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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: 12/03/2020

Ilumya™ (tildrakizumab-asmn)

FDA approval: March 20, 2018

HCPCS: J3245

Benefit: Medical

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 indication
 - b. FDA approved age
 - c. Diagnosis of psoriasis (PsO)
 - i. Trial and failure of topical steroids after a minimum 3-month trial
 - ii. Trial and failure, contraindication, or intolerance to light therapy
 - iii. Trial and failure of at least a 3-month trial of one generic oral systemic agent unless contraindicated or not tolerated. Examples include cyclosporine, methotrexate, acitretin
 - d. Not to be used in combination with other biologics or targeted disease-modifying anti-rheumatic drugs (DMARDs)
 - e. 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.

Therapeutic considerations:

A. FDA approved indication/Diagnosis

**Please refer to most recent prescribing information.*

B. Background Information

- a. Ilumya is an interleukin-23 antagonist indicated for the treatment of moderate-to-severe psoriasis in adults who are candidates for systemic therapy or phototherapy.
- b. 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.
- c. Per the 2019 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.
- d. 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. Certain factors can affect patient preference and should be discussed with patients including dosing frequency, cost, and immediate availability of/proximity to the respective phototherapy unit.
- e. 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.
- f. 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.
- g. 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 interleukin (IL)-12/IL-23, IL-23, and IL-17

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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.

- h. Although the advent of biologic therapies has changed the treatment landscape, oral nonbiologic medications are still widely used, either as monotherapy or in combination with biologic medications. These therapies can benefit widespread psoriasis, have a comparatively low cost (in the case of older medications), have increased availability, and ease of administration.

C. Efficacy

**Please refer to most recent prescribing information.*

D. Medication Safety Considerations

**Please refer to most recent prescribing information.*

E. Dosing and administration

**Please refer to most recent prescribing information.*

F. How supplied

**Please refer to most recent prescribing information.*

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

Policy History		
#	Date	Change Description
1.5	Effective Date: 12/03/2020	Previously approved criteria updated to align management between pharmacy and medical benefit for all listed indications
1.4	Effective Date: 08/13/2020	Annual Review of Medical Policy
1.3	Effective Date: 08/15/2019	Annual Review of Medical Policy

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1.2	Effective Date: 08/09/2018	New Drug Review										
1.1	Effective Date: 08/01/2018	PA added to BCBS and BCN <table><tr><th>Line of Business</th><th>PA Required (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>	Line of Business	PA Required (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required (Yes/No)											
BCBS	Yes											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.0	Effective Date: 05/03/2018	Preliminary Drug Review										

** 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



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		Address	
Pt weight (in kg) Date recorded: _____			
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

- Is this request for initiation or renewal of therapy? ☐ Initiation ☐ Continuation ☐ Date patient started therapy: _____
- Site of administration? ☐ Provider office/Home infusion ☐ Other: _____
☐ Hospital outpatient facility (go to #3) Reason for Hospital Outpatient administration: _____
- Please specify location of administration if hospital outpatient infusion: _____
- Initiation AND Continuation of therapy:**
 - Please check the patient's diagnosis: ☐ systemic plaque psoriasis ☐ psoriatic arthritis ☐ Other: _____
 - Has the patient previously experienced treatment failure with phototherapy, or photochemotherapy?
☐ yes ☐ no Comment: _____
 - Has the patient experienced treatment failure with topical steroids after 3 months?
☐ yes ☐ no Comment: _____
 - Which of the following immunomodulatory agents has the patient tried and failed?
☐ Methotrexate ☐ Sulfasalazine ☐ Azathioprine ☐ Cyclosporine ☐ Other: _____
 - Which of the following biological agents has the patient tried and failed?
☐ Enbrel ☐ Humira ☐ Remicade ☐ Stelara ☐ Cosentyx ☐ Other: _____
- Continuation request:** Ilumya start date: _____
 - Has the patient had documented beneficial clinical response to Ilumya?
☐ yes ☐ no Comment: _____
- Please attach any chart notes or additional documentation and submit to plan.

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

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5/9/2018;10/11/2018,11/28/2018