BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

apremilast (Otezla®)

Policy # 00436
Original Effective Date: 07/16/2014
Current Effective Date: 07/16/2014

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 the use of apremilast (Otezla®)‡ for the treatment of adult patients with active psoriatic arthritis to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility for apremilast (Otezla) 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
- Otezla is NOT used in combination with other biologic disease-modifying anti-rheumatic drugs (DMARDs), such as Humira or Enbrel; and
- Patient has failed treatment with one or more DMARDs; 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) AND etanercept (Enbrel) after at least two months of therapy with each product (unless there is clinical evidence or patient history that suggests that these products will be ineffective or cause an adverse reaction to the patient).
  *(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 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 apremilast (Otezla) 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 apremilast (Otezla) for indications other than those listed above to be **investigational.***

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of apremilast (Otezla) in the absence of a treatment failure with adalimumab (Humira) AND etanercept (Enbrel) after at least two months of therapy with each product to be **not medically necessary.****

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Background/Overview

Otezla is an oral small molecule inhibitor of phosphodiesterase 4 (PDE4) specific for cyclic adenosine monophosphate (cAMP) and is indicated for the treatment of adult patients with active psoriatic arthritis (PsA). The inhibition of PDE4 results in increased intracellular cAMP. The mechanism by which Otezla works is not well defined. Otezla is provided as 10mg, 20mg, and 30mg tablets. In order to reduce the risk of gastrointestinal symptoms, the dose should be titrated up to 30mg twice daily. The titration schedule can be found in the prescribing information. Patients with severe renal impairment should be dosed at 30mg once daily.

Psoriatic Arthritis
Psoriatic arthritis is an arthritis that is often associated with psoriasis of the skin. Typically first line treatments such as DMARDs are used to treat this condition.

Disease-Modifying Anti-Rheumatic Drugs
Disease-modifying anti-rheumatic drugs are used for the treatment of rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and lupus. 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)
Otezla was approved in March of 2014 by the FDA for the treatment of adult patients with active psoriatic arthritis.

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 Otezla was evaluated in 3 multi-center, randomized, double-blind, placebo-controlled trials of similar design. A total of 1493 adult patients with active psoriatic arthritis despite prior or current treatment with DMARD therapy were randomized. The primary endpoint was the percentage of patients achieving American College of Rheumatology (ACR) 20 responses at week 16. The proportion of patients achieving ACR 20 at week 16 in the placebo group in the three psoriatic arthritis trials was: 19%, 19%, and 18%, respectively. The proportion of patients achieving ACR 20 in the Otezla treatment group in the three psoriatic arthritis trials was 38%, 32%, and 41%, respectively (all of which reached statistical significance $p<0.05$).

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References

1. Otezla [package insert]. Celgene Corporation: Summit, New Jersey. Updated March 2014.

Policy History

Original Effective Date: 07/16/2014
Current Effective Date: 07/16/2014
07/10/2014 Medical Policy Committee review
07/16/2014 Medical Policy Implementation Committee approval. New policy.
Next Scheduled Review Date: 07/2015

*****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.