 and IGA response through week 52. Studies 3 and 4 were consistent with previous studies in which both doses of Cosentyx were superior to placebo in achieving PASI responses and IGA responses for induction. Cosentyx trials also included measurements of PASI 90 as secondary outcomes.

Pediatric Plaque Psoriasis Studies
A 52-week, multicenter randomized, double-blind, placebo and active-controlled trial enrolled 162 pediatric subjects 6 years of age and older, with severe plaque psoriasis who were candidates for systemic therapy. Subjects were randomized to receive placebo, Cosentyx, or a biologic active control. In the Cosentyx groups, subjects with body weight < 25 kg received 75 mg, subjects with body weight 25 to < 50 kg received either 75 mg or 150 mg (2 times the recommended dose), and subjects with body weight ≥ 50 kg received either 150 mg or 300 mg (2 times the recommended dose). Subjects in the Cosentyx and placebo groups received treatment at weeks 0, 1, 2, 3, and 4 followed by dosing every 4 weeks. At week 12, subjects randomized to placebo who were non-responders were switched to Cosentyx (dose based on body weight) and received Cosentyx at weeks 12, 13, 14, and 15, followed by the same dose every 4 weeks starting at week 16.

The co-primary endpoints were the proportion of subjects who achieved a PASI 75 at week 12 and the proportion of subjects who achieved an IGA modified 2011 score of ‘clear’ or ‘almost clear’ (0 or 1) with at least a 2 point improvement from baseline to week 12. In those with body weight <50 kg on Cosentyx 75 mg, 55% of subjects achieved PASI 75 vs. 10% in the placebo group. In those with body weight ≥50 kg on Cosentyx 150 mg, 86% of the subjects achieved PASI 75 vs 19% in the placebo group. In those with body weight <50 kg on Cosentyx 75 mg, 32% of subjects achieved

IGA of clear or almost clear vs. 5% in the placebo group. In those with body weight ≥50 kg on Cosentyx 150 mg, 81% of the subjects achieved IGA of clear or almost clear vs 5% in the placebo group.

Adult Psoriatic Arthritis Studies
The safety and efficacy of Cosentyx were assessed in 1,003 patients in 2 randomized, double-blind, placebo-controlled trials in adult patients, age 18 years and older with active psoriatic arthritis. Study 1 for psoriatic arthritis evaluated 397 patients who were treated with Cosentyx 75 mg, 150 mg, or 300 mg at weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks. Patients receiving placebo were re-randomized to receive 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 a 20% improvement in the American College of Radiology score (ACR20) at week 24. In this study, patients treated with 150 mg or 300 mg of Cosentyx demonstrated a greater clinical response including ACR20, ACR50, and ACR70 compared to placebo at week 24. The percentage of patients achieving ACR20 at week 24 was 51% in the Cosentyx 150 mg group, 54% in the Cosentyx 300 mg group, and 15% in the placebo group. Results of the second study were not included in the package insert due to an intravenous loading dose being used (which is not approved in the United States).

Ankylosing Spondylitis Studies
The safety and efficacy of Cosentyx were assessed in 590 patients in two randomized, double-blind, placebo-controlled studies in adult patients 18 years of age and older with active ankylosing spondylitis. The first study for ankylosing spondylitis evaluated 219 patients who were treated with Cosentyx 75 mg or 150 mg at weeks 0, 1, 2, 3, and 4, followed by the same dose every 4 weeks. At week 16, patients receiving placebo were re-randomized to either Cosentyx 75 mg or 150 mg every 4 weeks. The primary endpoint was the percentage of patients achieving a 20 percent improvement in the Ankylosing Spondylitis Disease Activity Score (ASAS20) response at week 16. In this study, patients treated with 150 mg of Cosentyx demonstrated greater improvements in ASAS20 and ASAS40 responses compared to placebo at week 16. At week 16, 61% of patients taking Cosentyx 150 mg achieved ASAS20 vs. 28% taking placebo. Results of the second study were not included in the package insert due to an intravenous loading dose being used (which is not approved in the United States).

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Non-Radiographic Axial Spondyloarthritis
The safety and efficacy of Cosentyx were assessed in 555 patients in one randomized, double-blind, placebo-controlled study in adult patients 18 years of age and older with active non-radiographic axial spondyloarthritis. Patients were treated with Cosentyx 150 mg with a loading dose (weeks 0, 1, 2, 3, and 4) or without a loading dose (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, dose adjustment or addition of concomitant NSAIDs and DMARDs was permitted. Starting at week 20, patients were allowed to switch to open-label Cosentyx 150 mg monthly or other biologic at the discretion of the investigator and patient. The primary endpoint was at least a 40% improvement in Assessment of Spondyloarthritis International Society (ASAS40) at week 52. At week 52, the Cosentyx without a loading dose group had 38% of subjects achieving the primary endpoint versus 34% in the Cosentyx with a loading dose group versus 19% of subjects in the placebo group.

Juvenile Psoriatic Arthritis and Enthesitis-Related Arthritis
The efficacy and safety of Cosentyx were assessed in 86 patients in a two year, 3-part, double-blind, placebo-controlled, event-driven, randomized, Phase 3 study in patients 2 to < 18 years of age with active enthesitis-related arthritis or juvenile psoriatic arthritis as diagnosed based on a modified International League of Associations for Rheumatology (ILAR) Juvenile Idiopathic Arthritis (JIA) classification criteria. The study consisted of an open-label portion (Part 1) followed by randomized withdrawal (Part 2) followed by open-label treatment (Part 3). The juvenile idiopathic arthritis patient subtypes at study entry were: 60.5% enthesitis-related arthritis and 39.5% juvenile psoriatic arthritis. In the study 67.6% of patients with juvenile psoriatic arthritis, and 63.5% of patients with enthesitis-related arthritis, were treated concomitantly with methotrexate. Patients were given a dose of 75 mg if weighing < 50 kg, or 150 mg if weighing ≥ 50 kg. The primary endpoint was time to flare in Part 2. Disease flare was defined as a ≥ 30% worsening in at least three of the six JIA ACR response criteria and ≥ 30% improvement in not more than one of the six JIA ACR response criteria and a minimum of two active joints. In open-label Part 1, all patients received Cosentyx until week 12. Patients classified as responders (achieving JIA ACR30 response) at week 12 entered into the Part 2 double-blind phase and were randomized 1:1 to continue treatment with Cosentyx or begin treatment with placebo. Similar responses were seen in each JIA subtype (juvenile psoriatic arthritis and enthesitis-related arthritis). The JIA ACR 30, 50, 70 and 90 responses for patients with juvenile psoriatic arthritis were 91%, 91%, 71%, and 47%, respectively. The JIA ACR 30, 50, 70 and 90 responses for patients with enthesitis-related arthritis were 85%, 79%, 65%, and 33% respectively.

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During Part 2, a total of 11 juvenile psoriatic arthritis patients in the placebo group experienced a flare event compared with 4 juvenile psoriatic arthritis patients in the Cosentyx group. The risk of flare was reduced by 85% for patients on Cosentyx compared with patients on placebo (Hazard Ratio = 0.15, 95% CI: 0.04 to 0.56). During Part 2, a total of 10 enthesitis-related arthritis patients in the placebo group experienced a flare event compared with 6 enthesitis-related arthritis patients in the Cosentyx group. The risk of flare was reduced by 53% for patients on Cosentyx compared with patients on placebo (Hazard Ratio = 0.47, 95% CI: 0.17 to 1.32). Supplementary analyses provided confirmatory evidence of the treatment effect in enthesitis-related arthritis.

References

1. Cosentyx [package insert]. Novartis Pharmaceuticals. East Hanover, New Jersey. Updated May 2023.
2. Cosentyx Drug Evaluation. Express Scripts. January 2015

Policy History

Original Effective Date: 05/20/2015
Current Effective Date: 09/11/2023

05/07/2015	Medical Policy Committee review
05/20/2015	Medical Policy Implementation Committee approval. New policy.
03/03/2016	Medical Policy Committee review
03/16/2016	Medical Policy Implementation Committee approval. Added new indications psoriatic arthritis, ankylosing spondylitis and associated criteria.
03/02/2017	Medical Policy Committee review
03/15/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. Removed the requirement for the use of Humira prior to Cosentyx. Updated TB test language.
12/06/2018	Medical Policy Committee review
12/19/2018	Medical Policy Implementation Committee approval. No change to coverage.
12/05/2019	Medical Policy Committee review
12/11/2019	Medical Policy Implementation Committee approval. No change to coverage.
11/05/2020	Medical Policy Committee review

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11/11/2020	Medical Policy Implementation Committee approval. Added a new FDA approved indication for non-radiographic axial spondyloarthritis. Updated relevant background information.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Updated the plaque psoriasis criteria to reflect the new FDA age expansion of 6 years of age and older (previously 18 years of and older). Also updated the relevant background information.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Added a new indication, enthesitis-related arthritis. Updated the age for psoriatic arthritis to 2 years of age and older (previously 18 years of age and older). Updated relevant portions of the policy secondary to these changes.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Updated the background information to reflect a new set of 300 mg dosage forms.

Next Scheduled Review Date: 08/2024

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.