BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – INJECTION:
ACTEMRA® (tocilizumab) IV & SQ
AMJEVITA™ (adalimumab-atto) SQ
CIMZIA® (certolizumab pegol) SQ
COSENTYX® (secukinumab) SQ
ENBREL® (etanercept) SQ
HUMIRA® (adalimumab) SQ
KEVZARA® (sarilumab) SQ
KINERET® (anakinra) SQ
ORENCIA® (abatacept) IV & SQ
SILIQ™ (brodalumab) SQ
SIMPONI® (golimumab) SQ
SIMPONI ARIA® (golimumab) IV
SKYRIZI™ (risankizumab-rzaa) IV & SQ
STELARA® (ustekinumab) IV & SQ
TALTZ® (ixekizumab) SQ
TREMFYA® (guselkumab) SQ

This Pharmacy Coverage Guideline (PCG):

- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope

- This PCG applies to Commercial and Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance

- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require precertification is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-

3126 or email it to Pharmacyprecert@azblue.com.

Criteria:

Section A. Applies for all indications and uses:

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

  1. Prescriber is a physician specializing in or is in consultation with a Rheumatologist, Dermatologist, Gastroenterologist, or Ophthalmologist, depending upon indication or use

  2. Age of individual is consistent with the FDA approved product labeling

  3. Meets other additional initial criteria per indication or use as described below in Sections B-O below

  4. Individual does **NOT** have **ANY** of the following:
     a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
        i. Serologic tests for hepatitis B and C (HB surface Ag, anti-HB surface Ab, anti-HB core Ab, and hepatitis C antibody tests) have been done within the previous 12 months
        ii. Screening for latent tuberculosis infection with a tuberculin skin test or blood test has been done and if positive, treatment has been initiated
     b. Concurrent use of live vaccines

  5. There are **NO** FDA-label contraindications

  6. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Otezla, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Rinvoq, Xeljanz IR, XR, solution), etc.

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

  1. Individual continues to be seen by a physician specializing in or is in consultation with a Rheumatologist, Dermatologist, Gastroenterologist, or Ophthalmologist depending upon indication or use

  2. Meets other additional continuation criteria per indication or use as described in Sections B-O below

  3. Individual has been adherent with the medication

  4. Individual has not developed any contraindications per FDA label or other significant adverse drug effects that may exclude continued use

  5. Individual does **NOT** have **ANY** of the following:

a. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
b. Concurrent use of live vaccines

6. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, methotrexate, Otezla, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Rinvoq, Xeljanz IR, XR, solution), etc.

Section B. Moderately to severely active Ankylosing Spondylitis (AS):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active ankylosing spondylitis:

1. Request is for **ONE** of the following: Amjevita, Cimzia, Cosentyx, Enbrel, Humira, Simponi, Simponi Aria, Taltz

2. Prescriber is a Rheumatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Clinical and diagnostic imaging evidence of ankylosing spondylitis as indicated by **ALL** of the following:
   a. Back pain of 3 months or more duration with an age of onset of 45 years or younger
   b. Sacroiliitis on x-ray imaging **showing** definitive radiographic evidence of **structural damage** of sacroiliac joints
   c. Spondyloarthritis signs or symptoms as indicated by **ONE or more** of the following:
      i. Arthritis
      ii. Elevated serum C-reactive protein
      iii. Enthesitis (e.g., inflammation of Achilles tendon insertion)
      iv. HLA-B27
      v. Limited chest expansion
      vi. Morning stiffness for one hour or more
   d. A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 or more, and spinal pain rated as at least 4 or more on a 0 to 10 numerical rating scale

5. Disease activity and treatment scenario as indicated by **ONE or more** of the following:
   a. Axial (spinal) disease
   b. Peripheral arthritis without axial involvement, and failure, contraindication per FDA label, or intolerance of 4 or more months of therapy with sulfasalazine

6. Individual has failure, contraindication per FDA label, intolerance, or not a candidate for **TWO or more** different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy

7. **Taltz** for ankylosing spondylitis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for **ONE** of the following preferred agents:
   a. Cimzia
   b. Enbrel
   c. Humira

d. Simponi or Simponi Aria
e. Xeljanz tab or Xeljanz XR or Rinvoq

8. **Cosentyx** for ankylosing spondylitis:
   a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for **TWO** of the following preferred agents:
      i. Cimzia
      ii. Enbrel
      iii. Humira
      iv. Simponi or Simponi Aria
      v. Xeljanz tab or Xeljanz XR or Rinvoq
   b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for **Taltz**

9. **Amjevita** for ankylosing spondylitis:
   a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for the preferred agent: **Humira**
   b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for **TWO** of the following preferred agents:
      i. Cimzia
      ii. Enbrel
      iii. Simponi or Simponi Aria
      iv. Xeljanz tab or Xeljanz XR or Rinvoq
   c. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or not a candidate for **Taltz**

Approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation**: AT LEAST a 20% improvement in BASDAI (see Definitions section)
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA Continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section C. Moderately to severely active Non-radiographic Axial Spondyloarthritis (nr-axSpA):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active non-radiographic axial spondyloarthritis:

  1. Request is for **ONE** of the following: Cimzia, Cosentyx, Taltz
  2. Prescriber is a Rheumatologist
  3. Meets other initial criteria per indication or use as described in Section A above
  4. Clinical and diagnostic imaging evidence of ankylosing spondylitis as indicated by **ALL** of the following:
     a. Back pain of 3 months or more duration and age of onset of 45 years or younger
     b. Sacroiliitis on x-ray imaging but **does not show** definitive radiographic evidence of **structural damage** of sacroiliac joints
     c. Spondyloarthritis signs or symptoms as indicated by **ONE or more** of the following:
        i. Arthritis
        ii. Elevated serum C-reactive protein
        iii. Enthesitis (e.g., inflammation of Achilles tendon insertion)
        iv. HLA-B27
        v. Limited chest expansion
        vi. Morning stiffness for one hour or more
     d. A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 4 or more, and spinal pain rated as at least 4 or more on a 0 to 10 numerical rating scale
  5. Individual has failure, contraindication per FDA label, or intolerance to **TWO or more** different NSAIDs (at maximum recommended doses) over a total period of at least 4 or more weeks of therapy
  6. **Taltz** for non-radiographic axial spondyloarthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **Cimzia**
  7. **Cosentyx** for non-radiographic axial spondyloarthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ALL** of the following agents:
     a. Cimzia
     b. Rinvoq
     c. Taltz

  Approval duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

  1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
    a. **With first request for continuation**: AT LEAST a 20% improvement in BASDAI (see Definitions section)
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section D. Moderately to severely active Crohn's Disease (CD):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active Crohn's disease:

1. Request is for **ONE** of the following: Amjevita, Cimzia, Humira, Skyrizi (IV&SQ), Stelara (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has a confirmed diagnosis of moderate to severe active Crohn's disease as indicated by **ONE** of the following:
    a. Crohn's disease activity index (CDAI) greater than 220 in adults
    b. Pediatric Crohn's disease activity index (PCDAI) greater than 30
    c. **At least 5** of the following signs and symptoms:
        i. Anemia
        ii. Chronic intermittent diarrhea (with or without food)
        iii. Crampy abdominal pain
        iv. Elevated serum C-reactive protein level and/or fecal calprotectin
        v. Extraintestinal manifestations such as arthritis or arthropathy, eye and skin disorders, biliary tract involvement, and kidney stones
        vi. Fatigue
        vii. Fistulas
        viii. Perianal disease (e.g., anal fissures, anorectal abscess)
        ix. Weight loss or growth failure in children

5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE or more** of the following [Note this criterion is waived if the individual already has tried an FDA-approved Crohn's disease biologic]:
    a. 6-mercaptopurine
    b. Azathioprine
    c. Methotrexate
    d. Oral corticosteroids

6. **Amjevita** for Crohn's disease:
    a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for preferred agent: **Humira**
    b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate to **TWO** of the following preferred agents:

i. Cimzia
ii. Skyrizi (IV&SQ)
iii. Stelara (IV&SQ)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation ONE of the following:**
      i. AT LEAST a 20% improvement in the signs and symptoms of Crohn's disease
      ii. Decrease in Crohn's disease activity index of more than 70 from baseline or a Crohn's disease activity index of < 150 (in remission) in adults
      iii. Pediatric Crohn disease activity index (PCDAI) ≤ 30 in children indicating mild disease or disease remission
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA Continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section E. Enthesitis Related Arthritis (ERA):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for enthesitis-related arthritis:

1. Request is for Cosentyx

2. Prescriber is a Rheumatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has a confirmed diagnosis of Enthesitis-related arthritis (ERA)

5. Age of onset of arthritis in a male is over 6 years of age

6. There is **ONE** of the following:
   a. Peripheral arthritis and enthesitis of ≥ 6 weeks duration in children aged < 18 years
   b. Arthritis or enthesitis, plus ≥ 3 months of inflammatory back pain and sacroiliitis on imaging
   c. Arthritis or enthesitis plus **TWO** of the following:
      i. Sacroiliac joint tenderness

ii. Inflammatory lumbosacral pain
iii. Presence of HLA-B27 antigen
iv. Anterior uveitis that is symptomatic with pain, redness, or photophobia
v. History of a spondyloarthritis in a first-degree relative

7. Active disease defined as having **BOTH** of the following:
   a. There are at least 3 active joints
   b. There is at least 1 site of active enthesitis at baseline or documented by history

8. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE or more** of the following
   a. At least **ONE** nonsteroidal anti-inflammatory drug (NSAID) such as diclofenac, indomethacin, naproxen, others
   b. At least **ONE** Disease-modifying antirheumatic drugs (DMARD) such as methotrexate, sulfasalazine, others

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation ONE of the following:**
      i. AT LEAST 30% improvement in at least 3 of the 6 JIA Core set variables
      ii. An increase in time to next flare
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section F. Moderate to severe chronic plaque Psoriasis (PsO):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderate to severe chronic plaque psoriasis:

1. Request is for **ONE** of the following: Amjevita, Cimzia, Cosentyx, Enbrel, Humira, Siliq, Skyrizi, Stelara (IV&SQ), Taltz, Tremfya

2. Prescriber is a Dermatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Diagnosis of moderate to severe plaque psoriasis, as indicated by **ALL** of the following:
   a. Individual is a candidate for photochemotherapy or phototherapy

b. Plaque psoriasis involves ≥ 10% body surface area (BSA) **or** plaque psoriasis involves < 10% BSA but includes sensitive areas or areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia)
c. A Psoriasis Area and Index (PASI) of at least 10

5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to a treatment regimen that includes **ALL** of the following:
   a. A trial of least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
   b. A trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
   c. A trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser)

6. No concomitant use of other systemic therapy

7. **Taltz** for plaque psoriasis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE** of the following preferred agents:
   a. Cimzia
   b. Enbrel
   c. Humira
   d. Skyrizi
   e. Stelara
   f. Tremfya

8. **Cosentyx or Siliq** for plaque psoriasis **ALL** of the following:
   a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **THREE** of the following preferred agents:
      i. Cimzia
      ii. Enbrel
      iii. Humira
      iv. Skyrizi
      v. Stelara
      vi. Tremfya
   b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to:
      i. Taltz

9. **Amjevita** for plaque psoriasis:
   a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for the preferred agent: **Humira**
   b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
      i. Cimzia
      ii. Enbrel
      iii. Skyrizi
      iv. Stelara
      v. Tremfya

c. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to:
    i. Taltz

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
    a. **With first request for continuation:** AT LEAST a 20% improvement in PASI (see Definitions section)
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section G. Polyarticular Juvenile Idiopathic Arthritis (pJIA):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for polyarticular juvenile idiopathic arthritis:

1. Request is for **ONE** of the following: Actemra (IV&SQ), Amjevita, Enbrel, Humira, Orencia (IV&SQ), Simponi Aria

2. Prescriber is a Rheumatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Treatment needed for disease severity, as indicated by **ONE or more** of the following:
    a. Four or fewer joints involved and has an inadequate response to **ALL** of the following:
        i. Glucocorticosteroid injection or NSAIDs
        ii. Methotrexate
    b. Five or more joints involved and has intolerance or inadequate response to methotrexate
    c. Sacroiliitis and has intolerance or inadequate response to methotrexate
    d. Uveitis and has an inadequate response to **ALL** of the following:
        i. Systemic corticosteroids
        ii. Systemic immunosuppressant (e.g., azathioprine or methotrexate)
        iii. Topical ophthalmic corticosteroids

5. **Actemra, Orencia (IV&SQ)** for polyarticular juvenile idiopathic arthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
    a. Enbrel
    b. Humira
    c. Simponi Aria

6. **Amjevita** for polyarticular juvenile idiopathic arthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to the **ALL** of the following preferred agents: **Humira**
    a. Enbrel
    b. Humira
    c. Simponi Aria

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
    a. **With first request for continuation:** AT LEAST a 30% improvement in JIA Core Set (see Definitions section)
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section H. Moderately to severely active Psoriatic Arthritis (PsA):

- **Criteria for initial therapy:** Biologic and Immunological Agents considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active psoriatic arthritis:

1. Request is for **ONE** of the following: Amjevita, Cimzia, Cosentyx, Enbrel, Humira, Orencia (IV&SQ), Simponi, Simponi Aria, Skyrizi, Stelara (IV&SQ), Taltz, Tremfya

2. Prescriber is a Rheumatologist or Dermatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has a confirmed diagnosis of moderate to severe active psoriatic arthritis is identified by **ONE or more** of the following:

a. Predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by **ALL** of the following:
    i. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
    ii. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months' duration
    iii. Failure, contraindication per FDA label, or intolerance of 1 or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy
b. Predominantly non-axial disease, and failure (used for ≥ 3 consecutive months), intolerance, or contraindication per FDA label to methotrexate or NSAIDs

5. **Taltz** for psoriatic arthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE** of the following preferred agents:
    a. Cimzia
    b. Enbrel
    c. Humira
    d. Simponi or Simponi Aria
    e. Skyrizi
    f. Stelara
    g. Tremfya
    h. Xeljanz tab or Xeljanz XR or Rinvoq

6. **Orencia (IV&SQ)** for psoriatic arthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
    a. Cimzia
    b. Enbrel
    c. Humira
    d. Simponi or Simponi Aria
    e. Skyrizi
    f. Stelara
    g. Tremfya
    h. Xeljanz tab or Xeljanz XR or Rinvoq

7. **Cosentyx** for psoriatic arthritis **ALL** of the following:
    a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
        i. Cimzia
        ii. Enbrel
        iii. Humira
        iv. Simponi or Simponi Aria
        v. Skyrizi
        vi. Stelara
        vii. Tremfya
        viii. Xeljanz tab or Xeljanz XR or Rinvoq
    b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **BOTH** of the following:
        i. Taltz
        ii. Orencia (IV or SQ)

8. **Amjevita** for psoriatic arthritis **ALL** of the following:

a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to the following preferred agent: **Humira**
b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
    i. Cimzia
    ii. Enbrel
    iii. Simponi or Simponi Aria
    iv. Skyrizi
    v. Stelara
    vi. Tremfya
    vii. Xeljanz tab or Xeljanz XR or Rinvoq
c. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **BOTH** of the following:
    i. Taltz
    ii. Orencia (IV or SQ)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
    a. **With first request for continuation**: AT LEAST a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID-3, SDAI (see Definitions section)
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section I. Moderately to severely active Rheumatoid Arthritis (RA):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active rheumatoid arthritis:

1. Request is for **ONE** of the following: Amjevita, Actemra (IV&SQ), Cimzia, Enbrel, Humira, Kevzara, Kineret, Orencia (IV&SQ), Simponi, Simponi Aria

2. Prescriber is a Rheumatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has a confirmed diagnosis of rheumatoid arthritis identified by **ONE** of the following:
    a. Clinical Disease Activity Index (CDAI) score greater than 10
    b. Disease Activity Score 28 (DAS28) of greater than 3.2
    c. Patient Activity Scale (PAS) of greater than 3.7
    d. Patient Activity Scale II (PASII) of greater than 3.7
    e. Routine Assessment of Patient Index Data 3 (RAPID-3) score greater than 2
    f. Simplified Disease Activity Index (SDAI) score greater than 11

5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **methotrexate**

6. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE** of the following: [Note this criterion is waived if the individual already has tried an FDA-approved Rheumatoid Arthritis biologic]
    a. Leflunomide
    b. Sulfasalazine

7. **Actemra, Orencia (IV&SQ)** for rheumatoid arthritis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
    a. Cimzia
    b. Enbrel
    c. Humira
    d. Simponi or Simponi Aria
    e. Xeljanz tab or Xeljanz XR tab or Rinvoq

8. **Kevzara or Kineret** for rheumatoid arthritis **ALL** of the following:
    a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
        i. Cimzia
        ii. Enbrel
        iii. Humira
        iv. Simponi or Simponi Aria
        v. Xeljanz tab or Xeljanz XR tab or Rinvoq
    b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **BOTH** of the following:
        i. Actemra
        ii. Orencia (IV or SQ)

9. **Amjevita** for rheumatoid arthritis **ALL** of the following:
    a. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to the following preferred agent: **Humira**
    b. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **TWO** of the following preferred agents:
        i. Cimzia
        ii. Enbrel
        iii. Simponi or Simponi Aria
        iv. Xeljanz tab or Xeljanz XR tab or Rinvoq
    c. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **BOTH** of the following:

i. Actemra
ii. Orencia (IV or SQ)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation**: AT LEAST a 20% improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID-3, SDAI (see Definitions section)
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section J. Moderately to severely active Ulcerative Colitis (UC):

- **Criteria for initial therapy:** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderately to severely active ulcerative colitis (UC):

1. Request is for **ONE** of the following: Amjevita, Humira, Simponi, Stelara (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has a confirmed diagnosis of moderate to severe active ulcerative colitis, as indicated by **ONE** of the following:
   a. American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults
   b. Pediatric ulcerative colitis activity index (PUCAI) greater than or equal to 35
   c. **At least 5** of the following signs and symptoms:
      i. Anemia
      ii. Bloody diarrhea or visible blood in stool
      iii. Bowel movements 4-6 or more times per day
      iv. Colicky abdominal pain
      v. Elevated fecal calprotectin
      vi. Elevated serum C-reactive protein or erythrocyte sedimentation rate
      vii. Fatigue
      viii. Fever

ix. Tenesmus
x. Urgency
xi. Weight loss or delayed growth in children

5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to **ONE or more** of the following: [Note this criterion is waived if the individual already has tried an FDA-approved Ulcerative Colitis biologic]
   a. 6-mercaptopurine
   b. Azathioprine
   c. Oral corticosteroids
   d. Salicylates (such as mesalamine, sulfasalazine, balsalazide, olsalazine)

6. **Amjevita** for ulcerative colitis: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **ALL** of the following the preferred agents:
   i. Humira
   ii. Simponi
   iii. Stelara (IV&SQ)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agents is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation ONE of the following:**
      i. AT LEAST a 20% improvement in signs and symptoms of ulcerative colitis
      ii. American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or disease in remission in adults
      iii. Pediatric ulcerative colitis activity index (PUCAI) of ≤ 34 in children indicating mild disease or disease remission
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

3. **For AMJEVITA continuation requests**: Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, intolerance, or not a candidate for **Humira**

Renewal Duration: 12 months

Section K. Cytokine Release Syndrome:

- **Criteria for initial therapy:** Actemra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for chimeric antigen receptor (CAR) T cell–induced severe or life-threatening cytokine release syndrome:

1. Request is for Actemra (IV)

2. No concurrent treatment with any other biological DMARDs such as TNF antagonists, IL-1R (interleukin 1) antagonists, anti-CD-20 monoclonal antibodies or co-stimulation modulators

Approval Duration: One time only

Section L. Moderate Giant Cell Arteritis:

- **Criteria for initial therapy:** Actemra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderate giant cell arteritis:

  1. Request is for Actemra (IV&SQ)

  2. Prescriber is a Rheumatologist

  3. Meets other initial criteria per indication or use as described in Section A above

  4. Diagnosis is confirmed by temporal artery biopsy

  5. Individual has failure (used for ≥ 3 consecutive months), contraindication per FDA label, or intolerance to glucocorticoids

  Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Actemra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy):**

  1. Meets other continuation criteria as described in Section A above

  2. Individual's condition responded while on therapy with response defined as the following:
     a. **With first request for continuation:** AT LEAST 20% improvement in signs and symptoms of giant cell arteritis
     b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

  Renewal duration: 12 months

Section M. Moderate to severe Hidradenitis Suppurativa:

- **Criteria for initial therapy:** Humira is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderate to severe hidradenitis suppurativa:

  1. Request is for Humira

2. Prescriber is a Dermatologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Diagnosis of moderate to severe disease as indicated by **ONE or more** of the following:
   a. Multiple interconnected tracts and abscesses in single anatomic area
   b. Widely separated and recurrent abscesses with sinus tracts and scarring

5. Individual has failure, contraindication per FDA label, or intolerance to oral antibiotics (at maximum recommended doses) for at least 3 consecutive months (i.e., clindamycin, minocycline, doxycycline, rifampin)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Humira is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
   a. **With first request for continuation:** AT LEAST a 20% improvement in the signs and symptoms of hidradenitis suppurativa
   b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section N. Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD):

- **Criteria for initial therapy:** Actemra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for systemic sclerosis-associated interstitial lung disease:

1. Request is for Actemra (SQ)

2. Prescriber is a Rheumatologist or Pulmonologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Diagnosis is confirmed by meeting **ALL** of the following:
   a. Systemic sclerosis-interstitial lung disease as defined by American College of Rheumatology/European League Against Rheumatism
   b. Disease onset (first non-Raynaud symptom) is less than or equal to 5 years
   c. Modified Rodnan Skin Score (mRSS) of 10 or more but less than or equal to 35
   d. Elevated inflammatory markers (e.g., CRP, ERS) or platelets
   e. Active disease based on **one** of the following:
      i. Disease duration is less than or equal to 18-months

ii. Increase in mRSS of greater than or equal to 3-units over 6-months
iii. Involvement of one new body area and increase in mRSS of greater than or equal to 2-units over 6-months
iv. Involvement of two new body areas over previous 6-months
v. Presence of at least one tendon friction rub

5. Individual has failure (used for ≥ 3 consecutive months), contraindication or intolerance to mycophenolate

6. Will not be used in combination with Ofev (nintedanib)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Actemra is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as **TWO** of the following:
   a. Improvement in mRSS over baseline of at least 4
   b. Improvement or stabilization in FVC over baseline
   c. Improvement or stabilization in percent predicted forced vital capacity (ppFVC) over baseline
   d. Improvement or stabilization in DLCO
   e. Improved or no decline in symptoms for fatigue, cough or dyspnea

3. Individual has been adherent with the medication

4. Individual has not developed any significant adverse drug effects that may exclude continued use such as liver toxicity

5. There are no significant interacting drugs

6. Will not be used in combination with Ofev (nintedanib)

Renewal duration: 12 months

Section O. Uveitis:

- **Criteria for initial therapy:** Humira is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for moderate non-infectious intermediate uveitis, non-infectious posterior uveitis or non-infectious panuveitis:

1. Request is for Humira

2. Prescriber is an Ophthalmologist

3. Meets other initial criteria per indication or use as described in Section A above

4. Individual has failure, contraindication per FDA label, or intolerance to **ONE** agent for **BOTH** categories:
    a. Corticosteroids (> 2-week trial at up to maximally indicated doses)
    b. Systemic immunosuppressant (i.e., methotrexate, cyclosporine, azathioprine, mycophenolate, cyclophosphamide, leflunomide, hydroxychloroquine, sulfasalazine, tacrolimus, sirolimus, or chlorambucil)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Humira is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met **(samples are not considered for continuation of therapy)**:

1. Meets other continuation criteria as described in Section A above

2. Individual's condition responded while on therapy with response defined as the following:
    a. **With first request for continuation:** AT LEAST a 20% improvement in the signs and symptoms of uveitis or panuveitis
    b. **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Renewal Duration: 12 months

Section P. Measurement of Antibodies to Biologic/Immunologic Agents:

- Measurement of antibodies for biologic or immunologic agents in an individual receiving treatment, either alone or as a combination test, which includes the measurement of serum levels for the biologic or immunologic agents is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
3. Insufficient evidence to support improvement of the net health outcome; or
4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
5. Insufficient evidence to support improvement outside the investigational setting.

These measurements include, *but are not limited to:*
- Anser™ ADA

Section Q. Other:

- Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – INJECTION

1. **Off-Label Use of Non-Cancer Medications**
2. **Off-Label Use of Cancer Medications**

Definitions:

Adult: Age 18 years and older.
Non-radiographic axial spondyloarthritis (nr-axSpA):

- Considered to be an early stage of ankylosing spondylitis (AS)
- The main difference between AS and nr-axSpA is that in AS bone damage can be seen on X-rays
- In nr-axSpA, an MRI is used to see swelling in the softer tissue

Enthesis: The place where a tendon or ligament meets bone

Enthesitis: Tenderness at the insertion of a tendon, ligament, joint capsule, or fascia to bone

Preferred and Non-Preferred Agents:

Disease State	Preferred Agents	Non-Preferred Agents
Ankylosing Spondylitis	Cimzia* Enbrel* Humira* Rinvoq* Simponi* Simponi Aria† Xeljanz tab* Xeljanz XR tab*	Amjevita* Cosentyx* Taltz*
Crohn's	Cimzia* Humira* Skyrizi (IV) † Skyrizi (SQ)* Stelara (IV)† Stelara (SQ)*	Amjevita*
Juvenile Idiopathic Arthritis	Enbrel* Humira* Simponi Aria† Xeljanz oral solution* Xeljanz tab*	Actemra (IV)† Actemra (SQ)* Amjevita* Orencia (IV)† Orencia (SQ)*
Non-radiographic Axial Spondyloarthritis (nr-axSpA)	Cimzia* Rinvoq*	Cosentyx* Taltz*
Psoriasis (PsO)	Cimzia* Enbrel* Humira* Otezla* Skyrizi* Stelara (IV)† Stelara (SQ)* Tremfya*	Amjevita* Cosentyx* Siliq* Sotyktu* Taltz*

Psoriatic Arthritis (PsA)	Cimzia* Enbrel* Humira* Otezla* Rinvoq* Simponi* Simponi Aria† Skyrizi* Stelara (IV)† Stelara (SQ)* Tremfya* Xeljanz tab* Xeljanz XR tab*	Amjevita* Cosentyx* Orencia (IV)† Orencia (SQ)* Taltz*
Rheumatoid Arthritis (RA)	Cimzia* Enbrel* Humira* Rinvoq* Simponi* Simponi Aria† Xeljanz tab* Xeljanz XR tab*	Actemra (IV)† Actemra (SQ)* Amjevita* Kevzara* Kineret* Olumiant* Orencia (IV)† Orencia (SQ)*
Ulcerative Colitis	Humira* Rinvoq* Simponi* Stelara (IV)† Stelara (SQ)* Xeljanz tab* Xeljanz XR tab*	Amjevita* Zeposia*
***Pharmacy Benefit:** Injectable and oral medications that can be self-administered are billed and processed through pharmacy benefit only. **† Medical Benefit:** Injectable medications that must be administered by a healthcare professional.		

Bath Ankylosing Spondylitis Disease Activity Index (BASDAI):

1.	How would you describe the overall level of fatigue/tiredness you have experienced? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
2.	How would you describe the overall level of ankylosing spondylitis **neck, back or hip pain** you have had? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
3.	How would you describe the overall level of pain/swelling you have had in joints other than neck, back and hips? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
4.	How would you describe the level of discomfort you have had from an area tender to touch or pressure? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
5.	How would you describe the level of morning stiffness you have had from the time you wake up? None 0 1 2 3 4 5 6 7 8 9 10 Very Severe
6.	How long does your morning stiffness last from the time you wake up? 0 hours 0 1 2 3 4 5 6 7 8 9 10 2 or more hours
Calculation of BASDAI: Compute the mean of questions 5 and 6 Calculate the sum of the values of question 1-4 and add the result to the mean of questions 5 and 6	

Crohn's Disease Activity Index:
Sum each factor after adjustment with a weighting factor

Clinical or laboratory variable	Weighting factor	Factor Sum
Number of liquid or soft stools each day for seven days	x 2	
Abdominal pain (graded 0 = none, 1 = mild, 2 = moderate, 3 = severe) each day for 7 days	x 5	
General well-being (assessed from 0 = well, 1 = slightly under par, 2 = poor, 3 = very poor, 4 = terrible) each day for 7 days	x 7	
Presence of complications†	x 20	
Taking Lomotil (diphenoxylate/atropine) or opiates for diarrhea (0 = No, 1 = Yes)	x 30	
Presence of an abdominal mass (0 = none, 2 = questionable, 5 = definite)	x 10	
Hematocrit of < 0.47 in men and < 0.42 in women	x 6	
Percentage deviation from standard weight [1 – (ideal/observed)] x 100	x 1	
† **Complications**: one point each is added for each: • the presence of joint pains (arthralgia) or frank arthritis • inflammation of the iris or uveitis • presence of erythema nodosum, pyoderma gangrenosum, or aphthous ulcers • anal fissures, fistulae or abscesses • other fistulae • fever during the previous week		
Total CDAI		
Remission of CD: CDAI < 150 Severe CD: CDAI > 450 CD response: decrease in CDAI of > 70		

Pediatric Crohn disease activity index (PCDAI):

HISTORY: Recall from previous week		
Abdominal Pain	None	0 points
	Mild – Brief, does not interfere with activities	5 points
	Moderate or severe – Daily, longer lasting, affects activities, nocturnal	10 points
Stools (per day)	0-1 liquid stools, no blood	0 points
	Up to 2 semi-formed stools with small blood, or 2-5 liquid stools without blood	5 points
	Gross bleeding, or ≥6 liquid stools, or nocturnal diarrhea	10 points
Patient functioning, general well-being	No limitations of activities, well	0 points
	Occasional difficulty in maintaining age-appropriate activities, below par	5 points
	Frequent limitation of activity, very poor	10 points
Laboratory		
Hematocrit (%) <10 years	>33	0 points
	28 t32	2.5 points
	<28	5 points
Hematocrit (%) 11-19 years (females)	≥34	0 points
	29 to 33	2.5 points

	<29	5 points
Hematocrit (%) 11-14 years (males)	≥ 35	0 points
	30 to 34	2.5 points
	<30	5 points
Hematocrit (%) 15 to 19 years (male)	≥37	0 points
	32 to 36	2.5 points
	<32	5 points
ESR (mm/hour)	<20	0 points
	20 to 50	2.5 points
	>50	5 points
Albumin (g/dl)	≥3.5	0 points
	3.1 to 3.4	5 points
	≤3	10 points
Examination		
Weight	Weight gain, weight stable, or voluntary weight loss	0 points
	Involuntary weight stable, or weight loss 1 to 9%	5 points
	Weight loss ≥10%	10 points
Height (at diagnosis)	<1 channel decrease*	0 points
	1 to 2 channel decrease	5 points
	≥2 channel decrease	10 points
Height (at follow-up)	High velocity ≥-1 SD	0 points
	High velocity between -1 and -2 SD	5 points
	High velocity ≤-2 SD	10 points
Abdomen	No tenderness, no mass	0 points
	Tenderness, or mass without tenderness	5 points
	Tenderness, involuntary guarding, definite mass	10 points
Perirectal disease	None, asymptomatic tags	0 points
	1 to 2 indolent fistula(e), scant drainage, no tenderness	5 points
	Active fistula, drainage, tenderness, or abscess	10 points
Extraintestinal manifestations (Fever ≥38.5°C for 3 days over past week, definite arthritis, uveitis, erythema nodosum, pyoderma gangrenosum)	None	0 points
	1	5 points
	≥2	10 points

The PCDAI is interpreted as follows: a score of 0 to 10 indicates inactive disease, 11 to 30 indicates mild disease activity, and >30 indicates moderate to severe disease activity. A decrease in PCDAI of ≥12.5 points reflects a clinical response (improvement from moderate/severe to mild/inactive disease)
ESR: erythrocyte sedimentation rate; SD: standard deviation.
* A "channel decrease" refers to serial height measurements that deviate across the width of a major curve on a standard height-for-age chart. For example, decreasing from the 40th to 20th percentile is a 1-channel decrease.

Psoriasis Area and Severity Index (PASI):

	Head	Upper Extremities	Trunk	Lower extremities
1. Redness[1]				
2. Thickness[1]				
3. Scale[1]				
4. Sum of rows 1,2 and 3				
5. Area score[2]				
6. Score of row 4 x row 5 x the area multiplier	row 4 x row 5 x 0.1	row 4 x row 5 x 0.2	Row 4 x row 5 x 0.3	Row 4 x row 5 x 0.4

7. Sum row 6 for each column for PASI score				

Steps in generating PASI score:
(a) Divide body into four areas: head, arms, trunk to groin, and legs to top of buttocks.
(b) Generate an average score for the erythema, thickness, and scale for each of the 4 areas (0 = clear; 1–4 = increasing severity)[1].
(c) Sum scores of erythema, thickness, and scale for each area.
(d) Generate a percentage for skin covered with psoriasis for each area and convert that to a 0–6 scale (0 = 0%; 1 = <10%; 2 = 10–<30%; 3 = 30–<50%; 4 = 50–<70%; 5 = 70–<90%; 6 = 90–100%).
(e) Multiply score of item (c) above times item (d) above for each area and multiply that by 0.1, 0.2, 0.3, and 0.4 for head, arms, trunk, and legs, respectively.
(f) Add these scores to get the PASI score.

[1] Erythema, induration and scale are measured on a 0–4 scale (none, slight, mild, moderate, severe)
[2] Area scoring criteria (score: % involvement)
0: 0 (clear)
1: <10%
2: 10–<30%
3: 30–<50%
4: 50–<70%
5: 70–<90%
6: 90–<100%

Feldman, SR and Krueger, GG. Psoriasis assessment tools in clinical trials. Ann Rheum Dis 2005; 64 (Suppl III): ii65-ii68.

JIA Core Set 30%:

At least 30 percent improvement in at least 3 of the 6 core set variables with no more than 1 remaining variable worsening by > 30%
1. Physician's global assessment of overall disease activity measured on a visual analog scale (VAS)
2. Parent or patient global assessment of overall well-being measured on VAS
3. Functional ability
4. Number of joints with active arthritis
5. Number of joints with limited range of motion
6. Erythrocyte sedimentation rate (ESR)
Giannini, EH, Ruperto, N, Ravelli A, et al. Preliminary Definition of Improvement in Juvenile Arthritis. Arthritis & Rheumatism 1997

Rheumatoid Arthritis Disease Activity Measurement Instruments:

Instrument	Threshold of Disease Activity
Clinical Disease Activity Index (CDAI)	Range: 0 to 76 Remission: ≤ 2.8 Low activity: >2.8 to ≤ 10 Moderate activity: >10 to ≤ 22 High activity: >22
Disease Activity Score 28 (DAS28)	Range: 0.5 to 9 Remission: < 2.6 Low activity: > 2.6 to ≤ 3.2 Moderate activity: > 3.2 to ≤ 5.1 High activity: > 5.1
Patient Activity Scale (PAS) Patient Activity Scale II (PASII)	Range 0 to 10 Remission: 0 to 0.25 Low activity: >0.25 to 3.7 Moderate activity: > 3.7 to < 8.0 High activity: ≥ 8.0

Routine Assessment of Patient Index Data 3 (RAPID-3)	Range: 0 to 10 Remission: 0 to 1.0 Low activity: > 1.0 to 2.0 Moderate activity: > 2.0 to 4.0 High activity: > 4.0 to 10
Simplified Disease Activity Index (SDAI)	Range: 0 to 90 Remission: ≤ 3.3 Low activity: > 3.3 to ≤ 11.0 Moderate activity: > 11.0 to ≤ 26 High activity: > 26

American College of Rheumatology 20 Percent Improvement Criteria (ACR20):

At least 20 percent improvement in the following:
1. Swollen joint count
2. Tender joint count
And three of the following five variables:
3. Patient-assessed global disease activity (e.g., by VAS)
4. Evaluator-assessed global disease activity (e.g., by VAS)
5. Patient pain assessment (e.g., by VAS)
6. Functional disability (e.g., by HAQ)
7. Acute phase response (ESR or CRP)
A 50 and 70 percent ACR response (ACR50 and ACR70, respectively) represents respective improvement of at least 50 or 70 percent[1].
 1. *Felson DT, Anderson JJ, Lange ML, et al. Should improvement in rheumatoid arthritis clinical trials be defined as fifty percent or seventy percent improvement in core set measures, rather than twenty percent?. Arthritis Rheum 1998; 41:1564.* 2. *Felson DT, Anderson JJ, Boers M, et al. American College of Rheumatology preliminary definition of improvement in rheumatoid arthritis. Arthritis Rheum 1995; 38:727.*

American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR) Classification Criteria for Systemic Sclerosis (SSc):

ACR-EULAR Criteria for the classification of Systemic Sclerosis		
These criteria are ***not*** applicable to: a) Patients having a SSc-like disorder better explaining their manifestations, such as: nephrogenic sclerosing fibrosis, generalized morphea, eosinophilic fasciitis, scleredema diabeticorum, scleromyxedema, erythromyalgia, porphyria, lichen sclerosis, graft versus host disease, and diabetic cheiropathy. b) Patients with `*Skin thickening sparing the fingers*' ***Patients having a total score of 9 or more are classified as having definite systemic sclerosis***		
Items	Sub-items	Weight score
Skin thickening of the fingers of both hands extending proximal to the metacarpophalangeal joints is a sufficient criterion to classify as having SSc		9
Skin thickening of the fingers *(only count the highest score)*	Puffy fingers Sclerodactyly of the fingers (distal to MCP but proximal to the PIPs)	2 4
Finger-tip lesions *(only count the highest score)*	Digital Tip Ulcers Finger Tip Pitting Scars	2 3
Telangiectasia		2

Abnormal nail-fold capillaries		2
Pulmonary arterial hypertension and/or Interstitial lung Disease (Maximum score is 2)	PAH ILD	2
Raynaud's phenomenon		3
Systemic sclerosis-related autoantibodies (any of anti-centromere, anti-topoisomerase I [anti-Sd 70], anti-RNA polymerase III) (Maximum score is 3)	Anti-centromere Anti-topoisomerase I Anti-RNA polymerase III	3
Total score		

PAH (pulmonary arterial hypertension) is defined as proven PAH by right heart catheterization

ILD (interstitial lung disease) is defined as pulmonary fibrosis on HRCT or chest radiograph, most pronounced in the basilar portions of the lungs, or presence of `velcro' crackles on auscultation not due to another cause such as congestive heart failure

Definitions of the SSc classification criteria items

Item	Definition
Skin thickening	Skin thickening or hardening not due to scarring after injury, trauma, etc.
Puffy fingers	Swollen digits - a diffuse, usually non-pitting increase in soft tissue mass of the digits extending beyond the normal confines of the joint capsule. Normal digits are narrowed distally with the tissues following the contours of the digital bone and joint structures. Swelling of the digits obliterates these contours. Not due to other reasons such as inflammatory dactylitis
Finger-tip ulcers or pitting scars	Ulcers or scars distal to or at the PIP joint not thought to be due to trauma. Digital pitting scars are depressed areas at digital tips as a result of ischemia, rather than trauma or exogenous causes.
Telangiectasia	Telangiectasia(e) in a scleroderma like pattern are round and well demarcated and found on hands, lips, inside of the mouth, and/or large matt-like telangiectasia(e). Telangiectasiae are visible macular dilated superficial blood vessels; which collapse upon pressure and fill slowly when pressure is released; distinguishable from rapidly filling spider angiomas with central arteriole and from dilated superficial vessels.
Abnormal nail-fold capillary pattern consistent with SSc	Enlarged capillaries and/or capillary loss with or without peri-capillary hemorrhages at the nail-fold and may be seen on the cuticle.
Pulmonary arterial hypertension	Pulmonary arterial hypertension diagnosed by right heart catheterization according to standard definitions.
Interstitial lung disease	Pulmonary fibrosis on HRCT or chest radiograph, most pronounced in the basilar portions of the lungs, or presence of `Velcro' crackles on auscultation not due to another cause such as congestive heart failure.
Raynaud's phenomenon	Self-report or reported by a physician with at least a two-phase color change in finger(s) and often toe(s) consisting of pallor, cyanosis and/or reactive hyperemia in response to cold exposure or emotion; usually one phase is pallor.
Systemic sclerosis-related autoantibodies	Anti-centromere antibody or centromere pattern on antinuclear antibody (ANA) testing; anti-topoisomerase I antibody (also known as anti-Scl70 antibody); or anti-RNA polymerase III antibody. Positive according to local laboratory standards.

Modified Rodnan Skin Score (mRSS):
Skin thickness assessment. The mRSS scores are rated as 0 = normal skin, 1 = mild thickness, 2 = moderate thickness, 3 = severe thickness with inability to pinch the skin into a fold across 17 different sites. The total score is the sum of the individual skin scores in the 17 body areas (e.g., face, anterior chest, abdomen, upper arm (left and right), forearm (left and right), hand (left and right), fingers (left and right), thigh (left and right), leg (left and right), and foot (left and right), giving a range of 0-51 units. It has been validated for participants with systemic sclerosis (SSc). A negative change from baseline indicates improvement.

Ulcerative Colitis Activity (Adults):

American College of Gastroenterology Ulcerative Colitis Activity Index				
	Remission	Mild	Moderate-severe	Fulminant
Stools (no./d)	Formed	< 4	> 6	> 10
Blood in stools	None	Intermittent	Frequent	Continuous
Urgency	None	Mild, occasional	Often	Continuous
Hemoglobin	Normal	Normal	< 75% of normal	Transfusion needed
ESR	< 30	< 30	> 30	> 30
CRP (mg/L)	Normal	Elevated	Elevated	Elevated
Fecal calprotectin (mg/g)	< 150-200	> 150-200	> 150-200	> 150-200
Endoscopy (Mayo sub-score)	0-1	1	2-3	3
UCEIS	0-1	2-4	5-8	7-8
The above factors are general guides for disease activity. With the exception of remission, a patient does not need to have all the factors to be considered in a specific category. CRP, C-reactive protein; ESR, erythrocyte sedimentation rate; UCEIS, Ulcerative Colitis Endoscopic Index of Severity.				

Endoscopic Assessment of Disease Activity		
Endoscopic Features	UCEIS Score	Mayo Score
Normal	0	0
Erythema, decreased vascular pattern, mild friability	1-3	1
Marked erythema, absent vascular pattern, friability, erosions	4-6	2
Spontaneous bleeding, ulceration	7-8	3

Pediatric ulcerative colitis activity index (PUCAI)

Abdominal pain	No pain	0 points
	Pain can be ignored	5 points
	Pain cannot be ignored	10 points
Rectal Bleeding	None	0 points
	Small amount only, in <50% of stools	10 points
	Small amount with most stools	20 points
	Large amount (>50% of the stool content)	30 points
Stool consistency of most stools	Formed	0 points
	Partially formed	5 points
	Completely unformed	10 points
Number of stools er 24 hours	0 to 2	0 points
	3 to 5	5 points
	6 to 8	10 points
	>8	15 points
Nocturnal stools (any episode causing wakening)	No	0 points
	Yes	10 points
Activity level	No limitation of activity	0 points
	Occasional limitation of activity	5 points
	Severe restricted activity	10 points

Sum (0-85) PUCAI scores are interpreted as follows: 0 to 9 – Remission 10 to 34 – Mild disease 35 to 64 – Moderate disease 65 to 85 – Severe disease

Uveitis:
Uveitis is characterized by inflammation of the uvea, which is the middle portion of the eye made up of the iris, ciliary body and choroid. The anterior portion of the uvea includes the iris and ciliary body, the posterior portion of the uvea is known as the choroid. There are several types of uveitis, defined by the part of the eye where it occurs:

- Iritis also called anterior uveitis, is the most common type of uveitis
- Intermediate uveitis or pars planitis is inflammation of the uvea in the middle or intermediate region of the eye
- Posterior uveitis affects the back parts of your eye
- Panuveitis occurs when all layers of the uvea are inflamed

Resources:

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