

Abrilada* (adalimumab-afzb)

Amjevita* (adalimumab-atto)

Cyltezo* (adalimumab-adbm)

Hadlima* (adalimumab-bwwd)

Hulio* (adalimumab-fkjp)

Hyrimoz (adalimumab-adaz)

Idacio* (adalimumab-aacf)

Simlandi* (adalimumab-ryvk)

Yuflyma* (adalimumab-aaty)

Yusimry* (adalimumab-aqvh)

Preferred products: Humira, adalimumab-fkjp, Hyrimoz, adalimumab-adaz

*Prior authorization for specific formulations applies only to formulary exceptions due to being a non-covered medication.

Pre - PA Allowance

None

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

Age 2 years of age or older

- Moderately to severely active Polyarticular Juvenile Idiopathic Arthritis (pJIA)
 - a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 2-17, weight 10kg to < 15kg: 10 mg every other week
 - ii. Age 2-17, weight 15kg to < 30kg: 20 mg every other week
 - iii. Age 2-17, weight ≥30kg: 40 mg every other week
 - iv. Age 18 and older: 40 mg every other week



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Preferred products: Humira, adalimumab-fkjp, Hyrimoz, adalimumab-adaz

2. Uveitis

- a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 2-17, weight 10kg to < 15kg: 10 mg every other week
 - ii. Age 2-17, weight 15kg to < 30kg: 20 mg every other week
 - iii. Age 2-17, weight ≥30kg: 40 mg every other week
 - iv. Age 18 and older: 40 mg every other week

Age <u>5 years of age or older</u>

- 1. Ulcerative Colitis (UC)
 - a. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 5-17, weight 20kg to <40kg: 40 mg every other week or 20 mg every week
 - ii. Age 5-17, weight ≥40kg: 80 mg every other week or 40 mg every week
 - iii. Age 18 and older: 40 mg every other week **OR** 20 mg every week, or 40 mg every week/80 mg every other week if patient was established and stable on pediatric dosing regimen

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Age 6 years of age or older

- 1. Moderate to severely active Crohn's Disease (CD)
 - a. Inadequate treatment response, intolerance or contraindication to at least **ONE** conventional therapy option (see Appendix 2)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 6-17, weight 17kg to < 40kg: 20 mg every other week
 - ii. Age 6-17, weight ≥40kg: 40 mg every other week
 - iii. Age 18 and older: 40 mg every other week

Age 12 years of age or older

- 1. Moderately to severely active Rheumatoid Arthritis (RA)
 - a. Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional disease-modifying antirheumatic drugs (DMARDs) (see Appendix 1)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Concurrent therapy with methotrexate: 40 mg every other week
 - ii. NO concurrent therapy with methotrexate: 40 mg every week or 80 mg every other week

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- 2. Active Psoriatic Arthritis (PsA)
 - Inadequate treatment response, intolerance, or contraindication to a 3-month trial of at least **ONE** conventional DMARD (see Appendix 1)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week
- 3. Active Ankylosing Spondylitis (AS)
 - Inadequate treatment response, intolerance, or contraindication to at least **TWO** non-steroidal antiinflammatory drugs (NSAIDs)
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week
- 4. Chronic moderate to severe Plaque Psoriasis (PsO)
 - a. Inadequate treatment response, intolerance, or contraindication to either conventional systemic therapy (see Appendix 1) or phototherapy
 - If the patient is intolerant or contraindicated to one therapy then the patient must have an inadequate treatment response, intolerance, or contraindication to the other treatment option
 - b. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week

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- 5. Hidradenitis Suppurativa (HS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 12-17, weight 30 kg to <60kg: 40 mg every other week
 - ii. Age 12-17, weight ≥60kg: 40 mg every week or 80 mg every other week
 - iii. Age 18 and older: 40 mg every week or 80 mg every other week

AND ALL of the following:

- Result for latent TB infection is negative OR result was positive for latent TB and patient completed treatment (or is receiving treatment) for latent TB
- Patient is not at risk for HBV infection OR patient is at risk for HBV infection and HBV infection has been ruled out or treatment for HBV infection has been initiated
- c. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- d. NOT to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)
- e. NOT given concurrently with live vaccines

Prior - Approval Limits Quantity

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Diagnosis	Starter Pack	Strength	Quantity
Rheumatoid Arthritis	No	40 mg/0.4 mL 40 mg/0.8 mL 80 mg/0.8mL	NO concurrent methotrexate: 12 x 40mg units per 84 days OR 6 x 80mg units per 84 days OR Concurrent methotrexate:
			6 x 40mg units per 84 days
Psoriatic Arthritis	No	40 mg/0.4 mL 40 mg/0.8 mL	6 x 40mg units per 84 days
Ankylosing Spondylitis	No	40 mg/0.4 mL 40 mg/0.8 mL	6 x 40mg units per 84 days
Plaque Psoriasis	Yes	40 mg/0.4 mL 40 mg/0.8 mL	1 Starter Pack and 6 x 40mg units per 84 days
Ulcerative Colitis	Yes	Age 5-17 (20 kg to < 40kg) 20 mg/0.2 mL 20 mg/0.4 mL 40 mg/0.4 mL 40 mg/0.8 mL Age 5-17 (≥ 40 kg) 40 mg/0.4 mL	1 Starter Pack and 12 x 20mg units per 84 days OR 6 x 40mg units per 84 days 1 Starter Pack and 12 x 40mg units per 84 days
		40 mg/0.8 mL	OR



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		80 mg/0.8mL	6 x 80mg units per 84 days
		Age 18+:	1 Starter Pack and
		20 mg/0.2 mL	6 x 40mg units per 84 days
		20 mg/0.4 mL	OR
		40 mg/0.4 mL	B. Patria matients of a
		40 mg/0.8 mL	Pediatric patients who
		80 mg/0.8mL	turn 18 years of age and are well-controlled on
			their Humira regimen:
			12 x 20 mg units per 84
			days OR
			12 x 40 mg units per 84
			days OR
			6 x 40mg units per 84 days
			OR
			6 x 80 mg units per 84
		A C 47 (47 km to	days
		Age 6-17 (17 kg to	1 Starter Pack and
		< 40kg)	6 x 20mg units per 84 days
Crohn's		20 mg/0.2 mL	OR
Disease	Yes	20 mg/0.4 mL	4 Otantan Dankan J
		Age 6-17 (≥ 40kg)	1 Starter Pack and
		40 mg/0.4 mL	6 x 40mg units per 84 days
		40 mg/0.8 mL	



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	I	10	1.0
		Age 18+:	1 Starter Pack and
		40mg/0.4 mL	6 x 40mg units per 84 days
		40 mg/0.8 mL	
		Age 2+ (10 kg to <	6 x 10mg units per 84 days
		<u>15 kg)</u>	
		10 mg/0.1 mL	
		10 mg/0.2 mL	
Polyarticular		Age 2+ (15 kg to <	6 x 20mg units per 84 days
Juvenile	No	30 kg)	
Idiopathic		20 mg/0.2 mL	
Arthritis (pJIA)		20 mg/0.4 mL	
		Age 2+ (≥ 30 kg)	6 x 40mg units per 84 days
		40 mg/0.4 mL	
		40 mg/0.8 mL	
		Age 2-17 (10 kg to	6 x 10mg units per 84 days
		< 15 kg)	
		10 mg/0.1 mL	
		10 mg/0.2 mL	
11 22		Age 2-17 (15 kg to	6 x 20mg units per 84 days
Uveitis		< 30 kg)	
	No	20 mg/0.2 mL	
		20 mg/0.4 mL	
		Age 2-17 (≥ 30 kg)	6 x 40mg units per 84 days
		40 mg/0.4 mL	
		40 mg/0.8 mL	
		1	



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		Age 18+:	1 Starter Pack and
	Yes	40 mg/0.4 mL	6 x 40mg units per 84 days
	163	40 mg/0.8 mL	
		Age 12-17 (30 kg to	
		< 60 kg)	1 Starter Pack and
		40 mg/0.4 mL	6 x 40mg units per 84 days
		40 mg/0.8 mL	
	Yes	Age 12-17 (≥ 60 kg)	1 Starter Pack and
Hidradenitis		40 mg/0.4 mL	12 x 40mg units per 84 days
Suppurativa		40 mg/0.8 mL	OR
		80mg/0.8mL	6 x 80mg units per 84 days
		Age 18+:	1 Starter Pack and
		40 mg/0.4 mL	12 x 40mg units per 84 days
		40 mg/0.8 mL	OR
		80 mg/0.8mL	6 x 80mg units per 84 days

Duration 12 months

Prior – Approval Renewal Requirements

Diagnoses

Patient must have **ONE** of the following:

Age 2 years of age or older



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Preferred products: Humira, adalimumab-fkjp, Hyrimoz, adalimumab-adaz

- 1. Polyarticular Juvenile Idiopathic Arthritis (pJIA)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 2-17, weight 10kg to < 15kg: 10 mg every other week
 - ii. Age 2-17, weight 15kg to < 30kg: 20 mg every other week
 - iii. Age 2-17, weight ≥30kg: 40 mg every other week
 - iv. Age 18 and older: 40 mg every other week

2. Uveitis

- a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - Age 2-17, weight 10kg to < 15kg: 10 mg every other week
 - ii. Age 2-17, weight 15kg to < 30kg: 20 mg every other week
 - iii. Age 2-17, weight ≥30kg: 40 mg every other week
 - iv. Age 18 and older: 40 mg every other week

Age 5 years of age or older

- 1. Ulcerative Colitis (UC)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 5-17, weight 20kg to <40kg: 40 mg every other week or 20 mg every week

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Preferred products: Humira, adalimumab-fkjp, Hyrimoz, adalimumab-adaz

- ii. Age 5-17, weight ≥40kg: 80 mg every other week or 40 mg every week
- iii. Age 18 and older: 40 mg every other week **OR** 20 mg every week, or 40 mg every week/80 mg every other week if patient was established and stable on pediatric dosing regimen

Age 6 years of age or older

- 1. Crohn's Disease (CD)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - Age 6-17, weight 17kg to < 40kg: 20 mg every other week
 - ii. Age 6-17, weight ≥40kg: 40 mg every other week
 - iii. Age 18 and older: 40 mg every other week

Age 12 years of age or older

- 1. Rheumatoid Arthritis (RA)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Concurrent therapy with methotrexate: 40 mg every other week
 - ii. NO concurrent therapy with methotrexate: 40 mg every week or 80 mg every other week

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- 2. Psoriatic Arthritis (PsA)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week
- 3. Ankylosing Spondylitis (AS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week
- 4. Plaque Psoriasis (PsO)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of 40 mg every other week
- 5. Hidradenitis Suppurativa (HS)
 - a. Prescriber will not exceed the FDA labeled maintenance dose of the following:
 - i. Age 12-17, weight 30 kg to <60kg: 40 mg every other week
 - ii. Age 12-17, weight ≥60kg: 40 mg every week or 80 mg every other week
 - iii. Age 18 and older: 40 mg every week or 80 mg every other week

AND ALL of the following:

- a. Condition has improved or stabilized with Humira
- b. Absence of active infection [including tuberculosis and hepatitis B virus (HBV)]
- NOT to be used in combination with any other biologic DMARD or targeted synthetic DMARD (see Appendix 1)

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d. NOT given concurrently with live vaccines

Prior - Approval Renewal Limits

Quantity

Diagnosis	Strength	Quantity
	40 mg/0.4 mL	NO concurrent
	40 mg/0.8 mL	methotrexate:
	80 mg/0.8mL	12 x 40mg units per 84 days
Rheumatoid		OR
Arthritis		6 x 80mg units per 84 days
Attilitis		OR
		Concurrent methotrexate:
		6 x 40mg units per 84 days
Psoriatic	40 mg/0.4 mL	6 x 40mg units per 84 days
Arthritis	40 mg/0.8 mL	
Ankylosing	40 mg/0.4 mL	6 x 40mg units per 84 days
Spondylitis	40 mg/0.8 mL	
Plaque	40 mg/0.4 mL	6 x 40mg units per 84 days
Psoriasis	40 mg/0.8 mL	
	Age 5-17 (20 kg to < 40kg)	12 x 20mg units per 84 days
Ulcerative Colitis	20 mg/0.2 mL	OR
	20 mg/0.4 mL	6 x 40mg units per 84 days
Contra	40 mg/0.4 mL	
	40 mg/0.8 mL	

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	Age 5-17 (≥ 40 kg) 40 mg/0.4 mL 40 mg/0.8 mL 80 mg/0.8mL Age 18+: 20 mg/0.2 mL	12 x 40mg units per 84 days OR 6 x 80mg units per 84 days 6 x 40mg units per 84 days OR
	20 mg/0.4 mL 40 mg/0.4 mL 40 mg/0.8 mL	Pediatric patients who turn 18 years of age and
	80 mg/0.8mL	are well-controlled on their Humira regimen: 12 x 20mg units per 84 days OR 12 x 40mg units per 84 days OR 6 x 40mg units per 84 days OR 6 x 80mg units per 84 days
	Age 6-17 (17 kg to < 40kg) 20 mg/0.2 mL 20 mg/0.4 mL	6 x 20mg units per 84 days
Crohn's Disease	Age 6-17 (≥ 40kg) 40 mg/0.4 mL 40 mg/0.8 mL	6 x 40mg units per 84 days
	Age 18+:	6 x 40mg units per 84 days



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	40mg/0.4 mL	
	40 mg/0.8 mL	
	Age 2+ (10 kg to < 15 kg)	6 x 10mg units per 84 days
	10 mg/0.1 mL	
Dalamin Inc.	10 mg/0.2 mL	
Polyarticular	Age 2+ (15 kg to < 30 kg)	6 x 20mg units per 84 days
Juvenile	20 mg/0.2 mL	
Idiopathic	20 mg/0.4 mL	
Arthritis (pJIA)	Age 2+ (≥ 30 kg)	6 x 40mg units per 84 days
	40 mg/0.4 mL	
	40 mg/0.8 mL	
	Age 2-17 (10 kg to < 15 kg)	6 x 10mg units per 84 days
	10 mg/0.1 mL	
	10 mg/0.2 mL	
	Age 2-17 (15 kg to < 30 kg)	6 x 20mg units per 84 days
	20 mg/0.2 mL	
Uveitis	20 mg/0.4 mL	
	Age 2-17 (≥ 30 kg)	6 x 40mg units per 84 days
	40 mg/0.4 mL	
	40 mg/0.8 mL	
	Age 18+:	6 x 40mg units per 84 days
	40 mg/0.4 mL	
	40 mg/0.8 mL	
	Age 12-17 (30 kg to < 60 kg)	6 x 40mg units per 84 days
Hidradenitis	40 mg/0.4 mL	
Suppurativa	40 mg/0.8 mL	



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Age 12-17 (≥ 60 kg)	12 x 40mg units per 84 days
40 mg/0.4 mL	OR
40 mg/0.8 mL	6 x 80mg units per 84 days
80mg/0.8mL	
Age 18+:	12 x 40mg units per 84 days
40 mg/0.4 mL	OR
40 mg/0.8 mL	6 x 80mg units per 84 days
80 mg/0.8mL	

Duration 18 months

Appendix 1 - List of DMARDs Conventional disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
azathioprine	Azasan, Imuran
cyclophosphamide	Cytoxan
cyclosporine	Neoral, Gengraf, Sandimmune
hydroxychloroquine	Plaquenil
leflunomide	Arava
methotrexate	Rheumatrex, Trexall
mycophenolate	Cellcept
sulfasalazine	Azulfidine, Sulfazine



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Biological disease-modifying antirheumatic drugs (DMARDs)

Generic Name	Brand Name
abatacept	Orencia
adalimumab	Humira
anakinra	Kineret
bimekizumab-bkzx	Bimzelx
brodalumab	Siliq
certolizumab	Cimzia
etanercept	Enbrel
golimumab	Simponi/Simponi Aria
guselkumab	Tremfya
infliximab	Remicade
ixekizumab	Taltz
risankizumab-rzaa	Skyrizi
rituximab	Rituxan
sarilumab	Kevzara
secukinumab	Cosentyx
spesolimab-sbzo	Spevigo
tildrakizumab-asmn	llumya
tocilizumab	Actemra
ustekinumab	Stelara
vedolizumab	Entyvio

Targeted synthetic disease-modifying antirheumatic drugs

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Federal Employee Program.

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Abrilada* (adalimumab-afzb)

Amjevita* (adalimumab-atto)

Cyltezo* (adalimumab-adbm)

Hadlima* (adalimumab-bwwd)

Hulio* (adalimumab-fkjp)

Hyrimoz (adalimumab-adaz)

Idacio* (adalimumab-aacf)

Simlandi* (adalimumab-ryvk)

Yuflyma* (adalimumab-aaty)

Yusimry* (adalimumab-aqvh)

Preferred products: Humira, adalimumab-fkjp, Hyrimoz, adalimumab-adaz

(DMARDs)

Generic Name	Brand Name
apremilast	Otezla
baricitinib	Olumiant
deucravacitinib	Sotyktu
tofacitinib	Xeljanz/XR
upadactinib	Rinvoq

Appendix 2 - List of Conventional Therapies

Conventional Therapy Options for CD 1. Mild to moderate disease – induction of remission: a. Oral budesonide, oral mesalamine b. Alternatives: metronidazole, ciprofloxacin 2. Mild to moderate disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternatives: oral budesonide, methotrexate intramuscularly (IM) 3. Moderate to severe disease – induction of remission: a. Prednisone, methylprednisolone intravenously (IV) b. Alternatives: methotrexate IM Moderate to severe disease – maintenance of remission: a. Azathioprine, mercaptopurine b. Alternative: methotrexate IM 5. Perianal and fistulizing disease – induction of remission c. Metronidazole ± ciprofloxacin 6. Perianal and fistulizing disease – maintenance of remission

Humira-Amjevita FEP Clinical Criteria

d. Azathioprine, mercaptopurinee. Alternative: methotrexate IM

^{*}Prior authorization for specific formulations applies only to formulary exceptions due to being a non-covered medication.



Federal Employee Program.

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Conventional Therapy Options for UC

- 1. Mild to moderate disease induction of remission:
 - a. Oral mesalamine (e.g., Asacol, Lialda, Pentasa), balsalazide, olsalazine
 - b. Rectal mesalamine (e.g., Canasa, Rowasa)
 - c. Rectal hydrocortisone (e.g., Colocort, Cortifoam)
 - d. Alternatives: prednisone, azathioprine, mercaptopurine, sulfasalazine
- 2. Mild to moderate disease maintenance of remission:
 - a. Oral mesalamine, balsalazide, olsalazine, rectal mesalamine
 - b. Alternatives: azathioprine, mercaptopurine, sulfasalazine
- Severe disease induction of remission:
 - a. Prednisone, hydrocortisone IV, methylprednisolone IV
 - b. Alternatives: cyclosporine IV, tacrolimus, sulfasalazine
- 4. Severe disease maintenance of remission:
 - a. Azathioprine, mercaptopurine
 - b. Alternative: sulfasalazine
- 5. Pouchitis:
 - a. Metronidazole, ciprofloxacin
 - b. Alternative: rectal mesalamine

Appendix 3 – Examples of Contraindications to Methotrexate

Contraindications to Methotrexate

- Alcoholism, alcoholic liver disease or other chronic liver disease
- 2. Breastfeeding



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	Blood dyscrasias (e.g., thrombocytopenia, leukopenia, significant anemia)
4.	Elevated liver transaminases
5.	History of intolerance or adverse event
6.	Hypersensitivity
7.	Interstitial pneumonitis or clinically significant pulmonary fibrosis
8.	Myelodysplasia
9.	Pregnancy or planning pregnancy (male or female)
10.	Renal impairment
11.3	Significant drug interaction