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: 10/03/2024

Ilumya™ (tildrakizumab-asmn)

HCPCS: J3245

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 psoriasis (PsO)
      i. Trial and failure, contraindication, or intolerance to one topical corticosteroid
   c. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs) for the same indication
   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 and approval duration 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:

- Ilumya is a an interleukin-23 (IL-23) antagonist indicated for the treatment of moderate-to-severe psoriasis in adults who are candidates for systemic therapy or phototherapy. Per the prescribing information, Ilumya should only be administered by a healthcare provider.

- Psoriasis is a chronic, painful and life-altering immune-mediated disease which predominantly manifests with skin and joint involvement. Patients may also experience significant cardiovascular and psychological comorbidities. Approximately 2% of U.S. adults are affected by psoriasis (men and women equally), and it can occur at any age. Approximately 90% of psoriasis-affected patients have plaque psoriasis, which is characterized by well-defined round or oval plaques that vary in size and often coalesce. The severity of psoriasis is defined as: mild = less than 3% of body affected; moderate = 3-10% of body affected; and severe being more than 10% of the body affected.

- Per the 2020 Joint American Academy of Dermatology - National Psoriasis Foundation (AAD/NPF) guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures: topical corticosteroids provide a high efficacy and good safety option for patients with localized disease. They are generally recommended as first-line therapy. Choice of steroid potency may depend on severity, location, patient preference, and patient age, while the duration of treatment may vary with steroid potency, location and severity of disease often ranging from 2-12 weeks. Therapeutic regimens may include 2-4 weeks with a topical steroid applied twice daily, followed by a maintenance regimen where topical steroids are alternated with a steroid-sparing topical agent. Treatment with topical steroids for over 12 weeks is recommended under careful supervision by a physician.

- Per the 2019 Joint AAD/NPF guidelines of care for the management and treatment of psoriasis with phototherapy: phototherapy serves as a reasonable and effective treatment option for patients requiring more than topical medications and/or those wishing to avoid systemic medications or simply seeking an adjunct to a failing regimen. Guidelines also state that the majority of patients with mild-to-moderate disease have adequate disease control with topical therapies and phototherapy alone.

- Per the Joint AAD/NPF guidelines of care for the management and treatment of psoriasis with systemic nonbiologic therapies: many oral medications, including methotrexate, cyclosporine, and acitretin, have been used for decades to treat psoriasis, each with its own benefits and risks. Most work by targeting the immune system, whereas others, such as acitretin, work predominantly by decreasing keratinocyte hyperproliferation, thus restoring the normal epidermal differentiation. Both methotrexate and cyclosporine are category A guideline recommendations for the treatment of moderate to severe psoriasis in adults and for severe, recalcitrant psoriasis, respectively. Studies examining the use of methotrexate and cyclosporine in psoriasis showed the primary efficacy endpoints met within 12-16 weeks. Acitretin is a category B guideline recommendation as monotherapy for plaque psoriasis, with full treatment response expected within 3-6 months.

- Per the 2019 Joint AAD/NPF guidelines of care for the management and treatment of psoriasis with biologics: biologic agents, as monotherapy or combined with other topical or systemic medications, have a high benefit-to-risk ration. Tumor necrosis factor (TNF)-alpha and IL-12/IL-23, IL-23, and IL-17 products have a category "A" recommendation as a monotherapy treatment option for adult patients with moderate-to-severe plaque psoriasis. Guidelines do not recommend one product over another and note the similar efficacy seen across biologics within the same class. There are no published, robust studies to support the use of more than one biologic product or targeted DMARD in combination.

References:

1. Ilumya [prescribing information]. Whitehouse Station, NJ, Merck & Co., Inc., March 2018.
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

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.0</td><td>Effective Date: 10/03/2024</td><td>Added “for the same indication” to the not to be used in combination with other biologics or targeted DMARDs criteria</td></tr>
<tr><td>1.9</td><td>Effective Date: 12/14/2023</td><td>Annual review of criteria performed, no changes were made</td></tr>
<tr><td>1.8</td><td>Effective Date: 12/01/2022</td><td>Annual review of criteria performed, no changes were made</td></tr>
<tr><td>1.7</td><td>Effective Date: 02/04/2021</td><td>Removed FDA approved indications criteria, phototherapy and oral DMARD criteria for psoriasis, and added trial of one topical corticosteroid for psoriasis</td></tr>
<tr><td>1.6</td><td>Effective Date: 02/04/2021</td><td>Removal of the topical steroid criteria for psoriasis indication</td></tr>
<tr><td>1.5</td><td>Effective Date: 12/03/2020</td><td>Previously approved criteria updated to align management between pharmacy and medical benefit for all listed indications</td></tr>
<tr><td>1.4</td><td>Effective Date: 08/13/2020</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.3</td><td>Effective Date: 08/15/2019</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.2</td><td>Effective Date: 08/09/2018</td><td>New Drug Review</td></tr>
<tr><td>1.1</td><td>Effective Date: 08/01/2018</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>
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<tr><td>1.0</td><td>Effective Date: 05/03/2018</td><td>Preliminary Drug Review</td></tr>
</table>

** 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
Ilumya™ (tildrakizumab-asmn) HCPCS CODE: J3245

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This form is to be used by participating physicians to obtain coverage for Ilumya. 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? ☐ Initiation ☐ Continuation ☐ *Date patient started therapy:* _____

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: ☐ Moderate to severe plaque psoriasis
      ☐ Other: _____

   b. Will the patient be receiving Ilumya with other biologic agents (for example: Infliximab, Humira, Kineret, Entyvio, or Tremfya, etc.) or with targeted DMARDs (for example: Otezla)?
      ☐ yes ☐ no Comment: _____

   c. Has the patient experienced treatment failure with one topical corticosteroid?
      ☐ Yes, Please list topical corticosteroids the patient has tried: _____
      ☐ No, Comment: _____

6. **Continuation request:** Ilumya start date: _____
   a. Have the patient's signs and symptoms improved with Ilumya?
      ☐ yes ☐ no Comment: _____

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**

5/9/2018;10/11/2018,11/28/2018; 2/4/2021; 12/9/2021