



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://pharmacy.envolvehealth.com/content/dam/centene/envolve-pharmacy-solutions/pdfs/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) <i>adalimumab-aacf (biosimilar, IDACIO)</i> adalimumab-aaty (YUFLYMA) <i>adalimumab-adaz (biosimilar, HYRIMOZ)</i> <i>adalimumab-adbm (biosimilar, CYLTEZO)</i> adalimumab-afzb (ABRILADA) <i>adalimumab-aqvh (YUSMIRY)</i> <i>adalimumab-atto (AMJEVITA)</i> <i>adalimumab-bwwd (HADLIMA)</i> adalimumab-fkjp (biosimilar, HULIO) anakinra (KINERET) apremilast (OTEZLA) baricitinib (OLUMIANT) bimekizumab (BIMZELX) brodalumab (SILIQ) canakinumab (ILARIS) certolizumab pegol (CIMZIA) deucravacitinib (SOTYKTU) etanercept (ENBREL) etrasimod (VELSIPITY)	Cytokine and CAM antagonists may be considered medically necessary when ALL of the following apply: <ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> ○ 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®)

<p>golimumab (SIMPONI, SIMPONI ARIA) guselkumab (TREMFYA) infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) infliximab-axxq (AVSOLA) ixekizumab (TALTZ) mirikizumab-mrkz (OMVOH) rilonacept (ARCALYST) risankizumab-rzaa (SKYRIZI) sarilumab (KEVZARA) secukinumab (COSENTYX) tildrakizumab-asmn (ILUMYA) tocilizumab (ACTEMRA) tofacitinib citrate (XELJANZ/ XR) upadacitinib (RINVOQ) ustekinumab (STELARA) vedolizumab (ENTYVIO)</p>	
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Clinical policy:

Clinical Criteria (Initial Approval)	
<p>Ankylosing Spondylitis (AS)</p>	<ol style="list-style-type: none"> 1. Diagnosis of active ankylosing spondylitis 2. History of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> 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 (\geq) 2 preferred biologic products 3. Not used in combination with ANY of the following: <ol style="list-style-type: none"> 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 rheumatology <p>Approve for 6 months</p> <p>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.</p>
<p>Crohn's Disease (CD)</p>	<ol style="list-style-type: none"> 1. Diagnosis of moderately to severely active Crohn's disease 2. History of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> a. Conventional therapy (e.g. azathioprine, corticosteroids, methotrexate, 6-mercaptopurine) b. For non-preferred products, Humira 3. Patient is not receiving in combination with any of the following:

	<ul style="list-style-type: none"> a. Biologic DMARD b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor <ul style="list-style-type: none"> 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 <p>Approve for 6 months</p> <p>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.</p>
<p>Hidradenitis Suppurativa (HS)</p>	<ul style="list-style-type: none"> 1. Diagnosis of moderate to severe hidradenitis suppurativa 2. History of failure, contraindication, or intolerance to ALL of the following: <ul style="list-style-type: none"> a. Conventional therapy (e.g. systemic antibiotics, topical therapies, corticosteroids) b. For non-preferred products, Humira 3. Patient is not receiving in combination with any of the following: <ul style="list-style-type: none"> 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 dermatology <p>Approve for 6 months</p> <p>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.</p>
<p>Juvenile Idiopathic Arthritis (JIA)</p>	<ul style="list-style-type: none"> 1. Diagnosis of moderately to severely active juvenile idiopathic arthritis 2. History of failure, contraindication, or intolerance to ALL of the following: <ul style="list-style-type: none"> a. NSAID or corticosteroid b. Greater than or equal to (\geq) 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: <ul style="list-style-type: none"> 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 rheumatology <p>Approve for 6 months</p> <p>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.</p>

<p>Nonradiographic Axial Spondyloarthritis (NAS)</p>	<ol style="list-style-type: none"> 1. Diagnosis of active nonradiographic axial spondyloarthritis 2. History of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> 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 3. Not used in combination with ANY of the following: <ol style="list-style-type: none"> 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 rheumatology <p>Approve for 6 months</p> <p>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.</p>
<p>Plaque Psoriasis (Ps)</p>	<ol style="list-style-type: none"> 1. Diagnosis of moderate to severe chronic plaque psoriasis 2. History of failure, contraindication, or intolerance to ALL the following: <ol style="list-style-type: none"> a. Phototherapy b. Other systemic therapies (e.g. methotrexate, cyclosporine, acitretin) 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: <ol style="list-style-type: none"> 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 dermatology or rheumatology <p>Approve for 6 months</p> <p>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.</p>
<p>Psoriatic Arthritis (PsA)</p>	<ol style="list-style-type: none"> 1. Diagnosis of active psoriatic arthritis 2. History of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> a. Non-biologic DMARDs b. For non-preferred products, greater than or equal to (\geq) 2 preferred biologic agents 3. Patient is not receiving in combination with any of the following: <ol style="list-style-type: none"> a. Biologic DMARD b. Janus kinase inhibitor

	<ul style="list-style-type: none"> 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 dermatology or rheumatology <p>Approve for 6 months</p> <p>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.</p>
<p>Rheumatoid Arthritis (RA)</p>	<ul style="list-style-type: none"> 1. Diagnosis of moderately to severely active rheumatoid arthritis 2. History of failure, contraindication, or intolerance to ALL of the following: <ul style="list-style-type: none"> a. Greater than or equal to (\geq) 1 non-biologic DMARD b. 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: <ul style="list-style-type: none"> 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 rheumatology <p>Approve for 6 months</p> <p>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.</p>
<p>Ulcerative Colitis (UC)</p>	<ul style="list-style-type: none"> 1. Diagnosis of moderately to severely active ulcerative colitis 2. History of failure, contraindication, or intolerance to ALL of the following: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 <p>Approve for 6 months</p>

	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)	<ol style="list-style-type: none"> 1. Diagnosis of non-infectious uveitis classified as one of the following: <ol style="list-style-type: none"> a. Intermediate b. Posterior c. Panuveitis 2. History of failure, contraindication, or intolerance to ALL of the following: <ol style="list-style-type: none"> a. Conventional therapy (e.g. ophthalmic corticosteroids, methotrexate, other DMARDs) b. For non-preferred products, Humira 3. Patient is not receiving in combination with any of the following: <ol style="list-style-type: none"> 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 rheumatology or ophthalmology <p>Approve for 6 months</p> <p>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.</p>
Clinical Criteria (Reauthorization)	
All Diagnosis	<p>Documentation of positive clinical response</p> <p>Approve for 12 months</p> <p>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.</p>

Dosage and quantity limits

Drug Name	Dose and Quantity Limits
abatcept (ORENCIA)	Initial for IV dosing: (1 time) <ul style="list-style-type: none"> • 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

	<p>Renewal for IV dosing:</p> <ul style="list-style-type: none"> 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 <p>Subcutaneous dosing:</p> <ul style="list-style-type: none"> 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
<p>adalimumab (HUMIRA) adalimumab-aacf (biosimilar, IDACIO) adalimumab-aaty (YUFLYMA) adalimumab-adaz (biosimilar, HYRIMOZ) adalimumab-adbm (biosimilar, CYLTEZO) adalimumab-afzb (ABRILADA) adalimumab-aqvh (YUSMIRY) adalimumab-atto (AMJEVITA) adalimumab-bwwd (HADLIMA) adalimumab-fkjp (biosimilar, HULIO)</p>	<p><u>Pediatric:</u></p> <ul style="list-style-type: none"> 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 <p>CD/HS Renewal:</p> <ul style="list-style-type: none"> 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 <p>JIA/UV Renewal:</p> <ul style="list-style-type: none"> 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 <p><u>Adult:</u> CD/HS/NAS/Ps/RA/UC/UV Initial (1 time):</p> <ul style="list-style-type: none"> RA: 80mg for 28-day supply CD/UC/HS: 240mg for 28-day supply Ps/UV: 160mg for 28-day supply <p>CD/HS/NAS/Ps/RA/UC/UV Renewal:</p> <ul style="list-style-type: none"> CD/Ps/UC/UV: 80mg per 28-day supply RA/HS: 160mg per 28-day supply <p>AS/JIA/PsA Renewal:</p> <ul style="list-style-type: none"> AS/JIA/PsA: 80mg per 28-day supply
anakinra (KINERET)	RA: 100 mg (1 syringe) per day; #28 syringes per 28-day supply
apremilast (OTEZLA)	PS/PsA: 60 mg per day; #60 tablets per 30-day supply
baricitinib (OLUMIANT)	RA: 2mg per day; #30 tablets per 30-day supply
bimekizumab (BIMZELX)	Ps Initial (5 months): <ul style="list-style-type: none"> Ps: 320 mg for 28-day supply x 5 months

	<p>Ps Renewal:</p> <ul style="list-style-type: none"> Ps: 320 mg for 56-day supply For patients > 120 kg, can be dosed 320 mg for 28-day supply
brodalumab (SILIQ)	<p>Ps Initial (1 time):</p> <ul style="list-style-type: none"> 630 mg (3 syringe) for 28-day supply <p>Ps Renewal:</p> <ul style="list-style-type: none"> 410 mg (2 syringe) per 28-day supply
canakinumab (ILARIS)	<ul style="list-style-type: none"> 300mg (2 vial) per 28-day supply
certolizumab pegol (CIMZIA)	<p>As/CD/NAS/Ps/PsA/RA Initial (1 time):</p> <p>First Month:</p> <ul style="list-style-type: none"> 1200mg for 28-day supply <p>As/CD/NAS/Ps/PsA/RA Renewal:</p> <ul style="list-style-type: none"> 400mg (2 syringes) per 28-day supply
deucravacitinib (SOTYKTU)	<p>Ps: #28 tabs per 28-day supply</p>
etanercept (ENBREL)	<p>Ps Initial (3 months):</p> <ul style="list-style-type: none"> Ps: 400mg for 28-day supply x3 months <p>Ps Renewal:</p> <ul style="list-style-type: none"> Ps: 200mg per 28-day supply <p>AS/PsA/RA Initial and Renewals:</p> <ul style="list-style-type: none"> 200mg per 28-day supply <p><u>Pediatric</u></p> <p>JIA (2 years or older, < 63 kg): 0.8 mg/kg once weekly JIA (2 years or older, ≥ 63 kg): 200 mg per 28-day supply</p>
etrasimod (VELSIPITY)	<p>UC: #28 tabs per 28-day supply</p>
golimumab (SIMPONI/SIMPONI ARIA)	<p><u>Pediatric</u></p> <p>JIA/PsA: 80mg/m² per infusion at weeks 0 and 4 and every 8 weeks thereafter</p> <p><u>Adult</u></p> <p><u>SIMPONI ARIA:</u> AS/PsA/RA: 2mg/kg per infusion at weeks 0 and 4, then every 8 weeks</p> <p><u>SIMPONI:</u> 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</p>
guselkumab (TREMFYA)	<p>Ps/PsA Initial (1 time):</p> <ul style="list-style-type: none"> 100mg (1 syringe) for 28-day supply <p>Ps/PsA Renewal:</p> <ul style="list-style-type: none"> 100mg (1 syringe) per 56-day supply
<p>infliximab (REMICADE)</p> <p>infliximab-abda (RENFLEXIS)</p> <p>infliximab-dyyb (INFLECTRA)</p> <p>infliximab-axxq (AVSOLA)</p>	<p>Initial (1 time):</p> <ul style="list-style-type: none"> AS/CD/Ps/PsA/UC: 5mg/kg per infusion; 3 infusions for 6 weeks RA: 3mg/kg per infusion; 2 infusions per 6 weeks <p>Renewal:</p> <ul style="list-style-type: none"> 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)	<p>Initial (1 time):</p> <ul style="list-style-type: none"> 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 <p>Renewal:</p> <ul style="list-style-type: none"> AS/NAS/Ps/PsA: 80mg (1 syringe) per 28-day supply
mirikizumab-mrkz (OMVOH)	<p>UC Initial (3 months):</p> <ul style="list-style-type: none"> 300 mg per 28-day supply x 3 months <p>UC Renewal:</p> <ul style="list-style-type: none"> 200 mg per 28-day supply
rizankizumab (SKYRIZI)	<p>Initial (1 time):</p> <p>CD: 600 mg per infusion at week 0, 4, and 8 Ps/PsA: 300 mg for 28-day supply</p> <p>Renewal:</p> <p>CD: 180 mg or 360 mg at week 12 and every 8 weeks thereafter Ps/PsA: 150 mg every 84 days</p>
sarilumab (KEVZARA)	RA: 400mg per 28-day supply
secukinumab (COSENTYX)	<p>Initial (1 time) :</p> <ul style="list-style-type: none"> Ps: 1200mg (#8 syringe) for 28-day supply AS/NAS/PsA: 600mg (#4 syringe) for 28-day supply <p>Renewal:</p> <ul style="list-style-type: none"> Ps: 300mg (#2 syringe) per 28-days thereafter AS/NAS/PsA: 150mg (#1 syringe) per 28-days thereafter
tildrakizumab-asmn (ILUMYA)	<p>Ps Initial (1 time):</p> <ul style="list-style-type: none"> 100mg (1 syringe) for 28-day supply <p>Ps Renewal:</p> <ul style="list-style-type: none"> 100mg (#1 syringe) every 84-days
tocilizumab (ACTEMRA)	<p>RA: 648mg (4 syringes) per 28-day supply RA: 800mg IV (1 infusion) per 28-day supply</p>
tofacitinib citrate (XELJANZ/ XR)	<p>Xeljanz:</p> <ul style="list-style-type: none"> 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 <p>Xeljanz XR:</p> <ul style="list-style-type: none"> 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)	<p>AS/NSA/PsA/RA: 15mg per day; #30 tablets per 30-day supply</p> <p>CD: 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)</p> <p>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)</p>
9ustekinumab9 (STELARA)	<p>Initial (1 time):</p> <ul style="list-style-type: none"> CD/UC: <55kg: 260 mg (2 vials) for 56-day supply

	<ul style="list-style-type: none"> • 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 <p>Renewal:</p> <ul style="list-style-type: none"> • 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)	<p>CD/UC Initial:</p> <ul style="list-style-type: none"> • 300 mg IV at weeks 0,2, and 6 (Loading dose) <p>CD/UC Renewal:</p> <ul style="list-style-type: none"> • 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, riloncept, 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

References

1. Van Den Bosch, F. Arthritis associated with gastrointestinal disease. Last updated February 2016. In: Sieper J. UpToDate, Waltham, MA, 2016.
2. Smith, E, Yazici, Y. Treatment of Behcet’s syndrome. Last updated June 2015. . In: Merkel P. UpToDate, Waltham, MA, 2016.
3. Hisamatsu, T, Ueno, F, Matsumoto, T, et al. The 2nd edition of consensus statements for the diagnosis and management of intestinal Behcet’s disease: indication of anti-TNFalpha monoclonal antibodies. Journal of gastroenterology. 2014 Jan;49(1):156-62. PMID: 23955155
4. Magnano, MD, Chakravarty, EF, Broudy, C, et al. A pilot study of tumor necrosis factor inhibition in erosive/inflammatory osteoarthritis of the hands. The Journal of rheumatology. 2007 Jun;34(6):1323-7. PMID: 17516620
5. Hoffman, GS, Cid, MC, Rendt-Zagar, KE, et al. Infliximab for maintenance of glucocorticosteroid-induced remission of giant cell arteritis: a randomized trial. Annals of internal medicine. 2007 May 1;146(9):621-30. PMID: 17470830
6. Couriel, DR, Saliba, R, de Lima, M, et al. A phase III study of infliximab and corticosteroids for the initial treatment of acute graft-versus-host disease. Biology of blood and marrow transplantation : journal of the American Society for Blood and Marrow Transplantation. 2009 Dec;15(12):1555-62. PMID: 19896079
7. R., B. Granuloma annulare. Last updated November 2015. In: Stratman E. UpToDate, Waltham, MA, 2016.
8. Sandborn, WJ, Colombel, JF, Sands, BE, et al. Abatacept for Crohn’s disease and ulcerative colitis. Gastroenterology. 2012 Jul;143(1):62-9 e4. PMID: 22504093
9. Hueber, W, Sands, BE, Lewitzky, S, et al. Secukinumab, a human anti-IL-17A monoclonal antibody, for moderate to severe Crohn’s disease: unexpected results of a 11 randomized, double-blind placebo-controlled trial. Gut. 2012 Dec;61(12):1693-700. PMID: 22595313
10. Burns, JC, Best, BM, Mejias, A, et al. Infliximab treatment of intravenous immunoglobulin-resistant Kawasaki disease. The Journal of pediatrics. 2008 Dec;153(6):833-8. PMID: 18672254
11. Son, MB, Gauvreau, K, Burns, JC, et al. Infliximab for intravenous immunoglobulin resistance in Kawasaki disease: a retrospective study. The Journal of pediatrics. 2011 Apr;158(4):644-9 e1. PMID: 21129756
12. Tremoulet, AH, Jain, S, Jaggi, P, et al. Infliximab for intensification of primary therapy for Kawasaki disease: a phase 3 randomised, double-blind, placebo-controlled trial. Lancet. 2014 May 17;383(9930):1731-8. PMID: 24572997
13. Aster, J, Brown, J., Munshi, N. Multicentric Castleman’s disease. Last updated January 2015. . In: Freedman A. UpToDate, Waltham, MA, 2016.
14. Van Den Bosch, F, Kruihof, E, Baeten, D, et al. Randomized double-blind comparison of chimeric monoclonal antibody to tumor necrosis factor alpha (infliximab) versus placebo in active spondylarthropathy. Arthritis and rheumatism. 2002 Mar;46(3):755-65. PMID: 11920412

15. Mease, P, Sieper, J, Van den Bosch, F, Rahman, P, Karunaratne, PM, Pangan, AL. Randomized controlled trial of adalimumab in patients with nonpsoriatic peripheral spondyloarthritis. *Arthritis Rheumatol*. 2015 Apr;67(4):914-23. PMID: 25545240
16. Paramarta, JE, De Rycke, L, Heijda, TF, et al. Efficacy and safety of adalimumab for the treatment of peripheral arthritis in spondyloarthritis patients without ankylosing spondylitis or psoriatic arthritis. *Annals of the rheumatic diseases*. 2013 Nov;72(11):1793-9. PMID: 23139265
17. Reich, K, Ortonne, JP, Gottlieb, AB, et al. Successful treatment of moderate to severe plaque psoriasis with the PEGylated Fab' certolizumab pegol: results of a phase II randomized, placebo-controlled trial with a re-treatment extension. *The British journal of dermatology*. 2012 Jul;167(1):180-90. PMID: 22413944
18. Mease, P, Genovese, MC, Gladstein, G, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial. *Arthritis and rheumatism*. 2011 Apr;63(4):939-48. PMID: 21128258
19. Judson, MA, Baughman, RP, Costabel, U, et al. Efficacy of infliximab in extrapulmonary sarcoidosis: results from a 12 randomized trial. *Eur Respir J*. 2008;31:1189-96. PMID: 18256069
20. Baughman, RP, Drent, M, Kavuru, M, et al. Infliximab therapy in patients with chronic sarcoidosis and pulmonary involvement. *American journal of respiratory and critical care medicine*. 2006 Oct 1;174(7):795-802. PMID: 16840744
21. Pariser, RJ, Paul, J, Hirano, S, Torosky, C, Smith, M. A double-blind, randomized, placebo-controlled trial of adalimumab in the treatment of cutaneous sarcoidosis. *Journal of the American Academy of Dermatology*. 2013 May;68(5):765-73. PMID: 23276549
22. Brooklyn, TN, Dunnill, MG, Shetty, A, et al. Infliximab for the treatment of pyoderma gangrenosum: a 12 randomized, double blind, placebo controlled trial. *Gut*. 2006 Apr;55(4):505-9. PMID: 16188920
23. Narshi, CB, Allard, SA. Sustained response to tocilizumab, anti-IL-6 antibody, following anti-TNF-alpha failure in a patient with relapsing polychondritis complicated by aortitis. *Rheumatology (Oxford)*. 2012 May;51(5):952-3. PMID: 22298790
24. Kawai, M, Hagihara, K, Hirano, T, et al. Sustained response to tocilizumab, anti-interleukin-6 receptor antibody, in two patients with refractory relapsing polychondritis. *Rheumatology (Oxford)*. 2009 Mar;48(3):318-9. PMID: 19106169
25. Genovese, MC, Durez, P, Richards, HB, et al. One-year efficacy and safety results of secukinumab in patients with rheumatoid arthritis: phase II, dose-finding, double-blind, randomized, placebo-controlled study. *The Journal of rheumatology*. 2014 Mar;41(3):414-21. PMID: 24429175
26. Genovese, MC, Durez, P, Richards, HB, et al. Efficacy and safety of secukinumab in patients with rheumatoid arthritis: a phase II, dose-finding, double-blind, 12 randomized, placebo controlled study. *Annals of the rheumatic diseases*. 2013 Jun;72(6):863-9. PMID: 22730366
27. Barkham, N, Keen, HI, Coates, LC, et al. Clinical and imaging efficacy of infliximab in HLA-B27-Positive patients with magnetic resonance imaging-determined early sacroiliitis. *Arthritis and rheumatism*. 2009 Apr;60(4):946-54. PMID: 19333933
28. Korhonen, T, Karppinen, J, Paimela, L, et al. The treatment of disc-herniation-induced sciatica with infliximab: one-year follow-up results of FIRST II, a randomized controlled trial. *Spine*. 2006 Nov 15;31(24):2759-66. PMID: 17108825
29. Korhonen, T, Karppinen, J, Paimela, L, et al. The treatment of disc herniation-induced sciatica with infliximab: results of a randomized, controlled, 3-month follow-up study. *Spine*. 2005 Dec 15;30(24):2724-8. PMID: 16371894
30. Genevay, S, Viatte, S, Finckh, A, Zufferey, P, Balague, F, Gabay, C. Adalimumab in severe and acute sciatica: a multicenter, randomized, double-blind, placebo-controlled trial. *Arthritis and rheumatism*. 2010 Aug;62(8):2339-46. PMID: 20506391
31. Genevay, S, Finckh, A, Zufferey, P, Viatte, S, Balague, F, Gabay, C. Adalimumab in acute sciatica reduces the long-term need for surgery: a 3-year follow-up of a 12 randomized double-blind placebo-controlled trial. *Annals of the rheumatic diseases*. 2012 Apr;71(4):560-2. PMID: 21998121

32. Khanna, D, Denton, CP, Jahreis, A, et al. Safety and efficacy of subcutaneous tocilizumab in adults with systemic sclerosis (13andomize): a phase 2, 13andomized, controlled trial. *Lancet*. 2016 Jun 25;387(10038):2630-40. PMID: 27156934
33. Moutsopoulos, NM, Katsifis, GE, Angelov, N, et al. Lack of efficacy of etanercept in Sjogren syndrome correlates with failed suppression of tumour necrosis factor alpha and systemic immune activation. *Annals of the rheumatic diseases*. 2008 Oct;67(10):1437-43. PMID: 18198195
34. Norheim, KB, Harboe, E, Goransson, LG, Omdal, R. Interleukin-1 inhibition and fatigue in primary Sjogren's syndrome—a double blind, 13andomized clinical trial. *PLoS one*. 2012;7(1):e30123. PMID: 22253903
35. Uppal, SS, Hayat, SJ, Raghupathy, R. Efficacy and safety of infliximab in active SLE: a pilot study. *Lupus*. 2009 Jul;18(8):690-7. PMID: 19502264
36. Illei, GG, Shirota, Y, Yarboro, CH, et al. Tocilizumab in systemic lupus erythematosus: data on safety, preliminary efficacy, and impact on circulating plasma cells from an open-label phase I dosage-escalation study. *Arthritis and rheumatism*. 2010 Feb;62(2):542-52. PMID: 20112381
37. Merrill, JT, Burgos-Vargas, R, Westhovens, R, et al. The efficacy and safety of abatacept in patients with non-life-threatening manifestations of systemic lupus erythematosus: results of a twelve-month, multicenter, exploratory, phase IIB, randomized, double-blind, placebo-controlled trial. *Arthritis and rheumatism*. 2010 Oct;62(10):3077-87. PMID: 20533545
38. Dick, AD, Tugal-Tutkun, I, Foster, S, et al. Secukinumab in the treatment of noninfectious uveitis: results of three randomized, controlled clinical trials. *Ophthalmology*. 2013 Apr;120(4):777-87. PMID: 23290985
39. de Menthon, M, Cohen, P, Pagnoux, C, et al. Infliximab or rituximab for refractory Wegener's granulomatosis: long-term follow up. A prospective 13andomized multicentre study on 17 patients. *Clinical and experimental rheumatology*. 2011 Jan-Feb;29(1 Suppl 64):S63-71. PMID: 21586199
40. 2010 update of the ASAS/EULAR recommendations for the management of ankylosing spondylitis. [cited 10/30/2013]; Available from: <http://ard.bmj.com/content/70/6/896.full>
41. 2011 American College of Rheumatology Recommendations for the Treatment of Juvenile Idiopathic Arthritis: Initiation and Safety Monitoring of Therapeutic Agents for the Treatment of Arthritis and Systemic Features. [cited 09/13/2013]; Available from: http://www.rheumatology.org/Practice/Clinical/Guidelines/Clinical_Practice_Guidelines/
42. European League Against Rheumatism recommendations for the management of psoriatic arthritis with pharmacological therapies. [cited 09/13/2013]; Available from: <http://ard.bmj.com/content/71/1/4.abstract>
43. 2012 Update of the 2008 American College of Rheumatology Recommendations for the Use of Disease-Modifying Antirheumatic Drugs and Biologic Agents in the Treatment of Rheumatoid Arthritis. [cited 09/13/2013]; Available from: http://www.rheumatology.org/Practice/Clinical/Guidelines/Clinical_Practice_Guidelines/
44. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs. [cited 09/13/2013]; Available from: <http://ard.bmj.com/content/early/2010/05/04/ard.2009.126532.abstract>
45. Villiger, PM, Adler, S, Kuchen, S, et al. Tocilizumab for induction and maintenance of remission in giant cell arteritis: a phase 2, 13andomized, double-blind, placebo-controlled trial. *Lancet*. 2016 Mar 4. PMID: 26952547
46. Ingram, JR, Woo, PN, Chua, SL, et al. Interventions for hidradenitis suppurativa: a Cochrane systematic review incorporating GRADE assessment of evidence quality. *The British journal of dermatology*. 2016 Jan 23. PMID: 26801356
47. [Poster] Evaluating optimal medium-term dosing strategy for adalimumab in moderate to severe hidradenitis suppurative based on analysis of integrated results from the PIONEER I and II phase 3, randomized, placebo-controlled trials. North Chicago, IL: AbbVie; 2015
48. Simonini, G, Taddio, A, Cattalini, M, et al. Prevention of flare recurrences in childhood-refractory chronic uveitis: an open-label comparative study of adalimumab versus infliximab. *Arthritis care & research*. 2011 Apr;63(4):612-8. PMID: 21452272

49. Diaz-Llopis, M, Salom, D, Garcia-de-Vicuna, C, et al. Treatment of refractory uveitis with adalimumab: a prospective multicenter study of 131 patients. United States, 2012. P. 1575-81.
50. Nigrovic, PA. Cryopyrin-associated periodic syndromes and related disorders. . In: UpToDate, Basow DS (Ed). UpToDate, Waltham, MA, 2013.
51. Sanclemente, G, Murphy, R, Contreras, J, Garcia, H, Bonfill Cosp, X. Anti-TNF agents for paediatric psoriasis. The Cochrane database of systematic reviews. 2015 Nov 24(11):CD010017. PMID: 26598969
52. European biotech gets boost as Genmab market value hits \$7 billion. [cited 11/20/2015]; Available from: <http://www.reuters.com/article/2015/11/17/us-genmab-europe-biotech-idUSKCN0T61RU20151117#7OexUWISTlozpu79.97>
53. Abe, K, Itoyama, Y, Sobue, G, et al. Confirmatory double-blind, parallel-group, placebo-controlled study of efficacy and safety of edaravone (MCI-186) in amyotrophic lateral sclerosis patients. Amyotrophic lateral sclerosis & frontotemporal degeneration. 2014 Dec;15(7-8):610-7. PMID: 25286015
54. Sibley, CH, Plass, N, Snow, J, et al. Sustained response and prevention of damage progression in patients with neonatal-onset multisystem inflammatory disease treated with anakinra: a cohort study to determine three- and five-year outcomes. Arthritis and rheumatism. 2012 Jul;64(7):2375-86. PMID: 22294344
55. Loftus, EV, Jr., Colombel, JF, Feagan, BG, et al. Long-term Efficacy of Vedolizumab for Ulcerative Colitis. J Crohns Colitis. 2017;11:400-11. PMID: 27683800
56. Vermeire, S, Loftus, EV, Jr., Colombel, JF, et al. Long-term Efficacy of Vedolizumab for Crohn’s Disease. J Crohns Colitis. 2017;11:412-24. PMID: 27683798
57. Arnett, FC, Edworthy, SM, Bloch, DA, et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis and rheumatism. 1988 Mar;31(3):315-24. PMID: 3358796
58. Kay, J, Upchurch, KS. ACR/EULAR 2010 rheumatoid arthritis classification criteria. England, 2012. P. vi5-9.
59. Felson, DT, Anderson, JJ, Boers, M, et al. American College of Rheumatology. Preliminary definition of improvement in rheumatoid arthritis. Arthritis and rheumatism. 1995 Jun;38(6):727-35. PMID: 7779114
60. Product Information: OTEZLA® oral tablets, apremilast oral tablets. Celgene Corporation (per FDA), Summit, NJ, 2017.
61. Product Information: ILUMYA™ subcutaneous injection, tildrakizumab-asmn subcutaneous injection. Merck & Co. Inc (per manufacturer), Whitehouse Station, NJ, 2018
62. Ward M., Deodhar A., Gensler L., et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research Association and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis & Rheumatology. 2019. 71(10):1599-1613.

History

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.

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 apremalast; 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