STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ANAKINRA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ANAKINRA	KINERET	22953		GPI-10 (6626001000)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for the treatment of coronavirus disease 2019 (COVID-19) in a hospitalized adult?

   If yes, **do not approve**. [NOTE: This indication is for hospital use only.]
   DENIAL TEXT: See initial denial text at the end of the guideline.

   If no, continue to #2.

2. 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 drugs), such as methotrexate dose greater than or equal to 20mg per week or maximally tolerated dose, leflunomide, hydroxychloroquine, or sulfasalazine

   If yes, continue to #3.
   If no, continue to #4.

3. Does the patient meet **ONE** of the following criteria?
   - 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 #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

4. Does the patient have a diagnosis of Cryopyrin-Associated Periodic Syndromes (CAPS) including Neonatal-Onset Multisystem Inflammatory Disease (NOMID) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *NLRP3* gene OR has inflammatory markers (i.e., elevated CRP, ESR, serum amyloid A protein (SAA) or S100 proteins)
   - The patient has TWO of the following: urticarial-like rash (neutrophilic dermatitis), cold-triggered episodes, sensorineural hearing loss, musculoskeletal symptoms, chronic aseptic meningitis, skeletal abnormalities
   - Kineret will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Ilaris [canakinumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

5. Does the patient have a diagnosis of Deficiency of Interleukin-1 Receptor Antagonist (DIRA) and meet **ALL** of the following criteria?
   - The patient has genetic testing for gain-of-function mutations in the *IL1RN* gene OR has inflammatory markers (i.e., elevated CRP, ESR)
   - The patient has ONE of the following: pustular psoriasis-like rashes, osteomyelitis, absence of bacterial osteomyelitis, nail changes (i.e., onychomadesis)
   - Kineret will NOT be used concurrently with other IL-1 inhibitors (e.g., Arcalyst [rilonacept], Ilaris [canakinumab])

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

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ANAKINRA

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 **ANAKINRA (Kineret)** 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. Cryopyrin-Associated Periodic Syndromes (CAPS) including Neonatal-Onset Multisystem Inflammatory Disease (NOMID: a type of immune disorder)
   3. Deficiency of Interleukin-1 Receptor Antagonist (DIRA: a type of immune system disorder)

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 at least 3 months of treatment with ONE DMARD (disease-modifying antirheumatic drugs), 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 had a trial of or 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

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ANAKINRA

INITIAL CRITERIA (CONTINUED)

C. **If you have Cryopyrin-Associated Periodic Syndromes including Neonatal-Onset Multisystem Inflammatory Disease, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *NLRP3* gene (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test], serum amyloid A protein [SAA: a type of protein] or S100 proteins [a type of protein])
   2. You have TWO of the following: urticarial-like rash (neutrophilic dermatitis: a type of skin condition), cold-triggered episodes, sensorineural hearing loss (SNHL: a type of hearing loss), musculoskeletal symptoms (symptoms related to the skin and bones), chronic aseptic meningitis (inflammation of the brain and spinal cord), and skeletal (bone) abnormalities
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

D. **If you have Deficiency of Interleukin-1 Receptor Antagonist, approval also requires:**
   1. You had genetic testing for gain-of-function mutations (abnormal change in gene) in the *IL1RN gene* (a type of gene) OR you have inflammatory markers (elevated C-reactive protein [CRP: sign of inflammation], erythrocyte sedimentation rate [ESR: a type of blood test])
   2. You have ONE of the following: pustular psoriasis-like rashes (a type of skin condition), osteomyelitis (bone infection), absence of bacterial osteomyelitis, nail changes (onychomadesis: fungal infection of toenail)
   3. Kineret will NOT be used concurrently (at the same time) with other IL-1 inhibitors (such as Arcalyst [rilonacept], Ilaris [canakinumab])

E. NOTE: Kineret will not be approved for the treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults

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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ANAKINRA

RENEWAL CRITERIA

NOTE: For the diagnoses of Cryopyrin-Associated Periodic Syndromes including Neonatal-Onset Multisystem Inflammatory Disease and Deficiency of Interleukin-1 Receptor Antagonist, 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 criteria?
   - 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 #0.67 mL per day.**
   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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ANAKINRA

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 **ANAKINRA (Kineret)** 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 had a trial of or 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 immediate release or extended release]) 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 Kineret.

REFERENCES

- Kineret [Prescribing Information]. SE-112 76 Stockholm, Sweden: Swedish Orphan Biovitrum AB (publ); December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/23
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