STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB	ACTEMRA		35486 45082	GPI-14 (6650007000E520) (6650007000D520)	

PAC NOTE: For requests for the IV dosage form of Actemra, please see the Actemra IV PA Guideline.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA) **AND** meet the following criterion?
   - The patient is 18 years of age or older

     If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #3.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient has a diagnosis of systemic sclerosis (SSc) according to American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   - Therapy is prescribed by or in consultation with a pulmonologist or rheumatologist
   - The patient does NOT have other etiologies of interstitial lung disease (ILD) [e.g., heart failure/fluid overload, drug-induced lung toxicity (cyclophosphamide, methotrexate, ACE-inhibitors), recurrent aspiration (such as from GERD), pulmonary vascular disease, pulmonary edema, pneumonia, chronic pulmonary thromboembolism, alveolar hemorrhage or ILD caused by another rheumatic disease, such as mixed connective tissue disease (MCTD)]

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #1.8mL per 28 days.**

   If no, continue to #5.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ALL** of the following criteria?
   - The patient is 2 years of age or older
   - Therapy is prescribed by or in consultation with a rheumatologist, dermatologist, or immunologist
   - The patient had a trial of or contraindication to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, **approve for 6 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, do not approve.

   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for approval:

   A. You have ONE of the following diagnoses:
      1. Moderate to severe rheumatoid arthritis (a type of joint condition)
      2. Giant cell arteritis (inflammation of blood vessels typically in and around the head)
      3. Systemic sclerosis-associated interstitial lung disease (disorder that causes hardening of lung tissue)
      4. Polyarticular juvenile idiopathic arthritis (a type of joint condition)
      5. Systemic juvenile idiopathic arthritis (a type of joint condition)

   B. **If you have moderate to severe rheumatoid arthritis, approval also requires:**
      1. You are 18 years of age or older
      2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
      3. You had a trial of or contraindication (harmful for) to 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
      4. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

   C. **If you have giant cell arteritis, approval also requires:**
      1. You are 18 years of age or older

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

D. **If you have systemic sclerosis-associated interstitial lung disease, approval also requires:**
   1. You are 18 years of age or older
   2. Your diagnosis of systemic sclerosis (SSc) is according to the American College of Rheumatology (ACR) and European League Against Rheumatism (EULAR)
   3. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or rheumatologist (a type of immune system doctor)
   4. Other causes of interstitial lung disease have been ruled out. Other causes may include heart failure or fluid overload, drug-induced lung toxicity [cyclophosphamide, methotrexate, ACE-inhibitors (class of blood pressure medications)], recurrent aspiration (inhaling) such as from GERD (acid reflux), pulmonary vascular disease (affecting blood vessels in lungs), pulmonary edema (excess fluid in the lungs), pneumonia (type of lung infection), chronic pulmonary thromboembolism (blood clot in lungs), alveolar hemorrhage (bleeding of a part of the lungs) or interstitial lung disease caused by another rheumatic (inflammatory) disease, such as mixed connective tissue disease

E. **If you have polyarticular juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

F. **If you have systemic juvenile idiopathic arthritis, approval also requires:**
   1. You are 2 years of age or older
   2. Therapy is prescribed by or in consultation with a rheumatologist (a type of immune system doctor), dermatologist (a type of skin doctor), or immunologist (a type of immune system doctor)
   3. You had a trial of or contraindication (harmful for) to ONE DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, continue to #2.

2. Does the patient have a diagnosis of giant cell arteritis (GCA)?

   If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #3.

3. Does the patient have a diagnosis of systemic sclerosis-associated interstitial lung disease (SSc-ILD) **AND** meet the following criterion?
   - The patient has experienced a clinical meaningful improvement or maintenance in annual rate of decline

   If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

   If no, continue to #4.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) and meet **ALL** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient had a trial of or contraindication to the preferred agent Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #1.8mL per 28 days.**

     If no, continue to #5.

5. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) and meet **ONE** of the following criteria?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   - The patient has shown maintained or improved systemic inflammatory disease (e.g., fevers, pain, rash, arthritis)

     If yes, **approve for 12 months by GPID or GPI-14 for all subcutaneous formulations (syringe and pen injector) with a quantity limit of #3.6mL per 28 days.**

     If no, do not approve.
     RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

     Our guideline named **TOCILIZUMAB - SQ (Actemra - SQ)** requires the following rule(s) be met for renewal:
     A. You have ONE of the following diagnoses:
        1. Moderate to severe rheumatoid arthritis (a type of joint condition)
        2. Giant cell arteritis (inflammation of blood vessels typically in and around the head)
        3. Systemic sclerosis-associated interstitial lung disease (disorder that causes hardening of lung tissue)
        4. Polyarticular juvenile idiopathic arthritis (a type of joint condition)
        5. Systemic juvenile idiopathic arthritis (a type of joint condition)

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RENEWAL CRITERIA (CONTINUED)

B. **If you have moderate to severe rheumatoid arthritis, renewal also requires:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

C. **If you have polyarticular juvenile idiopathic arthritis, renewal also requires:**
   3. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy
   4. You had a trial of or contraindication (harmful for) to the preferred medication Humira (adalimumab), Amjevita (adalimumab-atto), or Cyltezo (adalimumab-adbm)

D. **If you have systemic sclerosis-associated interstitial lung disease, renewal also requires:**
   1. You have experienced a clinically meaningful improvement or maintenance in annual rate of decline

E. **If you have Systemic Juvenile Idiopathic Arthritis, renewal also requires ONE of the following:**
   1. You have experienced or maintained a 20 percent or greater improvement in tender joint count or swollen joint count while on therapy
   2. You have shown maintained or improved systemic inflammatory disease (such as fevers, pain, rash, arthritis)

NOTE: The use of pharmaceutical samples (from the prescriber or manufacturer assistance program) will not be considered when evaluating the medical condition or prior prescription history for drugs that require prior authorization.

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Actemra.

REFERENCE

- Actemra [Prescribing Information]. South San Francisco, CA: Genentech, Inc.; December 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 08/28/23
Created: 11/13
Client Approval: 07/23
P&T Approval: 04/23