

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 2198-8
Program	Prior Authorization/Medical Necessity
Medication	<p>Adalimumab: Abrilada™ (adalimumab-afzb)*, Adalimumab-aacf (unbranded Idacio)*, Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-adbm (unbranded Cyltezo), Adalimumab-fkjp (unbranded Hulio)*, Amjevita™ (adalimumab-atto)**, Cyltezo® (adalimumab-adbm)*, Hadlima™ (adalimumab-bwwd), Hulio® (adalimumab-fkjp)*, Humira® (adalimumab), Hyrimoz® (adalimumab-adaz)*, Idacio® (adalimumab-aacf)*, Simlandi® (adalimumab-ryvk)*, Yuflyma® (adalimumab-aaty)*, and Yusimry™ (adalimumab-aqvh)*</p> <p>* Abrilada (adalimumab-afzb), Adalimumab-aacf (unbranded Idacio), Adalimumab-fkjp (unbranded Hulio), Cyltezo (adalimumab-adbm), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz), Idacio (adalimumab-aacf), Simlandi (adalimumab-ryvk), Yuflyma (adalimumab-aaty), Yusimry (adalimumab-aqvh) are excluded from coverage for the majority of our benefits.</p> <p>** Only Amjevita (adalimumab-atto) 10mg/0.1ml concentrations are covered. Amjevita (adalimumab-atto) 10mg/0.2ml concentrations are excluded from coverage for the majority of our benefits.</p>
P&T Approval Date	5/2020, 5/2021, 6/2021, 12/2021, 5/2022, 12/2022, 4/2023, 6/2023, 6/2024
Effective Date	9/1/2024

**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<sup>a</sup>:

### A. Rheumatoid Arthritis (RA)

#### 1. Initial Authorization

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

(1) Diagnosis of moderately to severely active rheumatoid arthritis

-AND-

(2) **One** of the following:

- (a) History of failure to a 3 month trial of **one** non-biologic disease modifying anti-rheumatic drug (DMARD) [e.g., methotrexate, leflunomide, sulfasalazine, hydroxychloroquine] at the maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)<sup>b</sup>

-OR-

- (b) Patient has been previously treated with a biologic or targeted immunomodulator FDA-approved for the treatment of rheumatoid arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Orencia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

-OR-

(c) **Both** of the following:

- i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (3) 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)]

-AND-

- (4) Prescribed by or in consultation with a rheumatologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

- a. **Adalimumab** will be approved based on **all** 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 **all** 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)]

-AND-

- (3) Prescribed by or in consultation with a rheumatologist

**Authorization will be issued for 12 months.**

## 2. Reauthorization

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

(1) Diagnosis of active psoriatic arthritis

**-AND-**

(2) **One** of the following:

(a) History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)<sup>b</sup>

**-OR-**

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of psoriatic arthritis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [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)]

**-OR-**

(c) **Both** of the following:

i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (3) 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)]

-AND-

- (4) Prescribed by or in consultation with **one** of the following:
  - (a) Rheumatologist
  - (b) Dermatologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

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

(1) Diagnosis of moderate to severe chronic plaque psoriasis

-AND-

(2) **One** of the following:

(a) **All** of the following:

i. Greater than or equal to 3% body surface area involvement, palmoplantar, facial, genital involvement, or severe scalp psoriasis

-AND-

ii. History of failure to **one** of the following topical therapies, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- a. Corticosteroids (e.g., betamethasone, clobetasol, desonide)
- b. Vitamin D analogs (e.g., calcitriol, calcipotriene)
- c. Tazarotene
- d. Calcineurin inhibitors (e.g., tacrolimus, pimecrolimus)
- e. Anthralin
- f. Coal tar

-AND-

iii. History of failure to a 3 month trial of methotrexate at the maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document date and duration of trial)<sup>b</sup>

-OR-

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of plaque psoriasis as documented by claims history or submission of medical records (document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Orenzia (abatacept), Stelara (ustekinumab), Skyrizi (risankizumab), Tremfya (guselkumab), Cosentyx (secukinumab), Taltz (ixekizumab), Siliq (brodalumab), Ilumya (tildrakizumab), Otezla (apremilast)]

-OR-

(c) **Both** of the following:

i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy)

-AND-

ii. Patient has **not** received a manufacturer supplied sample at no cost in the

prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

**-AND-**

- (3) 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)]

**-AND-**

- (4) Prescribed by or in consultation with a dermatologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

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

- (1) Diagnosis of active ankylosing spondylitis

**-AND-**

(2) **One** of the following:

- (a) History of failure to **two** NSAIDs (e.g., ibuprofen, naproxen) at maximally indicated doses, each used for at least 4 weeks, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trials)

**-OR-**

- (b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ankylosing spondylitis as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Enbrel (etanercept), Cimzia (certolizumab), Simponi (golimumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)]

**-OR-**

(c) **Both** of the following:

- i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

**-AND-**

(3) 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)]

**-AND-**

(4) Prescribed by or in consultation with a rheumatologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**



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

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

**-AND-**

(2) **One** of the following:

(a) History of failure to **one** of the following conventional therapies at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial):

- i. Corticosteroids (e.g., prednisone, methylprednisolone, budesonide)
- ii. 6-mercaptopurine (Purinethol)
- iii. Azathioprine (Imuran)
- iv. Methotrexate (Rheumatrex, Trexall)

**-OR-**

(b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of Crohn's disease as documented by claims history or submission of medical records (Document drug, date, and duration of therapy) [e.g., Cimzia (certolizumab), Stelara (ustekinumab), Skyrizi (risankizumab)]

**-OR-**

(c) **Both** of the following:

i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

**-AND-**

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (3) 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)]

-AND-

- (4) Prescribed by or in consultation with a gastroenterologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

- a. **Adalimumab** will be approved based on **all** 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) **One** of the following:

- (a) Patient has had prior or concurrent inadequate response to a therapeutic course of oral corticosteroids and/or immunosuppressants (e.g., azathioprine, 6-mercaptopurine)

-OR-

- (b) Patient has been previously treated with a targeted immunomodulator FDA-approved for the treatment of ulcerative colitis as documented by claims history or submission medical records (Document drug, date, and duration of therapy) [e.g., Simponi (golimumab), Stelara (ustekinumab), Xeljanz (tofacitinib), Rinvoq (upadacitinib)].

-OR-

- (c) **Both** of the following:

- i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (3) 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)]

-AND-

- (4) Prescribed by or in consultation with a gastroenterologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

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

- (1) Diagnosis of moderate to severe hidradenitis suppurativa (i.e., Hurley Stage II or III)

-AND-

- (2) **One** of the following:

- (a) History of failure to at least **one** oral antibiotic (e.g., doxycycline, clindamycin, rifampin) at maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-OR-

- (b) **Both** of the following:

- i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (3) 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)]

-AND-

- (4) Prescribed by or in consultation with a dermatologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

2. **Reauthorization**

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

(1) Diagnosis of non-infectious uveitis

**-AND-**

(2) Uveitis is classified as **one** of the following:

- (a) intermediate
- (b) posterior
- (c) panuveitis

**-AND-**

(3) **One** of the following:

(a) **Both** of the following:

- i. History of failure to at least **one** corticosteroid (e.g., prednisolone, prednisone) at maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-AND-

- ii. History of failure to at least **one** systemic non-biologic immunosuppressant (e.g., methotrexate, cyclosporine, azathioprine, mycophenolate) at up to a maximally indicated dose, unless contraindicated or clinically significant adverse effects are experienced (document drug, date, and duration of trial)

-OR-

(b) **Both** of the following:

- i. Patient is currently on adalimumab therapy as documented by claims history or submission of medical records (Document date and duration of therapy):

-AND-

- ii. Patient has **not** received a manufacturer supplied sample at no cost in the prescriber's office, or any form of assistance from a manufacturer sponsored program (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 adalimumab\*

-AND-

- (4) 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)]

-AND-

(5) Prescribed by or in consultation with **one** of the following:

- (a) Rheumatologist
- (b) Ophthalmologist

\* 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 a manufacturer sponsored program **shall be required** to meet initial authorization criteria as if patient were new to therapy.

**Authorization will be issued for 12 months.**

## 2. **Reauthorization**

a. **Adalimumab** will be approved based on **all** 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), Orenzia (abatacept), Xeljanz (tofacitinib), Olumiant (baricitinib), Rinvoq (upadacitinib)]

**Authorization will be issued for 12 months.**

<sup>a</sup> 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.

<sup>b</sup> For Connecticut, Kentucky and Mississippi business only a 30-day trial will be required.

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

\*\* Only Amjevita (adalimumab-atto) 10mg/0.1ml concentrations are covered. Amjevita (adalimumab-atto) 10mg/0.2ml concentrations 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 may be in place.

### 4. References:

1. Humira [package insert]. North Chicago, IL: AbbVie Inc.; February 2024.
2. Ward MM, Deodhar, A, Gensler, LS, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. *Arthritis & Rheumatology*. 2019; 71(10): 1599-1613.
3. Yu, DT, van Tubergen A. Treatment of axial spondyloarthritis (ankylosing spondylitis and nonradiographic axial spondyloarthritis) in adults. Sieper, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on October 10, 2019.)
4. Singh, JA, Guyatt, G, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. *Arthritis & Rheumatology*. 2019; 71(1): 5-32.
5. Menter A, Gottlieb A, Feldman SR, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol* 2008; 58(5):826-50.
6. Gottlieb A, Korman NJ, Gordon KB, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Psoriatic arthritis: Overview and guidelines of care for treatment with an emphasis on the biologics. *J Am Acad Dermatol* 2008;58(5):851-64.
7. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies. *J Am Acad Dermatol* 2009;60(4):643-59.

8. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the treatment of psoriasis with phototherapy and photochemotherapy. J Am Acad Dermatol 2010;62(1):114-35.
9. Menter A, Korman NJ, Elmets CA, et al. Guidelines of care for the management of psoriasis and psoriatic arthritis. Guidelines of care for the management and treatment of psoriasis with traditional systemic agents. J Am Acad Dermatol 2009;61(3):451-85.
10. Nast A, et al; European S3-Guidelines on the systemic treatment of psoriasis vulgaris – update 2015 – short version – EFF in cooperation with EADV and IPC, J Eur Acad Derm Venereol 2015;29:2277-94.
11. Menter A, Korman NJ, Elmets CA, Feldman SR, Gelfand JM, Gordon KB, Guidelines of care for the management of psoriasis and psoriatic arthritis: section 6. Guidelines of care for the treatment of psoriasis and psoriatic arthritis: case-based presentations and evidence-based conclusions. J Am Acad Dermatol. 2011 Jul;65(1):137-74.
12. Gossec L, et al; European League Against Rheumatism (EULAR) recommendations for the management of psoriatic arthritis with pharmacological therapies: 2015 update, Ann Rheum Dis 2016;75:499-510.
13. Ingram, JR. Hidradenitis suppurativa: Treatment. Dellavalle, RP, Dahl, MV (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on October 29, 2019.)
14. Rosenbaum, JT. Uveitis: Treatment. Trobe, J (Ed). UpToDate. Waltham, MA: UpToDate Inc. <http://www.uptodate.com> (Accessed on October 30, 2019).
15. Feuerstein JD, Isaacs KL, Schneider Y, et al. AGA clinical practice guidelines on the management of moderate to severe ulcerative colitis. Gastroenterology. 2020; 158(5):1450-61.
16. Lichtenstein GR, Loftus EV, Isaacs KL, et al ACG clinical guideline: management of Crohn’s disease in adults. Am J Gastroenterol. 2018; 113:481-517.
17. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80:1029-72.
18. Amjevita [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2023.
19. Cyltezo [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; June 2023
20. Hyrimoz [package insert]. Princeton, NJ: Sandoz, Inc.; April 2023.
21. Hadlima [package insert]. Jersey City, NJ: Organon & Co.; July 2023.
22. Hulio [package insert]. Morgantown, WV: Mylan Pharmaceuticals Inc.; December 2023.
23. Yusimry [package insert]. Redwood City, CA: Coherus BioSciences, Inc.; September 2023.
24. Yuflyma [package insert]. Jersey City, NJ: Celltrion USA, Inc.; December 2023.
25. Idacio [package insert], Lake Zurich, IL: Fresenius Kabi USA, LLC; October 2023.
26. Abrilada [package insert], New York, NY: Pfizer, Inc.; January 2024.
27. Simlandi [package insert], Leesburg, VA: Alvotech USA Inc.; February 2024.

Program	Prior Authorization/Medical Necessity - Adalimumab: Abrilada (adalimumab-afzb)*, Adalimumab-aacf (unbranded Idacio)*, Adalimumab-adaz (unbranded Hyrimoz), Adalimumab-adbm (unbranded Cyltezo), Adalimumab-fkjp (unbranded Hulio)*, Amjevita (adalimumab-atto)**, Cyltezo (adalimumab-adbm)*, Hadlima (adalimumab-bwwd), Hulio (adalimumab-fkjp)*, Humira (adalimumab), Hyrimoz (adalimumab-adaz)*, Idacio (adalimumab-aacf)*, Simlandi (adalimumab-ryvk)*, Yuflyma (adalimumab-aaty)*, and Yusimry (adalimumab-aqvh)*
<b>Change Control</b>	
5/2020	New Program
5/2021	Annual review. Updated Crohn’s disease coverage criteria according to



	FDA label. Removed preceding month requirement from failure criteria. Removed prescriber requirement from reauthorization criteria. Removed drug documentation where only one drug is required. References and background updated.
6/2021	Added coverage criteria for patients previously treated with a biologic DMARD. Added clarification that submission of medical records is required documenting previous or current therapy with a biologic DMARD in order to bypass step through non-biologic therapies if claim history not available.
12/2021	Updated conventional DMARD bypass language for rheumatoid arthritis, psoriatic arthritis, psoriasis and ulcerative colitis with no change to clinical intent. Updated initial authorization duration to 12 months for ulcerative colitis. Updated CT/KY footnote.
5/2022	Added targeted synthetic DMARD to bypass criteria for AS. Added Rinvoq and Xeljanz as JAK inhibitor examples where applicable. Added Mississippi to state mandate.
12/2022	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. 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 references. Updated not receiving in combination language to targeted immunomodulator and updated examples.
6/2024	Annual review. Added Adalimumab-aacf (unbranded Idacio), Adalimumab-adbm (unbranded Cyltezo), and Simlandi (adalimumab-ryvk) to the program. Noted Humira, Hadlima, Amjevita high concentration, Adalimumab-adbm (unbranded Cyltezo), and Adalimumab-adaz (unbranded Hyrimoz) as covered products. All other products are noted as excluded. Updated references and state mandate footnote.