Biologics for Chronic Inflammatory Diseases

Coverage Criteria – Commercial Programs Effective: January 1, 2024
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Please see healthpartners.com for Medicare coverage criteria.

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TABLE 1: Biologic Medications by Condition

Medications with preferred step requirements for specified conditions must meet coverage criteria in Section 1 and Section 2 to be eligible for coverage. Exceptions are notated in the footnotes below the table.

Condition	Preferred Step 1 May use any Step 1 medication.	Preferred Step 2 Must try **at least two Step 1** medications prior to coverage.	Non-Preferred Must try **all Preferred Step 1 and 2** medications prior to coverage.
Alopecia Areata (AA)	Olumiant		Litfulo
Axial Spondyloarthritis (axSpA)	Enbrel, Adalimumab[7], Cosentyx, Rinvoq		Adalimumab[7], Cimzia, Simponi, Taltz, Xeljanz
Atopic Dermatitis (AD)	Dupixent[1], Rinvoq		Cibinqo[2], Adbry[3]
Behcet's Disease (BD)	Otezla		
Crohn's Disease (CD)	Adalimumab[7], Stelara, Skyrizi, Rinvoq	Cimzia	Adalimumab[7], Zymfentra
Cryopyrin-Associated Periodic Syndromes (CAPS)	Kineret		
Deficiency of Interleukin-1 Receptor Antagonist (DIRA)	Kineret		
Giant Cell Arteritis (GCA)	Actemra SQ		
Hidradenitis Suppurativa (HS)	Adalimumab[7], Cosentyx		Adalimumab[7]
Juvenile Idiopathic Arthritis (JIA)	Enbrel, Adalimumab[7], Cosentyx	Actemra SQ, Orencia	Adalimumab[7], Xeljanz
Plaque Psoriasis (PsO)	Enbrel, Adalimumab[7], Cosentyx, Stelara, Skyrizi	Otezla	Adalimumab[7], Cimzia, Taltz, Tremfya, Siliq[4], Sotyktu, Bimzelx[4]
Polymyalgia Rheumatica (PMR)	Kevzara		
Psoriatic Arthritis (PsA)	Enbrel, Adalimumab[7], Cosentyx, Stelara, Skyrizi, Rinvoq	Orencia, Otezla	Adalimumab[7], Cimzia, Simponi, Taltz, Tremfya, Xeljanz,
Recurrent Pericarditis	Kineret		
Rheumatoid Arthritis (RA)	Enbrel, Adalimumab[7], Rinvoq	Actemra SQ, Olumiant, Orencia	Adalimumab[7], Cimzia, Kevzara, Kineret, Simponi, Xeljanz[5]
Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)	Actemra SQ		
Ulcerative Colitis (UC)	Adalimumab[7], Stelara, Rinvoq		Adalimumab[7], Xeljanz, Simponi, Zeposia[6], Entyvio SQ, Velsipity, Zymfentra, Omvoh
Uveitis	Adalimumab[7]		Adalimumab[7]

[1] Dupixent for Atopic Dermatitis: Please reference "Dupixent" pharmacy policy to review all indications and coverage criteria.

[2] Cibinqo for Atopic Dermatitis: Must try and fail **one** Preferred Step 1 medication.

[3] Adbry for Atopic Dermatitis: Must try and fail **one** Preferred Step 1 medication.

[4] Siliq or Bimzelx for Psoriasis: Must try and fail all Preferred Step 1 medications, **and** all Step 2 medications, **and** Taltz, **and** Tremfya.

[5] Xeljanz for Rheumatoid Arthritis: Must try and fail two Step 1 medications, one of which must be Rinvoq, **and** two Step 2 medications, one of which must be Olumiant.

[6] Zeposia for Ulcerative Colitis: Please reference "Zeposia" pharmacy policy to review all indications and coverage criteria.

[7] Adalimumab: Please see next page for product preferences.

TABLE 2: Reference and Biosimilar Product Preferences

Product	Preferred Medication	Non-Preferred Medication
Adalimumab	Adalimumab (Humira) – *AbbVie*	Adalimumab (Humira) – *Cordavis*
	Adalimumab-bwwd (Hadlima)	Adalimumab-afzb (Abrilada)
		Adalimumab-atto (Amjevita)
		Adalimumab-adbm (Cyltezo)
		Adalimumab-aacf (Idacio)
		Adalimumab-fkjp (Hulio)
		Adalimumab-adaz (Hyrimoz)
		Adalimumab-ryvk (Simlandi)
		Adalimumab-aaty (Yuflyma)
		Adalimumab-aqvh (Yusimry)

SECTION 1: Coverage Criteria

Coverage Criteria

Requests must meet **all** of the following criteria prior to approval:

1. Requested medication is FDA-approved for the patient's diagnosis (Table 2); and
2. The Condition-Specific Requirements (Section 2) below are met for the patient's diagnosed condition; and
3. The requested biologic is being prescribed according to the FDA-labeled regimen, and prescribed within the following specific dosing limits:
    a. Humira for Rheumatoid Arthritis (RA) dosing at more than 40 mg every other week (including doses of 40 mg every week or 80 mg every other week) is generally considered not medically necessary, because multiple alternatives are available for patients not meeting goals with standard Humira dosing of 40 mg every other week; and
4. No other biologic agent will be used concurrently; and
5. The requested medication is consistent with the following requirements and the Biologic Medications Table above (Table 1):
    a. **Preferred Step 1** medications are covered when all coverage criteria have been met.
    b. **Preferred Step 2** medications require trial and failure of **any two preferred Step 1** medications prior to coverage.
    c. **Non-Preferred** medications require trial and failure of **all preferred Step 1 and Step 2** medications prior to use of non-preferred agents unless other criteria are specified in Table 1.
    d. Failure is defined as using the FDA-approved regimen for a duration of at least 3 months with insufficient improvement in disease activity, documented in the medical record.

Renewal/Reauthorization Criteria

Renewals will be provided when the following criteria are met:

1. The patient continues to meet the above coverage criteria (1-4); and
2. The patient has been examined by the requesting provider's office within the last fourteen months; and
3. The medication continues to be effective, with provider attestation of one of the following:
    a. This patient has achieved low disease activity or remission; or
    b. This patient has achieved sufficient disease control to continue this agent; and
4. The patient has been adherent to therapy.

Requests for New to Market Medications

All requests for new medications will be considered non-preferred and must meet coverage criteria in Section 1 and Section 2 to be eligible for coverage. Non-preferred medications must try all Preferred Step 1 and 2 medications outlined in Table 1 for their FDA-approved indication. These medications will be considered non-preferred until reviewed by the Pharmacy & Therapeutics Committee and Medical Director Committee for a determination of medical necessity and may be added and/or removed from this policy as determined by the review. New to market medications are those drugs recently approved by the US Food and Drug Administration (FDA) for use in the United States. Drugs are approved when the FDA determines that sufficient efficacy and safety information is known to establish that the benefits of the drug outweigh the harms.

Requests for non-FDA Approved Indications and Regimens

All off-label requests (initial and reauthorization) will be reviewed on a case-by-case basis for medical necessity. Reviews will include an evaluation of the strength and quality of literature, along with previous therapies that have been tried and failed. Requests must be in writing and include supporting medical documentation, a statement of clinical rationale, and clinical literature. In general, if off-label biologic use is determined to be medically necessary, preferred (Step 1, then Step 2) biologic medications are required prior to use of non-preferred biologics and/or off-label dosing, if literature supports the use of the preferred biologics.

Other Criteria

The provision of pharmaceutical samples (from the prescriber or manufacturer assistance/free trial programs) does not guarantee coverage. All criteria must be met in order to obtain coverage. In addition, the use of pharmaceutical samples will not be considered when evaluating the member's medical condition or prior prescription history for medications.

SECTION 2: Condition-Specific Requirements

Alopecia Areata (AA)

1. Prescribed by or in consultation with a dermatologist; and,
2. Patient has been diagnosed with severe alopecia areata; and,
3. Provider attestation that patient has ≥ 50% scalp hair loss.

Atopic Dermatitis (AD)

Coverage Criteria:

1. Prescribed by or in consultation with a dermatologist, allergist, or immunologist; and,
2. Diagnosed with moderate to severe atopic dermatitis with medical chart documentation of at least 10% body surface area (BSA), or involvement with the face, neck, hands, feet, or genitals AND for both of these indications have at least two of the following:
    a. Intractable pruritus (itching); or,
    b. Cracking and oozing/bleeding of affected skin; or,
    c. Impaired activities of daily living; and,
3. Failure or intolerance to one prescription-strength topical corticosteroid; and,
4. The requested biologic will not be used in combination with another biologic medication for the treatment of atopic dermatitis; and,
5. The requested biologic will be used at the FDA approved dosing regimen.

Renewal Criteria:

1. Patient has been seen by a specialist (dermatologist, allergist, or immunologist) in the past 12 months; and,
2. Has documented improvement of symptoms, such as reduction pruritus or in area of skin affected; and,
3. The requested biologic will be used at the FDA approved dosing regimen.

Coverage Duration:

Initial authorizations will be for 6 months.
Reauthorizations for 12 months.

Axial Spondyloarthritis (AxSpA) – Ankylosing Spondylitis [AS], Non-radiographic Axial Spondyloarthritis [nr-AxSpA]

1. Prescribed and followed by a rheumatologist; and,
2. Patient has been diagnosed with an active form of axial spondyloarthritis; and,
3. Patient has had a trial and failure of or contraindications to **all** of the following first line therapies:
    a. Continuous treatment with a NSAID at therapeutic doses for one month; and,
    b. For patients with only peripheral disease, local corticosteroid injections when the disease process permits; and,
    c. For patients with only peripheral disease, methotrexate 20 mg for at least 3 months OR sulfasalazine titrated to 2000-3000 mg daily for at least 3 months.

Behcet's Syndrome (BD)

1. Prescribed and followed by a dermatologist or rheumatologist; and,
2. Patient has a diagnosis of Behcet's disease (BD); and,
3. Patient has oral ulcers or other mucocutaneous involvement; and,
4. Patient has tried and failed at least ONE conventional agent (e.g., topical corticosteroids, colchicine).

Crohn's Disease (CD)

1. Prescribed and followed by a gastroenterologist; and,
2. Patient is using the requested medication as first line therapy for fistulizing and severe disease [as defined by American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA) guidelines]; or,
3. Patient has had **one** of the following:
    a. Treatment with **one** of the following corticosteroid regimens for two weeks has been ineffective or is contraindicated:
        i. Prednisone 40-60 mg daily; or,
        ii. Oral budesonide 9 mg daily; or,
        iii. Budesonide rectal; or,
    b. Inability to taper off one of the corticosteroid regimens above; or,
    c. Breakthrough disease while stabilized for at least 3 months on **one** of the following therapies:
        i. Azathioprine 2-3 mg/kg daily; or,
        ii. 6-mercaptopurine 1-1.5 mg/kg daily; or,
        iii. Methotrexate 20 mg weekly (Note: GI intolerance requires trial of SC/IM methotrexate at 20 mg weekly).

Cryopyrin-Associated Periodic Syndromes (CAPS)

1. Prescribed by a specialist; and,
2. Patient has been diagnosed with Cryopyrin-Associated Periodic Syndromes (CAPS), including Familial Cold Auto-inflammatory Syndromes (FCAS) and Muckle-Wells Syndrome (MWS); and,
3. Patient is 4 years of age or older.

Deficiency of Interleukin-1 Receptor Antagonist (DIRA)

1. Prescribed by or in consultation with a rheumatologist, geneticist, dermatologist, or a physician specializing in the treatment of autoinflammatory disorders; and,
2. Patient has been diagnosed with deficiency of interleukin-1 receptor antagonist (DIRA), with genetic testing confirming mutation in the IL1RN gene; and,
3. Patient has bodyweight >10 kg (22 pounds).

Giant Cell Arteritis (GCA)

1. Prescribed and followed by a rheumatologist; and,
2. Patient has been diagnosed with giant cell arteritis (GCA); and,
3. The requested biologic medication is used in combination with a tapering course of corticosteroids OR as a single agent following discontinuation of corticosteroids due to intolerance or inadequate response.

Hidradenitis Suppurativa (HS)

1. Prescribed and followed by a dermatologist; and,
2. Patient has been diagnosed with moderate to severe hidradenitis suppurativa.

Juvenile Idiopathic Arthritis (JIA) – Polyarticular Juvenile Idiopathic Arthritis [PJIA], Systemic juvenile idiopathic arthritis [SJIA], Enthesitis-related Arthritis [ERA]

1. Prescribed and followed by a rheumatologist; and,
2. Patient has been diagnosed with a moderate to severe form of juvenile idiopathic arthritis; and,
3. Patient is using the requested biologic medication as first line therapy due to severe initial disease activity [as defined by American College of Rheumatology (ACR) guidelines], such as fever for >2 weeks plus at least one characteristic systemic feature or >4 affected joints; or,
4. Patient has had a trial and failure of or contraindications to an appropriate regimen of **all** of the regimens below for at least 1 month:
    a. Continuous treatment with a NSAID at therapeutic doses; and,
    b. Methotrexate 20 mg weekly (Note: GI intolerance requires trial of SC/IM methotrexate at 20 mg weekly).

Plaque Psoriasis (PsO)

1. Prescribed and followed by a dermatologist; and,
2. Patient has been diagnosed with severe psoriasis defined as at least 10% body surface area (BSA) or crucial body area involvement (palmar/plantar, scalp, or genitals), or pustular psoriasis; and,
3. Patient has had a trial and failure (BSA involvement is not improved) of or contraindications to concurrent use of at least **two** of the regimens below for at least 12 weeks:
    a. Topical corticosteroid therapy; or,
    b. Phototherapy for at least 20-30 treatments given 2-3 times weekly (Note: see the Home Phototherapy medical policy for coverage of home units); or,
    c. Methotrexate 5-15 mg weekly (Note: GI intolerance requires trial of SC/IM methotrexate at 5-15 mg weekly) in combination with folic acid supplementation; or,
    d. Cyclosporine at a dose of at least 2.5-5 mg/kg/day until disease control achieved; or,
    e. Acitretin at a dose of at least 25 mg daily.

Polymyalgia Rheumatica (PMR)

1. Prescribed and followed by a rheumatologist; and,
2. Patient has been diagnosed with polymyalgia rheumatica; and,
3. The requested biologic medication is used in combination with a tapering course of corticosteroids, OR as a single agent following discontinuation of corticosteroids due to intolerance or inadequate response.

Psoriatic Arthritis (PsA)

1. Prescribed and followed by a dermatologist or rheumatologist; and,
2. Patient has been diagnosed with psoriatic arthritis; and,
3. Patient has had a trial and failure of or contraindications to **all** of the regimens below for at least 1 month:
    a. Continuous treatment with a NSAID at therapeutic doses; and,
    b. Methotrexate 20 mg weekly (Note: GI intolerance requires trial of SC/IM methotrexate at 20 mg weekly).

Recurrent Pericarditis

1. Prescribed by a cardiologist; and,
2. Patient has recurrent pericarditis, defined as 3 or more episodes of symptomatic pericarditis in one year, each after at least a four- to six-week symptom-free interval; and,
3. Patient has an inflammatory phenotype, characterized by the presence of one or more of signs of an inflammatory process when presenting with a recurrence: fever, elevated CRP, elevated WBC count, elevated ESR, pericardial LGE on CMR, or pericardial contrast enhancement on CT; and,
4. Patient has no active infections, including but not limited to bacterial infections, fungal infections, viral infections, HIV, or TB; and,
5. Patient has tried and failed or has medical contraindications to the following therapies concurrently:
    a. Non-steroidal anti-inflammatory drugs for at duration of at least 3 months; and,
    b. Colchicine for a duration of at least 6 months; and,
    c. Corticosteroids for at least 2 months; and,
6. The prescriber attests that ongoing immunosuppressive therapy with Kineret is more appropriate for the patient than pericardiectomy.

Rheumatoid Arthritis (RA)

1. Prescribed and followed by a rheumatologist; and,
2. Patient has been diagnosed with moderate to severe rheumatoid arthritis; and,
3. Medication is being used first line in a patient who has high disease activity and features of poor prognosis [as defined by American College of Rheumatology (ACR) guidelines]; or,
4. Patient has had a trial and failure of or contraindication to an appropriate regimen of DMARD therapy including concurrent use of <u>at least **two** of the regimens below for at least 3 months</u>:
    a. Methotrexate 15 mg weekly (Note: GI intolerance requires trial of SC/IM methotrexate at 15 mg weekly); or,
    b. Hydroxychloroquine titrated to 200-400 mg daily; or,
    c. Sulfasalazine titrated to 2000-3000 mg daily; or,
    d. Leflunomide 10-20 mg daily.

Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)

1. Prescribed by a pulmonologist or rheumatologist; and,
2. Patient has been diagnosed with systemic sclerosis-associated interstitial lung disease (SSc-ILD); and,
3. Patient has early diffuse SSc and ILD, and early evidence of ILD progression (e.g., FVC<65%, DCLO<55%, HRCT showing ILD affecting >20% of the lung, and/or anti-topoisomerase I antibodies); and,
4. Patient has tried and failed or has medical contraindications to mycophenolate for at least 6 months.

Ulcerative Colitis (UC)

1. Prescribed and followed by a gastroenterologist; and
2. Patient is using the requested biologic medication as first line therapy for severe disease [as defined by American College of Gastroenterology (ACG) and American Gastroenterological Association (AGA) guidelines]; or,
3. Patient has breakthrough disease or trial and failure or contraindications to at least **two** of the systemic regimens below for at least 12 weeks:
    a. Sulfasalazine 4-6 gram daily; or,
    b. Mesalamine 2-4.8 gram daily; or,
    c. Balsalazide 6.75 grams daily; or,
    d. Corticosteroid regimens:
        i. Prednisone 40-60 mg daily; or,
        ii. Oral budesonide 9 mg daily; or,
        iii. Budesonide rectal; or
    e. Azathioprine 1.5-2.5 mg/kg daily; or,
    f. 6-mercaptopurine 1-1.5 mg/kg daily.

Uveitis

1. Prescribed and followed by an ophthalmologist, other retinal specialist, rheumatologist, or another specialist in consultation with a retinal specialist; and,
2. Patient has been diagnosed with non-infectious intermediate, posterior or panuveitis.

TABLE 3: Common FDA-Approved Diagnoses for Chronic Inflammatory Diseases

	AA	AD	AxSpA	CD	JIA	PsO	PsA	RA	UC	Other
Actemra					X			X		Giant Cell Arteritis, Systemic Sclerosis-Associated Interstitial Lung Disease
Adalimumab			X	X	X	X	X	X	X	Hidradenitis Suppurativa, Uveitis
Adbry		X								
Bimzelx						X				
Cibinqo		X								
Cimzia			X	X		X	X	X		
Cosentyx			X		X	X	X			Hidradenitis Suppurativa
Dupixent		X								
Enbrel			X		X	X	X	X		
Entyvio				X					X	
Kevzara								X		Polymyalgia Rheumatica (PMR)
Kineret								X		Cryopyrin-Associated Periodic Syndromes, Deficiency of Interleukin-1 Receptor Antagonist, Recurrent Pericarditis
Litfulo	X									
Olumiant	X							X		
Omvoh									X	
Orencia					X		X	X		
Otezla						X	X			Behcet's Disease
Rinvoq		X	X	X			X	X	X	
Siliq						X				
Simponi			X				X	X	X	
Skyrizi				X		X	X			
Sotyktu						X				
Stelara				X		X	X		X	
Taltz			X			X	X			
Tremfya						X	X			
Velsipity									X	
Xeljanz			X		X		X	X	X	
Zeposia									X	
Zymfentra				X					X	

Acronyms: AA = Alopecia Areata; AD = Atopic Dermatitis; AxSpA = Axial Spondyloarthritis; CD = Crohn's Disease; JIA = Juvenile Idiopathic Arthritis; PsO = Plaque Psoriasis; PsA = Psoriatic Arthritis; RA = Rheumatoid Arthritis; UC = Ulcerative Colitis