UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2144-12
Program	Prior Authorization/Medical Necessity
Medication	Ilumya® (tildrakizumab-asmn)* *Ilumya is excluded from coverage for the majority of our benefits
P&T Approval Date	5/2018, 2/2019, 9/2019, 5/2020, 5/2021, 6/2021, 12/2021, 11/2022, 1/2023, 4/2023, 7/2023, 10/2024
Effective Date	1/1/2025

1. Background:

Ilumya (tildrakizumab) is an interleukin-23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Initial Authorization**

a. **Ilumya** will be approved based on the following criteria:

(1) Submission of medical records (e.g., chart notes, laboratory values) documenting **all** of the following:

(a) Diagnosis of chronic moderate to severe plaque psoriasis

-AND-

(b) **One** of the following:

i. **All** of the following:

a. Greater than or equal to 3 % body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

b. History of failure to **one** of the following topical therapies unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- Vitamin D analogs (e.g., calcitriol, calcipotriene)
- Tazarotene
- Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)

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- Anthralin
- Coal tar

-AND-

c. History of failure to a 3 month trial of methotrexate at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)[b]

-OR-

ii. Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), adalimumab, Otezla (apremilast), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Enbrel (etanercept)]

-AND-

(c) History of failure, contraindication, or intolerance to **three** of the following preferred products (document drug, date, and duration of trial):

i. One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
ii. Cimzia (certolizumab)
iii. Cosentyx (secukinumab)
iv. Enbrel (etanercept)
v. Skyrizi (risankizumab)
vi. Sotyktu (deucravacitinib)
vii. Stelara (ustekinumab)
viii. Tremfya (guselkumab)

-AND-

(d) Patient is not receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

-AND-

(e) Prescribed by or in consultation with a dermatologist

Authorization will be issued for 12 months.

2. **Reauthorization**

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a. **Ilumya** will be approved based on **all** of the following criteria:

(1) Documentation of positive clinical response to Ilumya therapy

-AND-

(2) Patient is not receiving Ilumya in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), adalimumab, Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Reauthorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.
[b] For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- *Ilumya is excluded from coverage for the majority of our benefits
- Supply limits may be in place.

4. References:

1. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc; December 2022.
2. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008; 58(5):826-50.
3. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. J Am Acad Dermatol 2008;58(5):851-64.
4. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. J Am Acad Dermatol 2009;60(4):643-59.
5. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
6. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.

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7. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
8. Menter A, Korman NJ, Elmets CA,Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
9. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
10. 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.

Program	Prior Authorization/Medical Necessity-Ilumya (tildrakizumab)
Change Control	
Date	Change
5/2018	New program
2/2019	Annual review. Updated background and criteria adding Cimzia to list of preferred products for the treatment of plaque psoriasis.
9/2019	Updated criteria adding Skyrizi as preferred medication. Added coverage exclusion statement. Updated references.
5/2020	Updated formatting without change to clinical intent
5/2021	Annual review. Remove prescriber requirement for reauthorization. Removed drug documentation where only one drug is required. Updated references.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD.
12/2021	Updated the following with no change to clinical intent: updated conventional DMARD bypass language for psoriasis, removed "biologic" from required preferred product criteria language and updated CT/KY footnote.
11/2022	Added Enbrel as a preferred product step option. Added Enbrel as an example where appropriate. Added Mississippi to state mandate footnote. Updated reference.
1/2023	Updated step therapy requirements to Humira or Amjevita. Updated listed examples from Humira to adalimumab.
4/2023	Updated step therapy requirement from Humira or Amjevita to one of the preferred adalimumab products and added the footnote "For a list of preferred adalimumab products please reference drug coverage tools."
7/2023	Updated not receiving in combination language to targeted immunomodulator and updated examples.
10/2024	Updated step requirement noting Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, and Humira as preferred adalimumab products with no change to clinical intent. Removed preferred adalimumab footnote. Added Sotyktu as step therapy agent. Moved Cosentyx to preferred step agent and changed step to three agents. Updated state mandate footnote and reference.

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