UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3109-10
Program	Step Therapy
Medications	Ilumya® (tildrakizumab-asmn)* *Ilumya is excluded from coverage for the majority of our benefits
P&T Approval Date	5/2018, 2/2019, 9/2019, 12/2020, 12/2021, 11/2022, 1/2023, 4/2023, 4/2024, 10/2024
Effective Date	1/1/2025

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three preferred self-administered injectable products before providing coverage for Ilumya(tildrakizumab). Infused medications for any of the conditions referenced in this document are not part of the criteria.

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.

Adalimumab is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate.

Stelara® (ustekinumab) and Cosentyx® (secukinumab) are indicated for the treatment of patients 6 years or older with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Tremfya® (guselkumab), Cimzia® (certolizumab), and Skyrizi® (risankizumab) are indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Enbrel® (etanercept) is indicated for the treatment of plaque psoriasis in patients 4 years or older.

Sotyktu (deucravacitinib) is indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. Plaque Psoriasis

1. **Ilumya** will be approved based on the following criterion:

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

      (1) One of the preferred adalimumab products (i.e. Adalimumab-adaz (unbranded Hyrimoz), Amjevita for Nuvaila, Humira)
      (2) Cimzia (certolizumab)
      (3) Cosentyx (secukinumab)
      (4) Enbrel (etanercept)
      (5) Skyrizi (risankizumab)
      (6) Sotyktu (deucravacitinib)
      (7) Stelara (ustekinumab)
      (8) Tremfya (guselkumab)

   Authorization 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.

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
- Medical Necessity, Supply limits and/or Notification may be in place.

4. References:

1. Ilumya [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; December 2022.
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
4. Cosentyx [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp.; November 2023.
4. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; November 2023.
5. Cimzia [package Insert]. Smyrna, GA: UCB, Inc.; December 2022.
6. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; January 2024.
7. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; October 2023.

Program	Step Therapy - Ilumya (tildrakizumab)
Change Control	
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. Updated references.
9/2019	Updated background and criteria adding Skyrizi as preferred medication. Added coverage exclusion statement. Updated references.
12/2020	Annual review. Consolidated background to include only information on plaque psoriasis. Clarified documentation requirements for Cosentyx. Updated references.
12/2021	Annual review. Removed biologic language with no changes to step criteria. Updated background and references.
11/2022	Added Enbrel as a preferred product step option. Updated reference.
1/2023	Updated step therapy requirements to Humira or Amjevita . Updated background.
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.” Updated references.
4/2024	Annual review with no change to coverage criteria. Updated references.
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.