UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 3052-17
Program	Step Therapy
Medications	Cosentyx® (secukinumab) prefilled syringe or Sensoready pen
P&T Approval Date	2/2015, 3/2016, 8/2016, 5/2017, 2/2018, 2/2019, 9/2019, 7/2020, 11/2020, 7/2021, 11/2021, 3/2022, 6/2022, 11/2022, 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 one preferred self-administered injectable product before providing coverage for Cosentyx® (secukinumab). Infused medications for any of the conditions referenced in this document are not part of the criteria.

Cosentyx (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in patients 6 years and older who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older and adults with active ankylosing spondylitis (AS) or active 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.

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.

Simponi® (golimumab) is indicated for the treatment of adult patients with moderately to severely active RA in combination with methotrexate. Simponi, alone or in combination with methotrexate, is indicated for the treatment of adult patients with active PsA. It is also indicated for the treatment of adult patients with active AS. Simponi is also indicated in adult patients with moderate to severe UC who have require continuous steroid therapy or who have had an inadequate response to or intolerance to prior treatment. For UC, it is indicated for inducing and maintaining clinical response, improving endoscopic appearance of the mucosa during induction, inducing clinical remission, and achieving and sustaining clinical remission in induction responders.

Rinvoq® (upadacitinib) is indicated for the treatment of adults with moderately to severely active RA who have had an inadequate response or intolerance to one or more TNF blockers, adults with active PsA who have an inadequate response or intolerance to one or more TNF blockers, adults and pediatric patients 12 years of age and older with refractory, moderate to severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies are inadvisable, adults with moderately to severely active UC who have had an inadequate response or intolerance to one or more TNF blockers, adults with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more TNF blockers, and adults with active non-radiographic axial spondyloarthritis with objective signs of inflammation who have had an inadequate response or intolerance to TNF blocker therapy. Use of Rinvoq in combination with other JAK inhibitors, biologic DMARDs, biologic therapies for UC, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

Xeljanz/Xeljanz XR® (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active RA, active PsA, AS and moderately to severely active UC, who have had an inadequate response or intolerance to one or more TNF blockers. Xeljanz/Xeljanz Oral Solution is indicated for the treatment of active polyarticular course juvenile idiopathic arthritis in patients 2 years of age and older who have had an inadequate response or intolerance to one or more TNF blockers. The use of Xeljanz/Xeljanz XR/Xeljanz Oral Solution in combination with biologic DMARDs, biologic therapies for UC or potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

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, active PsA in adults, and moderately to severely active Crohn's disease in adults.

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.

Members currently on Cosentyx therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

2. Coverage Criteria [a]:

A. Plaque Psoriasis

1. **Cosentyx** will be approved based on **one** of the following criteria:

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

      (1) One of the preferred adalimumab products[b]
      (2) Stelara (ustekinumab)
      (3) Tremfya (guselkumab)
      (4) Cimzia (certolizumab)
      (5) Skyrizi (risankizumab)
      (6) Enbrel (etanercept)

-OR-

   b. **Both** of the following:

      (1) Patient is less than 18 years of age

-AND-

      (2) History of failure, contraindication, or intolerance to Stelara (ustekinumab) or Enbrel (etanercept) (document date and duration of trial)

-OR-

   c. **Both** of the following:

      (1) Patient is currently on Cosentyx therapy

-AND-

      (2) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

   * Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

B. Psoriatic Arthritis

1. **Cosentyx** will be approved based on **one** of the following criteria:

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

      (1) One of the preferred adalimumab products[b]
      (2) Stelara (ustekinumab)
      (3) Cimzia (certolizumab)
      (4) Simponi (golimumab)
      (5) Tremfya (guselkumab)
      (6) Skyrizi (risankizumab)
      (7) Rinvoq (upadacitinib)
      (8) Xeljanz/Xeljanz XR (tofacitinib)
      (9) Enbrel (etanercept)

-OR-

   b. **Both** of the following:

      (1) Patient is currently on Cosentyx therapy

-AND-

      (2) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

***** Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

C. Ankylosing Spondylitis

1. **Cosentyx** will be approved based on **one** of the following criteria:

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

      (1) One of the preferred adalimumab products[b]
      (2) Cimzia (certolizumab)
      (3) Simponi (golimumab)
      (4) Rinvoq (upadacitinib)
      (5) Xeljanz/Xeljanz XR (tofacitinib)
      (6) Enbrel (etanercept)

-OR-

b. **Both** of the following:

(1) Patient is currently on Cosentyx therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

D. Non-radiographic Axial Spondyloarthritis

1. **Cosentyx** will be approved based on **one** of the following criteria:

a. History of failure, contraindication, or intolerance Cimzia (certolizumab) or Rinvoq (upadacitinib) (document date and duration of trial)

-OR-

b. **Both** of the following:

(1) Patient is currently on Cosentyx therapy

-AND-

(2) Patient has **not** received a manufacturer supplied sample at no cost in prescriber office, or any form of assistance from the Novartis sponsored Cosentyx Connect (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) as a means to establish as a current user of Cosentyx*

* Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Novartis sponsored Cosentyx Connect **shall be required** to meet initial authorization criteria as if patient were new to therapy.

Authorization will be issued for 12 months.

E. Other Diagnoses

1. **Cosentyx** will be approved

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

4. References:

1. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
2. Stelara [package insert]. Horsham, PA: Janssen Biotech Inc.; August 2022.
3. Cosentyx [package insert]. East Hanover, NJ. Novartis Pharmaceuticals Corp.; December 2021.
4. Cimzia [package Insert]. Smyrna, GA: UCB, Inc; September 2019.
5. Simponi [package Insert]. Horsham, PA: Janssen Biotech Inc.; September 2019.
6. Tremfya [package insert]. Horsham, PA: Janssen Biotech Inc.; July 2020.
7. Skyrizi [package Insert]. North Chicago, IL: AbbVie Inc.; September 2022.
8. Rinvoq [package insert]. North Chicago, IL: AbbVie Inc.; April 2022.
9. Xeljanz/Xeljanz XR/Xeljanz Oral Solution [package insert]. New York, NY: Pfizer Labs; January 2022.
10. Enbrel [package insert]. Thousand Oaks, CA: Immunex Corp.; June 2022.

Program	Step Therapy - Cosentyx (secukinumab)
Change Control	
2/2015	New program.
3/2016	Annual review. Updated background information with 2 new indications for Cosentyx (active psoriatic arthritis and ankylosing spondylitis) and updated the indications for Stelara and Humira if they had the same indications. Updated clinical criteria so the step therapy would apply for the two new indications. Added Maryland Continuation of Care. Updated references.
8/2016	Updated criteria requiring trial of only 1 preferred alternative in plaque psoriasis. Added IN, WV coverage information. Updated references.
11/2016	Administrative change. Added California coverage information.
5/2017	Updated criteria for patients already receiving Cosentyx. Updated reference. Updated state mandate reference.
2/2018	Updated criteria adding Tremfya as an additional preferred agent for plaque psoriasis.
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 criteria for psoriasis, adding Skyrizi as preferred medication. Updated criteria for psoriatic arthritis and ankylosing spondylitis requiring trial of one preferred product prior to coverage for Cosentyx. Updated references.
7/2020	Updated background and criteria to include new indication for non-radiographic axial spondylarthritis. Added review criteria for psoriasis patients 12-18 years. Clarified documentation requirements. Updated references.
11/2020	Added Tremfya as a step therapy medication for psoriatic arthritis. Revised age requirements for psoriasis section due to expanded indication for Stelara. Updated background and references.
7/2021	Updated background to include expanded indication for moderate to severe plaque psoriasis to pediatric patients 6 years and older. Updated references.
11/2021	Updated age requirement language with no change to clinical intent. Updated background and references.
3/2022	Added Skyrizi as a preferred drug for active psoriatic arthritis. Updated conventional DMARD bypass language removing "biologic" from required preferred product criteria language. Added other diagnosis criteria. Updated reference.
6/2022	Added Rinvoq and Xeljanz to step therapy medication for ankylosing spondylitis and psoriatic arthritis. Updated background and references.
11/2022	Added Enbrel as a preferred product step option for AS, PsO, and PsA. Updated background and references. Added Rinvoq as a step option for non-radiographic axial spondyloarthritis.
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.