BlueCross BlueShield Arizona

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PHARMACY COVERAGE GUIDELINE

BIOLOGIC AND IMMUNOLOGICAL AGENTS – INJECTION:
ACTEMRA® (tocilizumab) IV & SQ
AVTOZMA® (tocilizumab) IV
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/or 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

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at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

NOTE: Subcutaneous injection products are covered under the pharmacy benefit only and **ALL** intravenous injection products are covered under the medical benefit only.

Section A. Ankylosing Spondylitis (AS):

Medical Necessity Requirements for BIMZELX (bimekizumab-bkzx), CIMZIA (certolizumab pegol), COSENTYX (secukinumab), ENBREL (etanercept), SIMPONI ARIA (golimumab), SIMPONI (golimumab), and TALTZ (ixekizumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

Indication

- Moderately to severely active Ankylosing Spondylitis

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- Back pain for greater than or equal to 3 months with onset at age less than or equal to 45 years
- Sacroiliitis on x ray showing structural damage
- Spondyloarthritis signs or symptoms (**ANY** of the following):
  - Arthritis
  - Elevated C reactive protein
  - Enthesitis
  - HLA B27
  - Limited chest expansion
  - Morning stiffness greater than or equal to 1 hour
- Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater than or equal to 4 on a 0 to 10 numerical scale
- Spinal pain greater than or equal to 4 on 0 to10 scale

Alternative Therapies

- Failure, contraindication, or intolerance **TWO** non-steroidal anti inflammatory drugs (NSAIDs) for a total of at least 4 weeks

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- **For BIMZELX and COSENTYX: BOTH** of the following:
  - Failure, contraindication, intolerance, or is not a candidate for **TWO** of the following preferred agents:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq
    5. Simponi or Simponi Aria
    6. Xeljanz IR/XR
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for:
    1. Taltz
- **For TALTZ: ONE** of the following:
  - Adalimumab product
  - Cimzia
  - Enbrel
  - Rinvoq
  - Simponi or Simponi Aria
  - Xeljanz IR/XR

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Rheumatologist or is in consultation with a Rheumatologist

Clinical Response

- **First renewal:** Greater than or equal to 20 percent improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
- **Subsequent renewals:** Disease stability or improvement

Adherence

- Adherence to the prescribed therapy regimen has been documented

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Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section B. Non-radiographic Axial Spondyloarthritis (nr-axSpA):

Medical Necessity Requirements for BIMZELX (bimekizumab-bkzx), CIMZIA (certolizumab pegol), COSENTYX (secukinumab), and TALTZ (ixekizumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

Indication

- Active Non Radiographic Axial Spondyloarthritis with objective signs of inflammation

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **ALL** of the following
  - Back pain for 3 or more months with onset at age less than or equal to 45 years
  - Sacroiliitis on x ray imaging but **does not show** definitive radiographic evidence of **structural damage** of sacroiliac joints
  - Spondyloarthritis signs or symptoms as indicated by **ONE or more** of the following:
    1. Arthritis
    2. Elevated serum C reactive protein
    3. Enthesitis (e.g., inflammation of Achilles tendon insertion)
    4. HLA B27
    5. Limited chest expansion

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6. Morning stiffness for one hour or more
  - Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) greater than or equal to 4 on 0 to 10 scale
  - Spinal pain greater than or equal to 4 on 0 to 10 scale

Alternative Therapies

- Failure, contraindication, intolerance, or is not a candidate for **TWO** non steroidal anti inflammatory drugs (NSAIDs) for a total of at least 4 weeks
- **For BIMZELX and COSENTYX: ALL** the following:
  - Cimzia
  - Rinvoq
  - Taltz
- **For TALTZ: ONE** of the following:
  - Cimzia
  - Rinvoq

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Rheumatologist or is in consultation with a Rheumatologist

Clinical Response

- **First renewal:** Greater than or equal to 20 percent improvement in Bath Ankylosing Spondylitis Disease Activity Index (BASDAI)
- **Subsequent renewals:** Disease stability or improvement

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

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- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section C. Crohn's Disease (CD):

Medical Necessity Requirements for CIMZIA (certolizumab pegol), OMVOH (mirikizumab-mrkz), SKYRIZI (IV&SQ) (risankizumab-rzaa), and TREMFYA (IV&SQ) (guselkumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Gastroenterologist or is in consultation with a Gastroenterologist

Indication

- Moderate to severe active Crohn's disease

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **ONE** of the following:
  - Crohn's disease activity index (CDAI) greater than 220 in adults
  - Pediatric Crohn's disease activity index (PCDAI) greater than 30
  - **At least 5** of the following signs and symptoms:
    1. Anemia
    2. Chronic intermittent diarrhea (with or without food)
    3. Crampy abdominal pain
    4. Elevated serum C reactive protein level and/or fecal calprotectin
    5. Extraintestinal manifestations (arthritis or arthropathy, eye and skin disorders, biliary tract involvement, and kidney stones)
    6. Fatigue
    7. Fistulas

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8. Perianal disease (e.g., anal fissures, anorectal abscess)
9. Weight loss or growth failure in children

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, 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]:
  - 6 mercaptopurine
  - Azathioprine
  - Methotrexate
  - Oral corticosteroids
- **For Omvoh (IV&SQ)**: Individual has documented failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **TWO** of the following preferred agents:
  - Adalimumab product
  - Rinvoq
  - Skyrizi (IV&SQ)
  - Tremfya (IV&SQ)
  - Ustekinumab product

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Gastroenterologist or is in consultation with a Gastroenterologist

Clinical Response

- Documentation of positive clinical response to therapy defined as the following:
  - **With first request for continuation ONE of the following:**

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1. AT LEAST a 20 percent improvement in the signs and symptoms of Crohn's disease
2. Decrease in Crohn's disease activity index of more than 70 from baseline or a Crohn's disease activity index of less than 150 (in remission) in adults
3. Pediatric Crohn disease activity index (PCDAI) less than or equal to 30 in children indicating mild disease or disease remission

- **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section D. Enthesitis Related Arthritis (ERA):

Medical Necessity Requirements for COSENTYX (secukinumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

Indication

- Enthesitis Related Arthritis (ERA)

Age Requirement

- 4 years of age or older

Baseline Clinical Evaluation

- **ONE** of the following:

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- Peripheral arthritis and enthesitis of greater than or equal to 6 weeks duration in children aged less than 18 years
- Arthritis or enthesitis, plus greater than or equal to 3 months of inflammatory back pain and sacroiliitis on imaging
- Arthritis or enthesitis plus **TWO** of the following:
  1. Sacroiliac joint tenderness
  2. Inflammatory lumbosacral pain
  3. Presence of HLA B27 antigen
  4. Anterior uveitis that is symptomatic with pain, redness, or photophobia
  5. History of a spondyloarthritis in a first-degree relative

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

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **ONE or more** of the following:
  - At least **ONE** nonsteroidal anti inflammatory drug (NSAID) such as diclofenac, indomethacin, naproxen, others
  - At least **ONE** Disease modifying antirheumatic drugs (DMARD) such as methotrexate, sulfasalazine, others

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Rheumatologist or is in consultation with a Rheumatologist

Clinical Response

- Documentation of positive clinical response to therapy defined as the following:

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- **With first request for continuation ONE of the following:**
  1. AT LEAST 30 percent improvement in at least 3 of the 6 Juvenile Idiopathic Arthritis (JIA) Core set variables
  2. An increase in time to next flare
- **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section E. Plaque Psoriasis (Ps also as PsO):

Medical Necessity Requirements for BIMZELX (bimekizumab-bkzx), **CIMZIA** (certolizumab pegol), **COSENTYX** (secukinumab), **ENBREL** (etanercept), **SILIQ** (brodalumab), **SKYRIZI** (risankizumab-rzaa), **TALTZ** (ixekizumab), and **TREMFYA** (guselkumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Dermatologist or is in consultation with a Dermatologist

Indication

- Plaque Psoriasis (Psoriasis or PsO)

Age Requirement

- **ONE** of the following:
  - **For Enbrel**: 4 years of age or older

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- **For Cosentyx, Taltz**: 6 years of age or older
- **For Bimzelx, Cimzia, Siliq, Skyrizi**: 18 years of age or older
- **For Tremfya**: 6 years of age or older and weighing at least 40kg

Baseline Clinical Evaluation

- Clinical documentation of moderate to severe plaque psoriasis, as indicated by **ALL** of the following:
  - Is a candidate for photochemotherapy or phototherapy
  - Plaque psoriasis involves greater than or equal to 10 percent body surface area (BSA) **or** plaque psoriasis involves less than 10 percent BSA but includes sensitive areas or areas that significantly impact daily function (e.g., palms, soles of feet, head/neck, or genitalia)
  - A Psoriasis Area and Index (PASI) of at least 10

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for a treatment regimen that includes **ALL** of the following:
  - Trial of at least **TWO** topical agents (e.g., anthralin, calcipotriene, coal tars, corticosteroids, tazarotene)
  - Trial of **ONE** immunosuppressive treatment (e.g., cyclosporine, methotrexate)
  - Trial of Ultraviolet Light therapy (e.g., Photochemotherapy (i.e., psoralen plus ultraviolet A therapy), Phototherapy (i.e., ultraviolet light therapy), or Excimer laser)
- **<u>For Taltz</u>**: Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for a treatment regimen that includes **ONE** of the following:
  - Adalimumab product
  - Cimzia
  - Enbrel
  - Skyrizi
  - Tremfya
  - Ustekinumab product
- **<u>For Bimzelx, Cosentyx, or Siliq</u>**: **BOTH** of the following:
  - Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **THREE** of the following preferred agents:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Skyrizi
    5. Tremfya
    6. Ustekinumab product
  - Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for:
    1. Taltz

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

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- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Dermatologist or is in consultation with a Dermatologist

Clinical Response

- Documentation of positive clinical response to therapy defined as the following:
  - **With first request for continuation:** AT LEAST a 20 percent improvement in Psoriasis Area and Index (PASI) (see Definitions section)
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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

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Medical Necessity Requirements for ACTEMRA (IV&SQ) (tocilizumab), **AVTOZMA (IV)** (tocilizumab-anoh), **CIMZIA** (certolizumab pegol), **ENBREL** (etanercept), **KEVZARA** (sarilumab), **ORENCIA (IV&SQ)** (abatacept), **SIMPONI ARIA** (golimumab), **TOFIDENCE (IV)** (tocilizumab-bavi), and **TYENNE (IV&SQ)** (tocilizumab-aazg)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

Indication
- Juvenile Idiopathic Arthritis (Polyarticular subtype or Systemic subtype)

Age Requirement
- 2 years or older

Baseline Clinical Evaluation
- **For polyarticular JIA:** Has arthritis in **five** or more joints during the first six months of disease and **NONE** of the following:
  - Fever, rash, lymphadenopathy, hepatosplenomegaly
  - Arthritis starting after 6 years of age in male individual who is positive for HLA B27
  - Personal history or first degree relative with psoriasis, ERA, ankylosing spondylitis, sacroiliitis with IBD, reactive arthritis, anterior uveitis
- **For systemic JIA:** 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:
  - Evanescent salmon colored erythematous rash
  - Generalized lymphadenopathy
  - Hepatomegaly and/or splenomegaly
  - Serositis

Alternative Therapies
- Failure, contraindication per FDA label, intolerance, or is not a candidate for methotrexate
- **For Polyarticular Juvenile Idiopathic Arthritis (pJIA):**
  - **For Actemra (IV&SQ), Avtozma (IV), Orencia (IV&SQ)**: Failure (used for 3 or more consecutive months), contraindication 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
  - **Additional criteria for intravenous Actemra (IV):** Individual is unable to use **subcutaneous Actemra (SQ)** administered by self or caregiver. (**Note:** See Exceptions To Self-Administered Drugs Evidence Based Criteria)

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- **For Tofidence (IV), Tyenne (IV&SQ): BOTH** of the following:
  1. Failure (used for 3 or more 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 Aria
     f. Xeljanz or Xeljanz Oral Solution
  2. Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for Actemra or Avtozma (IV)
- **For Kevzara**:
  1. Failure (used for 3 or more 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 Aria
     f. Xeljanz or Xeljanz Oral Solution
  2. Failure (used for 3 or more 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. Avtozma (IV)
        iii. Tofidence (IV)
        iv. Tyenne (IV&SQ)
     b. **Additional criteria for Tofidence (IV), Tyenne (IV&SQ):** Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
        i. Actemra
        ii. Avtozma (IV)
     c. Orencia (IV or SQ)

- **<u>For Systemic Juvenile Idiopathic Arthritis (sJIA)</u>:**
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **ALL** of the following:
    1. **ONE** of the following:
       a. Actemra (IV&SQ)
       b. Avtozma (IV)
       c. Avtozma (IV)
       d. Tyenne (IV&SQ)
  - **Additional criteria for Tofidence (IV), Tyenne (IV&SQ):**
    1. Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **ONE** of the following:
       a. Actemra
       b. Avtozma (IV)

Safety

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- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Rheumatologist or is in consultation with a Rheumatologist

Clinical Response

- Documentation of positive clinical response to therapy defined as the following:
  - **With first request for continuation:** AT LEAST a 30 percent improvement in Juvenile Idiopathic Arthritis (JIA) Core Set (see Definitions section)
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- **For Tofidence and Tyenne:** Failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **Actemra** or **Avtozma IV**
- **For intravenous Actemra (IV):** Unable to use subcutaneous **Actemra (SQ)** administered by self or caregiver. (**Note:** See Exceptions To Self-Administered Drugs Evidence Based Criteria)
- **For Cimzia, Enbrel, Kevzara, Orencia, Simponi Aria:** Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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Section G. Psoriatic Arthritis (PsA):

Medical Necessity Requirements for BIMZELX (bimekizumab-bkzx), **CIMZIA** (certolizumab pegol), **COSENTYX** (secukinumab), **ENBREL** (etanercept), **ORENCIA (IV&SQ)** (abatacept), **SIMPONI ARIA** (golimumab), **SIMPONI** (golimumab), **SKYRIZI** (risankizumab-rzaa), **TALTZ** (ixekizumab), and **TREMFYA** (guselkumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or Dermatologist or is in consultation with a Rheumatologist or Dermatologist

Indication

- Moderate to severe active psoriatic arthritis

Age Requirement

- **For Cosentyx, Enbrel, Orencia, Simponi Aria**: 2 years of age or older
- **For Bimzelx, Cimzia, Simponi, Skyrizi, Taltz**: 18 years of age or older
- **For Tremfya**: 6 years of age or older and weighing at least 40kg

Baseline Clinical Evaluation

- **ONE or more** of the following:
  - Predominantly axial disease (i.e., sacroiliitis or spondylitis) as indicated by **ALL** of the following:
    1. Radiographic evidence of axial disease (e.g., sacroiliac joint space narrowing or erosions, vertebral syndesmophytes)
    2. Symptoms (e.g., limited spinal range of motion, spinal morning stiffness more than 30 minutes) present for more than 3 months duration
    3. Failure, contraindication, intolerance, or is not a candidate for **ONE** or more different NSAIDs (at maximum recommended doses) over total period of at least 4 or more weeks of therapy
  - Predominantly non axial disease, and failure (used 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for methotrexate or NSAIDs

Alternative Therapies

- **For Taltz (IV&SQ)**:
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **ONE** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq or Rinvoq LQ
    5. Simponi or Simponi Aria
    6. Skyrizi
    7. Tremfya

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8. Ustekinumab product
9. Xeljanz tab or Xeljanz XR

- **For Orencia (IV&SQ):**
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **TWO** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq or Rinvoq LQ
    5. Simponi or Simponi Aria
    6. Skyrizi
    7. Tremfya
    8. Ustekinumab product
    9. Xeljanz tab or Xeljanz XR
- **For Cosentyx, Bimzelx**: **BOTH the following:**
  - Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **TWO** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq or Rinvoq LQ
    5. Simponi or Simponi Aria
    6. Skyrizi
    7. Tremfya
    8. Ustekinumab product
    9. Xeljanz tab or Xeljanz XR
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
    1. Orencia (IV or SQ)
    2. Taltz

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

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Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications

- Prescribed by a Rheumatologist or Dermatologist or is in consultation with a Rheumatologist or Dermatologist

Clinical Response

- Documentation of positive clinical response to therapy defined as the following:
  - **With first request for continuation**: AT LEAST a 20 percent improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID 3, SDAI (see Definitions section)
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section H. Rheumatoid Arthritis (RA):

Medical Necessity Requirements for ACTEMRA (IV&SQ) (tocilizumab), **AVTOZMA (IV)** (tocilizumab-anoh), **CIMZIA** (certolizumab pegol), **ENBREL** (etanercept), **KEVZARA** (sarilumab), **ORENCIA (IV&SQ)** (abatacept), **SIMPONI ARIA** (golimumab), **SIMPONI** (golimumab), **TOFIDENCE (IV)** (tocilizumab-bavi), and **TYENNE (IV&SQ)** (tocilizumab-aazg)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

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Indication
- Rheumatoid arthritis

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- **ONE** of the following:
  - Clinical Disease Activity Index (CDAI) score greater than 10
  - Disease Activity Score 28 (DAS28) of greater than 3.2
  - Patient Activity Scale (PAS) of greater than 3.7
  - Patient Activity Scale II (PASII) of greater than 3.7
  - Routine Assessment of Patient Index Data 3 (RAPID 3) score greater than 2
  - Simplified Disease Activity Index (SDAI) score greater than 11

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **BOTH** of the following:
  - Methotrexate
  - Leflunomide or Sulfasalazine
- **For Actemra (IV&SQ), Avtozma (IV), Orencia (IV&SQ)**:
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **TWO** of the following:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq
    5. Simponi or Simponi Aria
    6. Xeljanz tab or Xeljanz XR tab
  - For **intravenous Actemra (IV):** Individual is unable to **use subcutaneous Actemra (SQ)** administered by self or caregiver. (**Note:** See *Exceptions To Self-Administered Drugs Evidence Based Criteria*)
- **For Tofidence (IV), Tyenne (IV&SQ) BOTH** of the following:
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **TWO** of the following preferred agents:
    1. Adalimumab product
    2. Cimzia
    3. Enbrel
    4. Rinvoq
    5. Simponi or Simponi Aria
    6. Xeljanz tab or Xeljanz XR tab
  - Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **ONE** of the following:
    1. Actemra
    2. Avtozma (IV)
- **For Kevzara**: **BOTH** of the following:

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- Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **TWO** of the following preferred agents:
  1. Adalimumab product
  2. Cimzia
  3. Enbrel
  4. Rinvoq
  5. Simponi or Simponi Aria
  6. Xeljanz tab or Xeljanz XR tab
- Failure (used for 3 or more consecutive months), contraindication, intolerance, or is not a candidate for **ALL** of the following preferred agents:
  1. **ONE** of the following:
     a. Actemra (IV&SQ)
     b. Avtozma (IV)
     c. Tofidence (IV)
     d. Tyenne (IV&SQ)
  2. **Additional criteria for Tofidence (IV), Tyenne (IV&SQ):** Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **ONE** of the following:
     a. Actemra
     b. Avtozma (IV)
  3. Orencia (IV or SQ)

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Rheumatologist or is in consultation with a Rheumatologist

Clinical Response

- Positive clinical response documented to therapy defined as the following:

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- **With first request for continuation**: AT LEAST a 20 percent improvement in any of the following: ACR, CDAI, DAS28, PAS, PASII, RAPID 3, SDAI (see Definitions section)
- **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- **For Tofidence and Tyenne:** Failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **Actemra** or **Avtozma IV**
- **For intravenous Actemra (IV):** Unable to use subcutaneous **Actemra (SQ)** administered by self or caregiver. (**Note:** See Exceptions To Self-Administered Drugs Evidence Based Criteria)
- **For Cimzia, Enbrel, Kevzara, Orencia, Simponi, Simponi Aria:** Failure, contraindication or intolerance with three generic equivalents (if available) for at least three months each. **Note**: Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section I. Ulcerative Colitis (UC):

Medical Necessity Requirements for OMVOH (IV&SQ) (mirikizumab-mrkz), SIMPONI (golimumab), SKYRIZI (IV&SQ) (risankizumab-rzaa), and TREMFYA (IV&SQ) (guselkumab)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Gastroenterologist or is in consultation with a Gastroenterologist

Indication

- Moderate to severe active ulcerative colitis

Age Requirement

- 18 years or older

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Baseline Clinical Evaluation

- **ONE** of the following:
  - American College of Gastroenterology Ulcerative Colitis activity index rating of moderate to severe disease in adults
  - Pediatric ulcerative colitis activity index (PUCAI) greater than or equal to 35
  - **At least 5** of the following signs and symptoms:
    1. Anemia
    2. Bloody diarrhea or visible blood in stool
    3. Bowel movements 4 to 6 or more times per day
    4. Colicky abdominal pain
    5. Elevated fecal calprotectin
    6. Elevated serum C-reactive protein or erythrocyte sedimentation rate
    7. Fatigue
    8. Fever
    9. Tenesmus
    10. Urgency
    11. Weight loss or delayed growth in children

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **ONE** or more of the following:
  - 6 mercaptopurine
  - Azathioprine
  - Oral corticosteroids
  - Salicylates (such as mesalamine, sulfasalazine, balsalazide, olsalazine)
- **For Omvoh:** Failure (trial for at least three months duration), contraindication, intolerance, or is not a candidate for **TWO** of the following:
  - Adalimumab product
  - Rinvoq
  - Skyrizi (IV&SQ)
  - Simponi
  - Tremfya (IV&SQ)
  - Ustekinumab product
  - Xeljanz or Xeljanz XR

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

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Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Gastroenterologist or is in consultation with a Gastroenterologist

Clinical Response

- Documented positive clinical response to therapy defined as the following:
  - **With first request for continuation ONE of the following:**
    1. AT LEAST a 20 percent improvement in signs and symptoms of ulcerative colitis
    2. American College of Gastroenterology Ulcerative Colitis activity index rating of mild disease or disease in remission in adults
    3. Pediatric ulcerative colitis activity index (PUCAI) of less than or equal to 34 in children indicating mild disease or disease remission
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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

Medical Necessity Requirements for ORENCIA (abatacept)

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Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Transplant Specialist or is in consultation with a Transplant Specialist

Indication
- Prophylaxis of Acute Graft versus Host Disease

Age Requirement
- 2 years or older

Baseline Clinical Evaluation
- Undergoing hematopoietic stem cell transplantation (HSCT) with a matched or 1-allel-mismatched unrelated donor (URD)
- Documentation of high risk for acute graft versus host disease
- Has a Karnofsky/Lansky Performance Score greater than or equal to 80 percent

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Additional Requirements
- To be used in combination with a calcineurin inhibitor (e.g., cyclosporine or tacrolimus) and methotrexate with or without antithymocyte globulin (ATG)

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications
- Continues to be seen by a Transplant Specialist or is in consultation with a Transplant Specialist

Clinical Response
- Positive clinical response to therapy

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Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section**)**

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Additional Requirements

- To be used in combination with a calcineurin inhibitor (e.g., cyclosporine or tacrolimus) and methotrexate with or without antithymocyte globulin (ATG)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section K. Cytokine Release Syndrome:

Medical Necessity Requirements for ACTEMRA (IV) (tocilizumab), AVTOZMA (IV) (tocilizumab-anoh), TOFIDENCE (IV) (tocilizumab-bavi), and TYENNE (IV) (tocilizumab-aazg)

Criteria for Initial Therapy:

Indication

- Chimeric antigen receptor (CAR) T cell induced severe or life threatening cytokine release syndrome

Age Requirement

- 2 years or older

Baseline Clinical Evaluation

- Receiving treatment with a CAR T cell therapy

Alternative Therapies

- **For Tofidence (IV) Tyenne (IV)**: Failure, contraindication, intolerance, or is not a candidate for **Actemra (IV)** or **Avtozma (IV)**

Brand Specific Criteria

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- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- One time only

Section L. Giant Cell Arteritis:

Medical Necessity Requirements for ACTEMRA (IV) (tocilizumab), **AVTOZMA (IV)** (tocilizumab-anoh), **TOFIDENCE (IV)** (tocilizumab-bavi), and **TYENNE (IV&SQ)** (tocilizumab-aazg)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or is in consultation with a Rheumatologist

Indication

- New-onset or relapsing giant cell arteritis (CGA) (also known as temporal arteritis, cranial arteritis, Horton disease)

Age Requirement

- 50 years or older

Baseline Clinical Evaluation

- 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)
- Has **ALL** of the following:
  - 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
  - **ONE** of the following:
    1. Cranial symptoms of giant cell arteritis (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)

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2. Symptoms of polymyalgia rheumatica (PMR) (shoulder and/or hip girdle pain associated with inflammatory morning stiffness)

- For relapsing giant cell arteritis (GCA) is on high dose corticosteroid and giant cell arteritis is clinically stable

Alternative Therapies

- **For Actemra and Avtozma (IV)**: Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Rinvoq**
- **For intravenous Actemra (IV):** Unable to use subcutaneous **Actemra (SQ)** administered by self or caregiver. (**Note:** See Exceptions To Self-Administered Drugs Evidence Based Criteria)
- **For Tofidence (IV), Tyenne (IV&SQ)**: Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **BOTH** of the following:
  - Rinvoq
  - Actemra (IV&SQ) or Avtozma (IV)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Clinical Response

- Documented positive clinical response documented to therapy defined as the following:
  - **With first request for continuation:** AT LEAST 20 percent improvement in signs and symptoms of giant cell arteritis
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence

- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies

- **For Tofidence and Tyenne continuation requests:** Failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, intolerance, or is not a candidate for **Actemra** or **Avtozma (IV)**
- For **intravenous Actemra (IV):** Individual is unable to use subcutaneous **Actemra (SQ)** administered by self or caregiver. (**Note:** See *Exceptions To Self-Administered Drugs Evidence Based Criteria*

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Safety
- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

Section M. Hidradenitis Suppurativa:

Medical Necessity Requirements for BIMZELX (bimekizumab-bkzx) and COSENTYX (secukinumab)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Dermatologist or is in consultation with a Dermatologist

Indication
- Moderate to severe hidradenitis suppurativa

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- **ONE** of the following:
  - Multiple interconnected tracts and abscesses in single anatomic area
  - Widely separated and recurrent abscesses with sinus tracts and scarring

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, or 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)
- **Bimzelx, Cosentyx**: Failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for an adalimumab product

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety
- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):
Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification
- Continues to be seen by a Dermatologist or is in consultation with a Dermatologist

Clinical Response
- Documented positive clinical response documented to therapy defined as the following:
  - **With first request for continuation:** AT LEAST a 20 percent improvement in the signs and symptoms of hidradenitis suppurativa
  - **With subsequent request for continuation**: Documented evidence of disease stability and/or improvement with no evidence of disease progression

Adherence
- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration
- 12 months OR end of plan year

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

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Medical Necessity Requirements for ACTEMRA (SQ) (tocilizumab) and TYENNE (SQ) (tocilizumab-aazg)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Rheumatologist or Pulmonologist or is in consultation with a Rheumatologist or Pulmonologist

Indication

- Systemic Sclerosis Associated Interstitial Lung Disease (SSc ILD)

Age Requirement

- 18 years or older

Baseline Clinical Evaluation

- **ALL** of the following:
  - Systemic sclerosis interstitial lung disease as defined by American College of Rheumatology/European League Against Rheumatism
  - Disease onset (first non Raynaud symptom) is less than or equal to 5 years
  - Modified Rodnan Skin Score (mRSS) of 10 or more but less than or equal to 35
  - Elevated inflammatory markers (e.g., CRP, ERS) or platelets
  - Active disease based on **ONE** of the following:
    1. Disease duration is less than or equal to 18 months
    2. Increase in mRSS of greater than or equal to 3 units over 6 months
    3. Involvement of one new body area and increase in mRSS of greater than or equal to 2 units over 6 months
    4. Involvement of two new body areas over previous 6 months
    5. Presence of at least one tendon friction rub

Alternative Therapies

- Failure (trial for at least three months duration), contraindication, or intolerance or is not a candidate for mycophenolate
- **For Tyenne (SQ)**: Failure (used for 3 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra** (SQ)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed
- Will not be used in combination with Ofev (nintedanib)

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Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualifications

- Continues to be seen by a Rheumatologist or Pulmonologist or is in consultation with a Rheumatologist or Pulmonologist

Clinical Response

- Documented positive clinical response to therapy defined as **TWO** of the following:
  - Improvement in mRSS over baseline of at least 4
  - Improvement or stabilization in FVC over baseline
  - Improvement or stabilization in percent predicted forced vital capacity (ppFVC) over baseline
  - Improvement or stabilization in DLCO
  - Improved or no decline in symptoms for fatigue, cough or dyspnea

Adherence

- Adherence to the prescribed therapy regimen has been documented

Alternative Therapies

- **For Tyenne (SQ)**: Failure (used for 6 or more consecutive months), contraindication per FDA label, intolerance, or is not a candidate for **Actemra (SQ)**

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
  - Will not be used in combination with Ofev (nintedanib)

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Section O. Polymyalgia rheumatica (PMR):

Medical Necessity Requirements for KEVZARA (sarilumab)

Criteria for Initial Therapy:

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Prescriber Qualifications
- Prescribed by a Rheumatologist or in consultation with a Rheumatologist

Indication
- Polymyalgia Rheumatica (PMR)

Age Requirement
- 50 years or older

Baseline Clinical Evaluation
- **ALL** of the following:
  - 50 years of age or older at onset of symptoms
  - Bilateral shoulder and/or hip girdle pain
  - Morning stiffness lasting longer than 45 minutes
  - Symptoms present more than 2 weeks
  - Elevated ESR or CRP
  - Responded to corticosteroid but is unable to taper down dose without a PMR flare

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, or intolerance or is not a candidate for a corticosteroid (e.g., prednisone) with or without methotrexate

Brand Specific Criteria
- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants
- Tuberculosis and hepatitis screening completed

Initial Therapy Criteria Approval Duration
- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Clinical Response
- Documentation of positive clinical response to therapy as **TWO** of the following:
  - Sustained reduction in CRP
  - Reduction in number of PMR flares
  - Reduction in corticosteroid dose

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  - Absence of PMR symptoms (shoulder pain, hip pain, morning stiffness, etc.)

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- There is **NONE** of the following:
  - Active serious infections including tuberculosis, hepatitis B or hepatitis C
  - Use of live vaccines during therapy
  - Concomitant use with other biologics or potent immunosuppressants

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

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

Criteria for Off-Label Use Requests:

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

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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):

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:		

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• 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

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	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%

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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)

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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 Skin thickening of the fingers *(only count the highest score)*	 Puffy fingers Sclerodactyly of the fingers (distal to MCP but proximal to the PIPs)	9 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	

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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

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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:

Actemra (tocilizumab) injection product information, revised by Genentech, Inc. 08-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 23, 2025.

Avtozma (tocilizumab-anoh) injection product information, revised by CELLTRION USA, Inc. 08-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed October 23, 2025.

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