

ixekizumab (Taltz[®])

Policy # 00513

Original Effective Date: 09/01/2016

Current Effective Date: 04/01/2025

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 ixekizumab (Taltz[®])[‡] for the treatment of patients with plaque psoriasis to be **eligible for coverage**.**

Patient Selection Criteria

Coverage eligibility for ixekizumab (Taltz) will be considered when 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 (tuberculosis) test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Requested drug is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira[®], biosimilars)[‡] or etanercept (Enbrel[®])[‡] OR other drugs such as apremilast (Otezla[®])[‡] or tofacitinib (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)*

- For patients 18 years of age or older: Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: adalimumab (Humira, Simlandi[®], adalimumab-adaz)[‡], etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara[®])[‡], secukinumab (Cosentyx[®])[‡], guselkumab (Tremfya[™])[‡], or risankizumab (Skyrizi[™])[‡] 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)*

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- 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 these treatments will be ineffective or cause an adverse reaction to the patient:
 - Ultraviolet B; or
 - Psoralen positive Ultraviolet A; or
 - Systemic therapy (e.g., methotrexate, 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 ixekizumab (Taltz) for the treatment of patients with active psoriatic arthritis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for ixekizumab (Taltz) will be considered when 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., PPD, blood test) prior to treatment; AND
- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (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)*

- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq™)‡, or risankizumab-rzaa (Skyrizi) 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)*

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Ankylosing Spondylitis

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

Patient Selection Criteria

Coverage eligibility for ixekizumab (Taltz) will be considered when the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has a diagnosis of active ankylosing spondylitis; AND
- Patient has failed treatment with non-steroidal anti-inflammatory drugs (NSAIDs) 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)*

- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), secukinumab (Cosentyx) tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq) 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)*

Non-Radiographic Axial Spondyloarthritis

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

Patient Selection Criteria

Coverage eligibility for the use of ixekizumab (Taltz) 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 is 18 years of age or older; 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).*

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- Requested drug is NOT used in combination with other biologic DMARDs, such as adalimumab (Humira, biosimilars) or etanercept (Enbrel) OR other drugs such as apremilast (Otezla) or tofacitinib (Xeljanz/XR); AND
- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: NON-lyophilized (prefilled syringe) certolizumab pegol (Cimzia®)‡, secukinumab (Cosentyx), or upadacitinib (Rinvoq) 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)*

When Services Are Considered Not Medically Necessary

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

- For plaque psoriasis:
 - For patients 18 years of age or older: Patient has failed treatment with at least TWO of the following products after at least TWO months of therapy with each product: adalimumab (Humira, Simlandi, adalimumab-adaz), etanercept (Enbrel), apremilast (Otezla), ustekinumab (Stelara), secukinumab (Cosentyx), guselkumab (Tremfya), or risankizumab (Skyrizi)
 - Patient has greater than 10% of 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 (e.g., methotrexate, cyclosporine, acitretin).
- For psoriatic arthritis:
 - Patient has failed treatment with one or more traditional DMARDs
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), ustekinumab (Stelara), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), guselkumab (Tremfya), apremilast (Otezla), upadacitinib (Rinvoq), or risankizumab-rzaa (Skyrizi).
- For ankylosing spondylitis:
 - Patient has failed treatment with NSAIDs

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- Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: etanercept (Enbrel), adalimumab (Humira, Simlandi, adalimumab-adaz), secukinumab (Cosentyx), tofacitinib (Xeljanz/XR), or upadacitinib (Rinvoq).
- For 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).
 - Patient has failed treatment with TWO of the following after at least TWO months of therapy with EACH product: NON-lyophilized (prefilled syringe) certolizumab pegol (Cimzia), secukinumab (Cosentyx), or upadacitinib (Rinvoq).

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 ixekizumab (Taltz) when the 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 ixekizumab (Taltz) for indications other than those listed above to be **investigational.***

Background/Overview

Taltz is a humanized interleukin-17A (IL-17A) antagonist indicated for the treatment of patients 6 years of age or older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, for the treatment of adults with active psoriatic arthritis, for the treatment of adults with active ankylosing spondylitis, and for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Taltz inhibits the release of pro-inflammatory cytokines and chemokines. Taltz is administered by subcutaneous injection. The recommended dose is 160 mg (two 80 mg injections) at week 0, followed by 80 mg at weeks 2, 4, 6, 8, 10, and 12, then 80 mg every 4 weeks for adults with plaque psoriasis. Refer to the package insert for pediatric plaque psoriasis dosing. For psoriatic arthritis and ankylosing spondylitis, the dosage is 160 mg at week 0, followed by 80 mg every 4 weeks. For active non-radiographic axial spondyloarthritis, the dosage is 80 mg every 4 weeks.

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

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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 tumor necrosis factor-alpha (TNF-alpha). It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. 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 traditional DMARDs are used to treat this condition. An example of a traditional 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. NSAIDs, such as aspirin, 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.

Traditional Disease-Modifying Anti-Rheumatic Drugs

Traditional 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

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NSAIDs need to be tried as patient response to a particular NSAID isn't predictable. If a response to two NSAIDs has not proven beneficial, tumor necrosis factor (TNF) alpha inhibitors, such as Cimzia, or interleukin blockers, such as Taltz or Cosentyx, would be the next treatment option.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Taltz was approved in March of 2016 for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. In March of 2020, the plaque psoriasis indication was expanded to include those 6 years of age or older. In December of 2017, Taltz was approved for the treatment of adults with active psoriatic arthritis. In August of 2019, Taltz was approved for the treatment of adults with active ankylosing spondylitis. In May of 2020, Taltz was approved for the treatment of adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation.

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.

Plaque Psoriasis-Adults

Taltz was studied in three multicenter, randomized, double blind, placebo-controlled trials which enrolled 3,866 subjects 18 years of age and older with plaque psoriasis. These subjects were also candidates for phototherapy or systemic therapy. Subjects were randomized to either placebo or Taltz 80 mg every 2 weeks for 12 weeks, following a 160 mg loading dose. In two of the trials, subjects were also randomized to receive Enbrel 50 mg twice weekly for 12 weeks. All three trials assessed the changes from baseline to week 12 in two co-primary endpoints: 1. Psoriasis Area Severity Index (PASI) 75 (the proportion of subjects who achieved at least a 75% reduction in the PASI composite score, which takes into consideration both the percentage of body surface affected and the nature and severity of psoriatic changes), and 2. Static Physician's Global Assessment (sPGA) of "0" (clear) or "1" (minimal), the proportion of subjects with an sPGA of 0 or 1 and at least a 2 point improvement.

In trial 1, 89% of subjects receiving Taltz achieved a PASI 75 vs. 4% in the placebo group. In trials 2 and 3, the percentages are as follows: 90% vs. 2% and 87% vs. 7% in the Taltz vs. placebo groups, respectively. In trial 1, 82% of subjects receiving Taltz achieved an sPGA of "0" (clear) or "1" (minimal) vs. 3% in the placebo group. Similar numbers were reported in trials 2 and 3. In trial 1, 37% of those receiving Taltz had an sPGA of "0" (clear) vs. 0% in placebo. Again, similar results occurred in trials 2 and 3. Taltz also demonstrated superiority over Enbrel 50 mg twice weekly in

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sPGA and PASI scores during the 12 week treatment period. The respective response rates for Taltz and Enbrel 50 mg twice weekly were: sPGA of 0 or 1 (73% and 27%); PASI 75 (87% and 41%); sPGA of 0 (34% and 5%); PASI 90 (64% and 18%), and PASI 100 (34% and 4%).

Plaque Psoriasis-Pediatrics

Taltz was studied in a randomized, double-blind, multicenter, placebo-controlled trial in pediatric subjects 6 to less than 18 years of age, with moderate-to-severe plaque psoriasis who were candidates for phototherapy or systemic therapy or were inadequately controlled on topical therapy. Subjects were randomized to placebo or Taltz with dosing stratified by weight. Response to treatment was assessed at 12 weeks of therapy and was defined by the proportion of subjects who achieved an sPGA score of “0” (clear) or “1” (almost clear) with at least a 2 point improvement from baseline and the proportion of subjects that achieved a reduction in PASI score of at least 75% (PASI 75) from baseline. In the Taltz arm, 81% of subjects achieved an sPGA of 0 or 1 versus 11% in the placebo arm at week 12. In the Taltz arm, 89% of subjects achieved a PASI 75 versus 25% in the placebo arm at week 12.

Psoriatic Arthritis

The safety and efficacy of Taltz were assessed in 2 randomized, double-blind, placebo-controlled studies in adult patients with active psoriatic arthritis. In both studies, patients treated with Taltz 80 mg every 2 weeks or 80 mg every 4 weeks demonstrated a greater clinical response including American College of Rheumatology 20 (ACR20), ACR50, and ACR70 compared to placebo at week 24. In the second trial, responses were seen regardless of prior anti-TNF α exposure. The primary endpoint was the percentage of patients achieving ACR20 at week 24. In trial 1, the ACR20 was 58% in the Taltz group vs. 30% in the placebo group at week 24. In trial 2, the ACR20 was 53% at week 24 in the Taltz group vs. 20% in the placebo group.

Ankylosing Spondylitis

The safety and efficacy of Taltz were assessed in 567 patients, in 2 randomized, double-blind, placebo-controlled studies (AS1 and AS2) in adult patients, age 18 years and older with active ankylosing spondylitis. AS1 Study evaluated 341 biologic-naive patients, who were treated with either Taltz 80 mg or 160 mg at week 0 followed by 80 mg every 2 weeks or 4 weeks, Humira 40 mg every 2 weeks, or with placebo. Patients receiving placebo were re-randomized at week 16 to receive Taltz (160 mg starting dose, followed by 80 mg every 2 weeks or every 4 weeks). Patients receiving Humira were re-randomized at week 16 to receive Taltz (80 mg every 2 weeks or every 4 weeks). AS2 Study evaluated 316 TNF-inhibitor experienced patients (90% were inadequate responders and 10% were intolerant to TNF inhibitors). All patients were treated with Taltz 80 or 160 mg at week 0 followed by 80 mg every 2 weeks or every 4 weeks, or with placebo. Patients receiving placebo were re-randomized at week 16 to receive Taltz (160 mg initial dose, followed by 80 mg every 2 weeks or every 4 weeks). The primary endpoint in both studies was the percentage of patients achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at week 16.

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In both studies, patients treated with Taltz 80 mg every 4 weeks demonstrated greater improvements in ASAS40 and ASAS20 responses compared to placebo at week 16. In AS1, the 48% of Taltz every 4 week patients achieved ASAS40 versus 18% in the placebo group. In AS2, the 25% of Taltz every 4 week patients achieved ASAS40 versus 13% in the placebo group. Responses were seen regardless of concomitant therapies. In AS2, responses were seen regardless of prior TNF-inhibitor exposure.

Non-Radiographic Axial Spondyloarthritis

The efficacy and safety of Taltz were assessed in a randomized, double-blind, 52-week placebo-controlled study (nr-axSpA1) in patients with active axial spondyloarthritis for at least 3 months. Patients must have been intolerant to or had an inadequate response to at least two NSAIDs. Patients were treated with either placebo or Taltz 80 mg or 160 mg at week 0, followed by either 80 mg every 2 weeks or 80 mg every 4 weeks. Patients were allowed to transition to use of open-label Taltz 80 mg every 2 weeks starting at week 16 up to week 44 at the discretion of the investigator. The primary endpoint was the percentage of patients achieving an Assessment of Spondyloarthritis International Society 40 (ASAS40) response at week 52. At week 52, 30.2% of Taltz subjects achieved the ASAS40 response versus 13.3% of subjects in the placebo group.

References

1. Taltz [package insert]. Eli Lilly. Indianapolis, Indiana. September 2022.

Policy History

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08/04/2016 Medical Policy Committee review

08/17/2016 Medical Policy Implementation Committee approval. New Policy.

08/03/2017 Medical Policy Committee review

08/23/2017 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

10/05/2017 Medical Policy Committee review

10/18/2017 Medical Policy Implementation Committee approval. Updated tuberculosis test language. Added a new requirement for use of TWO other biologic products prior to Taltz.

04/05/2018 Medical Policy Committee review

04/18/2018 Medical Policy Implementation Committee approval. Added the new indication of active psoriatic arthritis.

12/06/2018 Medical Policy Committee review

12/19/2018 Medical Policy Implementation Committee approval. Added Xeljanz/XR as an option to use in psoriatic arthritis prior to Taltz.

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. Added Tremfya and Skyrizi as first line options in plaque psoriasis

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11/07/2019 Medical Policy Committee review
11/13/2019 Medical Policy Implementation Committee approval. Updated policy to reflect a new FDA approved indication of ankylosing spondylitis.
07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. Updated the plaque psoriasis indication to reflect an FDA age expansion to ages 6 years and older (previously only adults). Added new FDA approved indication: active non-radiographic axial spondyloarthritis with objective signs of inflammation. Updated relevant background and rationale information.
10/01/2020 Medical Policy Committee review
10/07/2020 Medical Policy Implementation Committee approval. Added a requirement to use Cimzia and Cosentyx prior to Taltz for active non-radiographic axial spondyloarthritis with objective signs of inflammation. Added Tremfya as an option for psoriatic arthritis. Added Enbrel as an option for psoriasis.
10/07/2021 Medical Policy Committee review
10/13/2021 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/06/2022 Medical Policy Committee review
01/12/2022 Medical Policy Implementation Committee approval. Added Xeljanz/XR to the list of products that can be tried and failed prior to the use of Taltz in ankylosing spondylitis. Added Rinvoq to the list of products that can be tried and failed prior to the use of Taltz in psoriatic arthritis.
03/03/2022 Medical Policy Committee review
03/09/2022 Medical Policy Implementation Committee approval. Added Skyrizi to the list of products that can be tried and failed prior to the use of Taltz in psoriatic arthritis.
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. Added Rinvoq to the list of products that can be tried and failed prior to use of Taltz in ankylosing spondylitis and non-radiographic axial spondyloarthritis.
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. Added Humira biosimilars, Simlandi and adalimumab-adaz, to the list of products that can be tried and failed prior to the use of Taltz where applicable.

Next Scheduled Review Date: 03/2026

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*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.

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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.

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.