guselkumab (Tremfya™)

Policy # 00588
Original Effective Date: 01/01/2018
Current Effective Date: 05/01/2018

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.*

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

Patient Selection Criteria
Coverage eligibility for guselkumab (Tremfya) will be considered when 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
- Tremfya 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 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 treatment with adalimumab (Humira) after at least TWO months of therapy unless there is clinical evidence or patient history that suggests the use of adalimumab (Humira) will be ineffective or cause an adverse reaction to the patient; 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).

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of guselkumab (Tremfya) when any of the following criteria are not met to be **not medically necessary**:**

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- Patient has failed treatment with adalimumab (Humira) after at least TWO months of therapy
- Patient has greater than 10% 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. MTX, 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 guselkumab (Tremfya) when patient selection criteria are not met (with the exception of those denoted as **not medically necessary****) to be **investigational.***

Background/Overview

Tremfya is an interleukin-23 (IL-23) blocker indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. IL-23 is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Tremfya inhibits the release of pro-inflammatory cytokines and chemokines. Tremfya is supplied as 100 mg in a single-dose prefilled syringe and is dosed at 100 mg at weeks 0 and 4 and every 8 weeks thereafter.

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 tumor necrosis factor-alpha (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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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Tremfya is an interleukin-23 blocker indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy.

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.

The safety and efficacy of Tremfya was assessed in two trials. In these trials, subjects were randomized to either Tremfya (100 mg at weeks 0 and 4, then every 8 weeks) or Humira (80 mg at week 0 and 40 mg at week 1, followed by 40 mg every other week thereafter). These two trials assessed the responses at week 16 compared to placebo for the PASI 90 (proportion of subjects who achieved at least a 90% reduction from baseline in the PASI composite score). Comparisons between Tremyfa and Humira were made via secondary endpoints at weeks 16 and 24. The PASI 90 response in trial 1 was 73% for the Tremfya group vs. 3% in the placebo group. In trial 2, the PASI 90 response was 70% in the Tremfya group vs. 2% in the placebo group. In regards to secondary endpoints vs. Humira, the Tremfya group had higher PASI 75 and PASI 90 responses at various timepoints.

References

1. Tremfya [package insert]. Jannsen Biotech, Inc. Horsham, Pennsylvania. Updated 2017.

Policy History

Original Effective Date: 01/01/2018
Current Effective Date: 05/01/2018
12/07/2017 Medical Policy Committee review
12/20/2017 Medical Policy Implementation Committee approval. New policy.
04/05/2018 Medical Policy Committee review
04/18/2018 Medical Policy Implementation Committee approval. Changed prerequisite from TWO products to Humira only for plaque psoriasis.
Next Scheduled Review Date: 04/2019

*****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.

**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: 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.