Washington State Health Care Authority

Cytokine & CAM Antagonists

Medical policy no. 66.27.00-3 Effective Date: TBD

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.*

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
Preferred adalimumab (HUMIRA) etanercept (ENBREL) **Non-Preferred** abatacept (ORENCIA) adalimumab-adaz (HYRIMOZ) anakinra (KINERET) apremilast (OTEZLA) baricitinib (OLUMIANT) brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) golimumab (SIMPONI, SIMPONI ARIA) guselkumab (TREMFYA) infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) infliximab-axxq (AVSOLA) ixekizumab (TALTZ) rilonacept (ARCALYST) risankizumab-rzaa (SKYRIZI) sarilumab (KEVZARA) secukinumab (COSENTYX) tildrakizumab-asmn (ILUMYA) tocilizumab (ACTEMRA) tofacitinib citrate (XELJANZ/ XR)	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 ○ 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®)

upadacitinib (RINVOQ) ustekinumab (STELARA) vedolizumab (ENTYVIO)	

Clinical policy:

Clinical Criteria (Initial Approval)	
Ankylosing Spondylitis (AS)	1. Diagnosis of active ankylosing spondylitis 2. 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 3. Not used 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 6. Prescribed by or in consultation with a specialist in rheumatology **Approve for 6 months**
Crohn's Disease (CD)	1. Diagnosis of moderately to severely active Crohn's disease 2. History of failure, contraindication, or intolerance to ALL of the following: a. Conventional therapy (e.g. azathioprine, corticosteroids, methotrexate, 6-mercaptopurine) b. 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 4. Greater than or equal to (≥) FDA approved age limit 5. Negative TB skin test 6. Prescribed by or in consultation with a specialist in gastroenterology **Approve for 6 months**
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. 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

	4. Greater than or equal to (≥) FDA approved age limit 5. Negative TB skin test **6.** Prescribed by or in consultation with a specialist in dermatology **Approve for 6 months**
Juvenile Idiopathic Arthritis (JIA)	1. Diagnosis of moderately to severely active juvenile idiopathic arthritis 2. History of failure, contraindication, or intolerance to ALL of the following: a. NSAID, non-biologic DMARD, or corticosteroid b. Greater than or equal to (≥) 1 non-biologic agent c. For non-preferred products, greater than or equal to (≥) 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 4. Greater than or equal to (≥) FDA approved age limit 5. Negative TB skin test 6. Prescribed by or in consultation with a specialist in rheumatology **Approve for 6 months**
Nonradiographic Axial Spondyloarthritis (NAS)	1. Diagnosis of active nonradiographic axial spondyloarthritis 2. 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. Humira 3. Not used 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 6. Prescribed by or in consultation with a specialist in rheumatology **Approve for 6 months**
Plaque Psoriasis (Ps)	7. Diagnosis of moderate to severe chronic plaque psoriasis 8. 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 9. Patient is not receiving in combination with any of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor 10. Greater than or equal to (≥) FDA approved age limit 11. Negative TB skin test

	12. Prescribed by or in consultation with a specialist in dermatology or rheumatology **Approve for 6 months**
Psoriatic Arthritis (PsA)	1. Diagnosis of active psoriatic arthritis 2. 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 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 (≥) FDA approved age limit 5. Negative TB skin test 13. Prescribed by or in consultation with a specialist in dermatology or rheumatology **Approve for 6 months**
Rheumatoid Arthritis (RA)	1. Diagnosis of moderately to severely active rheumatoid arthritis 2. 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 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 (≥) FDA approved age limit 5. Negative TB skin test 6. Prescribed by or in consultation with a specialist in rheumatology **Approve for 6 months**
Ulcerative Colitis (UC)	1. Diagnosis of moderately to severely active ulcerative colitis 2. History of failure, contraindication, or intolerance to **ALL** of the following: a. Conventional therapy (e.g. budesonide MMX, systemic corticosteroids, azathioprine, methotrexate, mesalamine, sulfasalazine) b. 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 4. Greater than or equal to (≥) FDA approved age limit 5. Negative TB skin test

	6. Prescribed by or in consultation with a specialist in gastroenterology **Approve for 6 months**
Uveitis (UV)	1. Diagnosis of non-infectious uveitis classified as one of the following: a. Intermediate b. Posterior c. Panuveitis 2. History of failure, contraindication, or intolerance to **ALL** of the following: a. Conventional therapy (e.g. ophthalmic corticosteroids, methotrexate, DMARDs) b. 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 4. Greater than or equal to (≥) FDA approved age limit 5. Negative TB skin test 6. Prescribed by or in consultation with a specialist in rheumatology or ophthalmology **Approve for 6 months**
Clinical Criteria (Reauthorization)	
All Diagnosis	Documentation of positive clinical response **Approve for 12 months**

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 Renewal for IV dosing: • Ps/RA: <60kg: 500mg IV per 28-day supply • PS/RA: 60 to 100kg: 750mg IV per 28-day supply • PS/RA: >100kg: 1,000mg IV per 28 day-supply • PS/RA: 500mg (4 syringes) subcutaneous per 28-day supply

	Subcutaneous dosing: • Ps/RA: 500mg (4 syringes) subcutaneous for 28-day supply • JIA: 10 to <25kg: 200mg subcutaneous per 28 day supply • JIA: 25 to < 50kg: 350mg subcutaneous per 28 day supply • JIA: ≥50kg: 500mg subcutaneous per 28 day supply
adalimumab (HUMIRA)	Pediatric: • CD/HS Initial (1 time): • CD: 6 years or older, 17kg to <40kg: 120 mg for 28-day supply • CD: 6 years or older, 40kg or greater: 240 mg for 28-day supply • HS: 12 years or older, 30kg to <60kg: 120mg for 14-day supply • HS: 12 years or older, 60kg or greater: 240mg for 28-day supply • JIA/UV: 2 years or older, 10kg to <15kg: 20mg per 28-day supply for 6 months • JIA/UV: 2 years or older, 15kg to <30kg: 40 mg per 28-day supply for 6 months • JIA/UV: 2 years or older, 30kg or greater: 80 mg per 28-day supply for 6 months CD/HS Renewal: • CD: 6 years, 17 to <40kg: 40 mg per 28-day supply • CD: 6 years, 40kg or greater: 80 mg per 28-day supply • HS: 12 years or older, 30kg to <60kg: 80 mg per 28-day supply • HS: 12 years or older, 60kg or greater: 160mg per 28-day supply • JIA/UV Renewal: • JIA/UV: 2 years or older, 10kg to <15kg: 20mg per 28-day supply • JIA/UV: 2 years or older, 15kg to <30kg: 40 mg per 28-day supply • JIA/UV: 2 years or older, 30kg or greater: 80 mg per 28-day supply Adult: CD/HS/NAS/Ps/RA/UC/UV Initial (1 time): • RA: 80mg for 28-day supply • CD/UC/HS: 240mg for 28-day supply • Ps/UV: 160mg for 28-day supply CD/HS/NAS/Ps/RA/UC/UV Renewal: • CD/Ps/UC/UV: 80mg per 28-day supply • RA/HS: 160mg per 28-day supply AS/JIA/PsA Renewal: • AS/JIA/PsA: 80mg per 28-day supply
anakinra (KINERET)	• 100 mg (1 syringe) per day; #28 syringes per 28-day supply
apremilast (OTEZLA)	• 60 mg per day; #60 tablets per 30-day supply
baricitinib (OLUMIANT)	• 2mg per day; #30 tablets per 30-day supply
brodalumab (SILIQ)	Initial (1 time): • 630 mg (3 syringe) for 28-day supply Renewal: • 410 mg (2 syringe) per 28-day supply
canakinumab (ILARIS)	• 300mg (2 vial) per 28-day supply
certolizumab pegol (CIMZIA)	Initial (1 time): First Month:

	• 800mg (4 syringe) for 28-day supply THEN 600mg (3 syringe) for 28-day supply Renewal: • 400mg (2 syringes) per 28-day supply
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 Renewal: • 200mg per 28-day supply
guselkumab (TREMFYA)	Initial (1 time): • 100mg (1 syringe) for 28-day supply Renewal: • 100mg (1 syringe) per 56-day supply
infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) infliximab-axxq (AVSOLA)	Initial (1 time): • AS/CD/Ps/PsA/UC: 5mg/kg per infusion; 2 infusions for 6 weeks • 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 **OR** 3mg/kg per infusion; 1 infusion per 4 weeks
ixekizumab (TALTZ)	Initial (1 time): • AS/PsA: 160mg (2 syringe) for 28-day supply (1 month) • Ps/PsA with Ps:240mg (3 syringe) for first 28 days THEN 160mg (2 syringe) per 28 days for 56 days Renewal: • AS/Ps/PsA: 80mg (1 syringe) per 28-day supply
rizankizumab (SKYRIZI)	Initial (1 time): • 150 mg for 28-day supply Renewal: • 150 mg every 84 days
sarilumab (KEVZARA)	• 400mg per 28-day supply
secukinumab (COSENTYX)	Initial (1 time) : • Ps: 1200mg (#8 syringe) for 28-day supply • AS/PsA: 600mg (#4 syringe) for 28-day supply Renewal: • Ps: 300mg (#2 syringe) per 28-days thereafter • AS/PsA: 150mg (#1 syringe) per 28-days thereafter
tildrakizumab-asmn (ILUMYA)	Initial (1 time): • 100mg (1 syringe) for 28-day supply Renewal: • 100mg (#1 syringe) every 84-days
tocilizumab (ACTEMRA)	• 648mg (4 syringes) per 28-day supply • 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
upadacitinib (RINVOQ)	• 15mg per day; #30 tablets per 30-day supply
ustekinumab (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)	Initial (1 time): • 600mg for 42-day supply Renewal: • 300mg per 56-day supply

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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History

Date	Action and Summary of Changes
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

Washington State Health Care Authority

Cytokine & CAM Antagonists

Please provide the information below, please print your answer, attach supporting documentation, sign, date, and return to our office as soon as possible to expedite this request. **Without this information, we may deny the request in seven (7) working days.**

Date of request:	Reference #:	MAS:	
Patient	Date of birth	ProviderOne ID	
Pharmacy name	Pharmacy NPI	Telephone number	Fax number
Prescriber	Prescriber NPI	Telephone number	Fax number
Medication and strength	Directions for use	Qty/Days supply	

1. Is client currently stable on therapy? ☐ Yes ☐ No
   If yes, is there documentation of positive clinical response? ☐ Yes ☐ No

2. What is patient's current weight? _____ kg Date taken: _____

3. Indicate patient's diagnosis:
   - ☐ Ankylosing Spondylitis (AS)
   - ☐ Crohn's Disease (CD)
   - ☐ Hidradenitis Suppurativa (HS)
   - ☐ Juvenile Idiopathic Arthritis (JIA)
   - ☐ Plaque Psoriasis (Ps)
   - ☐ Psoriatic Arthritis (PsA)
   - ☐ Rheumatoid Arthritis (RA)
   - ☐ Ulcerative Colitis (UC)
   - ☐ Non-radiographic axial spondyloarthritis
   - ☐ Non-infectious Uveitis (UV) classified as intermediate, posterior or panuveitis
   - ☐ Other. Specify: _____

4. Has patient tried and failed, has an intolerance or contraindication to any of the following(check all that apply):
   - ☐ Conventional therapies (e.g. azathioprine, 6-mercaptopurine, mesalamine, sulfasalazine)
   - ☐ Corticosteroids
   - ☐ Enbrel (etanercept)
   - ☐ Humira (adalimumab)
   - ☐ NSAIDs
   - ☐ Non-biologic DMARD(s)
   - ☐ Phototherapy
   - ☐ Other systemic therapies (e.g. methotrexate, cyclosporine, acitretin)

5. Will patient be taking any of the following in combination with this request (mark all that apply)?
   - ☐ Biologic DMARD
   - ☐ Phosphodiesterase (PDE 4) inhibitor
   - ☐ Janus kinase inhibitor
   - ☐ None

6. Does patient have a negative TB test? ☐ Yes ☐ No

7. Is this prescribed by or in consultation with any of the following (mark all that apply):
   - ☐ Dermatologist
   - ☐ Gastroenterologist
   - ☐ Ophthalmologist
   - ☐ Rheumatologist
   - ☐ Other. Specify: _____

CHART NOTES ARE REQUIRED WITH THIS REQUEST

Prescriber signature	Prescriber specialty	Date