risankizumab-rzaa (Skyrizi™)

Policy # 00677
Original Effective Date: 07/18/2019
Current Effective Date: 08/10/2020

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 risankizumab-rzaa (Skyrizi™)‡ for the treatment of adult patients with plaque psoriasis to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for risankizumab-rzaa (Skyrizi) 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 tuberculosis (TB) test (e.g., purified protein derivative [PPD], blood test) prior to treatment; AND
- Patient is a candidate for phototherapy or systemic therapy; AND
- The requested drug 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 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 [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)*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of risankizumab-rzaa (Skyrizi) when any of the following criteria are not met to be **not medically necessary****:

- 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., 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 risankizumab-rzaa (Skyrizi) when the patient selection criteria are not met to be **investigational*** (with the exception of those denoted above as **not medically necessary****).

Background/Overview

Skyrizi is an interleukin-23 (IL-23) antagonist indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Skyrizi therefore inhibits the release of pro-inflammatory cytokines and chemokines. Skyrizi is dosed at 150 mg administered subcutaneously at week 0, week 4, and every 12 weeks thereafter.

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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. Typical treatments for severe cases of plaque psoriasis include ultraviolet therapy or systemic therapies such as MTX or cyclosporine. Newer biologic therapies, such as Skyrizi, are also approved for the treatment of plaque psoriasis.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Skyrizi was approved in April of 2019 for the treatment of moderate to severe plaque psoriasis in adults 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. 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.

Multiple clinical trials evaluated the safety and efficacy of Skyrizi for the treatment of plaque psoriasis.

In ULTIMMA-1 and ULTIMMA-2, subjects were randomized to the Skyrizi 150 mg group, the placebo group, and to the biologic active control group. Subjects received treatment at weeks 0, 4, and every 12 weeks thereafter. Both studies assessed the responses at week 16 compared to placebo

for the two co-primary endpoints: 1.) the proportion of subjects who achieved a static Physician's Global Assessment (sPGA) score of 0 ("clear") or 1 ("almost clear") and 2.) the proportion of subjects who achieved at least a 90% reduction from baseline on the Psoriasis Area and Severity Index (PASI 90). In ULTIMMA-1, 88% of subjects in the Skyrizi group achieved sPGA of 0 or 1 vs. 8% in the placebo group at week 16. In the Skyrizi group, 75% of subjects achieved PASI 90 at week 16 vs. 5% in the placebo group. In ULTIMMA-2, 84% of subjects in the Skyrizi group achieved sPGA of 0 or 1 vs. 5% in the placebo group at week 16. In the Skyrizi group, 75% of subjects achieved PASI 90 at week 16 vs. 2% in the placebo group. In ULTIMMA-1 and ULTIMMA-2 at week 52, subjects receiving Skyrizi achieved sPGA 0 (58% and 60%, respectively), PASI 90 (82% and 81%, respectively), and PASI 100 (56% and 60%, respectively). In ULTIMMA-1 and ULTIMMA-2, among the subjects who received Skyrizi and had PASI 100 at week 16, 80% of the subjects who continued on Skyrizi had PASI 100 at week 52. For PASI 90 responders at week 16, 88% of the subjects had PASI 90 at week 52.

IMMHANCE randomized subjects to Skyrizi 150 mg or placebo. Subjects received treatment at weeks 0, 4, and every 12 weeks thereafter. At week 16, Skyrizi was superior to placebo on the co-primary endpoints of sPGA 0 or 1 (84% Skyrizi and 7% placebo) and PASI 90 (73% Skyrizi and 2% placebo). The respective response rates for Skyrizi and placebo at week 16 were: sPGA 0 (46% Skyrizi and 1% placebo); PASI 100 (47% Skyrizi and 1% placebo); and PASI 75 (89% Skyrizi and 8% placebo). In IMMHANCE, subjects who were originally on Skyrizi and had sPGA 0 or 1 at week 28 were rerandomized to continue Skyrizi every 12 weeks or withdrawal of therapy. At week 52, 87% (97/111) of the subjects re-randomized to continue treatment with Skyrizi had sPGA 0 or 1 compared to 61% (138/225) who were re-randomized to withdrawal of Skyrizi.

References

1. Skyrizi [package insert]. Abbvie, Inc. North Chicago, Illinois. April 2019.
2. Skyrizi Drug Evaluation. Express Scripts. Updated May 2019.

Policy History

Original Effective Date: 07/18/2019
Current Effective Date: 08/10/2020
07/03/2019 Medical Policy Committee review
07/18/2019 Medical Policy Implementation Committee approval. New policy.

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07/02/2020 Medical Policy Committee review
07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 07/2021

*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 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: 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.

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.