

Cytokine & CAM Antagonists

Medical policy no. 66.27.00-3

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 list of the current Apple Health Preferred Drug List (AHPDL), please visit: <https://www.hca.wa.gov/assets/billers-and-providers/apple-health-preferred-drug-list.xlsx>

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-aqvh (YUSMIRY) adalimumab-atto (AMJEVITA) adalimumab-bwwd (HADLIMA) 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) golimumab (SIMPONI, SIMPONI ARIA)	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 <p>Preferred biologic medications for the treatment of chronic inflammatory conditions include: adalimumab (Humira®) and etanercept (Enbrel®)</p>

<p>guselkumab (TREMFA) infiximab (REMICADE) infiximab-abda (RENFLXIS) infiximab-dyyb (INFLECTRA) infiximab-axxq (AVSOLA) ixekizumab (TALTZ) mirikizumab-mrkz (OMVOH) riloncept (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: <ol style="list-style-type: none"> a. Biologic DMARD

	<ul style="list-style-type: none"> b. Janus kinase inhibitor c. Phosphodiesterase 4 (PDE4) inhibitor <ol 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>	<ol 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>	<ol 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 c. Phosphodiesterase 4 (PDE4) inhibitor

	<ol 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 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>	<ol 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: <ol 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: <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>Ulcerative Colitis (UC)</p>	<ol 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: <ol 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: <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 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)	<p>Initial for IV dosing: (1 time)</p> <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

	<ul style="list-style-type: none"> 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></p> <p>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)	<p>Ps Initial (5 months):</p> <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</p> <p>JIA (2 years or older, ≥ 63 kg): 200 mg per 28-day supply</p>
etrasimod (VELSIPITY)	<p><u>UC: #28 tabs per 28-day supply</u></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></p> <p>AS/PsA/RA: 2mg/kg per infusion at weeks 0 and 4, then every 8 weeks</p> <p><u>SIMPONI:</u></p> <p>As/PsA/RA: 50 mg per 28-day supply</p> <p>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
infliximab (REMICADE) infliximab-abda (RENFLEXIS) infliximab-dyyb (INFLECTRA) infliximab-axxq (AVSOLA)	<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

	<ul style="list-style-type: none"> 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)</p>

	30 mg per day; #30 tablets per 30-day supply (Maintenance)
10ustekinumab10 (STELARA)	<p>Initial (1 time):</p> <ul style="list-style-type: none"> • 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 <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
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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

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History

Date	Action and Summary of Changes
02/07/2024	<ul style="list-style-type: none"> -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