



Louisiana

ustekinumab (Stelara™)

Policy # 00242

Original Effective Date: 11/18/2009

Current Effective Date: 12/20/2017

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 the use of ustekinumab (Stelara™)‡ for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility will be considered for ustekinumab (Stelara) for the treatment of plaque psoriasis when all of the following criteria are met:

- Patient is 12 years of age or older; AND
- Patient has moderate to severe plaque psoriasis; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- Stelara is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira®)‡ or etanercept (Enbrel®)‡ OR other drugs such as tofacitinib (Xeljanz/XR®)‡ or apremilast (Otezla®)‡; AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient has greater than 10% of body surface area or less than or equal to 10% body surface area 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, 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 the use of ustekinumab (Stelara) for the treatment of psoriatic arthritis to be **eligible for coverage**.

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Patient Selection Criteria

Coverage eligibility for the use of ustekinumab (Stelara) for the treatment of psoriatic arthritis will be considered when all of the following criteria are met:

- Patient is 18 years of age or older; AND
- Patient has active psoriatic arthritis; AND
- Stelara is used alone or in combination with methotrexate; AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment; AND
- Stelara is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as adalimumab (Humira) or etanercept (Enbrel) OR other drugs such as tofacitinib (Xeljanz/XR) or apremilast (Otezla); 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.)

Crohn's Disease

Based on review of available data, the Company may consider the use of ustekinumab (Stelara) for the treatment of moderately to severely active Crohn's disease to be **eligible for coverage**.

Patient Selection Criteria

Coverage eligibility for the use of ustekinumab (Stelara) for the treatment of Crohn's Disease will be considered when all of the following criteria are met:

- Patient has a diagnosis of moderately to severely active Crohn's disease; AND
- Patient is 18 years of age or older; AND
- Patient has failed or become intolerant to treatment with immunomodulators (e.g. azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker (e.g. Remicade^{®†}, Humira); AND
- Stelara is NOT being use concurrently with other biologic products (e.g. Humira, Remicade) for the treatment of moderately to severely active Crohn's disease; AND
- Patient has a negative TB test (e.g. purified protein derivative [PPD], blood test) prior to treatment.

When Services Are Considered Investigational

Note: 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 ustekinumab (Stelara) 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 ustekinumab (Stelara) for indications other than those listed above to be **investigational.***

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of ustekinumab (Stelara) 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
 - o Patient has greater than 10% of body surface area or less than or equal to 10% body surface area with plaque psoriasis involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck or genitalia)
 - o Patient has failed to respond to an adequate trial of one of the following treatment modalities:
 - Ultraviolet B; or
 - Psoralen positive Ultraviolet A; or
 - Systemic therapy (i.e. methotrexate, cyclosporine, acitretin).
- For psoriatic arthritis
 - o Patient has failed treatment with one or more disease-modifying anti-rheumatic drugs (DMARDs)

Background/Overview

Stelara is a monoclonal antibody that inhibits proteins that contribute to the overproduction of skin cells. It is a biologic drug that inhibits interleukin-12 and interleukin-23. Stelara is available in 45 mg and 90 mg subcutaneous dosage forms as well as 130 mg single dose vials. The vials are only used for the treatment of Crohn's Disease. Dosing varies per indication. In general, for adults with plaque psoriasis, for patients weighing less than or equal to 100kg, the dose of Stelara is 45 mg administered subcutaneously at week 0 and 4, then 45 mg administered subcutaneously every 12 weeks thereafter. For those adults with plaque psoriasis weighing greater than 100 kg, the dose is 90 mg subcutaneously at week 0 and 4, and then 90 mg subcutaneously every 12 weeks thereafter. For patients age 12 years of age or older with plaque psoriasis, weight based subcutaneous dosing is recommended (see package insert for details) and follows the same schedule (week 0 and 4, then 12 weeks thereafter). The recommended dose for psoriatic arthritis is 45 mg administered subcutaneously at week 0 and 4 and then 45 mg administered subcutaneously every 12 weeks thereafter. Those patients with coexistent moderate to severe plaque psoriasis that weigh over 100 kg should follow the plaque psoriasis dosing. Crohn's disease is dosed with a weight based intravenous loading dose at week 0 (see package insert for details) and then 90 mg subcutaneous every 8 weeks.

Plaque Psoriasis

Psoriasis is a common skin condition that 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 targets the body's own cells. It may be severe in immunosuppressed people or those who have other autoimmune disorders such as rheumatoid arthritis. The diagnosis is based on the appearance of the skin. A skin biopsy or scraping and culture of the skin patch may be needed to rule out other disorders. If joint pain is present and persistent, an x-ray may be

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used to evaluate for psoriatic 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.

Psoriatic Arthritis

Psoriatic arthritis is an inflammatory arthritis that occurs in individuals with psoriasis. The arthritic portion typically presents asymmetrically and the psoriasis may precede or follow joint involvement. The joints most commonly affected are the distal interphalangeal joints of the fingers and toes. Diagnosis of psoriatic arthritis requires both clinical and radiological observations. In patients with psoriatic arthritis, the arthritic remissions tend to be more frequent and complete than rheumatoid arthritis, but progression to chronic arthritis with crippling can occur. Treatment for psoriatic arthritis is similar to that of rheumatoid arthritis and included disease modifying anti-rheumatic drugs, such as methotrexate. Phototherapy may also be an effective treatment option.

Crohn's Disease

Crohn's disease is a chronic autoimmune disease that can affect any part of the gastrointestinal tract but most commonly occurs in the ileum. As a result of the immune attack, the intestinal wall becomes thick, and deep ulcers may form. In addition to the bowel abnormalities, Crohn's disease can also affect other organs in the body. Typically, first line treatments such as corticosteroids, 6-MP and azathioprine are used to treat this condition.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The FDA approved Stelara on September 25, 2009, for the treatment of adult patients (18 years of age or older) with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. In September of 2013, Stelara was approved for the treatment of adults with active psoriatic arthritis. In September of 2016, Stelara gained FDA approval for the treatment of moderately to severely active Crohn's disease in those that have failed standard therapy (corticosteroids, immunomodulators) or those that have failed therapy with a TNF blocker. Stelara was also approved in October of 2017 for the treatment of patients 12 years of age and older with plaque psoriasis.

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, 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

Stelara was evaluated for the treatment of plaque psoriasis in two multicenter, randomized, double-blind, placebo-controlled studies (Ps Study 1 and Ps Study 2). These studies enrolled 1,996 patients age 18 years of age and older with plaque psoriasis who had a minimum body surface area involvement of 10% and were candidates for phototherapy or systemic therapy. The patients were given either placebo, Stelara 45 mg of Stelara 90 mg. In both studies, the endpoints were the proportion of subjects who achieved at least a 75% reduction in the PASI score (PASI 75) from baseline to week 12 and treatment success on the Physician's Global Assessment. In regards to the primary endpoints in Ps Study 1, 3% of placebo patients reached PASI 75 vs. 67% in the Stelara 45 mg group vs. 66% in the Stelara 90 mg group. In regards to the primary endpoints in Ps Study 2, 4% of placebo patients reached PASI 75 vs. 67% in the 45 mg group vs. 76% in the 90 mg group.

Stelara in adolescent subjects (12-17 years of age) with plaque psoriasis was studied in a multi-center randomized, double-blind, placebo controlled study. Subjects were randomized to receive Stelara or placebo. The endpoints were the proportion of patients who achieved a PGA score of 0 or 1, PASI 75, and PASI 90 at week 12. Subjects were followed for up to 60 weeks. In regards to PGA, 69.4% of the Stelara group achieved a PGA of 0 or 1 vs. 5.4% in the placebo group. In regards to PASI 75, 80.6% of the Stelara group achieved a PASI 75 vs. 10.8% in the placebo group. In regards to PASI 90, 61.1% of the Stelara group achieved PASI 90 vs. 5.4% in the placebo group.

Psoriatic Arthritis

Stelara was evaluated in psoriatic arthritis in two randomized, double-blind, placebo-controlled studies in adult patients with psoriatic arthritis despite therapy with non-steroidal anti-inflammatory drugs or disease modifying anti-rheumatic agents. These studies included 927 patients, and those patients were randomized to receive Stelara 45 mg, 90 mg, or placebo. The primary endpoint of the studies was the percentage of patients achieving ACR20 response at week 24. In both studies, a greater proportion of patients achieved ACR 20, ACR 50, and PASI 75 response in the Stelara 45 mg and 90 mg groups compared to placebo at week 24. In PsA study 1, ACR20 was achieved in 23% of placebo patients, 42% of Stelara 45 mg patients, and 50% of Stelara 90 mg patients. In PsA study 2, ACR20 was achieved in 20% of placebo patients, 44% of Stelara 45 mg patients, and 44% of Stelara 90 mg patients.

Crohn's Disease

Stelara was evaluated in 3 randomized, double-blind, placebo-controlled clinical studies in adult patients with moderately to severely active Crohn's disease. There were two 8-week intravenous induction studies (CD-1 and CD-2) followed by a 44-week subcutaneous randomized withdrawal maintenance study (CD-3) representing 52 weeks of therapy.

For CD-1 and CD-2, induction of clinical response at week 6 and clinical remission at week 8 was evaluated. CD-1 included patients that had failed or were intolerant to TNF inhibitors, while CD-2 included patients that were intolerant or had failed treatment with steroids, an immunomodulator, or both. There were 1,409 patients randomized in these two trials. The clinical response at week 6 for the placebo groups was 21% and 29% in trials CD-1 and CD-2, respectively. The clinical response at week 6 in the Stelara

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group was 34% and 56% for trials CD-1 and CD-2, respectively. The clinical remission at week 8 was 7% and 20% in the placebo groups for trials CD-1 and CD-2, respectively. The clinical remission at week 8 was 21% and 40% for trials CD-1 and CD-2, respectively. In these two studies, a greater proportion of patients treated with Stelara achieved clinical response at week 6 and clinical remission at week 8 compared to placebo. Clinical response and remission were significant as early as week 3 in Stelara treated patients and continued to improve through week 8.

CD-3 (the maintenance study) evaluated 388 patients who achieved clinical response at week 8 of induction with Stelara in studies CD-1 and CD-2. Patients were randomized to receive subcutaneous Stelara 90 mg every 8 week of placebo for 44 weeks. At 52 weeks from initiation of the induction dose, 36% of placebo patients had reached a clinical remission vs. 53% of patients in the Stelara treatment group. At the same time point, 44% of placebo patients had a clinical response vs. 59% in the Stelara group. At week 44, 47% of patients who received Stelara were steroid free and in clinical remission compared to 30% of patients in the placebo group.

References

1. Ustekinumab (Stelara) [package insert]. Horsham, PA; Janssen Biotech, Inc., Revised September 2017.
2. U.S. Food and Drug Administration. Center for Drug Evaluation and Research. FDA Labeling Information. Ustekinumab (Stelara) <http://www.fda.gov>.

Policy History

Original Effective Date: 11/18/2009

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- 11/12/2009 Medical Policy Committee approval
- 11/18/2009 Medical Policy Implementation Committee approval. New policy.
- 11/04/2010 Medical Policy Committee approval
- 11/16/2010 Medical Policy Implementation Committee approval. No change to policy coverage.
- 11/03/2011 Medical Policy Committee review
- 11/16/2011 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 11/01/2012 Medical Policy Committee review
- 11/28/2012 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
- 05/02/2013 Medical Policy Committee review
- 05/22/2013 Medical Policy Implementation Committee approval. Reworded and reformatted the coverage section for clarity. Coverage eligibility unchanged.
- 10/10/2013 Medical Policy Committee review
- 10/16/2013 Medical Policy Implementation Committee approval. Added the new indication of Psoriatic Arthritis. Added criteria that requires Humira AND Enbrel prior to use of Stelara for Plaque psoriasis and psoriatic arthritis. Changed title since the drug gained a new indication. Modified the not medically necessary section to reflect changes.
- 10/02/2014 Medical Policy Committee review
- 10/15/2014 Medical Policy Implementation Committee approval. Removed the requirement that Humira AND Enbrel be used prior to Stelara.
- 10/08/2015 Medical Policy Committee review
- 10/21/2015 Medical Policy Implementation Committee approval. No change to coverage.
- 11/03/2016 Medical Policy Committee review

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11/16/2016 Medical Policy Implementation Committee approval. Added the new indication for Crohn's Disease. Updated Background info/rationale to coincide with new indication.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

12/07/2017 Medical Policy Committee review

12/20/2017 Medical Policy Implementation Committee approval. Changed the age to 12 years of age for plaque psoriasis. Updated TB language. Updated background info.

01/01/2018 Coding update

Next Scheduled Review Date: 12/2018

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2016 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.

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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	J3357, J3590 Code added eff 1/1/2018: J3358 Codes deleted eff 7/1/2017: C9487, Q9989
ICD-10 Diagnosis	K50.01-K50.81, L40.50-L40.59

*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:

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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.

****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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