UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3171-4
Program	Step Therapy
Medications	Sotyktu™ (deucravacitinib)
P&T Approval Date	1/2023, 4/2023, 4/2024, 7/2024
Effective Date	8/18/2024

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 preferred products before providing coverage for Sotyktu. Infused medications for any of the conditions referenced in this document are not part of the criteria.

Sotyktu is a tyrosine kinase 2 (TYK2) inhibitor indicated for the treatment of adults with moderate to severe plaque psoriasis (PsO) who are candidates for systemic therapy or phototherapy. Sotyktu is not recommended for use in combination with other potent immunosuppressants.

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

Cimzia® (certolizumab) is indicated for the treatment of adults with moderate to severe PsO who are candidates for systemic therapy or phototherapy.

Stelara® (ustekinumab) is indicated for the treatment of patients 6 years of age or older with moderate to severe PsO who are candidates for phototherapy or systemic therapy.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate-to-severe PsO who are candidates for systemic therapy or phototherapy.

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of moderate to severe PsO in adults who are candidates for systemic therapy or phototherapy.

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

Otezla® (apremilast) is indicated for the treatment of adult patients with PsO who are candidates for phototherapy or systemic therapy.

Members will be required to meet the coverage criteria below.

2. Coverage Criteria[a]:

A. <u>Plaque Psoriasis</u>

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

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

(a) Cimzia (certolizumab)
(b) Enbrel (etanercept)
(c) One of the preferred adalimumab products[b]
(d) Skyrizi (risankizumab)
(e) Stelara (ustekinumab)
(f) Tremfya (guselkumab)
(g) Otezla (apremilast)

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.
[b] For a list of preferred adalimumab products please reference drug coverage tools.

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

4. References:

1. Sotyktu [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; September 2022
2. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
4. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; Novemebr 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.
8. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; July 2023.

Program	Step Therapy - Sotyktu™ (deucravacitinib)
Change Control	
1/2023	New program.
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 background and references.
7/2024	Updated step therapy criteria.