secukinumab (Cosentyx™)

Policy # 00432
Original Effective Date: 05/20/2015
Current Effective Date: 01/01/2018

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 adult 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 18 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 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:
  - Ultraviolet B; or
  - Psoralen positive Ultraviolet A; or
  - Systemic therapy (i.e. Methotrexate (MTX), cyclosporine, acitretin).

  *(Note: This specific patient 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 adult 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 18 years of age or older; AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment; 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 failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDS).
  *(Note: This specific patient 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 adult 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. purified protein derivative [PPD], blood test) prior to treatment; 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 failed treatment with non-steroidal anti-inflammatory drugs (NSAIDS) or has documented contraindications to non-steroidal anti-inflammatory drugs (NSAIDS) usage.
  *(Note: This specific patient 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 psoriatic arthritis:
  - Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDS)
- For ankylosing spondylitis:
  - Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDS) or has documented contraindications to non-steroidal anti-inflammatory drugs (NSAIDS) usage
- 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)

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 for moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Cosentyx is also indicated for adults with active psoriatic arthritis or adults with active ankylosing spondylitis. 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 as 150mg dosages supplied as vials, pens, and prefilled syringes for subcutaneous injection. The recommended dose of Cosentyx for plaque psoriasis is 300mg by subcutaneous injection at weeks 0,1,2,3, and 4 followed by 300mg every 4 weeks. For some patients, a dose of 150mg may be acceptable. For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, the dosing information for plaque psoriasis should be followed. Otherwise, if the patient has psoriatic arthritis or ankylosing spondylitis alone, Cosentyx can be given with or without a loading dose. If a loading dose is given, it is a 150 mg loading dose at weeks 0, 1, 2, 3, and 4, and then 150 mg every 4 weeks thereafter. Without a loading dose, 150 mg every 4 weeks is recommended. For psoriatic arthritis, a dosage of 300 mg every 4 weeks can be considered.

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 psoriatic arthritis. These drugs slow the disease process by modifying the immune system.

- Methotrexate
- Cyclosporine
- Sulfasalazine
- Mercaptopurine
- Gold Compounds

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. FDA approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, Blue Cross and Blue Shield Association technology assessment program (TEC) and other non-affiliated technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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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 300mg, Cosentyx 150mg, 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 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 300mg, 150mg, and placebo groups was 82%, 71%, and 4%, respectively. The percentage of patients achieving an IGA of clear or almost clear for the Cosentyx 300mg, 150mg, and placebo groups was 65%, 51%, and 2%, respectively. In patients treated with Cosentyx 300mg and 150mg, 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 300mg and in 59% of subjects treated with Cosentyx 150mg.

Study 2 had a similar setup, however it also included a biologic active control (Enbrel). The PASI 75 response in the Cosentyx 300mg, 150mg, and placebo groups was 76%, 67%, and 5%, respectively. The percentage of patients achieving an IGA of clear or almost clear for the Cosentyx 300mg, 150mg, 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 regards to the biologic active control, Cosentyx 300mg and 150mg 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 response for induction. Cosentyx trials also included measurements of PASI 90 as secondary outcomes.

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 an ACR20 response 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).

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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 an 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).

References

1. Cosentyx [package insert]. Novartis Pharmaceuticals. East Hanover, New Jersey. September 2017.
2. Cosentyx Drug Evaluation. Express Scripts. January 2015

Policy History

Original Effective Date:	05/20/2015
Current Effective Date:	01/01/2018
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.
Next Scheduled Review Date:	12/2018

*****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. 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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**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.

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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.