secukinumab (Cosentyx™)

Policy # 00432
Original Effective Date: 05/20/2015
Current Effective Date: 05/01/2025

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:

Initial

- 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 adalimumab (Humira®‡, biosimilars) 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).*

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 3 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least TWO of the following:
  - Improvement in estimated body surface area involvement; OR
  - Decreased erythema; OR
  - Improvement in induration/thickness; OR
  - Improvement in scale of areas affected by psoriasis; OR
  - Decreased pain; OR
  - Decreased itching; OR
  - Decreased burning.

  *(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:

Initial

- 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 adalimumab (Humira, biosimilars) 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.; 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).*
- If the request if for the IV formulation, patient is 18 years of age or older; AND
- If the request is for the IV formulation, ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
  - Improvement evidenced by an objective measure (for example, Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], serum markers); OR
  - Less joint pain; OR
  - Decreased morning stiffness or fatigue; OR
  - Improved function or activities of daily living; OR
  - Decreased soft tissue swelling in joints or tendon sheaths; 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).*
- If the request is for the IV formulation, ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

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:

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Initial

- 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 adalimumab (Humira, biosimilars) 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; 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).*
- If the request is for the IV formulation ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
  - Improvement evidenced by an objective measure (for example, Ankylosing Spondylitis Disease Activity Score, Ankylosing Spondylitis Quality of Life Scale [ASQoL], Health Assessment Questionnaire for the Spondyloarthropathies [HAQ-S], serum markers); OR
  - Decreased pain or stiffness; OR
  - Improvement in function or activities of daily living; 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).*
- If the request is for the IV formulation ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

<u>Non-Radiographic Axial Spondyloarthritis</u>

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.****

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Patient Selection Criteria

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

Initial

- 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 adalimumab (Humira, biosimilars) 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; AND
- If the request is for the IV formulation, ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
  - Improvement evidenced by an objective measure (for example, Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], Bath Ankylosing Spondylitis Functional Index [BASFI], serum markers); OR
  - Decreased pain or stiffness; OR
  - Improvement in function or activities of daily living; 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).*

- If the request is for the IV formulation, ONE of the following dosing regimens will be used:
  - WITH a loading dose: 6 mg/kg at Week 0, followed by 1.75 mg/kg every 4 weeks thereafter; OR
  - WITHOUT a loading dose: 1.75 mg/kg every 4 weeks.

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:

Initial

- 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 adalimumab (Humira, biosimilars) 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).*

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 6 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
  - Improvement evidenced by an objective measure (for example, Juvenile Arthritis Disease Activity Score [JADAS]; Physician Global Assessment [MD global], Juvenile Arthritis Disease Activity Score [JDAS], Clinical Juvenile Arthritis Disease Activity Score [cJDAS], serum markers); OR
  - Improvement in limitation of motion; OR
  - Less joint pain or tenderness; OR
  - Decreased duration of morning stiffness or fatigue; OR

- Improved function or activities of daily living.

*(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).*

Hidradenitis Suppurativa

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

Patient Selection Criteria

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

Initial

- Patient has moderate to severe hidradenitis suppurativa; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or Enbrel OR other drugs such as Otezla or Xeljanz/XR; AND
- Patient has failed treatment with ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin) for hidradenitis suppurativa 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; 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 a negative TB test (e.g., PPD, blood test) prior to treatment.

Continuation

- Patient has received an initial authorization; AND
- Patient has received at least 3 months of therapy with the requested drug; 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).*
- Cosentyx is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira, biosimilars) or Enbrel, OR other drugs, such as Otezla or Xeljanz/XR; AND
- Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
  - Improvement evidenced by an objective measure (for example, Hurley staging, Sartorius score, Physician Global Assessment, Hidradenitis Suppurativa Severity Index); OR
  - Decreased pain of lesions, nodules, or cysts; OR
  - Decreased drainage of lesions, nodules, or cysts.

  *(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 continuation requests: Patient has received at least 3 months of therapy with the requested drug
  - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least TWO of the following:
    - Improvement in estimated body surface area involvement; OR
    - Decreased erythema; OR
    - Improvement in induration/thickness; OR
    - Improvement in scale of areas affected by psoriasis; OR
    - Decreased pain; OR
    - Decreased itching; OR
    - Decreased burning
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
  - For continuation requests: Patient has received at least 6 months of therapy with the requested drug
  - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
    - Improvement evidenced by an objective measure (for example, Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], serum markers); OR
    - Less joint pain; OR
    - Decreased morning stiffness or fatigue; OR
    - Improved function or activities of daily living; OR
    - Decreased soft tissue swelling in joints or tendon sheaths

- For ankylosing spondylitis:
    - Patient has failed treatment with NSAIDs
    - For continuation requests: Patient has received at least 6 months of therapy with the requested drug
    - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
        - Improvement evidenced by an objective measure (for example, Ankylosing Spondylitis Disease Activity Score, Ankylosing Spondylitis Quality of Life Scale [ASQoL], Health Assessment Questionnaire for the Spondyloarthropathies [HAQ-S], serum markers); OR
        - Decreased pain or stiffness; OR
        - Improvement in function or activities of daily living
- 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 continuation requests: Patient has received at least 6 months of therapy with the requested drug
    - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
        - Improvement evidenced by an objective measure (for example, Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], Bath Ankylosing Spondylitis Functional Index [BASFI], serum markers); OR
        - Decreased pain or stiffness; OR
        - Improvement in function or activities of daily living
- For enthesitis-related arthritis:
    - Patient has failed treatment with NSAIDs
    - For continuation requests: Patient has received at least 6 months of therapy with the requested drug
    - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
        - Improvement evidenced by an objective measure (for example, Juvenile Arthritis Disease Activity Score [JADAS]; Physician Global Assessment [MD global], Juvenile Arthritis Disease Activity Score [JDAS], Clinical Juvenile Arthritis Disease Activity Score [cJDAS], serum markers); OR
        - Improvement in limitation of motion; OR
        - Less joint pain or tenderness; OR
        - Decreased duration of morning stiffness or fatigue; OR
        - Improved function or activities of daily living

- For hidradenitis suppurativa:
    - Patient has failed treatment with ONE other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin)
    - For continuation requests: Patient has received at least 3 months of therapy with the requested drug
    - For continuation requests: Patient has received a beneficial clinical response from baseline (prior to initiating Cosentyx) as evidenced by at least ONE of the following:
        - Improvement evidenced by an objective measure (for example, Hurley staging, Sartorius score, Physician Global Assessment, Hidradenitis Suppurativa Severity Index); OR
        - Decreased pain of lesions, nodules, or cysts; OR
        - Decreased drainage of lesions, nodules, or cysts

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, active enthesitis-related arthritis in patients 4 years of age and older, and adults with moderate to severe hidradenitis suppurativa. 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 pens and prefilled syringes for subcutaneous injection as well as 300 mg dosages supplied as pens and prefilled syringes for subcutaneous injection. Cosentyx is also available as a 125 mg vial for intravenous infusion. Cosentyx for intravenous infusion may only be administered in adults with psoriatic arthritis, adults with ankylosing spondyloarthritis, and adults with non-radiographic axial spondyloarthritis. For pediatric patients, there is a 75 mg prefilled syringe available. Dosing information can be found in the package insert.

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.

Hidradenitis Suppurativa
Hidradenitis suppurativa is an inflammatory skin condition, also known as acne inversa. Hidradenitis suppurativa is a chronic, suppurative process involving the skin and subcutaneous tissues. The initial presentation of the disease typically includes recurrent, painful, and inflamed nodules. The pathogenesis of hidradenitis suppurativa is somewhat unknown, but it is thought that follicular occlusion, follicular rupture, and an associated immune response appear to be important events in the clinical manifestations of this disease. Hidradenitis suppurativa typically occurs on intertriginous skin. The most common site is usually the axilla. Non-intertriginous skin can be affected as well. In addition to Cosentyx, Humira is the only other treatment to be approved by the Food and Drug Administration for the treatment of moderate to severe hidradenitis suppurativa. Other agents typically used for the treatment of hidradenitis suppurativa include systemic antibiotics, intralesional or oral corticosteroids, or isotretinoin products.

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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. In 2023, Cosentyx received FDA approval for moderate to severe hidradenitis suppurativa in adults.

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 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).

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. 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.

Hidradenitis Suppurativa
The safety and efficacy of Cosentyx were assessed in two randomized, double-blind, placebo-controlled 52-week Phase 3 trials in adult patients with moderate to severe hidradenitis suppurativa (HS). In both trials, subjects were randomized to placebo or Cosentyx 300 mg by subcutaneous injection at Weeks 0, 1, 2, 3 and 4, followed by 300 mg every 2 weeks or every 4 weeks. At Week 16, subjects who were randomized to placebo were reassigned to receive Cosentyx 300 mg at Weeks 16, 17, 18, 19, and 20 followed by either Cosentyx 300 mg every 2 weeks or Cosentyx 300 mg every 4 weeks. The primary endpoint in both trials was the proportion of subjects who achieved a Hidradenitis Suppurativa Clinical Response (HiSCR50) defined as at least a 50% decrease in abscesses and inflammatory nodules (AN) count with no increase in the number of abscesses and/or in the number of draining fistulae relative to baseline at Week 16. In HS Trial 1 and HS Trial 2, a statistically significantly higher proportion of subjects (44.5% and 38.3%, respectively) treated with Cosentyx 300 mg every 2 weeks (after the first four weeks) achieved a HiSCR50 response at Week 16 compared to patients treated with placebo. In both HS trials, a higher proportion of subjects (41.3% in Trial 1 and 42.5% in Trial 2) treated with Cosentyx 300 mg every 4 weeks (after the first four weeks) achieved HiSCR50 at Week 16 compared to subjects treated with placebo, where statistical significance was reached in HS Trial 2. In Trial 1 and Trial 2, 29.4% and 26.1% of subjects in the placebo group achieved a HiSCR50 response at Week 16, respectively.

secukinumab (Cosentyx™)

Policy # 00432
Original Effective Date: 05/20/2015
Current Effective Date: 05/01/2025

References

1. Cosentyx [package insert]. Novartis Pharmaceuticals. East Hanover, New Jersey. Updated November 2023.
2. Cosentyx Drug Evaluation. Express Scripts. January 2015
3. UpToDate. "Hidradenitis suppurativa: Pathogenesis, clinical features, and diagnosis". Accessed 3/2024. www.uptodate.com

Policy History

Original Effective Date: 05/20/2015
Current Effective Date: 05/01/2025

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
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.

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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.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Added a new FDA approved indication for hidradenitis suppurativa. Updated relevant policy sections to reflect the new indication. Updated background information for Cosentyx IV formulation.
06/19/2024	Coding update
04/03/2025	Medical Policy Committee review
04/09/2025	Medical Policy Implementation Committee approval. Added dosing of Cosentyx vial where applicable. Added continuation criteria for each indication.

Next Scheduled Review Date: 04/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No codes
HCPCS	J3247 Delete code effective 07/01/2024: C9166 Delete codes effective 05/01/2025: C9399, J3490, J3590
ICD-10 Diagnosis	All Related Diagnoses

*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.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.