STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

SARILUMAB

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
SARILUMAB	KEVZARA	44183		GPI-10 (6650006000)	

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 at least 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

   If yes, continue to #2.
   If no, continue to #3.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

   If yes, **approve for 6 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

3. Does the patient have a diagnosis of polymyalgia rheumatica (PMR) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - The patient had an inadequate response to corticosteroids or cannot tolerate a corticosteroid taper

   If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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SARILUMAB

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 **SARILUMAB (Kevzara)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Moderate to severe rheumatoid arthritis (RA: a type of joint condition)
   2. Polymyalgia rheumatica (PMR: an inflammatory disorder causing muscle pain and stiffness)

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 have tried or have a contraindication (harmful for) to at least 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 meet ONE of the following:
      a. You have tried or have a contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
      b. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib] due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

C. **If you have polymyalgia rheumatica, approval also requires:**
   1. You are 18 years of age or older
   2. You had an inadequate response (drug did not work) to corticosteroids or cannot tolerate a corticosteroid taper

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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SARILUMAB

RENEWAL CRITERIA

NOTE: For the diagnosis of polymyalgia rheumatica, please refer to the initial criteria section.

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, continue to #2.
     If no, do not approve.
     DENIAL TEXT: See the renewal denial text at the end of the guideline.

2. Does the patient meet **ONE** of the following?
   - The patient had a trial of or contraindication to TWO of the following preferred agents: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib IR or XR), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   - The patient has tried a TNF inhibitor (e.g., Humira [adalimumab], Enbrel [etanercept]) AND the physician has indicated the patient cannot use a JAK inhibitor (e.g., Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality, malignancies, and serious cardiovascular events
     [**NOTE:** Pharmaceutical samples acquired from the prescriber or manufacturer assistance program do not qualify]

     If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2.28mL per 28 days.**

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

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SARILUMAB

RENEWAL CRITERIA (CONTINUED)

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 **SARILUMAB (Kevzara)** requires the following rule(s) be met for renewal:

A. You have moderate to severe rheumatoid arthritis (RA: a type of joint condition)
B. You have experienced or maintained a 20% or greater improvement in tender joint count or swollen joint count while on therapy.
C. You meet ONE of the following:
   1. You have tried or have a contraindication (harmful for) to TWO of the following preferred medications: Enbrel (etanercept), Humira (adalimumab), Rinvoq (upadacitinib), Xeljanz (tofacitinib immediate-release or extended-release), Amjevita (adalimumab-atto), Cyltezo (adalimumab-adbm)
   2. You have tried a tumor necrosis factor (TNF) inhibitor (such as Humira [adalimumab], Enbrel [etanercept]) AND your physician has indicated you cannot use a JAK inhibitor (such as Rinvoq [upadacitinib], Xeljanz [tofacitinib]) due to the black box warning for increased risk of mortality (death), malignancies (cancerous), and serious cardiovascular (heart-related) events

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 Kevzara.

REFERENCE

- Kevzara [Prescribing Information]. Bridgewater, NJ: Sanofi-Aventis US LLC; February 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
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