curative

Biologic Immunomodulators Prior Authorization

Drug(s) Applied:	**Adalimumab-fkjp**, **Adalimumab-adbm** **Tyenne** (tocilizumab-aazg) **Yesintek** (ustekinumab-kfce) **Imuldosa** (ustekinumab-srlf)

Criteria:
Drug(s) Applied will be approved when the requested medication is being used for a compendia-supported indication and all of the following criteria are met:

I. Initial Therapy Criteria

A. Rheumatoid Arthritis (RA) as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented testing (i.e., elevated ESR and/or CRP, positive for RF and/or anti-CCP, abnormal findings on imaging, baselines of CDAI, RAPID3, DAS28 scores) validates RA diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

B. Psoriatic Arthritis (PsA) as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., maximally tolerated methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **or**
2. PsA is classified as severe with at least **one** of the following features:
   a) Erosive disease
   b) Elevated markers of inflammation (e.g., ESR, CRP)

c) Long-term damage that interferes with function (i.e., joint deformities)
d) Rapidly progressive **and**

3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

C. **Moderate to Severe Plaque Psoriasis (PS)** as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., acitretin, anthralin, calcipotriene, calcitriol, coal tar products, cyclosporine, methotrexate, pimecrolimus, PUVA [phototherapy], tacrolimus, tazarotene, topical corticosteroids) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. PS is classified as severe with at least **ONE** of the following features:
   a) Greater than 10% body surface area involvement **or**
   b) Plaques occur on select locations [i.e., hands, feet, scalp, face, or genitals] **or**
   c) Symptoms include intractable pruritus **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 12 months

D. Moderate to Severe Hidradenitis Suppurativa (HS) as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., oral tetracyclines; oral contraceptives; clindamycin +/- rifampin +/- moxifloxacin; +/-metronidazole; oral isotretinoin or acitretin) or similarly-indicated biologic

immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**

2. Documented baseline characteristics of HS (i.e., hurley stage score, boils present, nodules, lesion number, frequency, locations) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 12 months

E. Moderately to Severely Active Crohn's Disease (CD) as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., 6-mercaptopurine, azathioprine, corticosteroids [e.g., prednisone, budesonide EC capsule], methotrexate) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented baseline characteristics of CD (i.e., CDAI score, abdominal pain or cramping, chronic diarrhea, positive ESR and/or fecal calprotectin, abnormal findings on endoscopy) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., gastroenterology)

Approval Duration: 12 months

F. Moderately to Severely Active Ulcerative Colitis (UC) as indicated by chart notes within past 6 months

1. Trial and failure of at least 3 months of a conventional therapy (i.e., 6-mercaptopurine, azathioprine, balsalazide, corticosteroids, cyclosporine, mesalamine, sulfasalazine) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**

2. Documented baseline characteristics of UC (i.e., UCEIS score, abdominal pain or cramping, chronic diarrhea, positive CRP, and/or fecal calprotectin, abnormal findings on sigmoidoscopy, corticosteroid-dependence) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., gastroenterology)

Approval Duration for TX Fully Insured members: 12 months
Approval Duration for all other members: 12 weeks

G. Uveitis (non-infectious intermediate uveitis, posterior uveitis, or panuveitis) as indicated by chart notes within past 6 months

1. Diagnosis of Uveitis & **BOTH** of the following applies:
   a) Trial and failure of at least 2 weeks of oral corticosteroid(s) unless contraindicated or clinical adverse effects are reported or trial and failure of periocular or intravitreal corticosteroid injections unless contraindicated or clinical adverse effects are reported **and**
   b) Trial and failure of at least 3 months of a conventional therapy (i.e., azathioprine, mycophenolate, methotrexate, cyclosporine, tacrolimus) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented baseline characteristics of uveitis (i.e., abnormal findings on ophthalmic exam, eye pain, photophobia, eye redness, floaters in vision, poor /decreased visual acuity, inflammation noted during slit lamp testing) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., ophthalmology)

Approval Duration: 12 months

H. Active Ankylosing Spondylitis (AS) as indicated by chart notes within past 6 months

1. Request is for adalimumab **and**
2. Trial and failure of at least 4 weeks of NSAIDs or a similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
3. Documented baseline characteristics of AS (i.e., lower back pain present for ≥ 3 months, poor functional status, abnormal findings on imaging, elevated CRP) validates diagnosis **and**
4. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
5. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

I. **Non-Radiographic Axial Spondyloarthritis (nr-axSpA)** as indicated by chart notes within past 6 months
   1. Trial and failure of at least 4 weeks of NSAID therapy (e.g., ibuprofen, celecoxib) or a similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
   2. Documented baseline characteristics of nr-axSpA (i.e., lower back pain present for ≥ 3 months, poor functional status, abnormal findings on imaging, elevated CRP) validates diagnosis **and**
   3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
   4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

   Approval Duration: 12 months

J. **Moderately To Severely Active Polyarticular Juvenile Idiopathic Arthritis (PJIA)** as indicated by chart notes within the past 6 months
   1. Trial and failure of at least 4 weeks of a conventional therapy (i.e., methotrexate, leflunomide) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**

2. Documented baseline characteristics of PJIA (i.e., arthritis in ≥ 5 joints during the first 6 months of illness, decreased mobility, positive RF, ANA, and/or CRP) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

K. Systemic Juvenile Idiopathic Arthritis (SJIA) as indicated by chart notes within past 6 months

1. Trial and failure of at least 1 month of NSAID (e.g., ibuprofen, celecoxib) therapy or at least 3 months of a conventional therapy (i.e., methotrexate, leflunomide, systemic corticosteroids) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented baseline characteristics of SJIA (i.e., arthralgia, abnormal findings on imaging, fifteen days or more of fever accompanied by rash, lymphadenopathy, hepatosplenomegaly, or serositis) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

L. Systemic sclerosis associated interstitial lung disease (SSc-ILD) as indicated by chart notes within past 6 months

1. Trial and failure of a conventional therapy for at least 3 months (i.e., mycophenolate mofetil, cyclophosphamide, azathioprine) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented baseline characteristics of SSc-ILD (i.e., exertional shortness of breath, cough, abnormal pulmonary function tests, positive ANA, abnormal

findings on high-resolution computed tomography (HRCT) or chest radiography) validates diagnosis **and**

3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., pulmonology, rheumatology)

Approval Duration: 12 months

M. Giant Cell Arteritis (GCA) as indicated by chart notes within past 6 months

1. Trial and failure of at least 7-10 days of a systemic corticosteroid (e.g., prednisone, methylprednisolone) or similarly-indicated biologic immunomodulator agent, unless contraindicated or clinical adverse effects are reported **and**
2. Documented baseline characteristics of GCA (i.e., medium-large sized superficial artery noted, constitutional symptoms, newly present headaches that frequently occur in temporal area, visual disturbances, abnormal ultrasound arterial findings) validates diagnosis **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

II. Continued Therapy Criteria

A. Rheumatoid Arthritis (RA) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improved functional status, decreased symptoms severity, lower than baseline scores of CDAI,

RAPID3, DAS28) **and**

3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

B. Psoriatic Arthritis (PsA) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improved functional status, decreased symptom severity, reduced psoriatic symptoms, improvement in inflammatory markers from baseline) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

C. **Moderate to Severe Plaque Psoriasis (PS)** as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., decreased symptom severity and/or % body surface area involvement from baseline) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full

documentation required]) **and**

4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 12 months

D. Moderate to Severe Hidradenitis Suppurativa (HS) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improved hurley stage score, decreased lesion number, frequency, locations) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 12 months

E. Moderately to Severely Active Crohn's Disease (CD) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improved CDAI score, decreased abdominal pain or cramping, lessened diarrhea severity and/or frequency, decreased CRP and/or fecal calprotectin) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., gastroenterology)

Approval Duration: 12 months

F. **Moderately to Severely Active Ulcerative Colitis (UC)** as indicated by chart notes within past 12 months
   1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
   2. Patient has documented clinical benefit with agent (i.e., improved UCEIS score, decreased abdominal pain or cramping, lessened diarrhea severity and/or frequency, decreased CRP and/or FC) **and**
   3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
   4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., gastroenterology)

   Approval Duration: 12 months

G. **Uveitis (non-infectious intermediate uveitis, posterior uveitis, or panuveitis)** as indicated by chart notes within past 12 months
   1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
   2. Patient has documented clinical benefit with agent (i.e., decreased eye pain, decreased photophobia, decreased eye redness, decreased floaters in vision, improved visual acuity, improvement in inflammation noted during slit lamp testing) **and**
   3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
   4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., ophthalmology)

   Approval Duration: 12 months

H. **Active Ankylosing Spondylitis (AS)** as indicated by chart notes within past 12 months
   1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical

benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., decreased severity of lower back pain, increased functional status, decreased CRP) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

I. **Non-Radiographic Axial Spondyloarthritis (nr-axSpA)** as indicated by chart notes within past 12 months
1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., decreased severity of lower back pain, increased functional status, decreased CRP) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

J. **Moderately To Severely Active Polyarticular Juvenile Idiopathic Arthritis (PJIA)** as indicated by chart notes within past 12 months
1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., decreased number of joints with arthritis, improved mobility) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has

provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**

4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

K. Systemic Juvenile Idiopathic Arthritis (SJIA) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., decreased arthralgia, improvement of fever accompanied by rash, lymphadenopathy, hepatosplenomegaly, or serositis) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

L. Systemic sclerosis associated interstitial lung disease (SSc-ILD) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improvement in breathing, decreased severity/frequency of cough) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., pulmonology, rheumatology)

Approval Duration: 12 months

M. Giant Cell Arteritis (GCA) as indicated by chart notes within past 12 months

1. Patient has met initial criteria for the requested agent **or** chart notes supplied from the past year indicate patient has been on requested drug with clinical benefit and attest the requested drug is a continuation of therapy **and**
2. Patient has documented clinical benefit with agent (i.e., improvement in constitutional symptoms, lessened frequency/severity of headaches, decreased visual disturbances) **and**
3. Chart notes and/or prescriber do not provide documentation that patient will be using the requested agent in combination with another immunomodulatory agent (e.g., TNF inhibitors, JAK inhibitors, IL inhibitors) or prescriber has provided information in support of the specific combination therapy requested (e.g., published peer reviewed clinical trials, national guidelines [full documentation required]) **and**
4. Prescriber is a specialist, or has consulted with a specialist, in the area of the patient's diagnosis (e.g., rheumatology)

Approval Duration: 12 months

Policy Owned by: Curative PBM team