

Cytokine & CAM Antagonists

WA.PHAR.49

Effective Date: October 1, 2019

Note: New-to-market drugs included in this class based on the Apple Health Preferred Drug List are non-preferred and subject to this prior authorization (PA) criteria. Non-preferred agents in this class require an inadequate response or documented intolerance due to severe adverse reaction or contraindication to at least TWO preferred agents. If there is only one preferred agent in the class documentation of inadequate response to ONE preferred agent is needed. If a drug within this policy receives a new indication approved by the Food and Drug Administration (FDA), medical necessity for the new indication will be determined on a case-by-case basis following FDA labeling.

To see the current publication of the Coordinated Care of Washington, Inc. Preferred Drug List (PDL), please visit: https://www.coordinatedcarehealth.com/content/dam/centene/centene-pharmacy/pdl/FORMULARY-CoordinatedCare Washington.pdf

Background:

Cytokines and cell-adhesion molecule (CAM) are chemical mediators involved in inflammatory processes throughout the body. Medications included in this policy are used to treat a group of diseases that may be caused or worsened by an overactive immune system such as rheumatoid arthritis, psoriasis, and ulcerative colitis. Administration is different for each medication, and may be administered subcutaneously (SC), intravenously (IV), or orally.

Medical necessity

Drug	Medical Necessity
abatacept (ORENCIA) adalimumab (HUMIRA) adalimumab-aacf (biosimilar, IDACIO) adalimumab-aaty (YUFLYMA) adalimumab-adaz (biosimilar, HYRIMOZ) adalimumab-adbm (biosimilar, CYLTEZO) adalimumab-afzb (ABRILADA) adalimumab-afzb (ABRILADA) adalimumab-afzb (ABRILADA) adalimumab-afy (YUSMIRY) adalimumab-atto (AMJEVITA) adalimumab-fkjp (biosimilar, HULIO) anakinra (KINERET) apremilast (OTEZLA) baricitinib (OLUMIANT) bimekizumab (BIMZELX) brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) deucravacitinib (SOTYKTU) etanercept (ENBREL)	 Cytokine and CAM antagonists may be considered medically necessary when ALL of the following apply: Prescribed for an FDA labeled or compendia supported indication History of failure, contraindication or intolerance to conventional therapy Not used in combination with other biologic DMARDs, janus kinase inhibitor, or phosphodiesterase 4 (PDE4) inhibitor Documentation of a negative TB skin test within the last year Requests for apremilast (Otezla) do not require TB skin test Preferred biologic medications for the treatment of chronic inflammatory conditions include: adalimumab (Humira[®]) and etanercept (Enbrel[®])

Policy: Cytokine & CAM Antagonists



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Clinical policy:

Clinical Criteria (Initial Approval)	
Ankylosing Spondylitis (AS)	 Diagnosis of active ankylosing spondylitis History of failure, contraindication, or intolerance to ALL of the following: a. Non-steroidal anti-inflammatory drugs (NSAIDs) b. For peripheral disease only: non-biologic DMARD (e.g., methotrexate, sulfasalazine) c. For non-preferred products, greater than or equal to (≥) 2 preferred biologic products Not used in combination with ANY of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor Reater than or equal to (≥) FDA approved age limit Negative TB skin test within the last year Prescribed by or in consultation with a specialist in rheumatology Approve for 6 months If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Crohn's Disease (CD)	 Diagnosis of moderately to severely active Crohn's disease History of failure, contraindication, or intolerance to ALL of the following: Conventional therapy (e.g. azathioprine, corticosteroids, methotrexate, 6-mercaptopurine) For non-preferred products, Humira

Policy: Cytokine & CAM Antagonists



	3. Patient is not receiving in combination with any of the following:
	a. Biologic DMARD
	 b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor
	4. Greater than or equal to (\geq) FDA approved age limit
	5. Negative TB skin test within the last year
	6. Prescribed by or in consultation with a specialist in gastroenterology
	Approve for 6 months
	If all criteria are not mot, but there are circumstances supported by clinical
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Hidradenitis Suppurativa (HS)	1. Diagnosis of moderate to severe hidradenitis suppurativa
	2. History of failure, contraindication, or intolerance to ALL of the following:
	a. Conventional therapy (e.g. systemic antibiotics, topical therapies, corticosteroids)
	b. For non-preferred products, Humira
	 Patient is not receiving in combination with any of the following: a. Biologic DMARD
	b. Janus kinase inhibitor
	c. Phosphodiesterase 4 (PDE4) inhibitor
	 Greater than or equal to (≥) FDA approved age limit Negative TB skin test within the last user
	 Negative TB skin test within the last year Prescribed by or in consultation with a specialist in dermatology
	Approve for 6 months
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Juvenile Idiopathic Arthritis (JIA)	 Diagnosis of moderately to severely active juvenile idiopathic arthritis History of failure, contraindication, or intolerance to ALL of the following:
	a. NSAID or corticosteroid
	 b. Greater than or equal to (≥) 1 non-biologic DMARD
	c. For non-preferred products, greater than or equal to $(\geq) 2$
	preferred biologic products 3. Patient is not receiving in combination with any of the following:
	a. Biologic DMARD
	b. Janus kinase inhibitor
	c. Phosphodiesterase 4 (PDE4) inhibitor
	 Greater than or equal to (≥) FDA approved age limit Negative TB skin test within the last year
	 6. Prescribed by or in consultation with a specialist in rheumatology
	Approve for 6 months
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical
	reviewer on a case-by-case basis up to the initial authorization duration.



Nonradiographic Axial Spondyloarthritis (NAS)	 Diagnosis of active nonradiographic axial spondyloarthritis History of failure, contraindication, or intolerance to ALL of the following: a. Non-steroidal anti-inflammatory drugs (NSAIDs) b. For peripheral disease only: non-biologic DMARD (e.g., methotrexate, sulfasalazine) c. For non-preferred products, Humira Not used in combination with ANY of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor Greater than or equal to (≥) FDA approved age limit S. Negative TB skin test within the last year Prescribed by or in consultation with a specialist in rheumatology Approve for 6 months If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Plaque Psoriasis (Ps)	 Diagnosis of moderate to severe chronic plaque psoriasis History of failure, contraindication, or intolerance to ALL the following: a. Phototherapy b. Other systemic therapies (e.g. methotrexate, cyclosporine, acitretin) c. For non-preferred products, greater than or equal to (≥) 2 preferred biologic products Patient is not receiving in combination with any of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor Greater than or equal to (≥) FDA approved age limit Negative TB skin test within the last year Prescribed by or in consultation with a specialist in dermatology or rheumatology
	Approve for 6 months If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Psoriatic Arthritis (PsA)	 Diagnosis of active psoriatic arthritis History of failure, contraindication, or intolerance to ALL of the following: a. Non-biologic DMARDs b. For non-preferred products, greater than or equal to (≥) 2 preferred biologic agents Patient is not receiving in combination with any of the following: a. Biologic DMARD b. Janus kinase inhibitor



	 c. Phosphodiesterase 4 (PDE4) inhibitor 4. Greater than or equal to (≥) FDA approved age limit
	5. Negative TB skin test within the last year
	6. Prescribed by or in consultation with a specialist in dermatology or
	rheumatology
	Approve for 6 months
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Rheumatoid Arthritis (RA)	 Diagnosis of moderately to severely active rheumatoid arthritis History of failure, contraindication, or intolerance to ALL of the following:
	 a. Greater than or equal to (≥) 1 non-biologic DMARD b. For non-preferred products, greater than or equal to (≥) 2 preferred biologic products
	 Patient is not receiving in combination with any of the following: a. Biologic DMARD b. Janus kinase inhibitor
	c. Phosphodiesterase 4 (PDE4) inhibitor
	4. Greater than or equal to (\ge) FDA approved age limit
	5. Negative TB skin test within the last year
	6. Prescribed by or in consultation with a specialist in rheumatology
	Approve for 6 months
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Ulcerative Colitis (UC)	1. Diagnosis of moderately to severely active ulcerative colitis
	 History of failure, contraindication, or intolerance to ALL of the following:
	following: a. Conventional therapy (e.g. budesonide MMX, systemic
	corticosteroids, azathioprine, methotrexate, mesalamine,
	sulfasalazine)
	b. For non-preferred products, Humira
	3. Patient is not receiving in combination with any of the following:
	a. Biologic DMARD
	b. Janus kinase inhibitor
	c. Phosphodiesterase 4 (PDE4) inhibitor
	 Greater than or equal to (≥) FDA approved age limit
	5. Negative TB skin test within the last year
	6. Prescribed by or in consultation with a specialist in gastroenterology
	Approve for 6 months



	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the initial authorization duration.
Uveitis (UV)	 Diagnosis of non-infectious uveitis classified as one of the following: Intermediate Posterior Panuveitis History of failure, contraindication, or intolerance to ALL of the following: Conventional therapy (e.g. ophthalmic corticosteroids, methotrexate, other DMARDs) For non-preferred products, Humira Patient is not receiving in combination with any of the following:
Clinical Criteria (Reauthorization)	
All Diagnosis	Documentation of positive clinical response
	Approve for 12 months
	If all criteria are not met, but there are circumstances supported by clinical judgement and documentation, requests may be approved by a clinical reviewer on a case-by-case basis up to the reauthorization duration.

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
abatacept (ORENCIA)	Initial for IV dosing: (1 time)
	 Ps/RA: <60kg: 1,000mg IV for 28-day supply
	 Ps/RA: 60 to 100 kg: 1,500mg IV for 28-day supply
	 Ps/RA: >100 kg: 2,000 mg IV for 28-day supply

Policy: Cytokine & CAM Antagonists



adalimumab-atto (AMJEVITA) adalimumab-bwwd (HADLIMA) adalimumab-fkjp (biosimilar, HULIO) CD/HS Rener CD: 6 ye CD: 6 ye HS: 12 y HS: 12 y JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: JIA/UV: CD/HS/NAS/ RA: 80m CD/UC/I PS/UV: 1 CD/HS/NAS/ CD/HS/NAS/	2 years or older, 30kg or greater: 80 mg per 28-day supply onths wal: ars, 17 to <40kg: 40 mg per 28-day supply ars, 40kg or greater: 80 mg per 28-day supply ears or older, 30kg to <60kg: 80 mg per 28-day supply ears or older, 60kg or greater: 160mg per 28-day supply Renewal: 2 years or older, 10kg to <15kg: 20mg per 28-day supply 2 years or older, 15kg to <30kg: 40 mg per 28-day supply 2 years or older, 30kg or greater: 80 mg per 28-day supply 2 years or older, 30kg or greater: 80 mg per 28-day supply 2 sears or older, 30kg or greater: 80 mg per 28-day supply 2 years or older, 30kg or greater: 80 mg per 28-day supply 2 sears or older, 28-day supply 45: 240mg for 28-day supply 160mg for 28-day supply 160mg per 28-day supply 160mg per 28-day supply
AS/JIA/F anakinra (KINERET) RA: 100 mg (
AS/JIA/F anakinra (KINERET) RA: 100 mg (ng per day; #60 tablets per 30-day supply
AS/JIA/F anakinra (KINERET) RA: 100 mg (apremilast (OTEZLA) PS/PsA: 60 m	ng per day; #60 tablets per 30-day supply day; #30 tablets per 30-day supply
AS/JIA/F anakinra (KINERET) RA: 100 mg (ng per day; #60 tablets per 30-day supply
RA/HS: 1	160mg per 28-day supply Renewal: PsA: 80mg per 28-day supply

Policy: Cytokine & CAM Antagonists



	Ps Renewal:
	 Ps: 320 mg for 56-day supply
	For patients > 120 kg, can be dosed 320 mg for 28-day supply
brodalumab (SILIQ)	Ps Initial (1 time):
	• 630 mg (3 syringe) for 28-day supply
	Ps Renewal:
	410 mg (2 syringe) per 28-day supply
canakinumab (ILARIS)	300mg (2 vial) per 28-day supply
certolizumab pegol (CIMZIA)	As/CD/NAS/Ps/PsA/RA Initial (1 time):
	First Month:
	• 1200mg for 28-day supply
	As/CD/NAS/Ps/PsA/RA Renewal:
deucravacitinib (SOTYKTU)	 400mg (2 syringes) per 28-day supply Ps: #28 tabs per 28-day supply
	r 3. #20 tabs per 20-day suppry
etanercept (ENBREL)	Ps Initial (3 months):
	 Ps: 400mg for 28-day supply x3 months
	Ps Renewal:
	 Ps: 200mg per 28-day supply
	AS/PsA/RA Initial and Renewals:
	 200mg per 28-day supply
	Dediatria
	<u>Pediatric</u> JIA (2 years or older, < 63 kg): 0.8 mg/kg once weekly
	JIA (2 years or older, \geq 63 kg): 0.0 mg per 28-day supply
etrasimod (VELSIPITY)	UC: #28 tabs per 28-day supply
golimumab (SIMPONI/SIMPONI	Pediatric
ARIA)	JIA/PsA: 80mg/m ² per infusion at weeks 0 and 4 and every 8 weeks
,	thereafter
	Adult
	SIMPONI ARIA:
	AS/PsA/RA: 2mg/kg per infusion at weeks 0 and 4, then every 8 weeks
	SIMPONI:
	As/PsA/RA: 50 mg per 28-day supply
	UC: 200 mg at week 0, 100 mg at week 2, then 100 mg per 28-day supply
guselkumab (TREMFYA)	Ps/PsA Initial (1 time):
	 100mg (1 syringe) for 28-day supply
	Ps/PsA Renewal:
	100mg (1 syringe) per 56-day supply
infliximab (REMICADE)	Initial (1 time):
infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA)	• AS/CD/Ps/PsA/UC: 5mg/kg per infusion; 3 infusions for 6 weeks
infliximab-axxq (AVSOLA)	 RA: 3mg/kg per infusion; 2 infusions per 6 weeks Renewal:
	 AS: 5mg/kg per infusion; 1 infusion per 6 weeks
	 CD: 10mg/kg per infusion; 1 infusion per 8 weeks
	 Ps/PsA/UC: 5mg/kg per infusion; 1 infusion per 8 weeks
	 RA: 10mg/kg per infusion; 1 infusion per 8 weeks
	infusion; 1 infusion per 4 weeks



ixekizumab (TALTZ)	Initial (1 time):
	 AS/PsA: 160mg (2 syringe) for 28-day supply (1 month)
	NAS: 80mg (1 syringe) per 28-day supply
	• Ps/PsA with Ps:240mg (3 syringe) for first 28 days THEN 160mg (2
	syringe) per 28 days for 56 days
	Renewal:
	 AS/NAS/Ps/PsA: 80mg (1 syringe) per 28-day supply
mirikizumab-mrkz (OMVOH)	UC Initial (3 months):
	 300 mg per 28-day supply x 3 months
	UC Renewal:
rizonkizumoh (SKV/DIZI)	200 mg per 28-day supply
rizankizumab (SKYRIZI)	Initial (1 time): CD: 600 mg per infusion at week 0, 4, and 8
	Ps/PsA: 300 mg for 28-day supply
	Renewal:
	CD: 180 mg or 360 mg at week 12 and every 8 weeks thereafter
	Ps/PsA: 150 mg every 84 days
sarilumab (KEVZARA)	RA: 400mg per 28-day supply
secukinumab (COSENTYX)	Initial (1 time) :
	 Ps: 1200mg (#8 syringe) for 28-day supply
	 AS/NAS/PsA: 600mg (#4 syringe) for 28-day supply
	Renewal:
	Ps: 300mg (#2 syringe) per 28-days thereafter
	AS/NAS/PsA: 150mg (#1 syringe) per 28-days thereafter
tildrakizumab-asmn (ILUMYA)	Ps Initial (1 time):
	100mg (1 syringe) for 28-day supply
	 Ps Renewal: 100mg (#1 syringe) every 84-days
tocilizumab (ACTEMRA)	RA: 648mg (4 syringes) per 28-day supply
	RA: 800mg IV (1 infusion) per 28-day supply
tofacitinib citrate (XELJANZ/ XR)	Xeljanz:
	 PsA/RA: 10mg per day; #60 tablets per 30-day supply
	• UC Initial: 20mg per day; #60 tablets per 30-day supply (4 months)
	• UC Maintenance: 10mg per day; #60 tablets per 30-day supply
	Xeljanz XR:
	 PsA/RA: 11mg per day; #30 tablets per 30-day supply
	• UC Initial: 22mg per day; #30 tablets per 30-day supply (4 months)
	 UC Maintenance: 11mg per day; #30 tablets per 30-day supply
9upadacitinib99 (RINVOQ)	AS/NSA/PsA/RA:
	15mg per day; #30 tablets per 30-day supply
	CD: 45 mg par day x 12 weaks: #20 tablets par 20 day supply (Industion)
	45 mg per day x 12 weeks; #30 tablets per 30-day supply (Induction) 30 mg per day; #30 tablets per 30-day supply (Maintenance)
	so mg per day, #so tablets per so-day supply (Maintenance)
	UC:
	45 mg per day x 8 weeks; #30 tablets per 30-day supply (Induction)
	30 mg per day; #30 tablets per 30-day supply (Maintenance)
9ustekinumab9 (STELARA)	Initial (1 time):
	• CD/UC: <55kg: 260 mg (2 vials) for 56-day supply



	• CD/UC: >55kg to 85kg: 390 mg (3 vials) for 56-day supply
	 CD/UC: >85 kg: 520 mg (4 vials) for 56-day supply
	 Ps: <100kg: 45mg/0.5mL (1 syringe) for 28-day supply
	 Ps: >100kg: 90mg/1mL (1 syringe) for 28-day supply
	 PsA: 45mg/0.5mL (1 syringe) for 28-day supply
	• PsA with moderate/severe Ps and >100kg: 90mg/ml (1 syringe) for
	28-day supply
	Renewal:
	CD/UC: 90mg/1mL (1 syringe) per 56-day supply
	 Ps: ≤100kg: 45mg/0.5mL (1 syringe) per 84-day supply
	 Ps: >100kg: 90mg/1mL (1 syringe) per 84-day supply
	PsA: 45mg/0.5mL (1 syringe) per 84-day supply
	• PsA with moderate/severe Ps and >100kg: 90mg/mL (1 syringe) per
	84-day supply
vedolizumab (ENTYVIO)	CD/UC Initial:
	• 300 mg IV at weeks 0,2, and 6 (Loading dose)
	CD/UC Renewal:
	300mg IV per 56-day supply
	 216mg subQ per 28-day supply (subQ formulation for UC)

Coding:

HCPCS Code	Description
J0129	Injection, abatacept, 10 mg
J0135	Injection, adalimumab, 20 mg
J0638	Injection, canakinumab, 1 mg
J0717	Injection, certolizumab pegol, 1 mg
J1438	Injection, etanercept, 25 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1628	Injection, guselkumab, 1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
J2793	Injection, rilonacept, 1 mg
J3262	Injection, tocilizumab, 1 mg
J3357	Ustekinumab, for subcutaneous injection, 1 mg
J3358	Ustekinumab, for intravenous injection, 1 mg
J3380	Injection, vedolizumab, 1 mg

Definitions

Term	Description
Disease modifying anti-rheumatic drugs (DMARDs)	A variety of drugs that work by altering the immune system function to halt the underlying processes that cause certain forms of inflammatory arthritis including rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis.
Conventional therapy	Treatments that are widely accepted and practiced by the medical community



Hidradenitis suppurativa (HS)	A chronic, inflammatory disease affecting sweat glands known as apocrine glands.
Immunomodulator drugs	A class of drugs that modifies or influences the immune system
Immunosuppressive drugs	subclass of immunomodulator drugs that reduce inflammation by affecting the immune system; includes 6-mercaptopurine (6-MP), azathioprine, cyclophosphamide, cyclosporine, methotrexate, and tacrolimus; also referred to as immunosuppressant drugs
Nonsteroidal anti-inflammatory drugs (NSAIDs)	A class of drugs used to treat pain, redness, swelling, and inflammation from conditions including different types of arthritis; includes over-the- counter (OTC) and prescription medicines, such as celecoxib, diclofenac, ibuprofen, indomethacin, meloxicam, naproxen, sulindac, tolmetin, and valdecoxib

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Policy: Cytokine & CAM Antagonists



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Date	Action and Summary of Changes	
02/07/2024	 -Added etanercept dosing for JIA -Added adalimumab biosimilars, Olumiant, Sotyktu, Velsipity, Bimzelx, and Omvoh to the policy -Updated quantity limits for Cimzia, Skyrizi, and Rinvoq 	
10/27/2023	 -Updated negative TB test criteria to say within the last year and reformatted history table. -Added dosage and quantity limits for golimumab -Updated dosage and quantity limits for Skyrizi 	
10/21/2021	Removed Hyrimoz from the policy and updated the initial dosing for infliximab.	
11/30/2020	Removed Preferred/Non-Preferred listing and added link to AHPDL publication.	
11/12/2020	Added language in clinical policy section for cases which do not meet policy criteria.	

History



09/01/2020	Updated wording in clinical criteria for products with only one preferred option.
08/19/2020	Approved by DUR Board.
08/20/2020	Update to dosing and limits section for all products and indications.
08/12/2020	Updated policy clinical criteria and dosing & quantity limits to include nonradiographic axial spondyloarthritis.
06/01/2020	Added new agents to class; updated age limit for Uveitis indication; updated dosing and quantity limits; updated HCPCS coding.
07.31.2019	Updated criteria that trial of preferred biologics only applies to non- preferred biologics
06.07.2019	Updates to TB skin test requirements for apremalist; updates to initial authorization clinical criteria
11.02.2018	Addition of Hyrimoz (adalimumab-adaz)
09.07.2018	Addition of new medication
08.16.2017	New Policy