

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)

<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

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: 2 of 2

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 r zaa	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:

Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, sexual orientation, or gender identity. We do not exclude people or treat them differently because of race, color, national origin, age, disability, sex, sexual orientation, or gender identity.

We will:

Provide 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)

Provide 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 us at the phone number shown on the inside cover of this contract, your id card, or aspirushealthplan.com.

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

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1.866.631.5404 (TTY: 711)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Nondiscrimination Grievance Coordinator 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

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1.866.631.5404 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلی رقم الهاتف 1.866.631.5404 (رقم هاتف الصم والبك : 711)

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelezle 1.866.631.5404 (ATS : 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.866.631.5404 (TTY: 711).

Hindi: _यान द_ : य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_। 1.866.631.5404 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.866.631.5404 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.866.631.5404 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 711)

Traditional Chinese: 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 1.866.631.5404 (TTY: 711)。

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 711).

Lao: ໄປດຊາຍ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1.866.631.5404 (TTY: 711).