BOSTON MEDICAL CENTER HEALTHNet PLAN

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Pharmacy Policy

Targeted Immunomodulators (TIMs) – Unified Formulary

Policy Number: 9.144
Version Number: 1.4
Version Effective Date: 9/1/2021

Product Applicability ☐ **All Plan[+] Products**

Well Sense Health Plan
☐ New Hampshire Medicaid

Boston Medical Center HealthNet Plan
☒ MassHealth - MCO
☒ MassHealth - ACO
☐ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Reference Table:

Drugs that require PA	No PA
Anti-Tumor Necrosis Factor (Anti-TNF)	
Cimzia® (certolizumab)	
Enbrel® (etanercept) PD	
Humira® (adalimumab) PD	
Simponi® (golimumab)	
Simponi Aria® (golimumab for infusion)	
Interleukin (IL) Antagonist	
IL-1 Antagonist	
Kineret® (anakinra)	
IL-6 Antagonist	
Actemra® (tocilizumab)	
Kevzara® (sarilumab)	
IL-12/23 Antagonist	

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Drugs that require PA	No PA
Stelara® (ustekinumab) [PD]	
IL-17A Antagonist	
Cosentyx® (secukinumab)	
Taltz® (ixekizumab) [PD]	
IL-23 Antagonist	
Ilumya® (tildrakizumab-asmn)	
Siliq® (brodalumab)	
Skyrizi® (risankizumab-rzaa)	
Tremfya® (guselkumab)	
Oral Janus Kinase Inhibitor	
Olumiant® (baricitinib)	
Rinvoq® (upadacitinib)	
Xeljanz® (tofacitinib) [PD]	
Xeljanz® XR (tofacitinib extended-release) [PD]	
Phosphodiesterase-4 (PDE-4) Inhibitor	
Otezla® (apremilast)	
Selective Co-Stimulation Modulator	
Orencia® (abatacept)	

[PD] Preferred Drug. In general, MassHealth requires a trial of the preferred drug or clinical rationale for prescribing a non-preferred drug within a therapeutic class. Please note, for Stelara®, Taltz® and interleukin antagonists, a trial with a preferred agent is not required prior to approval of a non-preferred agent. For Xeljanz® (tofacitinib), Xeljanz® XR (tofacitinib extended-release) and janus kinase inhibitors, a trial with a preferred agent is not required prior to approval of a non-preferred agent.

Procedure:

Approval Diagnosis:	• **Ankylosing Spondylitis:** Cimzia®, Cosentyx®, Enbrel®, Humira®, Simponi®, Simponi Aria®, Taltz® • **Cytokine Release Syndrome (CRS)**: Actemra® • **Deficiency of Interleukin-1 Receptor Antagonist (DIRA):** Kineret® • **Giant Cell Arteritis**: Actemra® • **Moderate-to-severe Crohn's Disease: :** Cimzia®, Humira®, Stelara® • **Moderate-to-severe Hidradenitis Suppurativa (HS):** Humira® • **Moderate-to-severe plaque psoriasis:** Cimzia®, Cosentyx®, Enbrel®, Humira®, Ilumya®, Otezla®, Siliq®, Skyrizi®, Stelara®, Taltz®, Tremfya® • **Moderate-to-severe Rheumatoid Arthritis (RA)**: Actemra® (IV and SQ), Cimzia®, Enbrel®, Humira®, Kevzara®, Kineret®, Olumiant®, Orencia®, Rinvoq®, Simponi®, Simponi Aria®, Xeljanz®, Xeljanz® XR • **Moderate-to-severe Polyarticular Juvenile Idiopathic Arthritis (pJIA):** Actemra, Enbrel®, Humira®, Orencia®, Simponi Aria, Xeljanz • **Moderate-to-severe Ulcerative colitis:** Humira®, Simponi®, Stelara®, Xeljanz®, Xeljanz XR® • **Neonatal-onset multisystem inflammatory disease (NOMID):** Kineret® • **Non-infectious Uveitis**: Humira® • **Non-radiographic axial spondyloarthritis**: Cimzia®, Cosentyx®, Taltz® • **Oral ulcers associated with Behçet's Disease (BD):** Otezla® • **Psoriatic Arthritis:** Cimzia®, Cosentyx®, Enbrel®, Humira®,Orencia®,

	Otezla®, Simponi®, Simponi Aria®, Stelara®, Taltz®, Tremfya®, Xeljanz®, Xeljanz® XR • **Systemic Juvenile Idiopathic Arthritis (sJIA)**: Actemra® • **Systemic Sclerosis-Associated Interstitial Lung Disease:** Actemra®
Approval Criteria: ***Moderate-to-severe Rheumatoid arthritis*** **Actemra®** (tocilizumab) **Cimzia®** (certolizumab) **Enbrel®** (etanercept) **Humira®** (adalimumab) **Kevzara®** (sarilumab) **Orencia®** (abatacept) **Simponi®** (golimumab) **Simponi Aria®** (golimumab for infusion) ***Moderate-to-severe Polyarticular juvenile idiopathic arthritis*** **Enbrel®** (etanercept) **Humira®** (adalimumab) **Orencia®** (abatacept) **Simponi Aria** (golimumab for infusion) **Xeljanz** (tofacitinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs(*History of claims is sufficient*) b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication (*History of claims is sufficient*) 3. Appropriate dosing 4. For all anti-TNF agents other than Enbrel® and Humira®, prescriber provides clinical rationale for use of the requested agent instead of Enbrel® and Humira® 5. If the request is for Xeljanz, quantity requested is ≤2 tablets/day
Psoriatic arthritis **Cimzia®** (certolizumab) **Cosentyx®** (secukinumab) **Enbrel®** (etanercept) **Humira®** (adalimumab) **Orencia®** (abatacept) **Otezla®** (apremilast) **Simponi®** (golimumab) **Simponi Aria®** (golimumab for infusion) **Stelara®** (ustekinumab) **Taltz®** (ixekizumab) **Tremfya®** (guselkumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. For Cosentyx®, Orencia®, Otezla®, Stelara®, Taltz®, and Tremfya®, **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication (*History of claims is sufficient*) b. Contraindication to **ALL** anti-TNF agents that are FDA-approved for the requested indication 3. Appropriate dosing 4. If the request is for Otezla®, quantity requested is ≤2 tablets/day 5. For all anti-TNF agents other than Enbrel® and Humira®, prescriber provides clinical rationale for use of the requested agent instead of Enbrel® and Humira® *Notes:* • *For all agents except Otezla®, DMARD trial is not required in members with active psoriatic arthritis with axial (spine) involvement (including sacroiliitis) whose condition is not*

	sufficiently controlled with NSAIDs (*History of claims is sufficient*).
Approval Criteria: ***Ankylosing spondylitis*** **Cimzia**® (certolizumab) **Cosentyx**® (secukinumab) **Enbrel**® (etanercept) **Humira**® (adalimumab) **Simponi**® (golimumab) **Simponi Aria**® (golimumab for infusion) **Taltz**® (ixekizumab) ***Non-radiographic axial spondyloarthritis:*** **Cimzia**® (certolizumab) **Cosentyx**® (secukinumab) **Taltz**® (ixekizumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to **TWO** NSAIDs or contraindication to **ALL** NSAIDs (*History of claims is sufficient*) 3. If the request is for Cosentyx® or Taltz®, inadequate response or adverse reaction to **ONE** anti-TNF agent that is FDA-approved for the requested indication (*History of claims is sufficient*) 4. Appropriate dosing (see appendix and availability and dosage section)† 5. For all anti-TNF agents other than Enbrel® and Humira®, prescriber provides clinical rationale for use of the requested agent instead of Enbrel® and Humira® *Notes:* • *Requests for Enbrel® and Humira® in non-radiographic axial spondylarthritis may be approved if all criteria are met.*
Approval Criteria: ***Moderate-to-severe Rheumatoid arthritis*** ***Psoriatic arthritis*** ***Moderate-to-severe Ulcerative colitis*** **Xeljanz**® (tofacitinib) **Xeljanz XR**® (tofacitinib extended-release)	**<u>Moderate-to-severe Rheumatoid arthritis, Psoriatic arthritis, and Moderate-to-severe Ulcerative Colitis</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs *(History of claims is sufficient)* b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication *(History of claims is sufficient)* 3. **ONE** of the following: a. If the request is for Xeljanz®, quantity requested is ≤2 tablets/day b. If the request is for Xeljanz XR®, quantity requested is ≤1 tablet/day
Approval Criteria: ***Moderate-to-severe Rheumatoid arthritis*** **Olumiant**® (baricitinib) **Rinvoq**® (upadacitinib)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to ONE traditional DMARD or contraindication to traditional DMARDs (*History of claims is sufficient*) 3. **ONE** of the following: a. Inadequate response or adverse reaction to ONE biologic DMARD that is FDA-approved for RA (*History of claims is sufficient*) b. Contraindication to ALL biologic DMARDs FDA-approved

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	for RA 4. Inadequate response, adverse reaction or contraindication to Xeljanz® (tofacitinib) or Xeljanz XR® (tofacitinib extended-release) (*History of claims is sufficient*) 5. Quantity requested is ≤1 tablet/day
Approval Criteria: ***Moderate-to-severe plaque psoriasis*** **Cimzia®** (certolizumab) **Cosentyx®** (secukinumab) **Enbrel®** (etanercept) **Humira®** (adalimumab) **Ilumya®** (tildrakizumab-asmn) **Otezla®** (apremilast) **Siliq®** (brodalumab) **Skyrizi®** (risankizumab-rzaa) **Stelara®** (ustekinumab) **Taltz®** (ixekizumab) **Tremfya®** (guselkumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE conventional therapy** (see appendix) (*History of claims is sufficient*): a. topical agent b. phototherapy c. systemic agent b. Contraindication to **ALL conventional therapies**: a. topical agents b. phototherapy c. systemic agents c. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for plaque psoriasis (*History of claims is sufficient*) 3. Appropriate dosing 4. If the request is for Otezla®, quantity requested is ≤2 tablets/day 5. For all anti-TNF agents other than Enbrel® and Humira®, prescriber provides clinical rationale for use of the requested agent instead of Enbrel® and Humira® • *Requests for Xeljanz® may be approved for moderate-to-severe plaque psoriasis if all criteria are met*
Approval Criteria: ***Moderate-to-severe Crohn's disease*** **Cimzia®** (certolizumab) **Humira®** (adalimumab) **Stelara®** (ustekinumab)	**<u>Crohn's disease</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. If the request is for Stelara®, **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for Crohn's disease (*History of claims is sufficient*) b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for Crohn's disease 3. Appropriate dosing 4. For all anti-TNF agents other than Humira®, prescriber provides clinical rationale for use of the requested agent instead of Humira® *Notes:* • ‡ *Requests for Humira® may be approved for fistulizing Crohn's disease if all criteria are met.*
Approval Criteria: ***Moderate-to-severe Ulcerative colitis***	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. If the request is for Stelara®, **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** biologic

Humira® (adalimumab) **Simponi**® (golimumab) **Stelara**® (ustekinumab)	DMARD that is FDA-approved for Crohn's disease (*History of claims is sufficient*) b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for Crohn's disease 3. Appropriate dosing 4. For all anti-TNF agents other than Humira, prescriber provides clinical rationale for use of the requested agent instead of Humira
Approval Criteria: ***Moderate-to-severe Hidradenitis Suppurativa (Hurley Stage II or Hurley Stage III disease)*** **Humira**® (adalimumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis* 2. Appropriate dosing *Notes:* • **For mild hidradenitis suppurativa (Hurley Stage I disease), requests for Humira® (adalimumab) may be approvable if the prescriber provides inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline) (History of claims is sufficient within 6 months)*
Approval Criteria: ***Non-infectious Uveitis*** **Humira**® (adalimumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** topical or systemic glucocorticoid *(History of claims is sufficient)* b. Contraindication to **ALL** topical and systemic glucocorticoids 3. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide) *(History of claims is sufficient)* b. Contraindication to **ALL** systemic immunosuppressive therapy (e.g., methotrexate, azathioprine, mycophenolate, cyclosporine, tacrolimus, cyclophosphamide) 4. Appropriate dosing
Approval Criteria: ***Moderate-to-severe Polyarticular juvenile idiopathic arthritis*** **Actemra**® (tocilizumab)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to ONE traditional DMARD or contraindication to traditional DMARDs (*History of claims is sufficient*) b. Inadequate response, adverse reaction or contraindication to Humira® (adalimumab) *(History of claims is sufficient)* • Appropriate dosing *Please see appendix for diagnoses of uveitis and scleritis.*
Approval Criteria:	Prescriber provides documentation of **ALL** of the following:

Systemic juvenile idiopathic arthritis **Actemra**® (tocilizumab)	1. Appropriate diagnosis 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs *(History of claims is sufficient)* b. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for the requested indication *(History of claims is sufficient)* 3. Appropriate dosing *Notes:* • *Please see appendix for diagnoses of uveitis and scleritis.*
Approval Criteria: ***Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD)*** **Actemra**® (tocilizumab) (SQ only)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to **ONE** of the following or contraindication to **ALL** of the following *(History of claims is not sufficient):* a. cyclophosphamide b. mycophenolate 3. Appropriate dosing (see appendix and availability and dosage section)* *Notes:* • **Requests for more frequent or higher doses (see appendix II)*
Approval Criteria: ***Giant cell arteritis*** **Actemra**® (tocilizumab) (SQ only)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis‡ 2. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** systemic glucocorticoid* *(History of claims within last two years is sufficient)* b. Contraindication to **ALL** systemic glucocorticoids 3. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** systemic immunosuppressive therapy (e.g. methotrexate, cyclophosphamide) *(History of claims is sufficient)* b. Contraindication to **ALL** systemic immunosuppressive therapy 4. Appropriate dosing *Notes:* • **Requests for members who satisfy the criteria with the exception of the corticosteroid trial will be evaluated on a case-by-case basis as corticosteroids are not intended for long-term therapy.* • ‡*Due to the life threatening nature of the giant cell arteritis, if a request is denied, the prescriber should be contacted and informed of the additional clinical documentation that is required on the resubmission.Please see appendix for diagnoses of uveitis and scleritis.*

Approval Criteria: ***Cytokine release syndrome*** **Actemra**® (tocilizumab) (IV only)	Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Concurrent therapy with CAR T-cell therapies (request must include anticipated date of administration) 3. Appropriate dosing *Notes:* • *Due to the seriousness of cytokine release syndrome associated with CAR T-cell therapies, if a request is denied the prescriber should be contacted and informed of the additional clinical documentation that is required on the resubmission.*
Approval Criteria: ***Deficiency of Interleukin-1 Receptor Antagonist (DIRA)*** ***Neonatal-onset multisystem inflammatory disease (NOMID)*** ***Moderate-to-severe Rheumatoid arthritis*** **Kineret**® (anakinra)	**<u>Deficiency of Interleukin-1 Receptor Antagonist (DIRA)</u>**‡ Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Confirmation of diagnosis through genetic testing 3. Appropriate dosing (see availability and dosage section) **<u>Neonatal-onset multisystem inflammatory disease (NOMID)</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Appropriate dosing (see appendix and availability and dosage section)[†] **<u>Rheumatoid arthritis</u>** Prescriber provides documentation of **ALL** of the following: 1. Appropriate diagnosis 2. Inadequate response or adverse reaction to **ONE** traditional DMARD or contraindication to traditional DMARDs* (*History of claims is sufficient*) 3. **ONE** of the following: a. Inadequate response or adverse reaction to **ONE** biologic DMARD that is FDA-approved for rheumatoid arthritis (*History of claims is sufficient*) b. Contraindication to **ALL** biologic DMARDs that are FDA-approved for rheumatoid arthritis 4. Appropriate dosing *Notes:* • [†]*Requests for more frequent or higher doses (see appendix)* • *NOMID is also known as chronic infantile neurological cutaneous and articular (CINCA) syndrome.* • *Requests for cryopyrin-associated periodic syndromes (CAPS) other than NOMID/CINCA (see appendix)* • *Please see appendix for diagnosis of acute gout*
Approval Criteria:	Prescriber provides documentation of **ALL** of the following:

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Oral ulcers associated with Behçet's Disease **Otezla**® (apremilast)	1. Appropriate diagnosis 2. Appropriate dosing 3. Quantity requested is ≤2 tablets/day
Denial Criteria:	Cases that do not meet the approval criteria will be denied.
	If a request is denied and the prescriber has additional clinical documentation, a **new** prior authorization request must be submitted.
Duration of Authorization:	<u>For all agents</u> Prior authorization may be issued initially for up to **6 months** for: • Ankylosing spondylitis, DIRA, hidradenitis suppurativa, Crohn's disease, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, NOMID, non-infectious uveitis, giant cell arteritis, non-radiographic axial spondyloarthritis, oral ulcers associated with Behçet's Disease Prior authorization may be issued for up to **3 months** for: • Plaque psoriasis • Off-label indications (referenced in appendices) <u>For Actemra® for cytokine release syndrome</u> Prior authorization may be issued up to **1 month** past anticipated date of CAR T-cell administration
Recertification Criteria:	Resubmission by prescriber for any of the following FDA-approved diagnoses will infer a positive response to therapy and request can be recertified if dosing is appropriate (see appendix and availability and dosage section): • Ankylosing spondylitis, DIRA, hidradenitis suppurativa, Crohn's disease, juvenile idiopathic arthritis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, NOMID, non-infectious uveitis, giant cell arteritis, non-radiographic axial spondyloarthritis, oral ulcers associated with Behçet's Disease: Approve for **1 year** • Plaque psoriasis: Enbrel® 50 mg twice weekly (see appendix) All other agents (including Enbrel® 25 mg twice weekly or 50 mg/week)**:** Approve for **1 year** • Cytokine release syndrome: reviewed on a case by case basis **All other (off-label) indications:** • Prescriber provides documentation of positive response to therapy: Approve for up to **1 year.**

Appendix:

Stability

Requests for the following medications for an FDA-approved indication at FDA-approved dosing that document stability can be approved without documentation of failed trials with the conventional therapies for that diagnosis:

- Actemra® (tocilizumab)
- Cosentyx® (secukinumab)
- Enbrel® (etanercept)
- Humira® (adalimumab)
- Ilumya® (tildrakizumab-asmn)
- Kevzara® (sarilumab)
- Kineret® (anakinra)
- Olumiant® (baricitinib)
- Orencia® (abatacept)
- Otezla® (apremilast)
- Rinvoq® (upadacitinib)
- Siliq® (brodalumab)
- Skyrizi® (risankizumab-rzaa)
- Stelara® (ustekinumab)
- Taltz® (ixekizumab)
- Tremfya® (guselkumab)
- Xeljanz®, Xeljanz® XR (tofacitinib)

Requests for Cimzia® (certolizumab), Simponi® (golimumab), and Simponi Aria® (golimumab) in members with a documented history of hospitalization for the immune condition (at any point) that document stability can be approved.

Stability on a non-preferred anti-TNF agent [Cimzia® (certolizumab), Simponi® (golimumab), and Simponi Aria® (golimumab)], with the exception of scenarios noted above, is generally not a rationale for approval. Members will be required to meet the new criteria.

Grandfathering

Information is not applicable

Additional Information

Appendix I. Conventional Therapies for Plaque Psoriasis

Conventional Treatment Lines	Agents Used
Topical Agents	emollients, keratolytics, corticosteroids, coal tar, anthralin, calcipotriene, tazarotene, calcitriol, calcineurin inhibitors

Systemic Agents	Traditional DMARDs: methotrexate, apremilast, acitretin,
Phototherapy	ultraviolet A and topical psoralens (topical PUVA), ultraviolet A and oral psoralens (systemic PUVA), narrow band UV-B (NUVB)

Appendix II. Requests for More Frequent or Higher Doses of Injectable Biologics

Requests for more frequent or higher doses of injectable biologics may be approved if **ALL** of the following is provided:

1. Documentation of severe disease
2. **ONE** of the following:
    a. Inadequate response or adverse reaction to **ONE** other injectable biologic which is FDA-approved for the requested indication*
    b. Contraindication to **ALL** other injectable biologics which are FDA-approved for the requested indication
3. Documented partial response to FDA-approved dosing of current biologic therapy
4. Documentation of specialist consult for the requested indication

Some examples include the following:

- Humira® 80 mg SQ every other week requested for moderate-severe plaque psoriasis
- Humira® 40 mg SQ every week requested for moderate-severe plaque psoriasis

*A trial with another injectable biologic may be bypassed if:

- The requested regimen is Enbrel® (etanercept) or Humira® (adalimumab) for any immune condition and the request documents low drug levels and no/low antibodies

Prior authorization may be issued for up to **3 months.** Upon recertification, if the prescriber provides documentation of positive response to therapy - Approve for up to **1 year.**

Appendix III. Kineret®, and Stelara® in Hidradenitis Suppurativa (HS)

Hidradenitis suppurativa (HS) is a chronic follicular occlusive disease involving the intertriginous skin of the axillary, groin, perianal, perineal and inframammary regions. The choice of therapy is based upon the site/severity/stage of the disease, the outcome of previous treatments, and patient preferences.

The North American guidelines provide the following recommendations for biologics:

- Adalimumab at the approved HS dosing is recommended in patients with moderate-to-severe HS
- Infliximab is recommended for moderate-to-severe disease; however, dose-ranging studies are needed to determine the optimal dosage for management
- Anakinra 100 mg daily may be effective for HS; however, dose-ranging studies are needed to determine the optimal dosage for management
- Ustekinumab 45 to 90 mg every 12 weeks may be effective; however, dose-ranging studies are needed to determine the optimal dosage for management
- Limited evidence does not support etanercept for management of HS

Requests for Kineret® (anakinra), or Stelara® (ustekinumab) in HS may be approved if the prescriber provides documentation of **ALL** of the following:

1. Diagnosis of moderate to severe hidradenitis suppurativa (Hurley Stage II and Hurley Stage III disease)

2. Inadequate response or adverse reaction to ONE oral antibiotic or contraindication to ALL oral antibiotics (e.g. rifampin, clindamycin, tetracycline, doxycycline, minocycline) *(History of claims is sufficient within 6 months)*
3. For Kineret® (anakinra), inadequate response, adverse reaction or contraindication to Humira® (adalimumab) *(History of claims is sufficient)*
4. For Stelara® (ustekinumab), inadequate response, adverse reaction or contraindication to Humira® (adalimumab) *(History of claims is sufficient)*
5. Appropriate dosing
    a. For Kineret® (anakinra): 100 mg daily
    b. For Stelara® (ustekinumab): 45 to 90 mg every 12 weeks

All other requests will be evaluated on a case-by-case basis

Appendix IV. Uveitis and Scleritis

TNF inhibitors have been shown to decrease inflammation associated with a number of rheumatologic conditions. According to the expert panel recommendations for the use of anti-TNF agents in ocular inflammatory disorders, infliximab and adalimumab can be considered as potential second-line immunomodulatory agents for the treatment of severe ocular inflammatory conditions including posterior uveitis, panuveitis, severe uveitis, and scleritis in patients requiring immunomodulation in patients who have failed or who are not candidates for traditional immunomodulation. Infliximab and adalimumab can be considered in these patients in preference to etanercept, which seems to be associated with lower rates of treatment success.

- Requests for and Humira® (adalimumab) in scleritis may be approved if the prescriber provides documentation of inadequate response, adverse reaction or contraindication to **ALL** of the following (History of claims is sufficient):
    1. Opthalmic (topical) or oral glucocorticoids
    2. Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)

IL-6 has been identified as of the cytokines overexpressed in patients with uveitis. Actemra® (tocilizumab) has been used in patients previously treated with remittive medications, such as anti-TNF agents (e.g., adalimumab). Patients received Actemra® (tocilizumab) 8 mg/kg every four weeks and after eight months of follow-up, 50% had improvement in visual acuity and 25% of affected eyes remained stable.

Requests for Actemra® (tocilizumab) in uveitis and scleritis may be approvable if the prescriber provides appropriate dosing and documentation of inadequate response, adverse reaction or contraindication to **ALL** of the following (History of claims is sufficient):

- Topical, oral or injectable glucocorticoids
- Oral or injectable immunosuppressive therapy (e.g., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus and cyclophosphamide)
- Rituxan® (rituximab) [if scleritis]

Prior Authorization may be issued for **3 months**. Recertifications may be approved for 1 year with documentation of positive response to therapy.

All other requests will be evaluated on a case-by-case basis.

If a request was approved prior to the appendices item, the request can be recertified without this additional documentation.

Appendix V. Xeljanz®, Xeljanz® XR and Otezla® Concurrent to Biologic DMARDs

Xeljanz® (tofacitinib) and Xeljanz XR® (tofacitinib) should not be used in combination with biologic DMARDs or with potent immunosuppressants such as azathioprine, tacrolimus, or cyclosporine.

- Given the warning/precaution regarding Xeljanz® (tofacitinib) and Xeljanz XR® (tofacitinib) with biologic DMARDs, requests for concurrent therapy will be evaluated on a case-by-case basis.

The 2020 AAD-NPF guidelines note adalimumab, etanercept, and ustekinumab may be combined with apremilast to augment for efficacy. Requests for concomitant use of Otezla® (apremilast) with one of the above injectable biologics for plaque psoriasis may be approved if there is documented partial response to the current therapy

Appendix VI. Cryopyrin-Associated Periodic Syndromes (CAPS)

While Kineret® (anakinra) is only FDA-approved for NOMID/CINCA, it has also been used off-label in the treatment of other types of CAPS, including familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS). In small clinical studies, Kineret® (anakinra) has prevented and alleviated symptoms and substantially reduced levels of inflammation. In one open-label study, a complete and persistent control of inflammation was observed with no further progression of the disease in all 14 patients treated with Kineret® (anakinra). The drug was given subcutaneously at the starting dosage of 1 mg/kg/day (maximum, 100 mg).

Requests for Kineret® (anakinra) in familial cold autoinflammatory syndrome (FCAS) and Muckle-Wells syndrome (MWS) may be approvable if the prescriber provides documentation of appropriate dosing.

Prior Authorization may be issued for **3 months**. Recertifications may be approved for 1 year with documentation of positive response to therapy.

Appendix VII. Acute Gout[5]

IL-1 inhibition may be beneficial in gout patients with frequent flares in whom all other available treatments have failed (NSAIDs, colchicine and glucocorticoids) or in whom rebound flares occur even when glucocorticoid treatment is used. In open-label pilot studies, Kineret® (anakinra) 100 mg was given subcutaneously daily until symptoms of acute gouty arthritis improved. According to patient assessments, pain improved within 24 to 48 hours with ranges of 50 to 100% improvement. After clinical assessment of joints, 90% of patients had complete resolution by the third day of treatment.

Requests for Kineret® (anakinra) in acute gout may be approvable if the prescriber provides documentation of inadequate response, adverse reaction or contraindication to **ALL** of the following (History of claims is sufficient):

- NSAIDs
- Colchicine
- Oral or intraarticular glucocorticoids

Prior Authorization may be issued for **3 months**. Recertifications may be approved for 1 year with documentation of positive response to therapy.

All other requests will be evaluated on a case-by-case basis.

If a request for Kineret® (anakinra) in acute gout was approved prior to the appendices item, the request can be recertified without this additional documentation.

Applicable Coding:

Code	Medication
J3262	Actemra® (tocilizumab injection)
J0717	Cimzia® (certolizumab pegol)
J1438	Enbrel ® (entanercept injection)
J0135	Humira® (adalimumab injection)
J0129	Orencia (abatacept injection)
J1602	Simponi Aria (golimumab injection for IV use)
J3358	Stelara (ustekinumab injection)

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date**	**Approved by**
12/1/2020	Created a single policy for all target immunomodulators to align with the MA PDL.	1/1/2021	P&T Committee
1/15/2021	Updated policy to reflect PUF changes as of 11/23/20	1/15/2021	P&T Committee
2/8/2021	Updated policy to reflect state update of preferred product designation for Stelara	2/8/2021	P&T Committee
4/22/2021	Added coding section for Buy & Bill functionality	4/22/2021	P&T Committee
5/13/2021	Updated policy to reflect 4/9/21 MH update of language changes	7/1/2021	P&T Committee
7/23/2021	Updated policy to reflect 6/10/21 changes from MH: Guideline updated to reflect new PA criteria for Actemra based on new indication for systemic sclerosis	9/1/2021	P&T Committee

Policy Revisions History			
	associated with interstitial lung disease.		

Next Review Date

2021

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.