Washington State Health Care Authority

Cytokine and CAM Antagonists: Tumor Necrosis Factor (TNF) Inhibitors

Medical policy no. 66.27.00.AA-4 Effective Date: Month, 1, Year

Related medical policies:

Policy Number	Policy Name
66.27.00.AB	Cytokine and CAM Antagonists: IL-4/IL-13 Inhibitors
66.27.00.AC	Cytokine and CAM Antagonists: IL-6 Inhibitors
66.27.00.AD	Cytokine and CAM Antagonists: IL-12/IL-23 Inhibitors
66.27.00.AE	Cytokine and CAM Antagonists: IL-17 Inhibitors
66.27.00.AF	Cytokine and CAM Antagonists: Oral PDE-4 Inhibitors
66.27.00.AG	Cytokine and CAM Antagonists: T-Lymphocyte Inhibitors
66.27.00.AH	Cytokine and CAM Antagonists: Janus Associated Kinase (JAK) Inhibitors
66.27.00.AI	Cytokine and CAM Antagonists: IL-1 Inhibitors
66.27.00.AJ	Cytokine and CAM Antagonists: Integrin Receptor Antagonists
66.27.00.AK	Cytokine and CAM Antagonists: S1-P Receptor Modulator

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

Medical necessity

Drug	Medical Necessity
adalimumab (Humira) certolizumab pegol (Cimzia) etanercept (Enbrel) golimumab (Simponi) golimumab (Simponi Aria) infliximab (Remicade)	**Tumor Necrosis Factor (TNF) Inhibitors – adalimumab, certolizumab, etanercept, golimumab, infliximab** may be considered medically necessary in patients who meet the criteria described in the clinical policy below.

<u>adalimumab Biosimilars:</u> adalimumab-aacf (Idacio) adalimumab-aaty (Yuflyma) adalimumab-adaz (Hyrimoz) adalimumab-adaz (Adalimumab-ADAZ) adalimumab-adbm (Cyltezo) adalimumab-afzb (Abrilada) adalimumab-aqvh (Yusimry) adalimumab-atto (Amjevita) adalimumab-bwwd (Hadlima) adalimumab-fkjp (Hulio) adalimumab-fkjp (Adalimumab-FKJP) <u>infliximab Biosimilars:</u> infliximab-abda (Renflexis) infliximab-dyyb (Inflectra, Zymfentra) infliximab-axxq (Avsola)	If not all criteria are met, but there are documented medically necessary or situational circumstances, based on the professional judgement of the clinical reviewer, requests may be approved on a case-by-case basis up to the initial or reauthorization duration. Clients new to Apple Health or new to an MCO who are requesting regimens for continuation of therapy are reviewed following the reauthorization criteria listed below.

Clinical policy:

Clinical Criteria	
Ankylosing Spondylitis (AS) **Non-radiographic axial spondyloarthritis** adalimumab (Humira) adalimumab biosimilars certolizumab pegol (Cimzia) etanercept (Enbrel) golimumab (Simponi) golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) or etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older, **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Ankylosing Spondylitis (AS); **OR** **5.** Diagnosis of Non-radiographic axial spondyloarthritis**; AND** 6. High disease activity as indicated by Bath Ankylosing Disease Activity Index (BASDAI) score of at least 4 or Ankylosing Spondylitis Disease Activity Score (ASDAS) score of at least 2.1; **AND** 7. Treatment with at least two different NSAIDs (e.g., indomethacin, meloxicam, celecoxib, naproxen, nabumetone, etc.) has been ineffective, contraindicated, or not tolerated [minimum trial of four weeks]; **AND** 8. Disease manifested as either of the following: a. Axial disease; **OR** b. Peripheral arthritis; **AND** i. Treatment with at least one non-Cytokine and CAM disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate, sulfasalazine, leflunomide) has been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. Adalimumab biosimilars, certolizumab pegol (Cimzia), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all of the following criteria are met:

	1. Criteria 1-3 above is met; **AND** 2. Criteria 4 or 5 above is met; **AND** 3. Criteria 6-8 above is met; **AND** 4. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) adalimumab (Humira), adalimumab biosimilars, certolizumab pegol (Cimzia), etanercept (Enbrel), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in BASDAI or ASDAS score). If ALL criteria are met, the request will be authorized for **12 months.**
Behcet's disease adalimumab (Humira) adalimumab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a rheumatologist, dermatologist, ophthalmologist, etc.; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of **ONE** of the following: a. Diagnosis of recurrent Behcet Syndrome manifesting as oral ulcers of the mouth; **AND** i. History of failure, contraindication, or intolerance to ALL the following: 1. Topical corticosteroids (e.g., triamcinolone) [minimum trial of 7 days]; **AND** 2. Sucralfate mouthwash [minimum trial of 7 days]; **AND** 3. Colchicine [minimum trial of 3 months]; **AND** 4. Oral corticosteroids (e.g., prednisone) [minimum trial of 1 month]; **OR** b. Diagnosis of Behcet Syndrome manifesting as uveitis; **AND** i. History of failure, contraindication, or intolerance to ALL the following: 1. Ophthalmic corticosteroids (e.g., prednisolone) and ophthalmic cyclopentolate [minimum trial of 1 month]; **AND** 2. Oral corticosteroids [minimum trial of 3 months]; **AND**

	3. At least one non-Cytokine and CAM DMARD (e.g., methotrexate, cyclosporine, acitretin, azathioprine, etc.) [minimum trial of 3 months] Adalimumab biosimilars may be approved when all the following documented criteria are met: 1. Criteria 1-4 above is met; **AND** 2. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 24 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Adalimumab (Humira) or adalimumab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in oral lesions, vitreous haze, visual acuity, corticosteroid usage, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Crohn's Disease (CD) adalimumab (Humira) adalimumab biosimilars certolizumab pegol (Cimzia) infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: 1. Patient is 6 years of age or older; **AND** 2. For patients 6 to 17 years of age, documentation of current weight is provided; **AND** 3. Prescribed by, or in consultation with a gastroenterologist; **AND** 4. Not used in combination with another Cytokine and CAM medication; **AND** 5. Diagnosis of moderate to severe Crohn's disease (CD); **AND** a. Treatment with conventional therapy has been ineffective, contraindicated, or not tolerated. Conventional therapy is defined as: i. Oral corticosteroids (e.g., prednisone, methylprednisolone) used short-term to induce remission or alleviate signs/symptoms of disease flare; **AND** ii. At least one immunomodulatory agent (e.g., methotrexate, azathioprine, 6-mercaptopurine) [minimum trial of 12 weeks]; **OR** b. Documentation of high-risk disease (e.g., symptoms despite conventional therapy, obstruction, abscess, stricture, phlegmon, fistulas, resection, extensive bowel involvement,

	early age of onset, growth retardation, Crohn's Disease Activity Index (CDAI) > 450, Harvey-Bradshaw index > 7). Adalimumab biosimilars, certolizumab pegol (Cimzia), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Criteria 3-5 above are met; **AND** 2. The patient meets the appropriate age limit for the requested product: a. For adalimumab biosimilars, infliximab, infliximab biosimilars: 6 years of age or older; **OR** b. For certolizumab pegol: 18 years of age or older; **AND** 3. For all adalimumab biosimilars (6-17 years of age), infliximab, and infliximab biosimilar requests, documentation of current weight is provided; **AND** 4. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Adalimumab (Humira), adalimumab biosimilars, certolizumab pegol (Cimzia), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in endoscopic activity, taper or discontinuation of corticosteroids, reduction in number of liquid stools, decrease in presence and severity of abdominal pain, decrease in CDAI, decrease in Harvey-Bradshaw index). If ALL criteria are met, the request will be authorized for **12 months.**
Hidradenitis Suppurativa (HS) adalimumab (Humira) adalimumab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: 1. Patient is 12 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Hidradenitis Suppurativa (HS); **AND** 5. Presence of inflammatory nodules and/or abscesses; **AND** 6. Diagnosis of one of the following: a. Hurley Stage III (severe) disease; **OR** b. Hurley Stage II (moderate) disease; **AND**

	7. History of failure, contraindication, or intolerance to at least one oral antibiotic (i.e., doxycycline, minocycline, tetracycline, clindamycin + rifampin, etc.) [minimum trial of 3 month trial] Adalimumab biosimilars may be approved when all the following documented criteria are met: 1. Criteria 1-7 above are met; **AND** 2. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Adalimumab (Humira) and adalimumab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., reduction in abscess or inflammatory nodules). If ALL criteria are met, the request will be authorized for **12 months.**
Juvenile Psoriatic Arthritis (JPsA) etanercept (Enbrel)	etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Patient is 2 to 17 years of age; **AND** 2. Prescribed by, or in consultation with a dermatologist or rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Juvenile Psoriatic Arthritis (JPsA); **AND** 5. Patient meets one of the following: a. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]; **OR** b. Presence of active, severe disease as indicated by provider assessment and the presence of at least ONE of the following: i. Erosive disease ii. Elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) iii. Long-term damage interfering with function (e.g., joint deformities, vision loss) iv. Major impairment of quality of life due to high disease activity at many sites (including dactylitis,

	enthesitis) or functionally limiting arthritis at a few sites. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Plaque Psoriasis adalimumab (Humira) adalimumab biosimilars certolizumab pegol (Cimzia) etanercept (Enbrel) infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) or etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For etanercept: 4 years of age or older; **OR** b. For adalimumab: 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of moderate to severe plaque psoriasis; **AND** 5. Presence of ongoing disease for greater than 6 months; **AND** 6. The patient meets one of the following: a. Disease affects at least 10% body surface area; **OR** b. Disease affects the face, ears, hands, feet, or genitalia; **AND** 7. Baseline assessments are included (e.g., body surface area (BSA), Psoriasis Area and Severity Index (PASI), Psoriasis Physician's Global Assessment (PGA), itch numeric rating scale, etc.); **AND** 8. History of failure, contraindication, or intolerance to one of the following: a. Phototherapy (UVB or PUVA) [minimum trial of 12 weeks]; **OR** b. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, cyclosporine, acitretin, azathioprine, etc.) [minimum trial of 12 weeks]. Adalimumab biosimilars, certolizumab pegol (Cimzia), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Criteria 2-8 above are met; **AND** 2. Patient is 18 years of age or older; **AND** 3. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks].

	If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, certolizumab pegol (Cimzia), etanercept (Enbrel), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in BSA, PSAI, Psoriasis PGA, itch numeric rating scale). If ALL criteria are met, the request will be authorized for **12 months.**
Polyarticular Juvenile Idiopathic Arthritis (PJIA) adalimumab (Humira) adalimumab biosimilars etanercept (Enbrel) golimumab (Simponi Aria)	Adalimumab (Humira) or etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Patient is 2 to 17 years of age; **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Polyarticular Juvenile Idiopathic Arthritis (PJIA); **AND** 5. Documentation of current weight is provided; **AND** 6. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, azathioprine, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. Adalimumab biosimilars or golimumab (Simponi Aria) may be approved when all the following documented criteria are met: 1. Criteria 1-6 above are met; **AND** 2. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, etanercept (Enbrel), or golimumab (Simponi Aria) may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Psoriatic Arthritis adalimumab (Humira) adalimumab biosimilars certolizumab pegol (Cimzia) etanercept (Enbrel) golimumab (Simponi) golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) or etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a dermatologist or rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Psoriatic Arthritis (PsA); **AND** 5. Patient meets one of the following: a. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, leflunomide, cyclosporine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]; **OR** b. Presence of active, severe disease as indicated by provider assessment and the presence of at least ONE of the following: i. Erosive disease ii. Elevated C-reactive protein (CRP) or erythrocyte sedimentation rate (ESR) iii. Long-term damage interfering with function (e.g., joint deformities, vision loss) iv. Major impairment of quality of life due to high disease activity at many sites (including dactylitis, enthesitis) or functionally limiting arthritis at a few sites. Adalimumab biosimilars, certolizumab pegol (Cimzia), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For golimumab: 2 years of age or older; **OR** b. For adalimumab biosimilars, certolizumab pegol, infliximab, infliximab biosimilars: 18 years of age or older; **AND** 2. For golimumab, documentation of current weight is provided; **AND** 3. Criteria 2-5 above are met; **AND** 4. For adult requests, treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks].

	If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, etanercept (Enbrel), certolizumab pegol (Cimzia), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., improvement in joint pain, swelling, activities of daily living, reduction in diseases flares, etc.). If ALL criteria are met, the request will be authorized for **12 months.**
Refractory Sarcoidosis adalimumab (Humira) adalimumab biosimilars infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: **1.** Patient is 18 years of age or older; **AND** **2.** Prescribed by, or in consultation with a pulmonologist**; AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** **4.** Diagnosis of pulmonary sarcoidosis; **AND** 5. History of failure, contraindication, or intolerance to ALL the following: a. Oral glucocorticoids (e.g., prednisone, prednisolone) [minimum trial of 3 months]; **AND** b. Immunosuppressive agents (e.g., methotrexate, azathioprine, leflunomide, mycophenolate) [minimum trial of 3 months]; **AND** 6. Baseline assessments of either of the following: a. Pulmonary function tests; **OR** b. Chest radiograph; **OR** c. Ambulatory oximetry Adalimumab biosimilars, infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 7. Criteria 1-6 above are met; **AND** 8. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of three months] **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND**

	2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g, improvement in pulmonary function tests, chest radiograph, oximetry measurements). If ALL criteria are met, the request will be authorized for **12 months.**
Rheumatoid Arthritis (RA) adalimumab (Humira) adalimumab biosimilars certolizumab pegol (Cimzia) etanercept (Enbrel) golimumab (Simponi) golimumab (Simponi Aria) infliximab (Remicade) infliximab biosimilars	Adalimumab (Humira) or etanercept (Enbrel) may be approved when all the following documented criteria are met: 1. Patient is 18 years of age or older; **AND** 2. Prescribed by, or in consultation with a rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of Rheumatoid Arthritis (RA); **AND** 5. Baseline assessments are included (e.g., Disease Activity Score for 28 joints (DAS28) with the CRP, DAS28 with ESR, Simplified Disease Activity Index (SDAI), Clinical Disease Activity Index (CDAI), Routine Assessment of Patient Index Data 3 (RAPID3), Patient Activity Scale (PAS) II; **AND** 6. Treatment with at least one non-Cytokine and CAM DMARD (e.g., methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, cyclosporine, azathioprine) have been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. Adalimumab biosimilars, certolizumab pegol (Cimzia), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Criteria 1-6 above are met; **AND** 2. Treatment with two preferred Cytokine & CAM Apple Health Preferred Drug List (AHPDL) medications has each been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, etanercept (Enbrel), certolizumab pegol (Cimzia), golimumab (Simponi/Simponi Aria), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g. improvement in DAS28 with CRP/ESR, SDAI, CDAI, RAPID3, PAS II scores). If ALL criteria are met, the request will be authorized for **12 months.**
Ulcerative Colitis (UC) adalimumab (Humira) adalimumab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: 1. Patient is 5 years of age or older; **AND**

golimumab (Simponi) infliximab (Remicade) infliximab biosimilars	2. For patients 5 to 17 years of age, documentation of current weight is provided; **AND** 3. Prescribed by, or in consultation with a gastroenterologist; **AND** 4. Not used in combination with another Cytokine and CAM medication; **AND** 5. Diagnosis of moderate-to-severe Ulcerative Colitis (UC); **AND** 6. Baseline assessments are included (e.g., stool frequency, endoscopy results, presence of rectal bleeding, disease activity scoring tool); **AND** 7. Treatment with conventional therapy (e.g., systemic corticosteroids, azathioprine, mesalamine, sulfasalazine) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. Adalimumab biosimilars, golimumab (Simponi), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: 1. The patient meets the appropriate age limit for the requested product: a. For adalimumab biosimilars: 5 years of age or older; **OR** b. For infliximab, infliximab biosimilars: 6 years of age or older; **OR** c. For golimumab: 18 years of age or older; **AND** 2. For all adalimumab biosimilars (5-17 years of age), infliximab, and infliximab biosimilar requests, documentation of current weight is provided; **AND** 3. Criteria 3-7 above are met; **AND** 4. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 12 weeks]. If ALL criteria are met, the request will be authorized for **6 months.** **Criteria (Reauthorization)** Adalimumab (Humira), adalimumab biosimilars, golimumab (Simponi), infliximab (Remicade), or infliximab biosimilars may be approved when all the following documented criteria are met: **1.** Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decreased stool frequency, decreased rectal bleeding, improvement in endoscopic activity, tapering or discontinuation of corticosteroid therapy, or improvement on a disease activity scoring tool). If ALL criteria are met, the request will be authorized for **12 months.**
Uveitis (UV)/panuveitis adalimumab (Humira) adalimumab biosimilars	Adalimumab (Humira) may be approved when all the following documented criteria are met: 1. Patient is 2 years of age or older, **AND**

	2. Prescribed by, or in consultation with an ophthalmologist or rheumatologist; **AND** 3. Not used in combination with another Cytokine and CAM medication; **AND** 4. Diagnosis of non-infectious intermediate, posterior, or panuveitis; **AND** 5. Treatment with at least one periocular injection, implant, topical, or systemic corticosteroid (i.e., triamcinolone, dexamethasone, prednisone, fluocinolone, difluprednate, etc.) has been ineffective, contraindicated, or not tolerated; [minimum trial of 1 week]; **AND** 6. Treatment with at least one non-corticosteroid systemic immunomodulatory therapy (i.e., mycophenolate mofetil, tacrolimus, cyclosporine, azathioprine, or methotrexate, etc.) has been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. Adalimumab biosimilars may be approved when all the following documented criteria are met: 7. Criteria 1-6 above are met; **AND** 8. Treatment with adalimumab (Humira) has been ineffective, contraindicated, or not tolerated [minimum trial of 3 months]. If ALL criteria are met, the request will be authorized for **6 months.**
	Criteria (Reauthorization) Adalimumab (Humira) or adalimumab biosimilars may be approved when all the following documented criteria are met: **1.** Not used in combination with another Cytokine and CAM medication; **AND** 2. Documentation is submitted demonstrating disease stability or a positive clinical response (e.g., decrease in ocular inflammation). If ALL criteria are met, the request will be authorized for **12 months.**

Dosage and quantity limits

Dosage Form	Indication	Quantity Limit
adalimumab (Humira®) [billed by each]		
80mg/0.8 mL pen kit (#2 pens per kit)	• Ankylosing Spondylitis • Crohn's Disease • Hidradenitis Suppurativa • Polyarticular Juvenile Idiopathic Arthritis • Pediatric Crohn's Disease • Plaque Psoriasis • Psoriatic Arthritis • Ulcerative Colitis • Pediatric Ulcerative Colitis • Rheumatoid Arthritis • Uveitis/Panuveitis • *Behcet's Syndrome: Compendia supported indication*	**<u>Hidradenitis Suppurativa*:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **<u>Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa/Uveitis*:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens or PFS per 28 days for months 2-6 *Renewal:* #2 pens or PFS per 28 days for one year **<u>Pediatric Ulcerative Colitis:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **<u>Plaque psoriasis:</u>** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **<u>All other indications:</u>** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year
40 mg/0.8 mL pen kit (#2 pens per kit)		
40 mg/0.4 mL pen kit (#2 pens per kit)		
40 mg/0.8 mL PFS kit (#2 PFS per kit)		
40 mg/0.4 mL PFS kit (#2 PFS per kit)		
20 mg/0.4 mL PFS kit (#2 PFS per kit)		
20 mg/0.2 mL PFS kit (#2 PFS per kit)		
10 mg/0.2 mL PFS kit (#2 PFS per kit)		
10 mg/0.1 mL PFS kit (#2 PFS per kit)		
40 mg/0.8 mL pen Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit (#6 pens per kit)		
40 mg/0.4 mL pen Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit (#6 pens per kit)		
80 mg/0.8 mL pen Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit (#3 pens per kit)		
40 mg/0.8 mL PFS Pediatric Crohn's starter kit (#6 PFS per kit)		
40 mg/0.8 mL PFS Pediatric Crohn's starter kit (#3 PFS per kit)		
80 mg/0.8 mL and 40 mg/0.4 mL PFS Pediatric Crohn's starter kit (#2 PFS per kit)		
80 mg/0.8 mL PFS Pediatric Crohn's starter kit (#3 PFS per kit)		
40 mg/0.8 mL pen Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa starter kit (#4 pens per kit)		

40 mg/0.4 mL pen Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa starter kit (#4 pens per kit)		*Starter kit loaded should be disease specific ^For Behcet's Syndrome can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit" options.
80 mg/0.8 mL and 40 mg/0.4 mL pen Psoriasis/Uveitis/Adolescent Hidradenitis Suppurativa/Pediatric Ulcerative Colitis starter kit (#3 pens per kit)		
80 mg/0.8 mL pen Pediatric Ulcerative Colitis starter kit (#4 pens per kit)		
adalimumab biosimilars		
adalimumab-aacf (adalimumab-aacf) **[billed by each]**		
40 mg/0.8 mL pen kit (#2 pens per kit)	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:** *Initial PA #1:* - Adults: #6 pens per 28 days for one month - Children and adolescents ≥ 12 years of age: o Weight 30 to < 60kg: #4 pens per 28 days for one month o Weight ≥ 60kg: #6 pens per 28 days for one month *Initial PA #2:* #4 pens per 28 days for months 2-6 *Renewal PA:* #4 pens per 28 days for one year **Uveitis*:** *Initial PA #1:* #4 pens per 28 days for one month *Initial PA #2:* #2 pens per 28 days for months 2-6 *Renewal:* #2 pens per 28 days for one year **Crohn's*/ Behcet's Disease^:** *Initial PA #1:* - Adults: #6 pens per 28 days for one month - Children and adolescents ≥ 6 years of age: o Weight 17 to < 40kg: #4 pens per 56 days for one month o Weight ≥ 40kg: #6 pens per 28 days for one month *Initial PA #2:* #2 pens per 28 days for months 2-6

		Renewal: #2 pens per 28 days for one year
		
		<u>Ulcerative Colitis (Adult and Pediatric)*:</u>
		Initial PA #1:
		- Adults: #6 pens per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens per 56 days for one month
		Initial PA #2: #2 or #4 pens (40mg) per 28 days for months 2-6
		
		Renewal: #2 or #4 pens (40mg) per 28 days for one year
		
		<u>Plaque psoriasis*:</u>
		Initial PA #1: #4 pens (40mg) (or 2 kits) per 28 days for one month
		Initial PA #2: #2 pens (40mg) (or 1 kit) per 28 days for months 2-6
		
		Renewal: #2 pens (40mg) (or 1 kit) per 28 days for one year
		
		<u>All other indications:</u>
		Initial PA: #2 pens per 28 days for six months
		
		Renewal: #2 pens per 28 days for one year
		
		*Starter kit not available for this specific product; QL built with total devices needed.
		^For Behcet's Syndrome can use the same instructions as the "Crohn's" adult option.

adalimumab-aacf (Idacio®) [billed by each]		
40 mg/0.8 mL pen kit (#2 pens per kit)	All Humira indications	**<u>Hidradenitis Suppurativa:</u>** *Initial PA #1:* 1 starter kit^ per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **<u>Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa^/Uveitis^:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month
40 mg/0.8 mL PFS kit (#2 PFS per kit)		

40 mg/0.8 mL pen Crohn's Disease/Ulcerative Colitis starter kit (#6 pens per kit)		*Initial PA #2:* #2 pens or PFS per 28 days for months 2-6 *Renewal:* #2 pens or PFS per 28 days for one year **<u>Pediatric Ulcerative Colitis:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **<u>Plaque psoriasis:</u>** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **<u>All other indications:</u>** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year ^Can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis starter kit"
40 mg/0.8 mL pen Plaque Psoriasis kit (#4 pens per kit)		
adalimumab-aaty (Yuflyma®) [billed by each]		
40 mg/0.4 mL pen kit (#1 pen per kit)	All Humira indications	**<u>Hidradenitis Suppurativa:</u>** *Initial PA #1:* 1 starter kit^ per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **<u>Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa/Uveitis^:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens or PFS per 28 days for months 2-6
80 mg/0.8 mL pen kit (#1 pen per kit)		

40 mg/0.4 mL pen kit (#2 pens per kit) 40 mg/0.4 mL PFS kit (#2 PFS per kit) 80 mg/0.8 mL pen Crohn's Disease/Ulcerative Colitis/ Hidradenitis Suppurativa starter kit (#4 pens per kit)		*Renewal:* #2 pens or PFS per 28 days for one year **<u>Pediatric Ulcerative Colitis:</u>** *Initial PA #1:* 1 starter kit^ per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **<u>Plaque psoriasis:</u>** *Initial PA #1:* #4 pens or PFS (40mg) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) per 28 days for one year **<u>All other indications:</u>** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year ^Can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis/ Hidradenitis Suppurativa starter kit"
adalimumab-adaz (Hyrimoz®) [billed by mL]		
10 mg/0.2 mL PFS kit (#1 PFS per kit) 20 mg/0.4 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL pen kit (#2 pens per kit) 10 mg/0.1 mL PFS kit (#2 PFS per kit) 20 mg/0.2 mL PFS kit (#2 PFS per kit) 40 mg/0.4 mL pen kit (#2 pens per kit) 80 mg/0.8 mL pen Crohn's Disease/Ulcerative Colitis starter pack (#3 pens per kit) 80 mg/0.8 mL pen and 40 mg/0.4 mL pen Plaque Psoriasis starter pack (#3 pens per kit; 80mg x1 and 40mg x2)	All Humira indications	**<u>Hidradenitis Suppurativa:</u>** *Initial PA #1:* 1 starter kit^ per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **<u>Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa/Uveitis^:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens or PFS per 28 days for months 2-6 *Renewal:* #2 pens or PFS per 28 days for one year

80 mg/0.8 mL PFS Pediatric Crohn's Disease Starter Pack (#3 PFS per kit) 80 mg/0.8 mL PFS and 40 mg/0.4 mL PFS Pediatric Crohn's Disease Starter Pack (#2 PFS per kit)		**<u>Pediatric Ulcerative Colitis:</u>** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **<u>Plaque psoriasis:</u>** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **<u>All other indications:</u>** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year ^Can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis starter kit"
adalimumab-adaz (Adalimumab-ADAZ) [billed by mL]		

40 mg/0.4 mL PFS kit (#2 PFS per kit)
 	
40 mg/0.4 mL pen kit (#2 pens per kit)
	All Humira indications	**<u>Hidradenitis Suppurativa (Adult and Pediatric)*:</u>**
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		<u>Uveitis*:</u>
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year

		<u>Crohn's*/ Behcet's Disease^:</u>
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		<u>Ulcerative Colitis (Adult and Pediatric)*:</u>
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) per 28 days for months 2-6
		
		Renewal: #2 or #4 pens or PFS (40mg) per 28 days for one year
		
		<u>Plaque psoriasis*:</u>
		Initial PA #1: #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month
		Initial PA #2: #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6
		
		Renewal: #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year
		
		<u>All other indications:</u>
		Initial PA: #2 pens or PFS per 28 days for six months
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		*Starter kit not available for this specific product; QL built with total devices needed.

		^For Behcet's Syndrome can use the same instructions as the "Crohn's" adult option.
adalimumab-adbm (Cyltezo®) [billed by each]		
10 mg/0.2 mL PFS kit (#2 PFS per kit) 20 mg/0.4 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL PFS kit (#1 PFS per kit) 40 mg/0.8 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL pen kit (#2 pens per kit) 40 mg/0.8 mL pen Psoriasis kit (#4 pens per kit) 40 mg/0.8 mL pen Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa kit (#6 pens per kit)	All Humira indications	**Hidradenitis Suppurativa*:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa/Uveitis^:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens or PFS per 28 days for months 2-6 *Renewal:* #2 pens or PFS per 28 days for one year **Pediatric Ulcerative Colitis:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **Plaque psoriasis:** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **All other indications:** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year *Starter kit loaded should be disease specific ^Can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit"
Adalimumab-adbm (Adalimumab-ADBM) [billed by each]		

10 mg/0.2 mL PFS kit (#2 PFS per kit) 20 mg/0.4 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL pen kit (#2 pens per kit) 40 mg/0.8 mL pen Psoriasis/Uveitis kit (#4 pens per kit) 40 mg/0.8 mL pen Crohn's Disease/Ulcerative Colitis/Hidradenitis Suppurativa kit (#6 pens per kit)	All Humira indications	**Hidradenitis Suppurativa*:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #4 pens or PFS per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS per 28 days for one year **Crohn's/Ulcerative Colitis/Behcet's Disease^/Adolescent Hidradenitis Suppurativa/Uveitis*:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens or PFS per 28 days for months 2-6 *Renewal:* #2 pens or PFS per 28 days for one year **Pediatric Ulcerative Colitis:** *Initial PA #1:* 1 starter kit per 28 days for one month *Initial PA #2:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for months 2-6 *Renewal:* #2 pens (40mg or 80mg) or #4 PFS (20mg or 40mg) or #4 pens (40mg) per 28 days for one year **Plaque psoriasis:** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **All other indications:** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year *Starter kit loaded should be disease specific ^For Behcet's Syndrome can use the same starter kit/instructions as the "Crohn's/Ulcerative Colitis/Hidradenitis Suppurativa starter kit"
Adalimumab-afzb (Abrilada™) [billed by each]		
20 mg/ 0.4 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL pen kit (#1 pen per kit)	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:** *Initial PA #1:*

40 mg/0.8 mL pen kit (#2 pen per kit)		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		Uveitis*:
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Crohn's*/ Behcet's Disease^:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Ulcerative Colitis (Adult and Pediatric)*:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for months 2-6

		Renewal: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for one year **Plaque psoriasis*:** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **All other indications:** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year *Starter kit not available for this specific product; QL built with total devices needed. ^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.
adalimumab-aqvh (Yusimry™) [billed by mL]		

40 mg/0.8 mL PFS kit (#2 PFS per kit)
 	
40 mg/0.8 mL pen kit (#2 pens per kit)
	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:**
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		Uveitis*:
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Crohn's*/ Behcet's Disease^:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month

		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Ulcerative Colitis (Adult and Pediatric)*:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) per 28 days for months 2-6
		
		Renewal: #2 or #4 pens or PFS (40mg) per 28 days for one year
		
		Plaque psoriasis*:
		Initial PA #1: #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month
		Initial PA #2: #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6
		
		Renewal: #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year
		
		All other indications:
		Initial PA: #2 pens or PFS per 28 days for six months
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		*Starter kit not available for this specific product; QL built with total devices needed.
		^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.

adalimumab-atto (Amjevita™) [billed by mL]		
10 mg/0.2 mL PFS kit (#1 PFS per kit) 20 mg/0.4 mL PFS kit (#1 PFS per kit) 20 mg/0.2 mL PFS kit (#1 PFS per kit)	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:** *Initial PA #1:* - Adults: #6 pens or PFS (40 mg) per 28 days for one month

40 mg/0.4 mL PFS kit (#1 PFS per kit) 40 mg/0.8 mL PFS kit (#1 PFS per kit) 80 mg/0.8 mL PFS kit (#1 PFS per kit) 40 mg/0.4 mL pen kit (#1 pen per kit) . 40 mg/0.8 mL pen kit (#1 pen per kit) . 80 mg/0.8 mL pen kit (#1 pen per kit)		- Children and adolescents ≥ 12 years of age: ○ Weight 30 to < 60kg: #4 pens or PFS (40 mg) per 28 days for one month ○ Weight ≥ 60kg: #6 pens or PFS (40 mg) per 28 days for one month *Initial PA #2:* #4 pens or PFS (40 mg) per 28 days for months 2-6 *Renewal PA:* #4 pens or PFS (40 mg) per 28 days for one year **Uveitis*:** *Initial PA #1:* #4 pens or PFS (40 mg) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40 mg) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40 mg) per 28 days for one year **Crohn's*/ Behcet's Disease^:** *Initial PA #1:* - Adults: #6 pens or PFS (40 mg) per 28 days for one month - Children and adolescents ≥ 6 years of age: ○ Weight 17 to < 40kg: #4 pens or PFS (40 mg) per 56 days for one month ○ Weight ≥ 40kg: #6 pens or PFS (40 mg) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40 mg) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40 mg) per 28 days for one year **Ulcerative Colitis (Adult and Pediatric)*:** *Initial PA #1:* - Adults: #6 pens or PFS (40 mg) per 28 days for one month - Children and adolescents ≥ 5 years of age: ○ Weight 20 to < 40kg: #4 pens or PFS (40 mg) per 56 days for one month ○ Weight ≥ 40kg: #8 pens or PFS (40 mg) per 56 days for one month *Initial PA #2:* #2 or #4 pens or PFS (40mg) per 28 days for months 2-6

		Renewal: #2 or #4 pens or PFS (40mg) per 28 days for one year **<u>Plaque psoriasis*:</u>** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **<u>All other indications:</u>** *Initial PA:* #2 pens or PFS (40 mg) per 28 days for six months *Renewal:* #2 pens or PFS (40 mg) per 28 days for one year *Starter kit not available for this specific product; QL built with total devices needed. ^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.
adalimumab-bwwd (Hadlima™) [billed by mL]		

40 mg/0.8 mL PFS kit (#2 PFS per kit)
40 mg/0.8 mL pen kit (#2 pens per kit)
40 mg/0.4 mL PFS kit (#2 PFS per kit)
40 mg/0.4 mL pen kit (#2 pens per kit)
	All Humira indications	**<u>Hidradenitis Suppurativa (Adult and Pediatric)*:</u>**
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		<u>Uveitis*:</u>
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		<u>Crohn's*/ Behcet's Disease^:</u>
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month

		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Ulcerative Colitis (Adult and Pediatric)*:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) per 28 days for months 2-6
		
		Renewal: #2 or #4 pens or PFS (40mg) per 28 days for one year
		
		Plaque psoriasis*:
		Initial PA #1: #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month
		Initial PA #2: #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6
		
		Renewal: #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year
		
		All other indications:
		Initial PA: #2 pens or PFS per 28 days for six months
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		*Starter kit not available for this specific product; QL built with total devices needed.
		^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.

adalimumab-fkjp (Hulio™) [billed by each]		
20 mg/0.4 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL PFS kit (#2 PFS per kit) 40 mg/0.8 mL pen kit (#2 pens per kit)	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:** *Initial PA #1:* - Adults: #6 pens or PFS per 28 days for one month

		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		Uveitis*:
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Crohn's*/ Behcet's Disease^:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Ulcerative Colitis (Adult and Pediatric)*:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for months 2-6

		Renewal: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for one year **Plaque psoriasis*:** *Initial PA #1:* #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month *Initial PA #2:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6 *Renewal:* #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year **All other indications:** *Initial PA:* #2 pens or PFS per 28 days for six months *Renewal:* #2 pens or PFS per 28 days for one year *Starter kit not available for this specific product; QL built with total devices needed. ^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.
adalimumab-fkjp (Adalimumab-FKJP) [billed by each]		

20 mg/0.4 mL PFS kit (#2 PFS per kit)	All Humira indications	**Hidradenitis Suppurativa (Adult and Pediatric)*:**
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 12 years of age:
		  ○ Weight 30 to < 60kg: #4 pens or PFS per 28 days for one month
		  ○ Weight ≥ 60kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #4 pens or PFS per 28 days for months 2-6
		
		Renewal PA: #4 pens or PFS per 28 days for one year
		
		Uveitis*:
		Initial PA #1: #4 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Crohn's*/ Behcet's Disease^:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month

40 mg/0.8 mL PFS kit (#2 PFS per kit)		
40 mg/0.8 mL pen kit (#2 pens per kit)		

		- Children and adolescents ≥ 6 years of age:
		  ○ Weight 17 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #6 pens or PFS per 28 days for one month
		Initial PA #2: #2 pens or PFS per 28 days for months 2-6
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		Ulcerative Colitis (Adult and Pediatric)*:
		Initial PA #1:
		- Adults: #6 pens or PFS per 28 days for one month
		- Children and adolescents ≥ 5 years of age:
		  ○ Weight 20 to < 40kg: #4 pens or PFS per 56 days for one month
		  ○ Weight ≥ 40kg: #8 pens or PFS per 56 days for one month
		Initial PA #2: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for months 2-6
		
		Renewal: #2 or #4 pens or PFS (40mg) or #4 pens or PFS (20mg) per 28 days for one year
		
		Plaque psoriasis*:
		Initial PA #1: #4 pens or PFS (40mg) (or 2 kits) per 28 days for one month
		Initial PA #2: #2 pens or PFS (40mg) (or 1 kit) per 28 days for months 2-6
		
		Renewal: #2 pens or PFS (40mg) (or 1 kit) per 28 days for one year
		
		All other indications:
		Initial PA: #2 pens or PFS per 28 days for six months
		
		Renewal: #2 pens or PFS per 28 days for one year
		
		*Starter kit not available for this specific product; QL built with total devices needed.
		^For Behcet's Syndrome can use the same QL as the "Crohn's" adult option.

certolizumab (Cimzia®) [billed by each]		
Dosage Form	**Indication**	**Quantity Limit**

200 mg vial kit (#2 vial) 200 mg/mL PFS kit (#2 PFS) 200 mg/mL PFS starter kit (#6 PFS)	• Ankylosing Spondylitis • Crohn's Disease • Non-radiographic Axial Spondyloarthritis • Plaque Psoriasis • Psoriatic Arthritis • Rheumatoid Arthritis	**Plaque psoriasis** *Initial PA #1:* 1 starter kit (#6 PFS) for the first 28 days *Initial PA #2*: 2 kits (#4 PFS) per 28 days supply for months 2-6 *Renewal:* 2 kits (#4 PFS) per 28 days supply for one year **All other indications:** *Initial PA #1:* 1 starter kit (#6 PFS) for the first 28 days *Initial PA #2:* 1 kit (#2 PFS) per 28 days for months 2-6 *Renewal:* 1 kit (#2 PFS) per 28 days for one year
etanercept (Enbrel®) [billed by mL]		
Dosage Form	**Indication**	**Quantity Limit**
50mg/mL Sureclick autoinjector (#4 per carton) 50mg/mL PFS (#4 per carton) 50mg/mL cartridge (#4 per carton) 25mg/0.5mL PFS (#4 per carton) 25mg MDV (#4 per carton)	• Ankylosing Spondylitis • Plaque Psoriasis • Polyarticular Juvenile Idiopathic Arthritis • Psoriatic Arthritis • Rheumatoid Arthritis	**Plaque Psoriasis:** *Initial #1:* 8 pens, PFS, or cartridge per 28 days for the first three months *Initial #2:* 4 pens, PFS or cartridge per 28 days for months 4-6 *Renewal:* 4 pens, PFS or cartridge per 28 days for one year **All Other Indications:** *Initial PA:* 4 pens, PFS, or cartridge per 28 days for six months *Renewal:* 4 pens, PFS, or cartridge per 28 days for one year 8 PFS or MDV per 28 days
golimumab (Simponi®/Simponi Aria®) [billed by mL]		
Dosage Form	**Indication**	**Quantity Limit**
50mg/0.5mL SmartJect autoinjector (#1 per box) 50mg/0.5mL PFS (#1 per box) 100mg/mL SmartJect autoinjector (#1 per box) 100mg/mL PFS (#1 per box)	• Ankylosing Spondylitis • Psoriatic Arthritis • Rheumatoid Arthritis • Ulcerative Colitis	**Ulcerative Colitis:** *Initial PA:* #3 (100mg/mL) autoinjectors or PFS per 28 days for the first month *Maintenance PA: #*1 (100mg/mL) autoinjector or PFS per 28 days for months 2-6 *Renewal PA: #*1 (100mg/mL) autoinjector or PFS per 28 days for one year **All Other Indications:**

		Initial PA: #1 (50mg/0.5mL) autoinjector or PFS per 28 days for six months *Renewal PA:* #1 (50mg/0.5mL) autoinjector or PFS per 28 days for one year
50mg/4mL single-dose vial (Simponi Aria®)	• Ankylosing Spondylitis • Psoriatic Arthritis • Rheumatoid Arthritis	10 vials first 28 days, then 5 vials per 56 days
infliximab (Remicade®) [billed by each]		
Dosage Form	**Indication**	**Quantity Limit**
100 mg single-dose vial	• Ankylosing spondylitis • Crohn's disease • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis	**<u>Rheumatoid Arthritis</u>** *Initial PA:* 3mg/kg per infusion; 2 infusions per 6 weeks *Renewal PA*: 10mg/kg per infusion; 1 infusion per 8 weeks OR 3mg/kg per infusion; 1 infusion per 4 weeks **<u>All Other Indications:</u>** *Initial PA*: 5mg/kg per infusion; 3 infusions for 6 weeks *Renewal PA*: • 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
infliximab biosimilars		
infliximab-abda (Renflexis™) [billed by each] **infliximab-dyyb (Inflectra®) [billed by each]** **infliximab-axxq (Avsola®) [billed by each]**		
100 mg single-dose vial	• Ankylosing spondylitis • Crohn's disease • Plaque psoriasis • Psoriatic arthritis • Rheumatoid arthritis • Ulcerative colitis	**<u>Rheumatoid Arthritis</u>** *Initial PA:* 3mg/kg per infusion; 2 infusions per 6 weeks *Renewal PA*: 10mg/kg per infusion; 1 infusion per 8 weeks OR 3mg/kg per infusion; 1 infusion per 4 weeks **<u>All Other Indications:</u>** *Initial PA*: 5mg/kg per infusion; 3 infusions for 6 weeks *Renewal PA*: • 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

Coding:

HCPCS Code	Description
J0135	Injection, adalimumab, 20 mg
J0717	Injection, certolizumab pegol, 1 mg
J1438	Injection, etanercept, 25 mg
J1602	Injection, golimumab, 1 mg, for intravenous use
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1748	Injection, infliximab-dyyb (zymfentra), 10 mg
Q5103	Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (renflexis), 10 mg
Q5109	Injection, infliximab-qbtx, biosimilar, (ixifi), 10 mg
Q5121	Injection, infliximab-axxq, biosimilar, (avsola), 10 mg
Q5131	Injection, adalimumab-aacf (idacio), biosimilar, 20 mg
Q5132	Injection, adalimumab-afzb (abrilada), biosimilar, 10 mg

Background:

Ankylosing spondylitis and non-radiographic axial spondyloarthritis

The 2019 American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network (ACR/SAA/SPARTAN) guidelines on the treatment of ankylosing spondylitis strongly recommend the use of NSAIDs as first-line treatment (with 70-80% responding). Recommendations against the use of non-biologic DMARDs are made for patients with active ankylosing spondylitis despite NSAID treatment. Some benefit has been seen in patients with peripheral arthritis, thus treatment with sulfasalazine or methotrexate may be considered in patients with predominantly peripheral disease; however, evidence is based on older RCTs with very low quality of evidence. For those patients with inadequate response despite continuous NSAID treatment, the ACR strongly recommends use of TNF inhibitors over no treatment with TNF inhibitors. In patients with secondary nonresponse to TNF inhibitors, the guidelines conditionally recommend treatment with a different TNF inhibitor over treatment with a non-TNF inhibitor biologic. The 2022 Assessment of SpondyloArthritis international Society (ASAS)-EULAR guidelines for the treatment of axial spondyloarthritis (axSpA) reference the use of JAK inhibitors in the treatment algorithm. The term axial spondyloarthritis (axSpA), encompasses both active ankylosing spondylitis (or radiographic AS) and nr-axSpA as one entity part of the same chronic inflammatory musculoskeletal spectrum with similar clinical presentations, comorbidities, disease burden, and treatment response. ASAS/EULAR recommends patients try and fail at least 2 NSAIDs over 4 weeks as first line therapy and treat local musculoskeletal inflammation with glucocorticoid injection; sulfasalazine may be considered in patients with peripheral symptoms, however use of conventional non-biologic DMARDS (e.g. sulfasalazine, leflunomide, methotrexate, etc.) is not recommended in axial disease. In contrast to ACR/SAA/SPARTAN, ASAS/EULAR guidelines highly recommend treatment with a TNF inhibitor, IL-17 inhibitor, or JAK inhibitor for patients with high disease activity, defined by a BASDAI of at least 4 or an ASDAS of at least 2.1, despite conventional treatment with NSAIDS. Starting with a TNF inhibitor or IL-17 inhibitor is preferred clinically, given long term data for use of JAK inhibitors in axSpA is still missing. There is no specific treatment algorithm after primary non-response to biologic (TNF inhibitor or IL-17 inhibitor) or JAK inhibitor therapy.

Bechet's Disease
Behcets syndrome, also known as Behcet disease, is an inflammatory disease with numerous potential manifestations involving the skin, mucosa, joints, eyes, arteries, veins, nervous system, and gastrointestinal system. Most clinical manifestations are believed to be due to vasculitis. The therapeutic approach is highly variable and guided by disease manifestation. For oral manifestations, the first line treatment is triamcinolone acetonide cream 0.1% in orabase or sucralfate mouthwash per the 2018 EULAR Recommendations. Colchicine is used as the first-line treatment for prevention of mucocutaneous lesions. Benzathine penicillin is often added to colchicine to increase the effectiveness. Additional treatment options include thalidomide, oral corticosteroids, oral DMARDs, and TNF-alpha inhibitors. Apremilast (Otezla) has been shown to be effective for prevention of oral ulcers and is currently FDA approved for this indication. Although apremilast is an FDA-approved medication for Behcet's syndrome, anti-TNF alpha therapies have equal or greater safety and efficacy data to support their use in this condition. Guidelines and key opinion leaders have consensus in regard to use of anti-TNF alpha therapies prior to use of apremilast. For ophthalmic manifestations, corticosteroids and oral DMARDS (typically azathioprine) have been mainstays of Behcet's syndrome.

Crohn's Disease
Therapeutic recommendations for patients with Crohn's disease (CD) are established based upon disease location, disease severity, disease associated complications, and future disease prognosis. The goals of therapy are to induce remission, prevent relapse, and prevent occurrence of disease complications, such as stricture and fistula. According to the 2018 American College of Gastroenterology (ACG) guidelines, for patients with moderate to severe disease and those with moderate to high-risk disease treatment with oral corticosteroids used short term to induce remission is recommended (strong recommendation, moderate level of evidence). However, it is noted that one in five patients will become steroid refractory which is thought to be the result of unreliable efficacy in healing of the mucosa associated with steroids (weak recommendation, low level of evidence). Corticosteroids are also implicated in the development of perforating complications (abscess and fistula) and are relatively contraindicated in those patients. The 2021 American Gastroenterological Association (AGA) clinical guidelines make similar recommendations and suggest the use of corticosteroids in adult outpatients with moderate to severe CD over no treatment for induction of remission (conditional recommendation, moderate level of evidence). In patients with moderate to severe CD who remain symptomatic despite current or prior corticosteroid therapy, 2018 ACG guidelines recommend immunomodulators such as azathioprine, 6-mercaptopurine (strong recommendation, moderate level of evidence), and methotrexate (conditional recommendation, low level of evidence) to be effective for maintenance of remission. Due to slow time to clinical response that may not be evident for as long as 12 weeks, these agents are not recommended for short-term induction. The 2021 AGA guidelines make similar suggestions and recommend use of thiopurines over no treatment for the maintenance of remission (conditional recommendation, low level of evidence). The timing of introduction of biologic agents is a matter of debate and more studies are needed to assess stepwise approach versus earlier administration of biologic agents in patients with moderate to severe disease. The 2019 British Society of Gastroenterology guidelines suggest that systemic corticosteroids are still an effective initial therapy for uncomplicated luminal moderate to severe disease, regardless of disease location; however, every effort should be made to limit exposure (strong recommendation, high-quality evidence). In patients with an aggressive disease course, or high risk, poor prognostic factors, early introduction of biologics may be considered (weak recommendation, moderate-quality evidence). High risk features include extensive disease, complex (stricturing or penetrating disease), perianal fistulizing disease, age under 40 years at diagnosis, and the need for steroids to control index flare; however, the predictive power of these features is limited.

Hidradenitis Suppurativa
Hidradenitis suppurativa (HS), also known as acne inversa, is a chronic, inflammatory disease affecting sweat glands characterized by recurrent, painful lesions that typically develop in intertriginous areas such as the axillae, groin, vulva, or gluteal cleft/anal region. Lesions usually start small and, over weeks to months, form into nodules, abscesses, or tunnels that can lead to scarring and fistulas overtime. The disease is classified in 3 clinical stages which help guide treatment: Hurley stage I (least severe), Hurley stage II (moderate severity), and Hurley stage III (most severe). Adalimumab (Humira) is FDA-approved in patients in 12 years or older with moderate to severe HS supported by results of the PIONEER I and II RCTs. The Unites States and Canadian Hidradenitis Suppurativa Foundation 2019 guidelines provide recommendations for the treatment of HS. For mild-to-moderate HS, systemic antibiotics including tetracyclines are recommended as monotherapy and clindamycin and rifampin in combination is recommended in the second-line setting. For severe disease, clindamycin and rifampin may be used as a first line or adjunct treatment. For moderate-to-severe disease, moxifloxacin, metronidazole, and rifampin in combination are recommended as second- or third-line treatment. This recommendation is based on moderate-quality evidence from RCTs and one systemic review of retrospective and prospective studies. In moderate-to-severe disease when systemic antibiotics are ineffective or insufficient, the guidelines recommend the use of biologics, with a strong recommendation for adalimumab based on high quality evidence. Limited evidence is available for infliximab, anakinra, and ustekinumab with limitations including considerable variability and validity of end points, lack of dose ranging studies, and short follow-up periods.

Plaque Psoriasis
Joint American Academy of Dermatology–National Psoriasis Foundation guidelines for the management of psoriasis with systemic nonbiologic therapies and for the management and treatment of psoriasis with biologics indicate that the majority of patients are capable of adequately controlling disease solely with topical medications or phototherapy. Phototherapy is recognized as a beneficial therapy for controlled plaque psoriasis and is a cost-effective treatment strategy. Additionally, oral immunomodulatory medications (e.g., methotrexate, cyclosporine, acitretin) are cost-effective therapies with a well-known safety profile for the treatment of plaque psoriasis. For moderate-to-severe disease, where a JAK inhibitor or biologics are warranted, deucravacitinib (Sotyktu) is one of many options. However, it would not be indicated for mild psoriasis given that patients are better managed from a safety perspective on well-established therapies (e.g., topical agents, phototherapy, conventional DMARDS, apremilast [Otezla]).

Polyarticular Juvenile Idiopathic Arthritis (PJIA)
Juvenile idiopathic arthritis (JIA) is a grouping of inflammatory disorders that affect children. Polyarticular juvenile idiopathic arthritis (PJIA) is a subset of JIA, which is defined by the presence arthritis in five or more joints during the first six months of illness. Other subsets of JIA include ERA, oligoarthritis (less than five joints affected), systemic juvenile idiopathic arthritis (SJIA; fever, rash, hepatic/splenic/lymphatic involvement) and psoriatic arthritis (psoriasis and dactylitis). While these are distinct disease states, their pathogenesis and presentation are similar so there is significant overlap in effective treatments. The 2019 American College of Rheumatology/Arthritis Foundation (ACR) guidelines for non-systemic polyarthritis (PJIA) strongly recommend initial therapy with a DMARD for all patients with JIA and active polyarthritis; methotrexate has the strongest evidence, but sulfasalazine and leflunomide can also be used. Regardless of disease activity, initial therapy with a DMARD is recommended over a biologic, though there may be certain situations where a biologic as initial therapy is preferred (i.e., high risk joints such as cervical spine, wrist, or hip involved). For patients with continued moderate to high disease activity, the guidelines recommend adding a TNF inhibitor, abatacept, or tocilizumab as second-line.

Psoriatic Arthritis
The 2018 American College of Rheumatology/National Psoriasis Foundation (ACR) guidelines for psoriatic arthritis make a conditional recommendation for starting a TNF inhibitor over an oral small molecule (OSM) as a first-line option for patients who are treatment-naïve with active psoriatic arthritis. This recommendation is based on low- to very-low quality of evidence. Many of the studies in which greater benefit was seen in terms of disease severity or radiographic progression compared methotrexate to TNF inhibitors, however, most patients included in these groups were not truly treatment naïve to OSM medications. Guidelines note that OSM can be used first-line in naïve patients who do not have severe PsA, severe PsO, prefers oral therapy, or has contraindications to TNF inhibitors. In patients who continue to have active disease despite OSM treatment, it is recommended to switch to a TNF inhibitor rather than trying a different OSM. The 2018 ACR guidelines for psoriatic arthritis also conditionally recommend for use of a TNF inhibitor biologics over IL-17 inhibitors (ixekizumab, secukinumab) or IL-12/23 inhibitors (ustekinumab).

Rheumatoid Arthritis
The 2021 American College of Rheumatology (ACR) guidelines for rheumatoid arthritis strongly recommend the use of conventional synthetic disease-modifying antirheumatic drug (csDMARD) monotherapy (methotrexate preferred) in patients who are DMARD-naïve with moderate-to-severe RA. Recommended csDMARDs include methotrexate, sulfasalazine, hydroxychloroquine, and leflunomide. Despite moderate evidence in the SELECT-EARLY study noting higher efficacy of upadacitinib over methotrexate in DMARD-naïve patients with moderate-to-severe RA, there is limited long-term safety data to strongly recommend the use of tsDMARDs (e.g., JAK inhibitors) as first line therapy. Therefore, methotrexate monotherapy remains the preferred first-line therapy over tsDMARDs in DMARD-naïve patients based on established safety and efficacy. Additionally, JAK inhibitors are not FDA approved for use in csDMARD-naïve patients. The 2019 European League Against Rheumatism (EULAR) guidelines follow similar recommendations to the 2021 ACR guidelines, and state that patients with highly active RA despite treatment with csDMARDs may receive a biologic DMARD or JAK inhibitor based on high level of evidence.

Ulcerative Colitis
The 2019 American College of Gastroenterology (ACG) clinical guideline on the management of ulcerative colitis in adults recommend oral systemic corticosteroids for induction of remission in moderate to severe disease (strong recommendation, moderate quality of evidence). TNF inhibitors (adalimumab, golimumab, and infliximab), vedolizumab (Entyvio), and tofacitinib (Xeljanz) are also recommended for induction of remission (strong recommendation, moderate quality of evidence). For maintenance of remission, thiopurines are recommended if remission was achieved after corticosteroid induction (conditional recommendation, low quality of evidence). The guidelines note a systematic review of 1,632 patients with ulcerative colitis demonstrated that azathioprine and mercaptopurine had a 76% mean efficacy in maintaining remission. If remission was achieved with anti-TNF therapy, vedolizumab (Entyvio), or tofacitinib (Xeljanz), clinical guidelines support continuing with the same agent to maintain remission (strong recommendation, moderate quality of evidence). The 2020 American Gastroenterology Association (AGA) guidelines make similar recommendations. Additionally, AGA recommends early use of biologic agents, rather than gradual step up after failure of 5-ASA in moderate to severe disease at high risk for colectomy. However, overall quality of evidence supporting this recommendation was rated as very low. Guidelines also note that for patients with less severe disease, 5-ASA therapy may still be a reasonable choice of therapy to start with. For maintenance of remission, AGA makes no recommendation in favor of, or against, using biologic monotherapy, rather than thiopurine monotherapy due to absence of evidence.

Uveitis/Panuveitis

The Fundamentals of Care for Uveitis (FOCUS) guideline recommends that the noncorticosteroid systemic immunomodulatory therapy (NCIST) agents listed above may be indicated for patients who have a failure or lack of tolerance to regional or systemic corticosteroids. Prior to initiation of alternative medications such as biologic agents, guidelines recommend dose escalation to the maximum tolerated/effective dose of NCIST. It is noted that use of biologic agents is supported for adalimumab, infliximab, and interferon alpha-2a.

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History

Approved Date	Effective Date	Version	Action and Summary of Changes
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Pending Approval (draft/unpublished version) -Updated clinical criteria for indication A to require Lab A. -Added indication for X. -Added new products in class which include Drug A and Drug B. -Updating dosing for Drug A. -Updating language at header note to include "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."
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by HCA. Updated dosing limits for expanded indication for drug X.
MM/DD/YYY	MM/DD/YYYY	XX.XX.XX-X	Approved by DUR Board.

Previous policy changes (relevant from Cytokine & CAM Antagonists Policy)	
Date	**Action and Summary of Changes**
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
8.20.2020	Update to dosing and limits section for all products and indications
08.12.2020	Updated policy clinical criteria and dosing & quantity limits to include nonradiographic axial spondyloarthritis
06.01.2020	Added new agents to class; updated age limit for Uveitis indication; updated dosing and quantity limits; updated HCPCS coding
07.31.2019	Updated criteria that trial of preferred biologics only applies to non-preferred biologics

06.07.2019	Updates to TB skin test requirements for apremalist; updates to initial authorization clinical criteria
11.02.2018	Addition of Hyrimoz (adalimumab-adaz)
09.07.2018	Addition of new medication
08.16.2017	New Policy