Adalimumab Biosimilars

Pharmacy Benefit Drug Policy

Drug Details

USP Category: Immunological Agents
Mechanism of Action: tumor necrosis factor (TNF) blocker

LABEL NAME & STRENGTH	QL
Abrilada 40 mg/0.8 mL auto-injector kit	2 syringes or pens/28 days
Abrilada 40mg/0.8ml auto-injector kit	2 syringes or pens/28 days
Abrilada 20mg/0.4ml prefilled syringe kit	2 syringes or pens/28 days
Amjevita 10 mg/0.2ml Soln Prsyr	2 syringes (0.4ML/28 days)
Amjevita 20mg/0.2ml prefilled syringe	2 syringes or pens/28 days
Amjevita 20 mg/0.4ml Soln Prsyr	2 syringes (0.8ML/28 days)
Amjevita 40mg/0.4ml prefilled syringe	2 syringes or pens/28 days
Amjevita 40mg/0.4ml auto-injector	2 syringes or pens/28 days
Amjevita 40 mg/0.8ml Soln Prsyr	2 syr (1.6ML/28 days)
Amjevita 40 mg/0.8ml Soln A-Inj	2 pens (1.6ML/28 days)
Amjevita 80 mg/0.8 mL auto-injector	2 syringes or pens/28 days
Adalimumab-adaz 40 MG/0.4ML SOLN A-INJ	0.8ml (2 pens)/28 days
Adalimumab-adaz 40 MG/0.4ML SOLN PRSYR	0.8ml (2 syr)/28 days
Adalimumab-fkjp 40 MG/0.8ML AUT-IJ KIT	6 pens/365 days
Adalimumab-fkjp 20 MG/0.4ML PREF SY KT	2 syringes/28 days
Adalimumab-fkjp 40 MG/0.8ML PREF SY KT	2 syringes/28 days
Cyltezo-CD/UC/HS Starter 40 MG/0.8ML AUT-IJ KIT	6 pens/365 days
Cyltezo-Psoriasis Starter 40 MG/0.8ML AUT-IJ KIT	4 pens/365 days
Cyltezo 40 MG/0.8ML AUT-IJ KIT	2 pens/28 days
Cyltezo 10 MG/0.2ML PREF SY KT	2 syringes/28 days
Cyltezo 20 MG/0.4ML PREF SY KT	2 syringes/28 days
Cyltezo 40 MG/0.8ML PREF SY KT	2 syringes/28 days
Hadlima PushTouch 40 MG/0.4ML SOLN A-INJ	0.8ml (2 pens)/28 days
Hadlima PushTouch 40 MG/0.8ML SOLN A-INJ	1.6ml (2 pens)/28 days
Hadlima 40 MG/0.4ML SOLN PRSYR	0.8ml (2 syr)/28 days
Hadlima 40 MG/0.8ML SOLN PRSYR	1.6ml (2 syr)/28 days
Hulio 40 MG/0.8ML AUT-IJ KIT	2 kits/28 days
Hulio 20 MG/0.4ML PREF SY KT	2 kits/28 days
Hulio 40 MG/0.8ML PREF SY KT	2 kits/28 days
Hyrimoz 40/0.8 ML PREF SY	1.6ml (2 pens)/28 days
Hyrimoz-Crohns/UC Starter Pack 80 MG/0.8ML SOLN A-INJ	1.6ml (2 pens)/28 days
Hyrimoz-Ped Crohns Starter 80 MG/0.8ML & 40MG/0.4ML SOLN PRSYR	1.2ml (1 carton)/365 days
Hyrimoz-Ped Crohns Starter 80 MG/0.8ML SOLN PRSYR	2.4ml (3 syr)/365 days

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Hyrimoz-Plaque Psoriasis Start 80 MG/0.8ML & 40MG/0.4ML SOLN A-INJ	1.6ml (1 carton)/365 days
Hyrimoz 40 MG/0.4ML SOLN A-INJ	0.8ml (2 pens)/28 days
Hyrimoz 80 MG/0.8ML SOLN auto-injector	1.6ml (2 pens)/28 days
Hyrimoz 10 MG/0.1 ML SOLN PRSYR	0.2ml (2 syr)/28 days
Hyrimoz 20 MG/0.2ML SOLN PRSYR	0.4ml (2 syr)/28 days
Hyrimoz 40 MG/0.4ML SOLN PRSYR	0.8ml (2 syr)/28 days
Idacio for Crohns Disease/UC 40 MG/0.8ML AUT-IJ KIT	3 kits/365 days
Idacio for Plaque Psoriasis 40 MG/0.8ML AUT-IJ KIT	2 kits/365 days
Idacio 40 MG/0.8ML AUT-IJ KIT	1 kit/28 days
Idacio 40 MG/0.8ML PREF SY KT	1 kit/28 days
Yuflyma 20 MG/0.2ML PREF SY KT	1 kit/28 days
Yuflyma 40 MG/0.4ML AUT-IJ KIT	2 pens/28 days
Yuflyma Starter Kit-CD/UC/HS	2 injectors/28 days (box of 1), 3 injectors per 365 days (starter kit)
Yusimry 40 MG/0.8ML SOLN PEN	1.6ml (2 pens)/28 days

Condition(s) listed in policy *(see coverage criteria for details)*

- Ankylosing spondylitis (AS)
- Crohn's disease (CD)
- Hidradenitis Suppurativa (HS)
- Juvenile Idiopathic Arthritis (JIA)
- Psoriatic Arthritis (PsA)
- Rheumatoid Arthritis (RA)
- Plaque Psoriasis (PsO)
- Ulcerative Colitis (UC)
- Uveitis; non-infectious

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

Members with Specialty Tier benefit must obtain specialty drugs through our contracted specialty pharmacies for medication to be covered.

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Coverage Criteria

Commercial Coverage Criteria:

1. **For diagnosis of ankylosing spondylitis:**

- Being prescribed by, or in consultation with, a rheumatologist, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- One of the following:
  - For patient with no bleeding or ulcer risk factors: Either inadequate response or non-GI related intolerable side effect with TWO prescription-strength oral NSAIDs, OR intolerable GI side effect with ONE prescription-strength oral NSAID monotherapy not relieved with addition of concomitant proton pump inhibitor (PPI) therapy, **or**
  - For patient with high-risk potential for development of GI bleed or ulcer: Inadequate response or intolerable side effect to ONE prescription-strength oral NSAID in combination with a proton pump inhibitor (PPI), **or**
  - Patient unable to use NSAIDs due to history of GI bleed or ulcer,

and

- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 40 mg every other week.

Coverage Duration: one year

2. **For diagnosis of moderate to severe Crohn's disease:**

- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 160 mg SQ given once on day #1 (week #0), then 80 mg SQ given once on day #15 (week #2), followed by 40 mg every other week starting on day #29 (week #4).

Coverage Duration: one year

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For a dose escalation request in moderate to severe Crohn's disease

- Patient either flared or had a loss in response after at least one maintenance dose, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors), **and**
- Dose does not exceed 40 mg SQ given once per week

Coverage Duration: one year

3. **For diagnosis of Hidradenitis Suppurativa (HS):**

- Being prescribed by, or in consultation, with a dermatologist, **and**
- Patient has moderate to severe HS disease as evidenced by Hurley stage II or III disease, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 160 mg SQ given once on day #1 (week #0), followed by 80 mg SQ given on day #15 (week #2), then starting day #29 (week #4) give 40 mg every week or 80 mg every other week.

Coverage Duration: one year

4. **For diagnosis of Juvenile Idiopathic Arthritis, approve if:**

- Being prescribed by, or in consultation with, a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR has a medical justification why methotrexate cannot be used, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed FDA labeled maximum:

10 kg (22 lbs) to less than 15 kg (33 lbs)	10 mg every other week
15 kg (33 lbs) to less than 30 kg (66 lbs)	20 mg every other week
30 kg (66 lbs) and greater	40 mg every other week

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Coverage Duration: one year

5. **For diagnosis of moderate to severe plaque psoriasis:**

INITIAL AUTHORIZATION

• Patient is at least 18 years old, **and**
• Being prescribed by or in consultation with a rheumatologist or dermatologist, **and**
• Inadequate response, intolerable side effect, or contraindication to one of the following: methotrexate, cyclosporine (Neoral), acitretin (Soriatane), **or** PUVA/UVB, **and**
• Not being used in combination with another targeted biologic, **and**
• Dose does not exceed 80 mg SQ given once on week #0, followed by 40 mg every other week starting one week after initial dose, **and**
• Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
• One of the following:
  ○ Baseline PASI score is 10 or more prior to initiating targeted immunomodulator (e.g. Enbrel, Humira, Stelara, Cosentyx, Otezla), **or**
  ○ Baseline BSA is 3% or more prior to initiating targeted immunomodulator (e.g. Enbrel, Humira, Stelara, Cosentyx, Otezla), **or**
  ○ Sensitive area is involved (i.e. groin, face, etc.), **or**
  ○ Disease is otherwise debilitating.
 	
Coverage Duration: 24 weeks

REAUTHORIZATION
• Patient has shown improvement in the baseline PASI (or BSA if provided on initial request), **and** • Not being used in combination with another targeted biologic, **and** • Dose does not exceed 40 mg SQ given once every other week. ***Coverage Duration:*** one year
DOSE ESCALATION BEYOND FDA MAXIMUM FOR MAINTENANCE
• Not being used in combination with another targeted biologic, **and** • Dose does not exceed 40 mg given SQ once every week, **and** • Documentation that maintenance treatment with 40 mg every other week has been ineffective.

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Coverage Duration: one year

6. **For diagnosis of psoriatic arthritis:**

- Being prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response or intolerable side effect with one DMARD agent OR patient has a medical reason why methotrexate, leflunomide, and sulfasalazine cannot be used, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 40 mg every other week

Coverage Duration: one year

7. **For diagnosis of rheumatoid arthritis:**

- Being prescribed by or in consultation with a rheumatologist, **and**
- Inadequate response, intolerable side effect, or contraindication to methotrexate, **and**
- Not being used in combination with another targeted immunomodulator (i.e. anti-TNFs, IL-6 inhibitors, JAK inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 40 mg every other week.

Coverage Duration: one year

8. **For diagnosis of moderate to severe ulcerative colitis:**

- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors, JAK inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**

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- Dose does not exceed 160 mg SQ given once on day #1 (week #0), then 80 mg SQ given once on day #15 (week #2), followed by 40 mg every other week starting on day #29 (week #4).

Coverage Duration: one year

9. **For diagnosis of non-infectious uveitis:**

- Being prescribed by or in consultation with an ophthalmologist, **and**
- Inadequate response, intolerable side effect, or contraindication to systemic corticosteroids, **and**
- Not being used in combination with other targeted immunotherapies (i.e. anti-TNFs, interleukin inhibitors), **and**
- Intolerable side effect or contraindication to the preferred adalimumab products (e.g., Hadlima and Humira) not expected with non-preferred adalimumab products, **and**
- Dose does not exceed 80 mg SQ given once on day #1 (week #0), followed by 40 mg SQ given on day #8 (week #1) and thereafter 40 mg every other week.

Coverage Duration: one year

Additional Information:

- Biosimilars are biological products approved based on data demonstrating that it is highly similar to an FDA-approved biological product known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of above drugs have been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

- Cyltezo is an interchangeable product (IP). Interchangeable means that the product has demonstrated that it is highly similar to an FDA-approved reference product (RP) and that there are no clinically meaningful differences between the products; it can be expected to produce the same clinical result as the RP in any given patient; and if administered more than once to a patient, the risk in terms of safety or diminished efficacy from alternating or switching between use of the RP and IP is not greater than that from the RP without such alternation or switch. Interchangeability of CYLTEZO has been demonstrated for the condition(s) of use,

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strength(s), dosage form(s), and route(s) of administration described in its Full Prescribing Information.

References

1. Amjevita. Prescribing information. Amgen Inc.: 2023.
2. Cyltezo. Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc.; 2023.
3. Hadlima. Prescribing Information. Samsung Bioepis Co.; 2023.
4. Hulio. Prescribing Information. Mylan Pharmaceuticals Inc.; 2023
5. Hyrimoz. Prescribing Information. Sandoz, Inc.; 2023
6. Idacio. Prescribing Information. Fresenius Kabi, USA; 2022.
7. Yuflyma. Prescribing Information. Celltrion; 2023.
8. Yusimry. Prescribing Information. Coherus BioSciences; 2023.
9. AHFS®. Available by subscription at http://www.lexi.com
10. DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch

Policy Update

Date of Last Annual Review: 2Q23
Date of last revision: 04/03/2024
Changes from previous policy version:

- Added new product Yuflyma 20 MG/0.2ML PREF SY KT to policy

Blue Shield of California Medication Policy to Determine Medical Necessity Reviewed by P&T Committee

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