risankizumab-rzaa (Skyrizi™)

Policy # 00677
Original Effective Date: 07/18/2019
Current Effective Date: 02/12/2024

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 risankizumab-rzaa (Skyrizi™)‡ for the treatment of 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 selection 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

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- Psoralen positive Ultraviolet A; OR
- Systemic therapy (e.g., methotrexate [MTX], 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 risankizumab-rzaa (Skyrizi) for the treatment of patients with active psoriatic arthritis 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 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) 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.
  *(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)*

Crohn's Disease

Based on review of available data, the Company may consider risankizumab-rzaa (Skyrizi) for the treatment of patients with Crohn's disease 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 moderately to severely active Crohn's disease; AND
- Patient is 18 years of age or older; AND

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- Patient has a negative TB test (e.g., PPD, blood test) prior to treatment; AND
- Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a tumor necrosis factor (TNF) blocker or another biologic for the treatment of Crohn's disease such as infliximab (Remicade®‡, biosimilar), adalimumab (Humira), or vedolizumab (Entyvio®)‡; 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 products such as infliximab (Remicade, biosimilar), adalimumab (Humira), or vedolizumab (Entyvio) for the treatment of moderately to severely active Crohn's disease.

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 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:
  - 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).
- For psoriatic arthritis:
  - Patient has failed treatment with one or more traditional DMARDs
- For Crohn's disease:
  - Patient has failed or become intolerant to treatment with traditional immunomodulators (e.g., azathioprine, 6-mercaptopurine) or corticosteroids OR the patient has failed or become intolerant to a TNF blocker or another biologic for the treatment of Crohn's disease such as infliximab (Remicade, biosimilar), adalimumab (Humira), or vedolizumab (Entyvio)

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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, for the treatment of active psoriatic arthritis in adults, and for the treatment of moderate to severely active Crohn's disease in adults. 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. For plaque psoriasis and psoriatic arthritis, Skyrizi is dosed at 150 mg administered subcutaneously at week 0, week 4, and every 12 weeks thereafter. For Crohn's disease, the recommended induction dosing is 600 mg administered by intravenous infusion at week 0, week 4, and week 8. The recommended maintenance dosage for Crohn's disease is 180 mg or 360 mg administered subcutaneously at week 12 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. 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.

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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.

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

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)
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. In early 2022, Skyrizi was approved for the treatment of active psoriatic arthritis in adults. In mid-2022, Skyrizi was approved for the treatment of moderately to severely active Crohn's disease.

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

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practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Plaque Psoriasis
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.

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Psoriatic Arthritis
The safety and efficacy of Skyrizi were assessed in 1,407 subjects in 2 randomized, double-blind, placebo-controlled studies in subjects (964 in PsA-1 and 443 in PsA-2) 18 years and older with active psoriatic arthritis. In both studies, subjects were randomized to receive Skyrizi 150 mg or placebo at weeks 0, 4, and 16. Starting from week 28, all subjects received Skyrizi every 12 weeks. Both studies included a long-term extension for up to an additional 204 weeks. Regarding use of concomitant medications, 59.6% of subjects were receiving concomitant methotrexate, 11.6% were receiving concomitant non-biologic DMARDs other than methotrexate, and 28.9% were receiving Skyrizi monotherapy. For both studies, the primary endpoint was the proportion of subjects who achieved an American College of Rheumatology (ACR) 20 response at week 24. In both studies, treatment with Skyrizi resulted in significant improvement in measures of disease activity compared with placebo at week 24. In PsA-1, 57.3% of subjects in the Skyrizi group achieved an ACR20 at week 24 vs. 33.5% in the placebo group. In PsA-2, 51.3% of subjects in the Skyrizi group achieved an ACR20 at week 24 vs. 26.5% in the placebo group.

Crohn's Disease
In two 12-week induction studies (CD-1 and CD-2), subjects with moderately to severely active Crohn's disease were randomized to receive Skyrizi 600 mg, Skyrizi 1,200 mg, or placebo as an intravenous infusion at week 0, week 4, and week 8. Moderately to severely active Crohn's disease was defined as a Crohn's Disease Activity Index (CDAI) of 220 to 450 and Simple Endoscopic Score for Crohn's disease (SES-CD) ≥6 (or ≥4 for isolated ileal disease). Subjects with inadequate response, loss of response, or intolerance to oral aminosalicylates, corticosteroids, immunosuppressants, and/or biologic therapy were enrolled. In CD-1, 58% (491/850) of subjects had failed or were intolerant to treatment with one or more biologic therapies (prior biologic failure). All subjects in CD-2 had prior biologic failure. At baseline, 30% and 34% of patients were receiving corticosteroids, 24% and 23% of patients were receiving immunomodulators (azathioprine, 6-mercaptopurine, methotrexate), and 31% and 19% of patients were receiving aminosalicylates in CD-1 and CD-2, respectively. In CD-1 and CD-2, the co-primary endpoints were clinical remission and endoscopic response at week 12. In CD-1, 45% of the Skyrizi treated population achieved clinical remission compared to 25% of the placebo treated population. For endoscopic response, 40% of the Skyrizi treated population achieved this outcome compared to 12% in the placebo group. In CD-2, 42% of the Skyrizi treated population achieved clinical remission compared to 20% of the placebo treated population. For endoscopic response, 29% of the Skyrizi treated population achieved this outcome compared to 11% in the placebo group. Results for CD-1 and CD-2 were both

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statistically significant. The Skyrizi 1,200 mg dosage did not demonstrate additional treatment benefit over the 600 mg dosage and is not a recommended regimen.

The maintenance study, CD-3, evaluated 382 subjects who achieved clinical response defined as a reduction in CDAI of at least 100 points from baseline after 12 weeks of induction treatment with intravenous Skyrizi in studies CD-1 and CD-2. Subjects were randomized to receive a maintenance regimen of Skyrizi 180 mg or 360 mg or placebo at week 12 and every 8 weeks thereafter for up to an additional 52 weeks. The co-primary endpoints in CD-3 were clinical remission and endoscopic response at week 52. In CD-3, 57% of the Skyrizi 360 mg treated population and 61% of the Skyrizi 180 mg treated population achieved clinical remission compared to 46% of the placebo treated population. For endoscopic response, 48% of the Skyrizi 360 mg treated population and 50% of the Skyrizi 180 mg treated population achieved this outcome compared to 22% in the placebo group. Both of the co-primary endpoints were statistically significant.

References

1. Skyrizi [package insert]. Abbvie, Inc. North Chicago, Illinois. June 2022.
2. Skyrizi Drug Evaluation. Express Scripts. Updated May 2019.

Policy History

Original Effective Date: 07/18/2019
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07/03/2019	Medical Policy Committee review
07/18/2019	Medical Policy Implementation Committee approval. New policy.
07/02/2020	Medical Policy Committee review
07/08/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/01/2021	Medical Policy Committee review
07/14/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/03/2022	Medical Policy Committee review
03/09/2022	Medical Policy Implementation Committee approval. Added criteria and background information for a new FDA approved indication, psoriatic arthritis.
08/04/2022	Medical Policy Committee review

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08/10/2022	Medical Policy Implementation Committee approval. Added a new FDA approved indication, Crohn's disease, along with criteria. Updated relevant portions of the policy due to the new indication. Coding added
12/05/2022	Coding update
01/05/2023	Medical Policy Committee review
01/11/2023	Medical Policy Implementation Committee approval. Updated dosing information in the background section. Updated clinical trial information for Crohn's disease.
01/04/2024	Medical Policy Committee review
01/10/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 01/2025

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 2023 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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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	NA
HCPCS	J2327 Delete codes effective 02/02/2024: J3490, J3590, C9399
ICD-10 Diagnosis	All related Diagnoses

*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;

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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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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.

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.

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