PreferredOne®

Department of Origin: Pharmacy	Effective Date: 12/06/2023
Approved by: Pharmacy and Therapeutics Quality Management Subcommittee	Date Approved: 12/06/2023
Pharmacy Clinical Policy Document: Ilumya Prior Authorization	Replaces Effective Policy Dated: 5/24/2023
Reference #: PC/I003	Page: 1 of 2

PURPOSE:
The intent of this Ilumya Prior Authorization Clinical Policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria – Must satisfy any of the following: I – II

Table 1: Ilumya (tildrakizumab-asmn)

Biologic	Molecule	Route of Administration	Drug Class
Ilumya	tildrakizumab- asmn	subcutaneous injection	IL – 23 antagonist

I. Initial request for Ilumya (tildrakizumab – asmn) – must satisfy all of the following A – C.

   A. Member must have diagnosis of moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy; and

   B. Prescribed by or in consultation with a dermatologist or rheumatologist; and

   C. The member has not responded to, is intolerant to, responds to but cannot tapper off without recurrent symptoms, or is a poor candidate for two self-administered biologic drugs with different mechanisms of action (ie, from different drug classes) (Table 2).

II. Continuation request – allow up to 12 months.

Table 2: Self- Administered Biologic Drugs for Plaque Psoriasis*

Drug	Generic/Molecule Name	Is this a Biosimilar?	Generic Available	Route of Administration	Recommended Age	Drug Class
Cimzia	certolizumab	N	N	subcutaneous injection	adult	TNFα blocker
Cosentyx	secukinumab	N	N	subcutaneous injection	adult	IL – 17A antagonist
Enbrel	etanercept	N	N	subcutaneous injection	not age specific	TNFα blocker
Humira	adalimumab	N	N	subcutaneous injection	adult	TNFα blocker
Siliq	brodalumab	N	N	subcutaneous injection	adult	IL – 17A antagonist

Table 2: Self- Administered Biologic Drugs for Plaque Psoriasis* continued

Drug	Generic/Molecule Name	Is this a biosimilar?	Generic Available	Route of Administration	Recommended Age	Drug Class
Skyrizi	risankizuamabrzaa	N	N	subcutaneous injection	adult	IL – 23 antagonist
Stelara	ustekinumab	N	N	subcutaneous injection	adult	IL – 12 & IL- 23 antagonist
Taltz	ixekizumab	N	N	subcutaneous injection	adult	IL – 17 antagonist
Tremfya	guselkumab	N	N	subcutaneous injection	adult	IL – 23 antagonist

* This list of drugs is not exhaustive, nor does it ensure coverage. Check member's prescription benefit.

DEFINITIONS:
Biologic/biological: Biological products include a wide range of products such as vaccines, blood, and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.

BACKGROUND:
This clinical policy is based on U.S. Food and Drug Administration (FDA) approved indications and dosing, expert consensus opinion and/or available reliable evidence.

Prior Authorization: Yes, per network provider agreement – up to 12 months. This is subject to the member's contract benefits.

CODING:
HCPCS – 2023
J3245 Injection, tildrakizumab-asmn, 1mg (Ilumya)

REFERENCES:
1. Ilumya (tildrakizumab-asmn) [package insert]. Whitehouse Station, NJ. Merck & Co., Inc.; 2020.
2. 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;80:1029-72.
3. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
4. Medical Policy: MP/C009 Coverage Determination Guidelines
5. Pharmacy Clinical Policy: PP/O001 Off-label Drug Use
6. Pharmacy Clinical Policy: PP/O002 Off-label Drug Use for Business Process Outsourced Clients
7. Pharmacy Clinical Policy: PP/T002 Therapeutic Equivalence

DOCUMENT HISTORY:

Created Date: 04/16/2021
Reviewed Date: 4/7/2022, 2/27/2023, 10/24/2023
Revised Date:

PreferredOne Community Health Plan Nondiscrimination Notice

PreferredOne Community Health Plan ("PCHP") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PCHP does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PCHP:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
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If you need these services, contact a Grievance Specialist.

If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013)·

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ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

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PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
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Fax: 763.847.4010
customerservice@preferredone.com

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You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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