MEDICATION POLICY

Generic Name: Anakinra

Therapeutic Class or Brand Name: Kineret®

Applicable Drugs (if Therapeutic Class)**:** N/A

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 11/21/17

GPI Code: 6626001000

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis:

A. Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 4 are met:

1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.).
2. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products).
3. Diagnosis must be established by a rheumatologist.
4. Minimum age requirement: 18 years old.

B. Cryopyrin-Associated Periodic Syndromes (CAPS) (including Neonatal-Onset Multisystem Inflammatory Disease [NOMID]) and criteria 1 through 3 are met:

1. Diagnosis must be established by a rheumatologist.
2. Documentation of laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1 – sometimes referred to as the NLRP-3).
3. Documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting at least ONE of the following described in a through c:

a. NOMID – Urticaria-like rash, CNS involvement (papilledema, cerebrospinal fluid [CSF] pleocytosis, or sensorineural hearing loss), elevated C-reactive protein, or epiphyseal and/or patellar overgrowth on radiographs.

b. Familial Cold Auto-Inflammatory Syndrome (FCAS) – Recurrent intermittent episodes of fever and rash that primarily followed natural, artificial (e.g., air conditioning) or both types of generalized cold exposure.

c. Muckle-Wells Syndrome (MWS) – Syndrome of chronic fever and rash that may wax and wane in intensity; sometimes exacerbated by generalized cold exposure. This syndrome may be associated with deafness or amyloidosis.

II. Absence of active serious infection or sepsis.

III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection.

Exclusion Criteria:

- Coadministration of Kineret® with another biologic DMARD, Otezla® (apremilast), or Xeljanz®/ XR (tofacitinib). Examples of biologic DMARDs include the following:
  - Actemra® (tocilizumab)
  - Cosentyx® (secukinumab)
  - Entyvio® (vedolizumab)
  - Kevzara® (sarilumab)
  - Orencia® (abatacept)
  - Rituxan® (rituximab)
  - Siliq™ (brodalumab)
  - Stelara® (ustekinumab)
  - Taltz® (Ixekizumab)
  - TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Inflectra® (infliximab-dyyb), Remicade® (infliximab), Renflexis™ (infliximab-abda), Simponi®/Simponi® Aria® (golimumab)]
  - Tremfya™ (guselkumab)
  - Tysabri® (natalizumab)

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- 28 syringes (one 4x7 syringe dispensing pack) per 28 days.

Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing improvement or maintenance with medication.

Appendix:

N/A

References:

1. http://blue.regence.com/trgmedpol/drugs/dru049.pdf.
2. NPS.
3. Medi-Span.
4. http://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf.

MEDICATION POLICY

Historical Tracking Of Changes Made To Policy	
11/21/2017	1. **Added** "Kevzara® (sarilumab)"**,** "Siliq™ (brodalumab)"**, and** "Tremfya™ (guselkumab)" **to list under Exclusion Criteria**. 2. **Added** "Inflectra® (infliximab-dyyb)" **and** "Renflexis™ (infliximab-abda)" **following TNF Inhibitors to list under Exclusion Criteria**. 3. **Updated** "http://www.kineretrx.com/fileadmin/user_upload/pdfs/PP-1322_Kineret_USPI_June_2016.pdf" **to** "http://www.kineretrx.com/pdf/Full-Prescribing-Information-English.pdf" **under References**.
9/20/2016	1. **Reinserted** "Refer to Plan for individual adoption of specific Medication Policies" **in disclaimer**.
8/27/2016	1. **Changed** "I. A. 2. History of treatment failure, intolerance, or contraindication to at least two separate preferred TNF inhibitors (refer to plan document for the list of preferred products)" **to** "I. A. 2. Documented failure, intolerance, or contraindication to two preferred biologic products (refer to plan document for the list of preferred products)" **under Prior Authorization Criteria**. 2. **Changed** "Coadministration of Kineret® with…Xeljanz® (tofacitinib)…" **to** "Coadministration of Kineret® with…Xeljanz®/ XR (tofacitinib)…" **under Exclusion Criteria**. 3. **Changed** "Cosentyx™" **to** "Cosentyx®" **under Exclusion Criteria**. 4. **Added** "Taltz® (Ixekizumab)" **to list under Exclusion Criteria**. 5. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Kineret%20RA%202014-12-26.pdf" **under References** (link no longer valid). 6. **Updated** "http://www.kineretrx.com/fileadmin/user_upload/pdfs/Kineret_100_mg_PatientInformation_US.PDF" **to** "http://www.kineretrx.com/fileadmin/user_upload/pdfs/PP-1322_Kineret_USPI_June_2016.pdf" **under References**.
3/2/2015	1. **Added** "Cosentyx™ (secukinumab)" **to list under Exclusion Criteria.**
2/28/2015	1. **Changed** "Moderate to Severe Rheumatoid Arthritis and criteria 1 through 5 are met:" **to** "Moderately to Severely Active Rheumatoid Arthritis and criteria 1 through 4 are met:" **and removed previously labeled criterion #3** "The number of swollen joints and tender joints must be 3 or more" **under Prior Authorization Criteria**. 2. **Reworded** "There is laboratory evidence" **to** "Documentation of laboratory evidence" **and** "There is clinical documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting at least one of the criteria described in a through c:" **to** "Documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting at least ONE of the following described in a through c:" in criteria below "Cryopyrin-Associated Periodic Syndromes (CAPS) (including Neonatal-Onset Multisystem Inflammatory Disease [NOMID])" diagnosis **under Prior Authorization Criteria**. 3. **Changed** "Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition" **to** "Absence of active serious infection or sepsis" **under Prior Authorization Criteria**. 4. **Changed** "Kineret® may not be given with other biologic agents such as Interferon, experimental medications, or combinations" **to** "Coadministration of Kineret® with another biologic DMARD, Otezla® (apremilast), or Xeljanz® (tofacitinib). Examples of biologic DMARDs include the following: Actemra® (tocilizumab); Entyvio® (vedolizumab); Orencia® (abatacept); Rituxan® (rituximab); Stelara® (ustekinumab); TNF inhibitors [Cimzia® (certolizumab pegol), Enbrel® (etanercept), Humira® (adalimumab), Remicade® (infliximab), Simponi®/Simponi® Aria® (golimumab)]; Tysabri® (natalizumab)" **under Exclusion Criteria**. 5. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Kineret.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Kineret%20RA%202014-12-26.pdf" **under References**. 6. **Updated** "http://www.kineretrx.com/fileadmin/user_upload/kineretus/documents/Kineret_Full_Prescribing_Information.pdf" **to**

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.

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Historical Tracking Of Changes Made To Policy	
	"http://www.kineretrx.com/fileadmin/user_upload/pdfs/Kineret_100_mg_PatientInformation_US.PDF" **under References**.
1/6/2014	1. **Adapted policy to new format.** 2. **Changed GPI Code from** "66260010002020" **to** "6626001000". 3. **Changed Prior Authorization Criteria from:** "Documented diagnosis of Moderate to Severe Rheumatoid Arthritis; The number of swollen joints must be 6 or more and the number of tender joints must be 9 or more (WRITE SPECIFIC NUMBER IN NOTES OR LETTER); Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition; Negative TB skin test within the previous 12 months or history of treatment for latent TB infection; History of treatment failure, incomplete response, or intolerance to Methotrexate, or one other DMARD or second line drug (azathioprine, sulphadiazine, leflunomide, penicillamine, hydroxychloroquine, etc.); Rheumatology consultation within the last 60 days. Must have trial and failure of methotrexate in combination with at least two separate preferred TNF inhibitors (i.e. Cimzia®, Humira®); Minimum age requirement: 18 years and older" **to** . "May be considered medically necessary when criteria I through III are met: I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. Moderate to Severe Rheumatoid Arthritis and criteria 1 through 5 are met: 1. History of treatment failure, intolerance, or contraindication to Methotrexate, or one other DMARD or second line drug (azathioprine, sulfasalazine, leflunomide, penicillamine, hydroxychloroquine, etc.); 2. History of treatment failure, intolerance, or contraindication to at least two separate preferred TNF inhibitors (refer to plan document for the list of preferred products); 3. The number of swollen joints and tender joints must be 3 or more; 4. Diagnosis must be established by a rheumatologist; 5. Minimum age requirement: 18 years old; B. Cryopyrin-Associated Periodic Syndromes (CAPS) (including Neonatal-Onset Multisystem Inflammatory Disease [NOMID]) and criteria 1 through 3 are met: 1. Diagnosis must be established by a rheumatologist; 2. There is laboratory evidence of a genetic mutation in the Cold-Induced Auto-inflammatory Syndrome 1 (CIAS1 – sometimes referred to as the NLRP-3); 3. There is clinical documentation that the patient is experiencing the classic symptoms of CAPS, defined as meeting at least one of the criteria described in a through c: a. NOMID – Urticaria-like rash, CNS involvement (papilledema, cerebrospinal fluid [CSF] pleocytosis, or sensorineural hearing loss), elevated C-reactive protein, or epiphyseal and/or patellar overgrowth on radiographs; b. Familial Cold Auto-Inflammatory Syndrome (FCAS) – Recurrent intermittent episodes of fever and rash that primarily followed natural, artificial (e.g., air conditioning) or both types of generalized cold exposure; c. Muckle-Wells Syndrome (MWS) – Syndrome of chronic fever and rash that may wax and wane in intensity; sometimes exacerbated by generalized cold exposure. This syndrome may be associated with deafness or amyloidosis; II. Absence of active bacterial or viral infection, malignancy, or immunosuppressive condition; III. Negative TB skin test within the previous 12 months or history of treatment for latent TB infection". 4. **Changed Quantity/Days Supply Restrictions from** "4x7 dispensing pack. 28 syringes per 28 days" **to** "28 syringes (one 4x7 syringe dispensing pack) per 28 days". 5. **Updated references** to include Medi-Span and package insert.