Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 08/10/2023

Skyrizi™ (risankizumab-rzaa) Intravenous Formulation

HCPCS: J2327

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age.
   b. Diagnosis of Crohn's disease (CD)
      i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated.
   c. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs)
   d. Trial and failure, contraindication, or intolerance to the preferred drugs as listed in BCBSM/BCN's utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing.
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Skyrizi is an interleukin (IL)-23 antagonist indicated for the treatment of moderate-to-severe 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 moderately to severely active Crohn's disease in adults.

- The 2018 American College of Gastroenterology guidelines establish therapeutic recommendations for patients with Crohn's disease (CD) based upon disease location, disease severity, disease-associated complications, and future disease prognosis. Therapeutic approaches are individualized according to the symptomatic response and tolerance to medical intervention. Current therapeutic approaches should be considered a sequential continuum to treat acute disease or induce clinical remission and then to maintain response/remission. In general, clinical evidence of improvement should be evident within 2 – 4 weeks and the maximal improvement should occur within 12 – 16 weeks. Those with continued symptoms should be treated with an alternative therapy for mild to moderate disease, have their medication dose adjusted in order to attempt to optimize therapy, or advance to treatment for moderate to severe disease according to their clinical status.

- Corticosteroids are used primarily for the treatment of flares of CD. Conventional corticosteroids are effective for reducing the signs and symptoms of active CD and induction of remission in patients with moderately to severely active CD. Oral corticosteroids are effective and can be used for short-term use in alleviating signs and symptoms of moderate to severely active disease. The guidelines recommend prednisone equivalent doses ranging from 40 to 60 mg per day. These doses are typically maintained for 1 –2 weeks and tapered at 5 mg weekly until 20 mg and then 2.5 –5 mg weekly. Once begun, care should be taken to ensure that corticosteroids are successfully discontinued, and steroid-sparing agents should be used.

- In patients with moderate-to-severe CD who remain symptomatic despite current or prior corticosteroid therapy, mercaptopurine, azathioprine, and intramuscular or subcutaneous methotrexate are effective steroid-sparing agents and guideline recommended. Maximum effectiveness of these agents can be seen between 8 to 12 weeks from therapy initiation. Methotrexate is also recommended in combination with steroids as an effective treatment for moderately active steroid-dependent/resistant CD. Cyclosporine, tacrolimus, and mycophenolate are not recommended for treatment of CD.

- Biologics, such as TNFi's are recommended to treat CD that is resistant to treatment with corticosteroids, thiopurines, or methotrexate. Guidelines also recommend the use of biologics in combination with immunosuppressants to help decrease the formation of antibodies against the biologic therapy. There are no robust, published studies to support use of biologic agents in combination

- Stelara is recommended in patients with moderate to severe CD who have prior treatment failures with, corticosteroids, thiopurines, methotrexate, or TNFi. Skyrizi has not been included in CD guidelines.

References:

1. Skyrizi [prescribing information]. North Chicago, IL. AbbVie Inc., June 2022.
2. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. J Am Acad Dermatol. 2019;81(3):775-804. doi:10.1016/j.jaad.2019.04.042
3. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. J Am Acad Dermatol. 2020;S0190-9622(20)32288-X. doi:10.1016/j.jaad.2020.07.087
4. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044
5. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057
6. Singh JA, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis Rheumatol. 2019 Jan; 71 (1): 5-32.

7. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of crohn's disease in adults. AJG. 2018 April; 113 (4): 481-517

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>1.2</td><td>Effective Date: 08/10/2023</td><td>Annual review of policy</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/04/2022</td><td>Updated to include Crohn’s disease indication and intravenous formulation</td></tr>
<tr><td>1.0</td><td>Effective Date: 07/28/2022</td><td>UM medical management system update for BCBS and BCN
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
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** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*

Blue Cross Blue Shield/Blue Care Network of Michigan
Medication Authorization Request Form
Skyrizi™ (risankizumab-rzaa) HCPCS CODE: J2327

Blue Cross Blue Shield Blue Care Network of Michigan

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This form is to be used by participating physicians to obtain coverage for Skyrizi. For commercial members only, please complete this form and submit via fax to 1-877-325-5979. If you have any questions regarding this process, please contact BCBSM Provider Relations and Servicing or the Medical Drug Helpdesk at 1-800-437-3803 for assistance.

PATIENT INFORMATION	PHYSICIAN INFORMATION
Name	**Name**
ID Number	**Specialty**
D.O.B. ☐Male ☐Female **Pt weight (in kg)** **Date recorded:**_____	**Address**
Diagnosis	**City /State/Zip**
Drug Name ☐	**Phone/Fax: P**: ( ) - **F**: ( ) -
Dose and Quantity	**NPI**
Directions	**Contact Person**
Date of Service(s)	**Contact Person Phone / Ext.**

STEP 1: DISEASE STATE INFORMATION

1. Is this request for initiation or renewal of therapy for **Skyrizi IV**?
   ☐ Initiation ☐ Continuation ☐ *Date patient started therapy:* _____ *How many doses has the patient received?* _____

2. Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
   ☐ Hospital outpatient facility (go to #3) *Reason for Hospital Outpatient administration:* _____

3. Please specify location of administration if hospital outpatient infusion: _____

4. Please provide the NPI number for the place of administration: _____

5. **Initiation AND Continuation of therapy:**
   a. Please check the patient's diagnosis: ☐ Crohn's disease ☐ Other:_____
   b. Has the patient tried and failed therapy with at least one conventional therapy?
      ☐ Systemic corticosteroid daily for 7 days: please list name of drug(s): _____, Date started: _____ Date ended: _____
      ☐ Mercaptopurine, Date started: _____ Date ended: _____
      ☐ Azathioprine, Date started: _____ Date ended: _____
      ☐ Methotrexate, Date started: _____ Date ended: _____
      ☐ Other: _____, Date started: _____ Date ended: _____
   c. Will the patient be receiving Skyrizi with other biologic agents (for example: Remicade, Humira, Stelara, Entyvio, etc.) or with targeted DMARD medications (for example: Otezla)?
      ☐ Yes, Please provide rationale: _____ ☐ No

6. **Continuation of therapy:** Skyrizi intravenous is administered for loading dose only by a healthcare professional, for continuation of therapy for Skyrizi subcutaneous please ***fax this completed form to pharmacy benefit with chart notes showing improvement of therapy to BCBSM at (866) 601-4425***

Please add any other supporting medical information necessary for our review

Coverage will not be provided if the prescribing physician's signature and date are not reflected on this document.

☐ Request for expedited review: I certify that applying the standard review time frame may seriously jeopardize the life or health of the member or the member's ability to regain maximum function

Physician's Name **Physician Signature** **Date**

Step 2: Checklist	☐ Form Completely Filled Out ☐ Attached Chart Notes	☐ BSA
Step 3: Submit	**By Fax: BCBSM Specialty Pharmacy Mailbox 1-877-325-5979**	**By Mail: BCBSM Specialty Pharmacy Program P.O. Box 312320, Detroit, MI 48231-2320**

8/4/2022; 10/5/2022