MEDICATION POLICY:

Targeted Immune Modulators (TIM)

for Dermatologic Diseases, Rheumatologic Diseases, and Inflammatory Bowel Diseases

Generic Name: N/A

Preferred: Adalimumab-aacf (unbranded), Adalimumab-aaty (unbranded), Cibinqo (abrocitinib), Cosentyx (secukinumab), Dupixent (dupilumab), Humira (adalimumab), Idacio (adalimumab-aacf), Rinvoq/Rinvoq LQ (upadacitinib), Skyrizi (risankizumab), Stelara (ustekinumab), Tremfya (guselkumab), Xeljanz/Xeljanz XR (tofacitinib), Yuflyma (adalimumab-aaty)

Non-preferred: Actemra (tocilizumab), Adalimumab-adaz (unbranded), Adalimumab-adbm (unbranded), Adalimumab-fkjp (unbranded), Adbry (tralokinumab-ldrm), Avsola (infliximab-axxq), Bimzelx (bimekizumab-bkzx), Cimzia (certolizumab pegol), Entyvio (vedolizumab), Hadlima (adalimumab-bwwd), Ilaris (canakinumab), Ilumya (tildrakizumab-asmn), Inflectra (infliximab-dyyb), Kevzara (sarilumab), Kineret (anakinra), Olumiant (baricitinib), Omvoh (mirzikizumab), Opzelura (ruxolitinib), Orencia (abatacept), Otezla (apremilast), Remicade (infliximab), Renflexis (infliximab-abda), Riabni (rituximab-arrx), Rituxan (rituximab), Ruxience (rituximab-pvvr), Siliq (brodalumab), Spevigo (spesolimab-sbzo), Taltz (ixekizumab), Tofidence (tocilizumab-bavi), Truxima (rituximab-abbs), Tyenne (tocilizumab-aazg), Tysabri (natalizumab), Velsipity (etrasimod), Yusimry (adalimumab-aqvh), Zeposia (ozanimod), Zymfentra (infliximab-dyyb)

VSI Excluded Drugs: Enbrel (etanercept), Simponi/Simponi Aria (golimumab), Sotyktu (deucravacitinib)

Formulary Shield Drugs: Abrilada (adalimumab-afbz), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Humira (adalimumab, Co-branded Cordavis), Hulio (adalimumab-fkjp), Hyrimoz (adalimumab-adaz),

Date of Origin: 5/3/2022

Date Last Reviewed / Revised: 8/26/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met.)

I. Documented diagnosis of one of the following conditions A through O AND must meet ALL criteria listed under applicable diagnosis.

A. Atopic dermatitis (AD)

1. Mild to moderate disease

a. Documentation that the patient has Body Surface Area (BSA) involvement of 3% to 20%.

b. Documented treatment failure or contraindication to two topical corticosteroids as appropriate for disease severity i or ii:

i. Mild disease: low or lower-mid potency topical corticosteroids (eg, betamethasone valerate 0.1% cream or lotion, desonide 0.05% cream or ointment, or hydrocortisone 0.1% cream, etc).

ii. Moderate disease: medium or high potency topical corticosteroids (eg, fluocinolone 0.025% ointment, triamcinolone 0.1% cream or ointment, betamethasone dipropionate 0.05% cream, etc).

c. Documented treatment failure or contraindication to one topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus).

d. The request is for Opzelura.

2. Moderate to severe disease

a. Documentation that the patient has Body Surface Area (BSA) involvement of at least 10% OR that the atopic dermatitis is impairing the patient's activities of daily living (ADLs).

b. Documented treatment failure or contraindication to one high or very high potency topical corticosteroids (eg, betamethasone dipropionate augmented 0.05% cream or ointment, triamcinolone acetonide 0.5% cream or ointment, etc) for adults or one medium potency topical corticosteroid for pediatric patients age 2 and under.

c. Documented treatment failure or contraindication to one topical calcineurin inhibitor (eg, pimecrolimus, tacrolimus).

d. If the request is for a JAK inhibitor FDA-approved for atopic dermatitis, there must documentation moderate-severe atopic dermatitis is not adequately controlled with other systemic drug products, including biologics, or when those therapies are inadvisable.

3. Treatment must be prescribed by or in consultation with a dermatologist, allergist, or immunologist.

B. Active ankylosing spondylitis (AS) or non-radiographic axial spondyloarthritis (nr-axSpA)

1. If the request is for a Janus Kinase (JAK) inhibitor, there must be documented treatment failure or contraindication to a tumor necrosis factor (TNF) inhibitor.

2. Treatment must be prescribed by or in consultation with a rheumatologist.

C. Behcet's Disease

1. Documentation of recurrent oral ulcers caused by Behcet's disease

2. Documentation of recurrence despite the use of oral, topical corticosteroids.

3. Documented treatment failure to one or contraindication to all systemic non-biologic agent(s) (eg, colchicine, azathioprine, etc).

4. Treatment must be prescribed by or in consultation with a rheumatologist or dermatologist.

5. Request is for Otezla.

D. Moderately to severely active Crohn's disease (CD)

1. Patient meets disease criteria a OR b:
    a. Documentation of at least one of the following:
        i. Deep ulceration
        ii. Extensive anatomical involvement
        iii. Fistula and/or perianal abscess
        iv. Prior hospitalization due to Crohn's disease
        v. Penetrating and/or stricturing behavior
        vi. Prior surgical resection
    b. Treatment when at least one of criteria i through iii is met:
        i. Documented treatment failure or contraindication to a trial of corticosteroids (eg, oral budesonide 9 mg daily, rectal budesonide, or oral prednisone 40 mg to 60 mg daily) for a duration of at least 7 days.
        ii. Documentation that the patient is unable to taper corticosteroids without disease worsening.
        iii. Documented treatment failure after a trial of conventional therapy (eg, azathioprine, balsalazide, mercaptopurine, mesalamine, methotrexate, sulfasalazine, etc) for a duration of at least 8 weeks.
2. If the request is for Tysabri or a JAK inhibitor, there must be documented treatment failure or contraindication to a TNF inhibitor.
3. Treatment must be prescribed by or in consultation with a gastroenterologist.

E. Generalized pustular psoriasis (GPP)
1. Documentation of all of the following:
    a. Presence of primary, sterile, macroscopically visible pustules on non-acral skin
    b. Pustulation is not restricted to psoriatic plaques
    c. Biopsy confirming psoriasiform changes, neutrophilic subcorneal pustules, and Kogoj's spongiform pustules
2. Treatment of active GPP flares
    a. Documentation of all of the following:
        i. Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of at least 3
        ii. Presence of fresh pustules (new appearance or worsening of pustules)
        iii. GPPPGA pustulation sub-score of at least 2
        iv. At least 5% of body surface area covered with erythema and the presence of pustules

b. Patient is not experiencing a life-threatening flare and is not receiving intensive care

c. Patient has not already received more than two infusions of Spevigo for a single flare

3. Treatment of stable GPP

a. Documentation of all of the following;

i. Patient is not currently experiencing a GPP flare

ii. Patient has a GPPPGA total score of 0 or 1

iii. History of at least two GPP flares of moderate-to-severe intensity

iv. Documented treatment failure with one or contraindications to all treatments for GPP (ie, acitretin, methotrexate, cyclosporine, tumor necrosis factor inhibitors, other biologics)

4. Minimum age requirement: 12 years

5. Minimum weight requirement: 40 kg

6. Prescribed by or in consultations with a dermatologist

F. Moderate to severe hidradenitis suppurativa (HS)

1. Documentation of Hurley stage II or III

2. Documented treatment failure to one or contraindication to all of the following oral antibiotic regimen(s) at maximally indicated doses for a duration of at least 8 weeks:

a. Tetracyclines (eg, doxycycline, minocycline, tetracycline)

b. Combination of clindamycin with rifampin

c. Combination of metronidazole, moxifloxacin, and rifampin

2. Treatment must be prescribed by or in consultation with a dermatologist.

G. Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)

1. Documented treatment failure to one or contraindication to all conventional DMARD(s) (eg, leflunomide, methotrexate, sulfasalazine, etc).

2. If the request is for a JAK inhibitor, there must be documented treatment failure or contraindication to a TNF inhibitor.

3. Treatment must be prescribed by or in consultation with a rheumatologist.

H. Polymyalgia rheumatica (PMR)

1. Documentation of either a or b:

a. Inadequate response to systemic corticosteroids.

b. Unable to taper corticosteroids without disease worsening.

2. The request is for Kevzara.

I. Prurigo nodularis (PN)

1. Documented history of chronic, severe pruritus and meets criteria a and b:
    a. Worst Itch Numeric Rating Scale score >7
    b. Documentation of ≥20 nodular lesions in total on both legs and/or both arms and/or trunk
2. Documented treatment failure or contraindication to at least one high or very high potency topical corticosteroids.
3. Documented treatment failure or contraindication to one or contraindication to all of the following: gabapentinoids, serotonin and norepinephrine reuptake inhibitors (SNRI), selective serotonin reuptake inhibitors (SSRI), and tricyclic antidepressants (TCA).
4. Documented treatment failure to one or contraindication to all conventional therapies (ie, phototherapy, azathioprine, cyclosporine, methotrexate, mycophenolate mofetil).
5. Treatment must be prescribed by or in consultation with a dermatologist.

J. Moderate to severe chronic plaque psoriasis (PsO)

1. Documented treatment failure or contraindication to phototherapy or photochemotherapy.
2. Documented treatment failure to one or contraindication to all conventional systemic immunosuppressant(s) (eg, acitretin, cyclosporine, methotrexate, etc).
3. Treatment must be prescribed by or in consultation with a dermatologist or a rheumatologist.

K. Generalized pustular psoriasis (GPP)

1. Documentation of at least two GPP flares of moderate-to-severe intensity
2. Documented Generalized Pustular Psoriasis Physician Global Assessment (GPPPGA) total score of 0 or 1 at screening and randomization.
3. Documented treatment failure on concomitant treatment for GPP (ie, retinoids, methotrexate, cyclosporin)or a history of flaring upon dose reduction or discontinuation of these concomitant medications.

L. Active psoriatic arthritis (PsA)

1. Patient meets disease criteria a OR b below:
    a. Patient has active axial disease.
    b. Patient has moderate to severe PsA and meets criteria i and ii:

i. Documentation of at least 1 symptom(s) from either severe psoriatic arthritis or severe psoriasis. See Appendix Figure 1.

ii. Documented treatment failure to one or contraindication to all conventional systemic immunosuppressant(s) (eg, cyclosporine, leflunomide, methotrexate, sulfasalazine, etc).

2. If the request is for a JAK inhibitor, there must be documented treatment failure or contraindication to a TNF inhibitor.
3. Treatment must be prescribed by or in consultation with a rheumatologist or dermatologist.

M. Moderately to severely active rheumatoid arthritis (RA)

1. Documented treatment failure to one or contraindication to all conventional immunosuppressant(s) (eg, azathioprine, hydroxychloroquine, leflunomide, methotrexate, sulfasalazine, etc).
2. If the request is for a JAK inhibitor or rituximab, there must be documented treatment failure or contraindication to a TNF inhibitor.
3. Treatment must be prescribed by or in consultation with a rheumatologist.

N. Moderately to severely active ulcerative colitis (UC)

1. Patient meets at least one of the treatment criteria a through c:
   a. Documented treatment failure or contraindication to a course of corticosteroids (eg, oral budesonide 9 mg daily, rectal budesonide, or oral prednisone 40 to 60 mg daily) for a duration of at least 7 days.
   b. Documentation that the patient is unable to taper corticosteroids without disease worsening.
   c. Documented treatment failure after a trial of conventional therapy (eg, azathioprine, balsalazide, mercaptopurine, mesalamine, methotrexate, sulfasalazine, etc) for a duration of at least 8 weeks.
2. If the request is for a JAK inhibitor, there must be documented treatment failure or contraindication to a TNF inhibitor.
3. Treatment must be prescribed by or in consultation with a gastroenterologist.

O. Non-infectious uveitis (intermediate, posterior, or panuveitis)

1. Documented treatment failure or contraindication to corticosteroids (ophthalmic or systemic).
2. Documented treatment failure to one or contraindication to all noncorticosteroid systemic immunosuppressant(s) (eg, azathioprine, cyclosporine, methotrexate, mycophenolate, etc).
3. Treatment must be prescribed by or in consultation with an ophthalmologist.

4. The request is for Humira or an adalimumab biosimilar.

II. Absence of active serious infection or sepsis.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines. Refer to Table 1 for medication-specific criteria.

IV. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection prior to initiation of therapy. Exceptions include Adbry, Dupixent, Opzelura, Otezla, Rituxan (and biosimilars), Tysabri, Velsipity, Zeposia, and Zoryve.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- Coadministration with another TIM.
- Treatment of alopecia areata.
- Treatment of vitiligo.
- Medication-specific exclusion criteria as listed in Table 1.

OTHER CRITERIA

Table 1. Select FDA indications and quantity limits for TIM. Please see alternative medication policies for FDA indications not listed below.

BIOLOGICS: INJECTABLE AND INFUSION AGENTS
CD20-directed cytolytic antibody

Rituxan(rituximab) and biosimilars
Riabni (rituximab-arrx), Ruxience (rituximab-pvvr), Truxima (rituximab-abbs)
• Indications:
  • RA in combination with methotrexate, Age ≥ 18 years
• Quantity limits:
  • Two 1,000 mg intravenous infusions separated by 2 weeks (one course) every 24 weeks
• Other:
  • Documented treatment failure with at least one TNF inhibitor.
  • Rituxan Hycela is indicated for malignant conditions only.
• Medical benefit for IV infusion

Interleukin 1 (IL-1) inhibitors

Ilaris (canakinumab)
• Indications:
  • SJIA, Still's disease, Age ≥ 2 years
  • Gout, Age ≥ 18 years

- Quantity limits:
  - SJIA, Still's disease: 2 vials per 28 days
  - Gout: 1 vial per 90 days

Kineret (anakinra)
- Indications:
  - RA, Age ≥ 18 years
- Quantity limits:
  - 28 syringes per 28 days

Interleukin 6 (IL-6) inhibitors

Actemra (tocilizumab) and biosimilars
Tofidence (tocilizumab-bavi), Tyenne (tocilizumab-aazg)
- Indications:
  - PJIA, SJIA, Age ≥ 2 years
  - GCA, RA, Age ≥ 18 years
- Quantity limits:
  - PJIA: 2 syringes or autoinjectors every 28 days
  - SJIA: 4 syringes or autoinjectors every 28 days
  - RA: 4 syringes or autoinjectors every 28 days

Kevzara (sarilumab)
- Indications:
  - PMR, RA, Age ≥ 18 years
- Quantity limits:
  - 2 syringes or pens every 28 days

Interleukin 12/Interleukin 23 (IL-12/IL-23) inhibitors

Stelara (ustekinumab)
- Indications:
  - CD, UC, Age ≥ 18 years
  - PsO, PsA Age ≥ 6 years
- Quantity limits:
  - PsO, PsA:
    - Adults ≤ 100 kg: One 45 mg syringe or vial for the first 28 days, then one 45 mg syringe or vial every 12 weeks
    - Adults > 100 kg: One 90 mg syringe for the first 28 days, then one 90 mg syringe every 12 weeks
    - Pediatrics < 60 kg: 0.75 mg/kg
    - Pediatrics 60 kg to 100 kg: One 45 mg syringe or vial for the first 28 days, then one 45 mg syringe or vial every 12 weeks
    - Pediatrics > 100 kg: One 90 mg syringe for the first 28 days, then one 90 mg syringe every 12 weeks
  - Concurrent PsA and PsO for adults and pediatrics > 100 kg: One 90 mg syringe for the first 28 days, then one 90 mg syringe every 12 weeks
  - CD and UC:
    - Single intravenous infusion induction dose:

- ≤ 55 kg: 260 mg (two 130 mg vials)
- 55.1 kg to 85 kg: 390 mg (three 130 mg vials)
- > 85 kg: 520 mg (four 130 mg vials)
- Maintenance: One 90 mg syringe at week 8, then every 8 weeks

- Medical benefit for IV infusion loading dose for CD and UC

Interleukin 13 (IL-13) inhibitors

Adbry (tralokinumab-ldrm)
- Indications:
  - AD, Age ≥ 12 years
- Quantity limits:
  - Adults: 6 syringes for the first 28 days, then 4 syringes every 28 days
  - Age 12-17: 3 syringes for the first 28 days, then 2 syringes every 28 days.

Dupixent (dupilumab)
- Indications:
  - AD, Age ≥ 6 months
  - PN, Age ≥ 18 years
- Quantity limits:
  - Adult AD: Two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days
  - Pediatric AD, patients 6 months to 5 years:
    - 5 to < 15 kg: One 200 mg syringe or pen every 28 days
    - 15 to < 30 kg: One 300 mg syringe or pen every 28 days
  - Pediatric AD, patients 6 to 17 years:
    - 15 to < 30 kg: Two 300 mg syringes or pens for the first 28 days, then one 300 mg syringe or pen every 28 days
    - 30 to < 60 kg: two 200 mg syringes or pens for the first 14 days, then two 200 mg syringes or pens every 28 days
    - ≥ 60 kg: Two 300 mg syringes or pens for the first 14 days, then two 300 mg syringes or pens every 28 days
  - PN: Two syringes or pens for the first 14 days, then 2 syringes or pens every 28 days

Interleukin 17 (IL-17) inhibitors

Bimzelx (bimekizumab-bkzx)
- Indications
  - PsO, Age ≥ 18 years
- Quantity Limits
  - Two syringes or pen per 28 days for the first 5 months, then 2 syringes or pens every 56 days.
- Required documentation
  - Baseline LFT, bilirubin, alkaline phosphatase

Cosentyx (secukinumab)
- Indications:
  - AS, nr-axSpA, HS, Age ≥ 18 years
  - Active ERA, Age ≥ 4 years
  - PsO, Age ≥ 6 years

- PsA, Age ≥ 2 years
- Quantity limits:
  - Adult active ERA, patients ≥ 50 kg: Four 150 mg single-dose syringes for the first 28 days, then one 150 mg syringe or pen every 28 days
  - AS, nr-axSpA, PsA: Four 150 mg syringes or pens for the first 28 days, then one 150 mg syringe or pens every 28 days
  - PsO or (PsA with PsO): Eight 150 mg syringes or pens for the first 28 days, then two 150 mg syringes or pens every 28 days
  - Pediatric active ERA, PsO, PsA
    - 15 kg to < 50 kg: Four 75 mg syringes for the first 28 days, then one 75 mg syringe or pen every 28 days
    - ≥ 50 kg: Four 150 mg syringes for the first 28 days, then one 150 mg syringe or pen every 28 days
  - HS: Four 300 mg syringes or pens for the first 28 days, then one 300 mg syringe or pen every 4 weeks

Taltz (ixekizumab)
- Indications:
  - AS, nr-axSpA, PsA, Age ≥ 18 years
  - PsO, Age ≥ 6 years
- Quantity Limits:
  - AS and PsA: 2 syringes or pens for the first 28 days, then 1 syringe or pen every 28 days
  - nr-axSpA: 1 syringe or pen every 28 days
  - PsO: 3 syringes or pens for the first 28 days, then 2 syringes or pens every 28 days for the next 56 days, then 1 syringe or pen every 28 days
  - Pediatric PsO: 2 syringes or pens for the first 28 days, then 1 syringe or pen every 28 days

Siliq (brodalumab)
- Indications:
  - PsO, Age ≥ 18 years
- Quantity Limits:
  - 3 syringes for the first 28 days, then 2 syringes every 28 days
- Exclusions:
  - Concurrent diagnosis of CD

Interleukin 23 (IL-23) inhibitors

Ilumya (tildrakizumab-asmn)
- Indications:
  - PsO, Age ≥ 18 years
- Quantity limits:
  - 1 syringe for the first 28 days, then 1 syringe every 12 weeks

Omvoh (mirikizumab-mrkz)
- Indications:
  - UC, Age ≥ 18 years
- Quantity limits:
  - 1 vial every 28 days for the first 56 days

- 2 pens every 28 days beginning week 12
- Medical benefit for IV infusion
- Required documentation
  - Baseline LFT

Skyrizi (risankizumab)
- Indications:
  - CD, PsO, PsA, UC, Age ≥ 18 years
- Quantity limits:
  - PsO, PsA: One 150mg/ml pen or syringe for the first 28 days, then one 150 mg/ml pen or syringe every 12 weeks
  - CD: One 600 mg/10 ml vial per 28 days for 3 months, then one 180 mg/1.2 ml or one 360 mg/2.4 ml cartridge every 8 weeks
  - UC: Two 600 mg/10 ml vials per 28 days for 3 months, then one 180mg/1.2 ml or one 360 mg/2.4 ml cartridge every 8 weeks
  - Medical benefit for IV infusion loading dose for CD and UC.

Tremfya (guselkumab)
- Indications:
  - PsO, PsA, Age ≥ 18 years
- Quantity limits:
  - 1 syringe or autoinjector for the first 28 days, then 1 syringe or autoinjector every 8 weeks

Interleukin 36 (IL-36) inhibitors

Spevigo (spesolimab-sbzo)
- Indications:
  - GPP, Age ≥ 12 years
- Quantity limits:
  - For treatment of GPP flare: 900 mg (two 450 mg/7.5 mL single-dose vials) for a single IV infusion dose. For persistent symptoms, may repeat 900 mg (2 vials) after 1 week.
  - Subcutaneous treatment for patients not experiencing a GPP flare: 4 syringes for the first 28 days, then 2 syringes every 4 weeks
  - Initiating or reinitiating subcutaneous dosing after IV spesolimab: Beginning 4 weeks after IV administration, 2 syringes every 4 weeks
- Exclusions:
  - Treatment of Synovitis-acne-pustulosis-hyperostosis-osteitis (SAPHO) syndrome
  - Treatment of non-GPP types of psoriasis
  - Treatment with more than two infusions of Spevigo for a single flare
- Medical benefit for IV infusion

Integrin Receptor Antagonists

Entyvio (vedolizumab)
- Indications:
  - CD, UC, Age ≥ 18 years
- Quantity limits:
  - 2 vials for the first 42 days, then 1 vial every 8 weeks.
  - 1 syringe or pen every 2 weeks beginning week 6
- Medical benefit for IV infusion

Tysabri (natalizumab)
- Indications:
  - CD, Age ≥ 18 years
- Quantity limits:
  - 1 vial every 28 days
- Exclusions:
  - Concurrent use of immunosuppressants (eg, mercaptopurine, azathioprine, cyclosporine, or methotrexate)
- Medical benefit for IV infusion

Selective T-cell costimulation modulators

Orencia (abatacept)
- Indications:
  - PJIA, PsA, Age ≥ 2 years (subcutaneous), Age ≥ 6 years (IV)
  - RA, Age ≥ 18 years
- Quantity limits:
  - 4 syringes or autoinjectors every 28 days
- Medical benefit for IV infusion

Tumor Necrosis Factor (TNF) inhibitors

Cimzia (certolizumab pegol)
- Indications:
  - AS, CD, nr-axSpA, PsO, PsA, RA, Age ≥ 18 years
- Quantity limits:
  - PsO patients weighing > 90 kg: Four 200 mg syringes or vials every 28 days
  - All other diagnoses, including PsO patients weighing < 90 kg: 1 starter pack (six 200 mg syringes) for the first 28 days, then two 200 mg syringes or vials every 28 days

Enbrel (etanercept)
- Indications:
  - AS, RA, Age ≥ 18 years
  - PsO, Age ≥ 4 years
  - PJIA, PsA, Age ≥ 2 years
- Quantity limits:
  - PsO: Eight 50 mg syringes or autoinjectors every 28 days for the first 3 months, then four 50 mg syringes (or eight 25 mg syringes or vials) every 28 days
  - Other diagnoses: Four 50 mg syringes or autoinjectors (or eight 25 mg syringes or vials) every 28 days

Humira (adalimumab) and biosimilars
Abrilada (adalimumab-afbz), Adalimumab-aacf, Adalimumab-aaty, Adalimumab-adaz, Adalimumab-adbm, Adalimumab-fkjp, Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm), Hadlima (adalimumab - bwwd), Hulio (adalimumab – fkjp), Hyrimoz (adalimumab – adaz), Idacio (adalimumab-aacf), Yuflyma (adalimumab-aaty), Yusimry (adalimumab - aqvh)
- Indications:
  - AS, PsO, PsA, RA, Age ≥ 18 years
  - CD, Age ≥ 6 years
  - HS, Age ≥ 12 years
  - PJIA, Uveitis, Age ≥ 2 years
  - UC, Age ≥ 5 years
- Quantity Limits:
  - AS, PsA: Two 40 mg pens or syringes every 28 days
  - RA: Two 40 mg pens or syringes every 28 days
    - A maintenance dose of 40 mg every week or 80 mg every other week may be considered in patients not taking methotrexate.
  - Adult PsO or uveitis: Four 40 mg pens or syringes (or one 80 mg pen plus two 40 mg pens or syringes) for the first 28 days, then two 40 mg pens or syringes every 28 days
  - Adult CD or UC: Six 40 mg (or three 80 mg) pens or syringes for the first 28 days, then two 40 mg pens or syringes every 28 days
  - HS: Six 40 mg (or three 80 mg) pens or syringes for the first 28 days, then four 40 mg (or two 80 mg) pens or syringes every 28 days
  - PJIA or pediatric uveitis: Two 10 mg, 20 mg, or 40 mg syringes every 28 days
  - Pediatric CD:
    - 17 kg to 39 kg: Three 40 mg (or one 80 mg plus one 40 mg) pens or syringe for the first 28 days, then two 20 mg syringes every 28 days
    - ≥40 kg: Six 40 mg (or three 80 mg) pens or syringes for the first 28 days, then two 40 mg pens or syringes every 28 days
  - Pediatric UC:
    - 20 kg to 39 kg: Four 40 mg (or one 80 mg plus two 40 mg) pens or syringes for the first 28 days, then four 20 mg (or two 40 mg) pens or syringes every 28 days
    - ≥ 40 kg: Four 80 mg pens or syringes for the first 28 days, then four 40 mg (or two 80 mg) pens or syringes every 28 days

Remicade (infliximab) and biosimilars
Avsola (infliximab-axxq), Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)

- Indications:
  - AS, PsO, PsA, RA, Age ≥ 18 years
  - CD, UC Age ≥ 6 years
- Quantity limit:
  - Two doses of 5 mg/kg in the first 42 days, then one dose of 5 mg/kg every 8 weeks
- Exclusions:
  - Doses > 5 mg/kg in moderate or severe heart failure
- Medical benefit for IV infusion

Simponi (golimumab)

- Indications:
  - AS, PsA, RA, UC, Age ≥ 18 years
- Quantity limits:
  - AS, PsA, RA: One 50 mg syringe or autoinjector every 28 days
  - UC: Three 100 mg syringes or autoinjectors for the first 28 days, then one 100 mg syringe or autoinjector every 28 days

Simponi Aria (golimumab)

- Indications:
  - AS, RA, Age ≥ 18 years
  - PJIA, PsA, Age ≥ 2 years
- Quantity limits:
  - Adults: One dose of 2 mg/kg for the first 28 days, then one dose of 2 mg/kg every 8 weeks
  - Pediatrics: One dose of 80 mg/m^2 for the first 28 days, then one dose of 80 mg/m^2 every 8 weeks
- Medical benefit for IV infusion

Zymfentra (infliximab-dyyb)

- Indications:
  - CD, UC, Age ≥ 18 years
- Quantity limits:
  - CD, UC: 2 syringes or pens every 28 days
- Exclusions:
  - Use for treatment induction
- Other:
  - Documented response to infliximab infusion induction
  - Use for maintenance dosing beginning at week 10

ORAL TARGETED SYNTHETIC DMARDS

Janus Kinase (JAK) inhibitors

Cibinqo (abrocitinib)
- Indications:
  - AD, Age ≥ 12 years
- Quantity limits:
  - 30 tablets per 30 days
- Exclusions:
  - Concurrent use of antiplatelet therapy (other than aspirin ≤ 81 mg) during the first 3 months of therapy
  - Concurrent use of potent immunosuppressants (ie, azathioprine or cyclosporine)

Olumiant (baricitinib)
- Indications:
  - RA, Age ≥ 18 years
- Quantity limits:
  - 30 tablets per 30 days
- Exclusions:
  - Concurrent use of potent immunosuppressants (ie, azathioprine or cyclosporine)

Rinvoq (upadacitinib)
- Indications:
  - AD, Age ≥ 12 years
  - AS, nr-axSpA, CD, RA, UC, Age ≥ 18 years
  - PsA, Age ≥ 2 years
  - PJIA, Age ≥ 2 years
- Quantity limits:
  - AD, Thirty 15 mg tablets per 30 days
    - A maintenance dosage of 30 mg once daily may be considered for patients with inadequate response to the 15 mg dose.
  - AS, nr-axSpA, RA: Thirty 15 mg tablets per 30 days
  - CD: Thirty 45 mg tablets per 30 days for 12 weeks, then thirty 15 mg tablets per 30 days
    - A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease.
  - PJIA: 360 ml per 30 days or thirty 15 mg tablets per 30 days.
  - PsA: 360 ml per 30 days or thirty 15 mg tablets per 30 days.
  - UC: Thirty 45 mg tablets per 30 days for 8 weeks, then thirty 15 mg tablets per 30 days
    - A maintenance dosage of 30 mg once daily may be considered for patients with refractory, severe, or extensive disease.
- Exclusions:
  - Concurrent use of potent immunosuppressants (ie, azathioprine or cyclosporine)

Xeljanz/Xeljanz XR (tofacitinib)
- Indications:
  - AS, PsA, RA, UC, Age ≥ 18 years
  - PJIA, Age ≥ 2 years (oral solution only)
- Quantity limits:

- AS, PsA, RA: Sixty 5 mg IR tablets per 30 days or thirty 11 mg XR tablets per 30 days
- UC: Sixty 10 mg IR tablets per 30 days for 16 weeks, then sixty 5 mg IR tablets per 30 days OR thirty 22 mg XR tablets per 30 days for 16 weeks, then thirty 11 mg XR tablets per 30 days. (Discontinue 10 mg twice daily or XR 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved.)
- PJIA: 300 ml per 30 days or sixty 5 mg tablets per 30 days

- Exclusions:
  - Concurrent use of potent immunosuppressants (ie, azathioprine or cyclosporine)

Phosphodiesterase 4 (PDE4) inhibitors

Otezla (apremilast)
- Indications:
  - Behcet's disease, PsO, PsA, Age ≥ 18 years
- Quantity limits:
  - 60 tablets per 30 days

Sphingosine-1-phosphate (S1P) receptor modulators

Zeposia (ozanimod)
- Indications:
  - UC, Age ≥ 18 years
- Required documentation:
  - Evidence of varicella-zoster vaccination, or history of chickenpox, or evidence of immunity
  - Baseline LFT, bilirubin levels, and CBC
  - Baseline electrocardiogram
  - Ophthalmologic examination
- Quantity limits:
  - Loading dose: One 7-day starter pack including 7 capsules (Four 0.23 mg capsules and three 0.46 mg capsules) or One starter kit (37-capsule starter kit including four 0.23 mg capsules and three 0.46 mg capsules and thirty 0.92 mg capsules)
  - Maintenance: Thirty 0.92 mg capsules per 30 days
- Exclusions:
  - Severe untreated sleep apnea
  - History of myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in past 6 months
  - Presence of Mobitz type II second-degree or third-degree atrioventricular block, sick sinus syndrome, or sino-atrial block in members without a functioning pacemaker
  - Concurrent use of monoamine oxidase inhibitor

Velsipity (etrasimod)

- Indications:
  - UC, Age ≥ 18 years
- Required documentations:
  - Evidence of varicella-zoster vaccination, or history of chickenpox, or evidence of immunity
  - Baseline LFT and CBC
  - Baseline electrocardiogram
  - Ophthalmologic examination
- Quantity limits:
  - 30 tablets per 30 days
- Exclusions:
  - Myocardial infarction, unstable angina pectoris, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III or IV heart failure in the previous 6 months.
  - History or presence of Mobitz type II second-degree or third-degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block without a functioning pacemaker

Tyrosine Kinase 2 (TYK2) inhibitors

Sotyktu (deucravacitinib)

- Indications:
  - PsO, Age ≥ 18 years
- Quantity Limits: 30 tablets per 30 days
- Exclusions:
  - Severe hepatic impairment (Child-Pugh C)
  - Concurrent use of potent immunosuppressants

TOPICAL TARGETED SYNTHETIC DMARDS

Janus Kinase (JAK) inhibitors

Opzelura (ruxolitinib)

- Indications:
  - AD, Age ≥ 12 years
- Quantity Limits:
  - One 60 g tube per 7 days for 8 weeks.
- Exclusions:
  - Long-term, continuous use

AD: atopic dermatitis, AS: ankylosing spondylitis AST: aspartate aminotransferase CBC: complete blood count, CD: Crohn's disease, DMARD: disease-modifying antirheumatic drug, ERA: enthesitis-related arthritis, FDA: U.S. Food and Drug Administration, GCA: giant cell arteritis, GPP: generalized pustular psoriasis; HS: hidradenitis suppurativa, IL: interleukin, IR: immediate release, IV: intravenously, JAK: janus kinase, LFT: liver function test, nr-axSpA: non-radiographic axial spondylarthritis, PJIA: polyarticular juvenile idiopathic arthritis, PsO: plaque psoriasis, PMR: polymyalgia rheumatica, PN: prurigo nodularis, PsA: psoriatic arthritis, RA: rheumatoid arthritis, S1P: sphingosine-1-phosphate, SJIA: systemic juvenile idiopathic arthritis, TIM: targeted immune modulator, TNF: tumor necrosis factor, UC: ulcerative colitis, XR: extended release

Targeted Immune Modulators (TIM)

for Dermatologic Diseases, Rheumatologic Diseases, and Inflammatory Bowel Diseases

Quantity / Days Supply Restrictions

- Requested quantities not exceeding limits listed in Table 1.

Approval Length

- **Authorization:**
  - Opzelura: One-time approval for 8 weeks.
  - All other drugs: 4 months
- **Re-Authorization:** 1 year, with an updated letter of medical necessity or progress notes showing improvement or maintenance with the medication.

Appendix

- Figure 1 - Examples of severe PsO and severe PsA.

Severe Psoriatic Arthritis	Severe Psoriasis
• Erosive disease • Elevated markers of inflammation (ESR, CRP) attributable to PsA • Long-term damage that interferes with function (i.e., joint deformities) • Highly active disease that causes a major impairment in quality of life • Active PsA at many sites including dactylitis, enthesitis • Function-limiting PsA at a few sites • Rapidly progressive disease	• PASI of 12 or more • BSA of 5-10% or more • Significant involvement in specific areas • (e.g., face, hands or feet, nails, intertriginous areas, scalp) where the burden of the disease causes significant disability • Impairment of physical or mental functioning can warrant a designation of moderate-to-severe disease despite the lower amount of surface area of skin involved

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