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
BIMZELX® (bimekizumab-bkzx) SQ
CIMZIA® (certolizumab pegol) SQ
COSENTYX® (secukinumab) IV & SQ
ENBREL® (etanercept) SQ
KEVZARA® (sarilumab) SQ
OMVOH™ (mirikizumab-mrkz) IV & SQ
ORENCIA® (abatacept) IV & SQ
SILIQ™ (brodalumab) SQ
SIMPONI® (golimumab) SQ
SIMPONI ARIA® (golimumab) IV
SKYRIZI™ (risankizumab-rzaa) IV & SQ
TALTZ® (ixekizumab) SQ
TOFIDENCE™ (tocilizumab-bavi) IV
TREMFYA® (guselkumab) IV & SQ
TYENNE® (tocilizumab-aazg) IV & 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 prior authorization 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. 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: Bimzelx, Cimzia, Cosentyx, Enbrel, Simponi, Simponi Aria, Taltz

2. Prescriber is a Rheumatologist

3. Individual is 18 years of age or older

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 to 4 or more months of therapy with sulfasalazine

6. 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

7. Individual has documented failure, contraindication per FDA label, intolerance, or is 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

8. **For Taltz**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following preferred agents:
    a. Adalimumab product
    b. Cimzia
    c. Enbrel
    d. Rinvoq
    e. Simponi or Simponi Aria
    f. Xeljanz tab or Xeljanz XR

9. **For Cosentyx, Bimzelx**: **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
        i. Adalimumab product
        ii. Cimzia
        iii. Enbrel
        iv. Rinvoq
        v. Simponi or Simponi Aria
        vi. Xeljanz tab or Xeljanz XR
    b. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Taltz**

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

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

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

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

b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section B. 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: Bimzelx, Cimzia, Cosentyx, Taltz

2. Prescriber is a Rheumatologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure, contraindication per FDA label, intolerance, or is 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. **For Taltz**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following agents:
    a. Cimzia
    b. Rinvoq

8. **For Cosentyx, Bimzelx**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following agents:
    a. Cimzia
    b. Rinvoq
    c. Taltz

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

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

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. Individual's condition has 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. 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:
    b. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
    c. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section C. 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: Cimzia, Omvoh, Skyrizi (IV&SQ), Tremfya (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **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

7. **For Omvoh (IV&SQ)**: Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
    a. Adalimumab product
    b. Rinvoq

c. Skyrizi (IV&SQ)
d. Tremfya (IV&SQ)
e. Ustekinumab product

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

4. Individual does **NOT** have **ANY** of the following:
    c. Evidence of active serious infections including, opportunistic infections, fungal infections, tuberculosis, clinically important localized infections, sepsis, Hepatitis B, or Hepatitis C
    d. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section D. 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. Individual is 18 years of age or older

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 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

9. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **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

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

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

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

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
   b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section E. Plaque Psoriasis (Ps also as 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 plaque psoriasis:

1. Request is for **ONE** of the following: Bimzelx, Cimzia, Cosentyx, Enbrel, Siliq, Skyrizi, Taltz, Tremfya

2. Prescriber is a Dermatologist

3. Individual is **ONE** of the following:
   a. **For Enbrel**: 4 years of age or older
   b. **For Cosentyx, Taltz**: 6 years of age or older
   c. **For Bimzelx, Cimzia, Siliq, Skyrizi, Tremfya**: 18 years of age or older

4. Individual has a 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 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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for a treatment regimen that includes **ALL** of the following:
   a. A trial of at 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)

7. **For Taltz**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following preferred agents:
   a. Adalimumab product
   b. Cimzia
   c. Enbrel
   d. Skyrizi
   e. Tremfya
   f. Ustekinumab product

8. **For Bimzelx, Cosentyx, or Silig**: **BOTH** of the following:
   a. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **THREE** of the following preferred agents:
      i. Adalimumab product
      ii. Cimzia
      iii. Enbrel
      iv. Skyrizi
      v. Tremfya
      vi. Ustekinumab product
   b. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for: **Taltz**

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

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

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

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
   b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section F. Juvenile Idiopathic Arthritis (JIA) subtypes: Polyarticular (pJIA) & Systemic (sJIA):

- **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 juvenile idiopathic arthritis:

1. Request is for **ONE** of the following:
   a. **For polyarticular juvenile idiopathic arthritis (pJIA):** Actemra (IV&SQ), Enbrel, Kevzara, Orencia (IV&SQ), Simponi Aria, Tofidence (IV), Tyenne (IV&SQ)
   b. **For systemic juvenile idiopathic arthritis (sJIA):** Actemra (IV&SQ), Tofidence (IV), Tyenne (IV&SQ)

2. Prescriber is a Rheumatologist

3. Individual is 2 years of age or older

4. **ONE** of the following:
   a. **For polyarticular JIA:** Individual has arthritis in **five** or more joints during the first six months of disease and **NONE** of the following:
      i. Fever, rash, lymphadenopathy, hepatosplenomegaly
      ii. Arthritis starting after 6 years of age in male individual who is positive for HLA-B27
      iii. Personal history or first degree relative with psoriasis, ERA, ankylosing spondylitis, sacroiliitis with IBD, reactive arthritis, anterior uveitis
   b. **For systemic JIA:** Individual has arthritis in **one** or more joints, a daily, high, spiking fever of at least two weeks' duration (with at least three days of an intermittent or quotidian pattern), is negative for rheumatoid factor, and has **ONE** or more of the following features:

i. Evanescent salmon-colored erythematous rash
ii. Generalized lymphadenopathy
iii. Hepatomegaly and/or splenomegaly
iv. Serositis

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
      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

6. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for methotrexate

7. **Treatments for Polyarticular Juvenile Idiopathic Arthritis (pJIA):**
   a. **For Actemra (IV&SQ), Orencia (IV&SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
      i. Adalimumab product
      ii. Cimzia
      iii. Enbrel
      iv. Rinvoq or Rinvoq LQ
      v. Simponi Aria
      vi. Xeljanz or Xeljanz Oral Solution
   b. **For Tofidence (IV), Tyenne (IV&SQ) BOTH** of the following:
      i. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
         1. Adalimumab product
         2. Cimzia
         3. Enbrel
         4. Rinvoq or Rinvoq LQ
         5. Simponi Aria
         6. Xeljanz or Xeljanz Oral Solution
      ii. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Actemra
   c. **For Kevzara**:
      i. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
         1. Adalimumab product
         2. Cimzia
         3. Enbrel
         4. Rinvoq or Rinvoq LQ
         5. Simponi Aria
         6. Xeljanz or Xeljanz Oral Solution
      ii. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:

1. **ONE** of the following:
    a. Actemra
    b. Tofidence (IV)
    c. Tyenne (IV&SQ)
2. Additional criteria for Tofidence (IV), Tyenne (IV&SQ): Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Actemra
3. Orencia (IV or SQ)

8. **Treatments for Systemic Juvenile Idiopathic Arthritis (sJIA):** Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
    a. **ONE** of the following:
        i. Actemra (IV&SQ)
        ii. Tofidence (IV)
        iii. Tyenne (IV&SQ)
    b. Additional criteria for Tofidence (IV), Tyenne (IV&SQ): Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Actemra

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

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

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. Individual's condition has 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

2. **For Tofidence and Tyenne continuation requests:** Individual meets **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for Actemra
    b. Provider has submitted justification as to why the non-preferred agent would be more effective than Actemra (IV&SQ)

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., adalimumab, Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section G. 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: Bimzelx, Cimzia, Cosentyx, Cyltezo, Enbrel, Orencia (IV&SQ), Simponi, Simponi Aria, Skyrizi, Taltz, Tremfya

2. Prescriber is a Rheumatologist or Dermatologist

3. Individual is **ONE** of the following:
    a. **For Cosentyx, Orencia, Simponi Aria**: 2 years of age or older
    b. **For Bimzelx, Cimzia, Cyltezo, Enbrel, Simponi, Skyrizi, Tremfya**: 18 years of age or older

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 to 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. 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

6. **For Taltz**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following preferred agents:
    a. Adalimumab product
    b. Cimzia
    c. Enbrel
    d. Rinvoq or Rinvoq LQ
    e. Simponi or Simponi Aria
    f. Skyrizi
    g. Tremfya
    h. Ustekinumab product
    i. Xeljanz tab or Xeljanz XR

7. **For Orencia (IV&SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
    a. Adalimumab product
    b. Cimzia
    c. Enbrel
    d. Rinvoq or Rinvoq LQ
    e. Simponi or Simponi Aria
    f. Skyrizi
    g. Tremfya
    h. Ustekinumab product
    i. Xeljanz tab or Xeljanz XR

8. **For Cosentyx, Bimzelx**: **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
        i. Adalimumab product
        ii. Cimzia
        iii. Enbrel
        iv. Rinvoq or Rinvoq LQ
        v. Simponi or Simponi Aria
        vi. Skyrizi
        vii. Tremfya
        viii. Ustekinumab product
        ix. Xeljanz tab or Xeljanz XR
    b. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
        i. Orencia (IV or SQ)
        ii. Taltz

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

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

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

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
    b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section H. 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: Actemra (IV&SQ), Cimzia, Enbrel, Kevzara, Orencia (IV&SQ), Simponi, Simponi Aria, Tofidence (IV), Tyenne (IV&SQ)

2. Prescriber is a Rheumatologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **methotrexate**

7. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **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

8. **For Actemra (IV&SQ), Orencia (IV&SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
    a. Adalimumab product
    b. Cimzia
    c. Enbrel
    d. Rinvoq
    e. Simponi or Simponi Aria
    f. Xeljanz tab or Xeljanz XR tab

9. **For Tofidence (IV), Tyenne (IV&SQ)** **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
        i. Adalimumab product
        ii. Cimzia
        iii. Enbrel
        iv. Rinvoq
        v. Simponi or Simponi Aria
        vi. Xeljanz tab or Xeljanz XR tab
    b. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra**

10. **For Kevzara**: **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
        i. Adalimumab product
        ii. Cimzia
        iii. Enbrel
        iv. Rinvoq

v. Simponi or Simponi Aria
vi. Xeljanz tab or Xeljanz XR tab

b. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ALL** of the following:
   i. **ONE** of the following:
      1. Actemra
      2. Tofidence (IV)
      3. Tyenne (IV&SQ)
   ii. Orencia (IV or SQ)
   iii. **Additional criteria for Tofidence (IV), Tyenne (IV&SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra**

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

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

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. Individual's condition has 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

2. **For Tofidence and Tyenne continuation requests:** Individual meets **BOTH** of the following:
   a. Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Actemra
   b. Provider has submitted justification as to why the non-preferred agent would be more effective than Actemra (IV&SQ)

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., adalimumab, Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Renewal Duration: 12 months

Section I. 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: Omvoh (IV&SQ), Simponi, Skyrizi (IV&SQ), Tremfya (IV&SQ)

2. Prescriber is a Gastroenterologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **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)

7. **For Omvoh (IV&SQ)**: Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **TWO** of the following preferred agents:
   a. Adalimumab product
   b. Rinvoq
   c. Skyrizi (IV&SQ)
   d. Simponi
   e. Tremfya (IV&SQ)
   f. Ustekinumab product
   g. Xeljanz or Xeljanz XR

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

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

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. Individual's condition has 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

2. Individual has been adherent with the medication

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

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
   b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

Section J. Prophylaxis of Acute Graft versus Host Disease (aGVHD):

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

1. Request is for Orencia for prophylaxis of acute graft versus host disease (aGVHD)
2. Prescriber is a Transplant Specialist
3. Individual is 18 years of age or older
4. Individual has undergone hematopoietic stem cell transplantation (HSCT) with a matched or 1-allel-mismatched unrelated donor (URD)
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
        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
6. Orencia will be used in combination with a calcineurin inhibitor (ex., cyclosporine or tacrolimus) and methotrexate with or without antithymocyte globulin (ATG)
7. Individual has a Karnofsky/Lansky Performance Score ≥80%
8. There are **NO** FDA-label contraindications
9. There is no concomitant use with biologic immunomodulators or other potent immunosuppressants (e.g., adalimumab, Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Sotyktu, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Orencia 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's condition has responded while on therapy

2. Individual has been adherent with the medication

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

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
    b. Concurrent use of live vaccines

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

Renewal duration: 12 months

Section K. Cytokine Release Syndrome:

- **Criteria for initial therapy:** Actemra (IV), Tofidence (IV), or Tyenne (IV) 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) or Tofidence (IV) or Tyenne (IV)

2. Individual is 2 years of age or older

3. 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

4. **Additional criteria for Tofidence (IV) Tyenne (IV)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra** (IV)

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

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

Approval Duration: One time only

Section L. Giant Cell Arteritis:

- **Criteria for initial therapy:** Actemra (IV&SQ), or Tofidence (IV), or Tyenne (IV&SQ) 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), or Tofidence (IV), or Tyenne (IV&SQ)
2. Prescriber is a Rheumatologist
3. Individual is 50 years of age or older
4. Has a diagnosis of new-onset or relapsing giant cell arteritis (also known as temporal arteritis)
5. Diagnosis is confirmed by temporal artery biopsy or evidence of large vessel vasculitis by angiography or cross-sectional imaging such as ultrasound, magnetic resonance imaging (MRI), computed tomography (CT) or positron emission tomography (PET)
6. Individual is on high-dose corticosteroid and giant cell arteritis is clinically stable
7. Individual has **ALL** of the following:
    a. History of erythrocyte sedimentation rate (ESR) of at least 50 mm/hour or high sensitivity C-reactive protein (hsCRP)/CRP of at least 1 mg/dL
    b. **ONE** of the following:
        i. Cranial symptoms of GCA (new-onset localized headache, scalp tenderness, temporal artery tenderness or decreased pulsation, ischemia-related vision loss, or otherwise unexplained mouth or jaw pain upon mastication)
        ii. Symptoms of polymyalgia rheumatica (PMR) (shoulder and/or hip girdle pain associated with inflammatory morning stiffness)
8. **Additional criteria for Actemra**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Rinvoq**
9. **Additional criteria for Tofidence (IV), Tyenne (IV&SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
    a. **Rinvoq**
    b. **Actemra** (IV&SQ)
10. There are **NO** FDA-label contraindications
11. 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

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

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Actemra (IV&SQ), or Tofidence (IV), or Tyenne (IV&SQ) 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 has been adherent with the medication

2. Individual's condition has 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

3. **For Tofidence and Tyenne continuation requests:** Individual meets **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **Actemra**
    b. Provider has submitted justification as to why the non-preferred agent would be more effective than **Actemra** (IV&SQ)

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
    b. Concurrent use of live vaccines

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

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

Renewal duration: 12 months

Section M. Hidradenitis Suppurativa:

- **Criteria for initial therapy:** Biologic and Immunological Agent 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 Bimzelx, Cosentyx

2. Prescriber is a Dermatologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure, contraindication per FDA label, intolerance, or is not a candidate for oral antibiotics (at maximum recommended doses) for at least 3 consecutive months (i.e., tetracycline, clindamycin plus rifampin, minocycline, doxycycline)

7. **Bimzelx, Cosentyx**: Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for an Adalimumab product

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

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

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Biologic and Immunological Agent 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's condition has 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

2. Individual has been adherent with the medication

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

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
    b. Concurrent use of live vaccines

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

Renewal Duration: 12 months

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

- **Criteria for initial therapy:** Actemra (SQ) or Tofidence or Tyenne (SQ) 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) or Tofidence or Tyenne (SQ)

2. Prescriber is a Rheumatologist or Pulmonologist

3. Individual is 18 years of age or older

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 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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication, intolerance, or is not a candidate for mycophenolate

7. **Additional criteria for** Tofidence or **Tyenne (SQ)**: Individual has documented failure (used for ≥ 3 consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra** (SQ)

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

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

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

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Actemra (SQ) or Tofidence or Tyenne (SQ) 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's condition has 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

2. **For** Tofidence or **Tyenne (SQ) continuation requests:** Individual meets **BOTH** of the following:
    a. Individual has documented failure (used for ≥ 6 consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **Actemra**
    b. Provider has submitted justification as to why the non-preferred agent would be more effective than Actemra (IV&SQ)

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

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

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

9. 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

Renewal duration: 12 months

Section O. Polymyalgia rheumatica (PMR)

- **Criteria for initial therapy:** Kevzara is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met for polymyalgia rheumatica (PMR):

1. Request is for Kevzara

2. Prescriber is a Rheumatologist

3. Individual is 18 years of age or older

4. Individual has confirmed diagnosis of polymyalgia rheumatica (PMR) diagnosis and meets **ALL** of the following:
    a. 50 years of age or older
    b. Bilateral shoulder and/or hip girdle pain
    c. Morning stiffness lasting longer than 45 minutes
    d. Symptoms present more than 2 weeks
    e. Elevated ESR or CRP
    f. Responded to corticosteroid but is unable to taper down dose without a PMR flare

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
        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

6. Individual has documented failure (used for ≥ 3 consecutive months), contraindication, intolerance, or is not a candidate for methotrexate

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

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

Approval Duration: 6 months

- **Criteria for continuation of coverage (renewal request):** Kevzara 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's condition has responded while on therapy with response defined as **TWO** of the following:
    a. Sustained reduction in CRP
    b. Reduction in number of PMR flares
    c. Reduction in corticosteroid dose
    d. Absence of PMR symptoms (shoulder pain, hip pain, morning stiffness, etc.)
2. Individual has been adherent with the medication
3. Individual has not developed any significant adverse drug effects that may exclude continued use such as liver toxicity
4. There are no significant interacting drugs
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., adalimumab, Adbry, azathioprine, cyclosporine, Dupixent, rituximab, infliximab, Enbrel, Otezla, Vtama, Xolair, or JAK inhibitors (Cibinqo, Olumiant, Opzelura, Rinvoq, Rinvoq LQ, Xeljanz IR, XR, solution), etc.)

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:

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

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

Definitions:

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

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	
© 2018 UpToDate, Inc. *Originally published in: Garrett S, Jenkinson T, Kennedy LG, et al. A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. J Rheumatol 1994; 21:2286. Reproduced with permission from: the Royal National Hospital for Rheumatic Diseases NHS Foundation Trust, Bath. www.rnhrd.nhs.uk. Copyright ©*	

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
	≥37	0 points

Hematocrit (%) 15 to 19 years (male)	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].
© 2018 UpToDate, Inc. 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, scleroderma 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

Resources:

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