STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

TOCILIZUMAB - SQ

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TOCILIZUMAB - SQ	ACTEMRA - SQ		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 given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least 3 months of treatment with at least **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 previous trial of or contraindication to any **TWO** of the following preferred immunomodulators: Enbrel, Humira, Rinvoq, Xeljanz (IR/XR) [**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 with a quantity limit of 3.6mL per 28 days. APPROVAL TEXT:** Renewal for moderate to severe rheumatoid arthritis (RA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   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 with a quantity limit of 3.6mL per 28 days. APPROVAL TEXT:** Renewal requires a diagnosis of giant cell arteritis (GCA).

   If no, continue to #3

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INITIAL CRITERIA (CONTINUED)

3. 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 given in consultation with a rheumatologist
   - The patient had a previous trial of or contraindication to at least **ONE** DMARD (disease-modifying antirheumatic drug), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   - The patient had a previous trial of or contraindication to **BOTH** of the following preferred immunomodulators: Enbrel AND Humira [**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 with a quantity limit of 1.8mL per 28 days.**
   APPROVAL TEXT: Renewal for polyarticular juvenile idiopathic arthritis (PJIA) requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, continue to #4.

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

   If yes, **approve for 6 months by GPID or GPI-14 with a quantity limit of 3.6mL per 28 days.**
   APPROVAL TEXT: Renewal for systemic juvenile idiopathic arthritis requires that the patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.

   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

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 (RA: inflammation and stiffness in joints)
   2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
   3. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
   4. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)

B. **For patients with moderate to severe rheumatoid arthritis (RA), approval also requires:**
   1. You are 18 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (muscle/joint inflammation doctor)
   3. You have previously tried at least 3 months of treatment with at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried any TWO of the following preferred immunomodulators (class of drugs), unless there is a medical reason why you cannot (contraindication): Enbrel, Humira, Rinvoq, Xeljanz (immediate release/extended release)

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

D. **If you have polyarticular juvenile idiopathic arthritis (PJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (muscle/joint inflammation doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), such as methotrexate, leflunomide, hydroxychloroquine, or sulfasalazine
   4. You have previously tried BOTH of the following preferred immunomodulators, unless there is a medical reason why you cannot (contraindication): Enbrel AND Humira

(Initial denial text continued on next page)

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TOCILIZUMAB - SQ

INITIAL CRITERIA (CONTINUED)

E. **If you have systemic juvenile idiopathic arthritis (SJIA), approval also requires:**
   1. You are 2 years of age or older
   2. The medication is prescribed by or given in consultation with a rheumatologist (muscle/joint inflammation doctor)
   3. You have previously tried at least ONE DMARD (disease-modifying antirheumatic drug), unless there is a medical reason why you cannot (contraindication), 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.

RENEWAL CRITERIA

1. Does the patient have a diagnosis of moderate to severe rheumatoid arthritis (RA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 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 with a quantity limit of 3.6mL per 28 days.**
   If no, continue to #3.

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TOCILIZUMAB - SQ

RENEWAL CRITERIA (CONTINUED)

3. Does the patient have a diagnosis of polyarticular juvenile idiopathic arthritis (PJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 with a quantity limit of 1.8mL per 28 days.**
   If no, continue to #4.

4. Does the patient have a diagnosis of systemic juvenile idiopathic arthritis (SJIA) **AND** meet the following criterion?
   - The patient has experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   If yes, **approve for 12 months by GPID or GPI-14 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 (RA: inflammation and stiffness in joints)
      2. Giant cell arteritis (GCA: inflammatory disease affecting the large blood vessels of the scalp, neck and arms)
      3. Polyarticular juvenile idiopathic arthritis (PJIA: swelling and stiffness in many joints in children)
      4. Systemic juvenile idiopathic arthritis (SJIA: swelling and stiffness in joints in children that can affect organs)
   B. **If you have moderate to severe rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, or systemic juvenile idiopathic arthritis, renewal also requires:**
      1. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy

   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

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 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 11/13
Client Approval: 02/20
P&T Approval: 01/20

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