UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3171-2
Program	Step Therapy
Medications	Sotyktu™ (deucravacitinib)
P&T Approval Date	1/2023, 4/2023
Effective Date	7/1/2023; Oxford only: N/A

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 who are candidates for systemic therapy or phototherapy. Sotyktu is not recommended for use in combination with other potent immunosuppressants.

Adalimumab is indicated for RA: reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active RA. Adalimumab can be used alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs); Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderately to severely active polyarticular JIA in patients 2 years of age and older. Adalimumab can be used alone or in combination with methotrexate; PsA: reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA; AS: reducing signs and symptoms in adult patients with active AS. Adalimumab can be used alone or in combination with non-biologic DMARDs; Crohn's Disease (CD): treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older; Ulcerative Colitis (UC): treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older; PsO: treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate; Hidradenitis Suppurativa (HS): treatment of moderate to severe hidradenitis suppurativa in patients 12 years of age and older; Uveitis (UV): treatment of non-infectious intermediate, posterior, and panuveitis in adults and pediatric patients 2 years of age and older. In ulcerative colitis, effectiveness has not been established in patients who have lost response to or were intolerant to TNF blockers.

Cimzia® (certolizumab) is indicated for reducing signs and symptoms of CD and maintaining clinical response in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy. Cimzia is also indicated for the treatment of adults with moderately to severely active RA, treatment of adult patients with active PsA, treatment of adults with active ankylosing spondylitis (SpA), treatment of adults with moderate to severe PsO who are candidates for systemic therapy or phototherapy, and for the treatment of adults with non-radiographic axial spondyloarthritis (nr-axSpA), with objective signs of inflammation.

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, adult patients with active

PsA, alone or in combination with methotrexate, adult patients with moderately to severely active CD and for moderately to severely active UC.

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

Skyrizi® (risankizumab-rzaa) is indicated for the treatment of moderate to severe PsO in adults who are candidates for systemic therapy or phototherapy, moderately to severely active Crohn's disease in adults and active PsA in adults.

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe PsO in patients 6 years and older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of active PsA in patients 2 years of age and older, adults with active AS or non-radiographic axial spondyloarthritis (nr-axSpA) with objective signs of inflammation. Cosentyx is also indicated for the treatment of active enthesitis-related arthritis (ERA) in patients 4 years of age and older.

Enbrel® (etanercept) is a tumor necrosis factor (TNF) blocker indicated for the treatment of rheumatoid arthritis (RA), polyarticular juvenile idiopathic arthritis (PJIA) in patients 2 years of age or older, psoriatic arthritis (PsA), ankylosing spondylitis (AS), and plaque psoriasis (PsO) in patients 4 years or older.

Otezla® (apremilast) is a phosphodiesterase 4 (PDE4) inhibitor indicated for the treatment of adult patients with active psoriatic arthritis, for the treatment of patients with plaque psoriasis who are candidates for phototherapy or systemic therapy, and for the treatment of adult patients with oral ulcers associated with Behçet's disease.

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 **<u>both</u>** of the following criterion:

   a. History of failure, contraindication, or intolerance to **<u>three</u>** 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)

      -AND-

   b. History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document date and duration of trial)

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 2021.
3. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
4. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; December 2021.
5. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
6. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2019.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; September 2022.
8. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.
9. Otezla [package insert]. Thousand Oaks, CA: Amgen Inc.; December 2021.

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.