

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

<i>Biologic</i>	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 taper 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

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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	risankizuamab raa	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:

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

## 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
- Information written in other languages

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](mailto: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>.

## Language Assistance Services

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).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, taiaajiila qarqaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂບດຊາບ: ຖ້າວ່າທ່ານເວົ້າພາສາລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສຍຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.800.940.5049 (TTY: 763.847.4013).

ማስታወሻ፡ የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፡ በነጻ ሊያግዝዎት ተዘጋጅተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው፡ 763.847.4013 ) .

ဟ်သုာ်ဟ်သး- နမာ်ကတိ၊ ကညီ ကိာ်အယံ၊ နမာ် ကိာ်အတၢ်မၤစၢၤလၢ တလၢာ်ဘၣ်လၢာ်စၢၤ နီတမံၤဘၣ်သန့လီၤ. ကိံး 1.800.940.5049 (TTY: 763.847.4013).

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតល្បួល គឺអាចមានសំរាប់បំរើអ្នក។ ចរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013)។

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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If you believe that PIC 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 Insurance Company  
PO Box 59212  
Minneapolis, MN 55459-0212  
Phone: 1.800.940.5049 (TTY: 763.847.4013)  
Fax: 763.847.4010  
[customerservice@preferredone.com](mailto: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  
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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်မိသည့်သို့လိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

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