Cytokine & CAM Antagonists

WA.PHAR.49 Cytokine & CAM Antagonists

Background:

Cytokines and cell-adhesion molecule (CAM) antagonists 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 a subcutaneous injection (SC), intravenous injection (IV), or administered by mouth.

Medical necessity

Drug	Medical Necessity
abatacept (ORENCIA) adalimumab (HUMIRA) anakinra (KINERET) apremilast (OTEZLA) brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) etanercept (ENBREL) golimumab (SIMPONI) guselkumab (TREMFYA) infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) ixekizumab (TALTZ) rilonacept (ARCALYST) sarilumab (KEVZARA) secukinumab (COSENTYX) tocilizumab (ACTEMRA) tofacitinib citrate (XELJANZ/ XR) ustekinumab (STELARA) vedolizumab (ENTYVIO)	Cytokine and CAM antagonists may be considered medically necessary when **ALL** of the following apply: • Used for the treatment of moderately to severely active 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), or uveitis (UV) • History of failure, contraindication or intolerance to conventional therapy • Documentation of a negative TB skin test Preferred biologic medications for the treatment of chronic inflammatory conditions include: adalimumab (Humira®) and etanercept (Enbrel®)

Clinical policy:

Drug	Clinical Criteria (Initial Approval)
abatacept (ORENCIA) adalimumab (HUMIRA) anakinra (KINERET) apremilast (OTEZLA)	**Ankylosing Spondylitis (AS)** may be covered when ALL of the following are met: 1. Diagnosis of active ankylosing spondylitis a. Greater than or equal to (≥) 18 years of age

brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) etanercept (ENBREL) golimumab (SIMPONI) guselkumab (TREMFYA) infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) ixekizumab (TALTZ) rilonacept (ARCALYST) sarilumab (KEVZARA) secukinumab (COSENTYX) tocilizumab (ACTEMRA) tofacitinib citrate (XELJANZ/ XR) ustekinumab (STELARA) vedolizumab (ENTYVIO)	2. History of failure, contraindication, or intolerance to ALL of the following: a. Non-steroidal anti-inflammatory drugs (NSAIDs) b. Nonbiologic DMARD (e.g., methotrexate, acetretin, or cyclosporine) 3. Not used in combination with **ANY** of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor 4. Negative TB skin test 5. Prescribed by or in consultation with a rheumatologist **Approve for 6 months**
	Crohn's Disease (CD) may be covered when **ALL** of the following are met: 1. Diagnosis of moderately to severely active Crohn's disease a. For Humira, Entyvio, or Remicade i. Greater than or equal to (≥) 6 years of age b. For Cimzia i. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to ALL of the following: a. Conventional therapy 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. Negative TB skin test 5. Prescribed by or in consultation with a gastroenterologist **Approve for 6 months**
	Hidradenitis Suppurativa (HS) may be covered when ALL of the following are met: 1. Diagnosis of moderate to severe hidradenitis suppurativa a. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to ALL of the following: a. Conventional therapy 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. Negative TB skin test **5.** Prescribed by or in consultation with a dermatologist **Approve for 6 months**
	Juvenile Idiopathic Arthritis (JIA) may be covered when ALL of the following are met: 1. Diagnosis of moderately to severely active juvenile idiopathic arthritis

	a. ≥ 2 years of age 2. History of failure, contraindication, or intolerance to ALL of the following: a. NSAID or corticosteroid b. Greater than or equal to (≥) 1 nonbiologic agent 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. Negative TB skin test 5. Prescribed by or in consultation with a rheumatologist **Approve for 6 months**
	Plaque Psoriasis (Ps) may be covered when ALL of the following are met: 1. Diagnosis of moderate to severe chronic plaque psoriasis a. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to the following: a. Phototherapy b. Other systemic therapies 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. Negative TB skin test 5. Prescribed by or in consultation with a dermatologist or rheumatologist **Approve for 6 months**
	Psoriatic Arthritis (PsA) may be covered when ALL of the following are met: 1. Diagnosis of active psoriatic arthritis a. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to **ALL** of the following a. Non-biologic DMARDs b. 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. Negative TB skin test 5. Prescribed by or in consultation with a dermatologist or rheumatologist **Approve for 6 months**
	Rheumatoid Arthritis (RA) may be covered when ALL of the following are met: 1. Diagnosis of moderately to severely active rheumatoid arthritis a. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to ALL of the following: a. Greater than or equal to (≥) 1 nonbiologic DMARD b. 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. Negative TB skin test 5. Prescribed by or in consultation with a rheumatologist **Approve for 6 months**
	Ulcerative Colitis (UC) may be covered when ALL of the following are met: 1. Diagnosis of moderately to severely active ulcerative colitis a. Greater than or equal to (≥) 18 years of age 2. History of failure, contraindication, or intolerance to conventional therapy 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. Negative TB skin test 5. Prescribed by or in consultation with a gastroenterologist **Approve for 6 months**
	Uveitis (UV) may be covered when ALL of the following are met: 1. Diagnosis of non-infectious uveitis classified as one of the following: a. Intermediate b. Posterior c. Panuveitis 2. Greater than or equal to (≥) 18 years of age 3. History of failure, contraindication, or intolerance to conventional therapy 4. Patient is not receiving in combination with any of the following: a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor 5. Negative TB skin test 6. Prescribed by or in consultation with a rheumatologist or ophthalmologist **Approve for 6 months**
	Criteria (Reauthorization)
	May be continued when ALL of the following are met: 1. Currently stable on therapy 2. Documentation of positive clinical response **Approve for 12 months**

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
abatacept (ORENCIA)	#4 syringe per 28-day supply
adalimumab (HUMIRA)	Initial authorization (1 time): • RA/PsA/AS/JIA: 80mg for 28-day supply • CD/UC: 240mg for 28-day supply • Ps/UV: 160mg for 28-day supply • HS initial: 240mg for 28-day supply Renewal: • RA/PsA/AS/JIA/CD/UC/Ps/UV: o 80mg per 28-day supply • HS: 160mg every week per 28-day supply
anakinra (KINERET)	#1 syringe per day; #28 syringes per 28-day supply
apremilast (OTEZLA)	#60 tablets per 30-day supply
brodalumab (SILIQ)	Initial (1 time): #3 syringe per 28-day supply Renewal: #2 syringe per 28-day supply
canakinumab (ILARIS)	#2 syringe/vial per 28-day supply
certolizumab pegol (CIMZIA)	Initial(1 time): #6 syringe per 28-day supply Renewal: #2 syringes per 28-day supply
etanercept (ENBREL)	Initial Authorization • Ps: 400mg per 28-day supply x3 months • AS/PsA/RA: 200mg per 28-day supply Renewal: • AS/Ps/PsA/RA: 200mg per 28-day supply
guselkumab (TREMFYA)	Initial (1 time): #2 syringes per 28-day supply Renewal: #1 syringe per 56-day supply
ixekizumab (TALTZ)	Initial authorization: • Ps #1: #4 syringe per 28-day supply (1 month) • Ps #2: # 2 syringe per 28-day supply (2 months) • PsA: #3 syringe per 28-day supply (1 month) Renewal: • Ps/PsA: #1 syringe per 28-day supply
rilonacept (ARCALYST)	Initial (1 month): 800mg per 28-day supply Renewal: 640mg per 28-day supply
sarilumab (KEVZARA)	400mg per 28-day supply
secukinumab (COSENTYX)	Initial Authorization (1 time) : • Ps: 1200mg (#8 syringe) per 28-day supply • AS/PsA: 600mg (#4 syringe) per 28-day supply Renewal: • Ps: 600mg (#2 syringe) per 28-days thereafter • AS/PsA: 150mg (#1 syringe) per 28-days thereafter
tocilizumab (ACTEMRA)	#4 syringes per 28-day supply after initial approval
tofacitinib citrate (XELJANZ/ XR)	IR: 10mg per day; #60 tablets per 30-day supply XR: 11mg per day; #30 tablets per 30-day supply
ustekinumab (STELARA)	Initial Authorization (1 time): • <100kg: 45mg/0.5mL per 28-day supply • >100kg: 90mg/1mL per 28-day supply Renewal: • <100kg: 45mg per 84-day supply

	• >100kg: 90mg per 84-day supply
vedolizumab (ENTYVIO)	Initial: 900mg per 42-day supply Renewal: 300mg per 56-day supply

Coding:

HCPCS Code	Description
J0129	Injection, abatacept, 10 mg, for intravenous use
J0135	Injection, adalimumab, 20 mg (to be used only when drug is given under direct supervision of a physician)
J0717	Injection, certolizumab pegol, 1 mg (to be used only when drug is given under direct supervision of a physician)
J1438	Injection, etanercept, 25 mg and 50 mg (to be used only when drug is given under direct supervision of a physician)
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, 10 mg
J2323	Injection, natalizumab, 1 mg
J3262	Injection, tocilizumab, 1 mg, for intravenous use
J3357	Injection, ustekinumab, 1 mg
J9310	Injection, rituximab, 100 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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