UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1041-16
Program	Prior Authorization/Notification
Medication	Adalimumab: Abrilada (adalimumab-afzb)*, Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-fkjp (unbranded Hulio)*, Amjevita™ (adalimumab-atto), Cyltezo® (adalimumab-adbm), Hadlima™ (adalimumab-bwwd), Hulio® (adalimumab-fkjp)*, Humira® (adalimumab), Hyrimoz® (adalimumab-adaz)*, Idacio (adalimumab-aacf)*, Yuflyma (adalimumab-aaty)*, and Yusimry (adalimumab-aqvh)* * Abrilada (adalimumab-afzb), Adalimumab-fkjp (unbranded Hulio), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh) are excluded from coverage for the majority of our benefits.
P&T Approval Date	1/2007, 6/2008 , 4/2009, 6/2009, 12/2009, 7/2010, 11/2010, 7/2011, 11/2011, 7/2012, 11/2012, 2/2014, 2/2015, 11/2015, 3/2016, 8/2016, 8/2017, 8/2018, 8/2019, 4/2020, 5/2021, 12/2021, 12/2022, 4/2023, 6/2023
Effective Date	7/1/2023; Oxford only: N/A

1. **Background:**
   Adalimumab is a tumor necrosis factor (TNF) blocker indicated for:
   - Rheumatoid Arthritis (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.
   - Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA.
   - Ankylosing Spondylitis (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.
   - Plaque Psoriasis (Ps): 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.

2. Coverage Criteria[a]:

A. Rheumatoid Arthritis (RA)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator. [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

B. Polyarticular Juvenile Idiopathic Arthritis (PJIA)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted

immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

C. Psoriatic Arthritis (PsA)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of active psoriatic arthritis

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab),

Simponi (golimumab), Orencia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Otezla (apremilast)]

Authorization will be issued for 12 months.

D. Plaque Psoriasis

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

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

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

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

Authorization will be issued for 12 months.

E. Ankylosing Spondylitis (AS)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of active ankylosing spondylitis

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

F. Crohn's Disease (CD)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderately to severely active Crohn's disease

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

G. Ulcerative Colitis

1. **Initial Authorization**

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

(1) Diagnosis of moderately to severely active ulcerative colitis

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib), Stelara (ustekinumab), Skyrizi (risankizumab)]

Authorization will be issued for 12 months.

H. Hidradenitis Suppurativa (HS)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of moderate to severe hidradenitis suppurativa

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy.

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

I. Uveitis (UV)

1. **Initial Authorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Diagnosis of non-infectious uveitis

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Adalimumab** will be approved based on **both** of the following criteria:

(1) Documentation of positive clinical response to adalimumab therapy.

-AND-

(2) Patient is not receiving adalimumab in combination with another targeted immunomodulator [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

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.

* Abrilada (adalimumab-afzb), Adalimumab-fkjp (unbranded Hulio), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh) are excluded from coverage for the majority of our benefits.

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 Medical Necessity may be in place.

4. References:

1. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2021.
2. Rubin DT, Ananthakrishnan AN, Siegel CA, Sauer BG, Long MD. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol*. 2019;114(3):384-413.
3. Lichtenstein GR, Abreu MT, Cohen R, Tremaine W. American Gastroenterological Association Institute medical position statement on corticosteroids, immunomodulators, and infliximab in inflammatory bowel disease. Gastroenterology 2006 Mar;130(3):935-9.
4. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; April 2023.
5. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; May 2023
6. Hyrimoz [package insert]. Princeton, NJ: Sandoz, Inc.; March 2023.
7. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; August 2022.
8. Hulio [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; July 2020.
9. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; December 2021.
10. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; May 2023.
11. Idacio [package insert], Lake Zurich, IL: Fresenius Kabi USA, LLC; December 2022.
12. Abrilada [package insert], New York, NY: Pfizer, Inc.; November 2019.

Program	Prior Authorization/Notification – Adalimumab: Abrilada (adalimumab-afzb)*, Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-fkjp (unbranded Hulio)*, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp)*, Humira (adalimumab), Hyrimoz (adalimumab-adaz)*, Idacio (adalimumab-aacf)*, Yuflyma (adalimumab-aaty)*, and Yusimry (adalimumab-aqvh)*

Change Control	
2/2014	Background updated. Concomitant therapy criterion condensed to list four biologic DMARDs and revised to include Xeljanz. Reauthorization criteria revised to standard verbiage and to include concomitant therapy criterion. Extended reauthorization duration to 24 months.
9/2014	Administrative change – Tried/Failed exemption for State of New Jersey removed.
2/2015	Annual review with no change to coverage criteria. Minor reformatting. Updated background and references.
11/2015	Added the indication and criteria for hidradenitis suppurativa. Updated criteria to align with the Indication Section of the FDA label. Updated background and references.
3/2016	Annual review. Added criteria back with language that Humira cannot be used in combination with biologic DMARDs, a Janus Kinase Inhibitor, or a Phosphodiesterase 4 inhibitor for the applicable indications. Added "polyarticular" to juvenile idiopathic arthritis. Updated reference.
8/2016	Added the indication and criteria for uveitis. Updated background and references.
8/2017	Annual review. Reformatted criteria for Crohn's Disease without changes in clinical intent. Updated reference.
8/2018	Annual review. Added Olumiant (baricitinib) to the applicable criteria. Updated reference.
8/2019	Annual review with no changes to coverage criteria. Updated background and references.
4/2020	Updated criteria to allow for pediatric Crohn's disease. Updated reauthorization approval duration for all diagnoses.
5/2021	Updated Crohn's disease and ulcerative colitis coverage criteria according to FDA label.
12/2021	Updated initial authorization for UC to 12 months.
12/2022	Annual review. Renamed program to Adalimumab: Humira® (adalimumab) and Amjevita™ (adalimumab-atto) to add Amjevita to the program. Replaced Humira with adalimumab throughout the program to allow coverage for either Humira or Amjevita with no change to overall coverage criteria. Added Rinvoq as JAK inhibitor example. Added state mandate footnote. Updated reference.
4/2023	Added Cyltezo to the program. Updated references.
6/2023	Added Abrilada (adalimumab-afzb), Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-fkjp (unbranded Hulio), Hyrimoz (adalimumab-adaz), Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp), Idacio (adalimumab-aacf), Yusimry (adalimumab-aqvh), and Yuflyma (adalimumab-aaty). Added notation some are excluded from coverage for the majority of our benefits. Updated refefrences. Updated not receiving in combination language to targeted immunomodulator and updated examples.