09-J2000-88

Original Effective Date: 09/15/17

Reviewed: 11/12/25

Revised: 01/01/26

Subject: Sarilumab (Kevzara®) Injection

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DESCRIPTION:

Sarilumab (Kevzara) is an injectable human monoclonal antibody that binds specifically to both soluble and membrane-bound interleukin-6 (IL-6) receptors. The IL-6 receptor plays a major role in regulating the underlying disease pathophysiology and clinical manifestations of rheumatoid arthritis (RA). In patients with RA, elevated levels of IL-6 in serum and synovial fluid are closely associated with synovitis, systemic inflammation, bone metabolism, fatigue, and joint destruction. Sarilumab was first approved by the US Food and Drug Administration (FDA) in May 2017 for “treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs).” Sarilumab is the second anti-IL-6 agent to be approved by the FDA for the treatment of RA. Tocilizumab (Actemra) was the first anti-IL-6 agent to be approved by the FDA for RA in January 2010. Siltuximab (Sylvant) is also an anti-IL-6 agent but works by binding to IL-6 itself as opposed to the IL-6 receptor. Siltuximab is FDA-approved for the treatment of multicentric Castleman disease only. In February 2023, sarilumab was granted FDA approval for “treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper”. While corticosteroids are recommended and routinely used for the treatment of PMR, sarilumab is the first drug to be specifically approved by the FDA for the treatment of PMR. In June 2024, the FDA approved a third indication for the "treatment of patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (PJIA)”. Sarilumab is not approved in pediatric patients weighing less than 63 kg because of the lack of an appropriate dosage form. In 2018 the National Comprehensive Cancer Network (NCCN) began publishing its guideline Management of Immunotherapy-Related-Toxicities. The NCCN eventually separated this guidelines into two separate guidelines - Management of Immune Checkpoint Inhibitor-Related Toxicities and Management of CAR T-Cell and Lymphocyte Engager-Related Toxicities. The NCCN guidelines on Management of Immune Checkpoint Inhibitor--Related Toxicities include sarilumab as a category 2A recommendation as consideration as additional disease modifying

antirheumatic therapy for the management of the following immunotherapy-related toxicities: (1) moderate or severe inflammatory arthritis if unable to taper corticosteroids after 1 week, (2) polymyalgia rheumatica if unable to taper prednisone or no improvement in symptoms, and (3) giant cell arteritis (urgent referral to rheumatology recommended even in mild cases).

Rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is an inflammatory autoimmune disease that primarily affects the joints but can also damage extra-articular organs. The main goal of therapy is to achieve remission, but additional goals include decreased disease activity, prevention of systemic complications, and improved physical functioning. The choice of therapy depends on several factors, including the severity of disease activity when therapy is initiated and the response of the patient to prior therapeutic interventions. American College of Rheumatology (ACR) guidelines list the following guiding principles in the treatment of RA:

- RA requires early evaluation, diagnosis, and management
- Treatment decisions should follow a shared decision-making process
- Treatment decisions should be reevaluated within a minimum of 3 months based on efficacy and tolerability of the disease-modifying antirheumatic drug(s) (DMARDs) chosen
- Recommendations are limited to DMARDs approved by the US FDA for treatment of RA:
    - Conventional synthetic DMARDs (csDMARDs): hydroxychloroquine, sulfasalazine, methotrexate (MTX), leflunomide
    - Biologic DMARDs (bDMARDs): Tumor necrosis factor (TNF) inhibitors (e.g., etanercept, adalimumab, infliximab, golimumab, certolizumab pegol), T cell costimulatory inhibitor (e.g., abatacept), Interleukin (IL)-6 receptor inhibitors (e.g., tocilizumab, sarilumab), anti-CD20 antibody* (e.g., rituximab)

        *Recommendations referring to bDMARDs exclude rituximab unless patients have had an inadequate response to TNF inhibitors (in order to be consistent with FDA approval) or have a history of lymphoproliferative disorder for which rituximab is an approved therapy

    - Targeted synthetic DMARDs (tsDMARDs): Janus kinase (JAK) inhibitors (e.g., tofacitinib, baricitinib, upadacitinib)
- Triple therapy refers to hydroxychloroquine, sulfasalazine, and either methotrexate or leflunomide
- Biosimilars are considered equivalent to FDA-approved originator bDMARDs
- Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modifications of treatment to minimize disease activity with the goal of reaching a predefined target (low disease activity or remission)

ACR guidelines (2021) are broken down by previous treatment and disease activity:

- DMARD-naïve patients with moderate-to-high disease activity initial treatment:
    - MTX monotherapy is strongly recommended over hydroxychloroquine, sulfasalazine, bDMARDs monotherapy, tsDMARD monotherapy, or combination of MTX plus a non-TNF bDMARD or tsDMARD

    - MTX monotherapy is conditionally recommended over leflunomide, dual or triple csDMARD therapy, or combination MTX plus a TNF inhibitor
- DMARD-naïve patients with low disease activity initial treatment
    - Hydroxychloroquine is conditionally recommended over other csDMARDs
    - Sulfasalazine is conditionally recommended over MTX
    - MTX is conditionally recommended over leflunomide
- Initial therapy in csDMARD-treated patients, but MTX naïve, with moderate-to high disease activity:
    - MTX monotherapy is conditionally recommended over combination MTX and a bDMARD or tsDMARD
- Treatment modifications in patients treated with DMARDs who are not at target:
    - Addition of a bDMARD or tsDMARD is conditionally recommended over triple therapy for patients taking maximally tolerated doses of MTX who are not at target
    - Switching to a bDMARD or tsDMARD of a different class is conditionally recommended over switching to a bDMARD or tsDMARD belonging to the same class for patients taking a bDMARD or tsDMARD who are not at target.

The European Alliance of Associations for Rheumatology (EULAR) guidelines for RA (2022 update) also recommend a treat-to-target approach in therapy. MTX is recommended as first line therapy and should be initiated as soon as the diagnosis of RA is made. If MTX is not clinically appropriate, then an alternative csDMARD should be used as part of the (first) treatment strategy. If initial csDMARD therapy does not produce adequate improvement after 3 months, another csDMARD may be added or switched to as long as poor prognosis factors are absent. In the presence of poor prognosis factors, a bDMARD or JAK inhibitor should be added to csDMARD therapy. If treatment failure occurs with the initial bDMARD or JAK inhibitor, another bDMARD or JAK inhibitor should be considered. If a TNF- or IL-6 receptor inhibitor therapy was initially failed, patients may receive an agent with another mode of action or a second TNF- or IL-6 receptor inhibitor.

Initial dosing of MTX for RA should optimally be 15 mg once weekly, with the dose increased as tolerated and as needed to control signs and symptoms. A fast dose escalation of 5 mg/month to 25-30 mg/week has been associated with higher efficacy, but toxicity with this dosing regimen is a limiting factor. In the presence of sufficient folic acid supplementation, the MTX dose can be rapidly escalated to 25 mg once weekly. The MTX target dose is 25 mg weekly, or the highest tolerable dose.

Polyarticular Juvenile Idiopathic Arthritis (PJIA)

Juvenile idiopathic arthritis (JIA) is arthritis that begins before the 16th birthday and persists for at least 6 weeks with other known conditions excluded. Polyarticular juvenile idiopathic arthritis (PJIA) is a subset of JIA. The ACR defines PJIA as arthritis in more than 4 joints during their disease course and excludes systemic JIA. Treatment goals are aimed at achieving clinically inactive disease and to prevent long-term morbidities, including growth disturbances, joint contractures and destruction, functional limitations, and blindness or visual impairment from chronic uveitis.

The American College of Rheumatology guidelines (2019) (ACR)/Arthritis Foundation recommend the following treatment approach for PJIA:

- Nonsteroidal anti-inflammatory drugs (NSAIDs) are conditionally recommended as adjunct therapy
- Disease modifying antirheumatic drug (DMARD) therapy:
    - Methotrexate (MTX) is conditionally recommended over leflunomide and sulfasalazine
    - Subcutaneous MTX is conditionally recommended over oral MTX
- Intraarticular glucocorticoids are conditionally recommended as adjunct therapy and conditionally recommended for bridging only in patients with moderate to high disease activity
- Strongly recommend against chronic low-dose glucocorticoid use, irrespective of disease activity and/or risk factors
- Strongly recommend combination use of a DMARD and infliximab
- Initial therapy for all patients:
    - DMARD is strongly recommended over NSAID monotherapy
    - MTX monotherapy is conditionally recommended over triple DMARD therapy
    - DMARD is conditionally recommended over a biologic
    - Initial biologic therapy may be considered for patients with risk factors and involvement of high-risk joints (e.g., cervical spine, wrist, hip), high disease activity, and/or those judged by their physician to be at high risk of disabling joint damage
- Subsequent therapy:
    - Low disease activity:
        - Escalating therapy (e.g., intraarticular glucocorticoid injections, optimization of DMARD dose, trial of MTX if not already done, and adding or changing biologic agent)
    - Moderate to high disease activity:
        - Add a biologic to original DMARD over changing to a second DMARD or changing to triple DMARD therapy
        - Switch to a non- tumor necrosis factor (TNF) biologic if currently treated with first TNF-inhibitor ± DMARD over switching to another TNF-inhibitor (unless the patient had good initial response to first TNF-inhibitor)
        - TNF-inhibitor, abatacept, or tocilizumab (depending on prior biologics received) over rituximab after trial of second biologic

Polymyalgia Rheumatica (PMR)

Polymyalgia rheumatica (PMR) is a rheumatic disorder associated with musculoskeletal pain and stiffness in the neck, shoulder, and hip area. The etiology is not fully understood, but there are associated environmental and genetic factors. The incidence of PMR increases with age and is rarely seen in people under the age of 50. Women are approximately 2-3 times more likely to be affected by PMR than men. A characteristic feature of PMR is a new and relatively acute onset of proximal muscle pain and stiffness in the neck, shoulders, upper arms, hips and thighs. Patients often suffer from a pronounced morning stiffness with difficulty turning in or getting out of bed in the morning with some

spontaneous relief of symptoms later in the day. The nonspecific clinical presentation and the absence of specific laboratory findings or serologic features often leads to some diagnostic delay.

The American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) guidelines recommend the following for the treatment of PMR:

- Strongly recommends using glucocorticoids over NSAIDs for long term care of patients with PMR and used for the minimum effective duration
- Conditionally recommends using the minimum effective glucocorticoid dose within a range of 12.5 to 25 mg prednisone equivalent daily as the initial treatment of PMR. A higher initial prednisone dose within this range may be considered in patients with a high risk of relapse and low risk of adverse events, whereas in patients with relevant comorbidities (e.g., diabetes, osteoporosis, glaucoma, etc.) and other risk factors for glucocorticoid -related side effects, a lower dose may be preferred. The guideline discourages conditionally the use of initial doses less than or equal to 7.5 mg/day and strongly recommends against the use of initial doses greater than 30 mg/day.
- Strongly recommends individualizing dose tapering schedules, predicated to regular monitoring of patient disease activity, laboratory markers and adverse events. The following principles of glucocorticoid dose tapering are suggested:
    - Initial tapering: Taper dose to an oral dose of 10 mg/day prednisone equivalent within 4 to 8 weeks.
    - Relapse therapy: Increase oral prednisone to the pre-relapse dose and decrease it gradually (within 4 to 8 weeks) to the dose at which the relapse occurred.
    - Tapering once remission is achieved (following initial and relapse therapies): Taper daily oral prednisone by 1 mg every 4 weeks (or by 1.25 mg decrements using schedules such as 10/7.5 mg alternate days, etc.) until discontinuation given that remission is maintained.
- Conditionally recommends considering intramuscular (IM) methylprednisolone as an alternative to oral glucocorticoids. The choice between oral glucocorticoids and IM methylprednisolone remains at the discretion of the prescriber.
- Conditionally recommends using a single rather than divided daily doses of oral glucocorticoids for the treatment of PMR, except for special situations such as prominent night pain while tapering glucocorticoids below the low-dose range (prednisone or equivalent less than 5 mg daily).
- Conditionally recommends considering early introduction of methotrexate (MTX) in addition to glucocorticoids, particularly in patients at a high risk for relapse and/or prolonged therapy as well as in cases with risk factors, comorbidities and/or concomitant medications where glucocorticoid-related adverse events are more likely to occur. MTX may also be considered during follow-up of patients with a relapse, without significant response to glucocorticoid or experiencing glucocorticoid-related adverse events.
- Strongly recommends against the use of tumor necrosis factor (TNF)-alpha blocking agents for treatment of PMR.

POSITION STATEMENT:

Comparative Effectiveness

The FDA has deemed the drug(s) or biological product(s) in this coverage policy to be appropriate for self-administration or administration by a caregiver (i.e., not a healthcare professional). Therefore, coverage (i.e., administration) in a provider-administered setting such as an outpatient hospital, ambulatory surgical suite, physician office, or emergency facility is not considered medically necessary.

NOTE: The list of self-administered products with prerequisites for certain indications can be found at Preferred Agents and Drug List.

Initiation of sarilumab (Kevzara) meets the definition of medical necessity when **ALL** of the following are met ("1" to "5"):

1. **ONE** of the following ("a", "b", or "c"):
    a. The member has been treated with sarilumab (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with sarilumab (starting on samples is not approvable) within the past 90 days **AND** is at risk if therapy is changed
    c. **BOTH** of the following ('i" and "ii"):
        i. Sarilumab will be used for the treatment of an indication listed in Table 1, and **ALL** of the indication-specific criteria are met
        ii. **EITHER** of the following if the member has an FDA-approved indication ("I" or "II")
            I. The member's age is within FDA labeling for the requested indication for sarilumab
            II. The prescriber has provided information in support of using sarilumab for the member's age for the requested indication
2. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PJIA, RA, or PMR) or the prescriber has consulted with a specialist in the area of the member's diagnosis
3. Member does **NOT** have any FDA labeled contraindications to sarilumab
4. Member will **NOT** be using sarilumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
5. **ANY** of the following ("a", "b", "c", or "d"):
    a. The dosage does not exceed 200 mg once every 2 weeks (14 days)
        - QL: 150 mg/1.14 mL pen – 2 pens (2.28 mL)/28 days
        - QL: 200 mg/1.14 mL pen – 2 pens (2.28 mL)/28 days
        - QL: 150 mg/1.14 mL syringe – 2 syringes (2.28 mL)/28 days
        - QL: 200 mg/1.14 mL syringe – 2 syringes (2.28 mL)/28 days
    b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. **ALL** of the following ("1", "2", and "3"):

1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication
2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)
3. **EITHER** of the following ("a" or "b"):

a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

d. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

Table 1

Diagnosis	Criteria

Moderately to severely active rheumatoid arthritis (RA)	**BOTH** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to maximally tolerated methotrexate (e.g., titrated to 25 mg weekly) after at least a 3-month duration of therapy **OR** b. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA after at least a 3-month duration of therapy **OR** c. The member has an intolerance or hypersensitivity to **ONE** conventional agent (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** d. The member has an FDA labeled contraindication to **ALL** conventional agents (i.e., methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) used in the treatment of RA **OR** e. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of RA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **TWO** preferred products after at least a 3-month trial per product **OR** b. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **ONE** preferred product **OR** c. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **TWO** preferred products

	OR d. The member has an FDA labeled contraindication to **ALL** preferred products **OR** e. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred RA products are:** • Adalimumab-aaty • Adalimumab-adaz • Enbrel (etanercept) • Hadlima (adalimumab-bwwd) • Humira (adalimumab) • Rinvoq (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz/Xeljanz XR (tofacitinib)
Polymyalgia rheumatica (PMR)	**EITHER** of the following: 1. The member has tried and had an inadequate response to systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone used in the treatment of PMR after at least an 8-week duration of therapy **OR** 2. The member is currently treated with systemic corticosteroids at a dose equivalent to at least 7.5 mg/day of prednisone and cannot tolerate a corticosteroid taper
Moderately to severely active polyarticular juvenile idiopathic arthritis (PJIA)	**ALL** of the following: 1. **ONE** of the following: a. The member has tried and had an inadequate response to **ONE** conventional agent (i.e., methotrexate, leflunomide) used in the treatment of PJIA after at least a 3-month duration of therapy **OR** b. The member has an intolerance or hypersensitivity to **ONE** conventional agent used in the treatment of PJIA **OR**

	c. The member has a labeled contraindication to **ALL** conventional agents used in the treatment of PJIA **OR** d. The member's medication history indicates use of another biologic immunomodulator agent that is FDA labeled or supported in DrugDex with 1 or 2a level of evidence or AHFS for the treatment of PJIA **AND** 2. **ANY** of the following (submitted medical records/chart notes are required for confirmation): a. The member has tried and had an inadequate response to at least **THREE** preferred products after at least a 3-month trial per product: **OR** b. The member has tried and had an inadequate response to **TWO** preferred products after at least a 3-month duration of therapy per products, **AND** an intolerance or hypersensitivity to **ONE** preferred product **OR** c. The member has tried and had an inadequate response to **ONE** preferred product after at least a 3-month duration of therapy, **AND** an intolerance or hypersensitivity to **TWO** preferred products **OR** d. The member has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to **THREE** preferred products **OR** e. The member has an FDA labeled contraindication to **ALL** preferred products **OR** f. **ALL** preferred products are not clinically appropriate for the member, **AND** the prescriber has provided a complete list of previously tried products for the requested indication **The preferred PJIA products are:** • Adalimumab-aaty • Adalimumab-adaz • Enbrel (etanercept) • Hadlima (adalimumab-bwwd)

	• Humira (adalimumab) • Rinvoq/Rinvoq LQ (upadacitinib) • Simlandi (adalimumab-ryvk) • Xeljanz (tofacitinib) **AND** 3. The member weighs 63 kg (139 lbs) or greater
Other indications	The member has another FDA labeled indication or an indication supported in DrugDex with 1 or 2a level of evidence, AHFS, or NCCN compendium recommended use 1 or 2a

Continuation of sarilumab (Kevzara) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "8"):

1. An authorization or reauthorization for sarilumab has been previously approved by Florida Blue[Note: members not previously approved for the requested agent will require initial evaluation review]
2. Member has had clinical benefit with sarilumab therapy
3. For polymyalgia rheumatica **ONLY** – the member does **NOT** have any of the following ("a", "b", and "c"):
   a. Neutropenia (ANC less than 1,000 per mm^3 at the end of the dosing interval)
   b. Thrombocytopenia (platelet count is less than 100,000 per mm^3)
   c. AST or ALT elevations 3-times the upper limit of normal (ULN)
4. For polyarticular juvenile idiopathic arthritis (PJIA) **ONLY** – the member weighs 63 kg (139 lbs) or greater
5. The prescriber is a specialist in the area of the member's diagnosis (e.g., rheumatologist for PJIA, RA or PMR) or the prescriber has consulted with a specialist in the area of the member's diagnosis
6. Member does **NOT** have any FDA labeled contraindications to sarilumab
7. Member will **NOT** be using sarilumab in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Olumiant (baricitinib), Opzelura (ruxolitinib), Olumiant (baricitinib), Rinvoq/Rinvoq LQ (upadacitinib), and Xeljanz/Xeljanz XR (tofacitinib)]; Otezla/Otezla XR (apremilast); Sotyktu (deucravacitinib); or sphingosine-1-phosphate (S1P) modulator [Velsipity (etrasimod) and Zeposia (ozanimod)]
8. **ANY** of the following ("a", "b", "c", or "d"):
   a. The dosage does not exceed 200 mg once every 2 weeks (14 days)
      • QL: 150 mg/1.14 mL pen – 2 pens (2.28 mL)/28 days
      • QL: 200 mg/1.14 mL pen – 2 pens (2.28 mL)/28 days

- QL: 150 mg/1.14 mL syringe – 2 syringes (2.28 mL)/28 days
- QL: 200 mg/1.14 mL syringe – 2 syringes (2.28 mL)/28 days

b. The member has an FDA labeled indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum FDA labeled dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. **ALL** of the following ("1", "2", and "3"):

      1. The requested quantity (dose) exceeds the FDA maximum labeled dose for the requested indication

      2. The member has tried and had an inadequate response to at least a 3-month trial of the maximum FDA labeled dose for the requested indication (medical records required)

      3. **EITHER** of the following ("a" or "b"):

         a. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

         b. The requested quantity (dose) exceeds the maximum FDA labeled dose **AND** the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested

b. he member has a compendia supported indication for the requested agent, **AND EITHER** of the following ("i" or "ii"):

   i. The requested quantity (dose) does **NOT** exceed the maximum compendia supported dose for the requested indication, **AND** the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength/and or package size that does not exceed the program quantity limit

   ii. The requested quantity (dose) exceeds the maximum compendia supported dose for the requested indication, **AND** there is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

c. The member does **NOT** have an FDA labeled indication **NOR** a compendia supported indication for the requested agent, **AND BOTH** of the following ("i" and "ii"):

   i. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength and/or package size that does not exceed the program quantity limit

   ii. There is support for therapy with a higher dose or shortened dosing interval for the requested indication (submitted copy of clinical trials, phase III studies, guidelines required)

Compendia Allowed: AHFS, DrugDex 1 or 2a level of evidence, or NCCN 1 or 2a recommended use

Approval duration: 12 months

DOSAGE/ADMINISTRATION:

THIS INFORMATION IS PROVIDED FOR INFORMATIONAL PURPOSES ONLY AND SHOULD NOT BE USED AS A SOURCE FOR MAKING PRESCRIBING OR OTHER MEDICAL DETERMINATIONS. PROVIDERS SHOULD REFER TO THE MANUFACTURER'S FULL PRESCRIBING INFORMATION FOR DOSAGE GUIDELINES AND OTHER INFORMATION RELATED TO THIS MEDICATION BEFORE MAKING ANY CLINICAL DECISIONS REGARDING ITS USAGE.

FDA-approved

- Treatment of – (1) adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs), (2) adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper, and (3) patients who weigh 63 kg or greater with active polyarticular juvenile idiopathic arthritis (PJIA).
    - RA – The recommended dosage is 200 mg once every two weeks given as a subcutaneous injection. Reduce dose to 150 mg once every two weeks for management of neutropenia, thrombocytopenia and elevated liver enzymes. Sarilumab may be used as monotherapy or in combination with methotrexate (MTX) or other conventional DMARDs.
    - PMR – The recommended dosage is 200 mg once every two weeks given as a subcutaneous injection in in combination with a tapering course of corticosteroids. Can be used as monotherapy following discontinuation of corticosteroids. Discontinue if the patient develops neutropenia (ANC below 1,000 per mm^3 at the end of the dosing interval), thrombocytopenia (platelet count below 100,000 per mm^3), or AST or ALT elevations 3-times above the ULN.
    - PJIA – The recommended dosage is 200 mg once every two weeks given as a subcutaneous injection. Dosage in this patient population can be achieved by administering the 200 mg/1.14 mL pre-filled syringe. The pre-filled pen is not intended for use in pediatric patients. Sarilumab is not approved in pediatric patients weighing less than 63 kg because of the lack of an appropriate dosage form. Sarilumab can be used alone or in combination with conventional DMARDs.
- Sarilumab initiation is NOT recommended in patients with a baseline absolute neutrophil count (ANC) less than 2,000/mm^3, platelet count less than 150,000/ mm^3, or who have ALT or AST above 1.5 times the upper limit of normal (ULN).
- Prior to initiating. Test patients for latent tuberculosis. A patient may self-inject after proper training on preparation and administration. The pre-filled syringe should sit at room temperature for 30 minutes prior to injection. Rotate injection sites with each injection.
- Avoid using sarilumab with biological DMARDs because of the possibility of increased immunosuppression and increased risk of infection.

Dose Adjustments for Patients with RA

- Low Absolute Neutrophil Count (ANC)
    - ANC greater than 1,000/mm^3 – maintain current dosage
    - ANC 500 to 1,000/mm^3 – hold treatment until ANC greater than 1,000/mm^3. Resume at 150 mg every two weeks and increased to 200 mg every two weeks as clinically appropriate.
    - ANC less than 500/mm^3 – discontinue
- Low Platelet Count

- 50,000–100,000/mm^3 – hold treatment until platelets greater than 100,000/mm^3. Resume at 150 mg every two weeks and increased to 200 mg every two weeks as clinically appropriate.
- Less than 50,000/mm^3 – discontinue if confirmed by repeat testing

- Liver Enzyme Abnormalities
  - ALT greater than ULN to 3 times ULN or less – consider dosage modification of concomitant DMARDs as clinically appropriate.
  - ALT greater than 3 times ULN to 5 times ULN or less – hold treatment until ALT less than 3 times ULN. Resume at 150 mg every two weeks and increased to 200 mg every two weeks as clinically appropriate.
  - ALT greater than 5 times ULN – discontinue

Drug Availability

- 150 mg/1.14 mL and 200 mg/1.14 mL as single-dose pre-filled syringes or pre-filled pens that come in a package of two syringes or pens
- Refrigerate at 36°F to 46°F (2°C to 8°C) in original carton to protect from light. If needed, sarilumab may be stored at room temperature up to 77°F (25°C) up to 14 days in the outer carton.

PRECAUTIONS:

Boxed Warning

- **WARNING: RISK OF SERIOUS INFECTIONS**
  - Patients treated with Kevzara are at increased risk for developing serious infections that may lead to hospitalization or death. Opportunistic infections have also been reported in patients receiving Kevzara. Most patients who developed infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
  - Avoid use of Kevzara in patients with an active infection.
  - Reported infections include:
    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before Kevzara use and during therapy. Treatment for latent infection should be initiated prior to Kevzara use.
    - Invasive fungal infections, such as candidiasis, and pneumocystis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral and other infections due to opportunistic pathogens.
  - Closely monitor patients for signs and symptoms of infection during treatment with Kevzara. If a serious infection develops, interrupt Kevzara until the infection is controlled.
  - Consider the risks and benefits of treatment with Kevzara prior to initiating therapy in patients with chronic or recurrent infection.

Contraindications

- Patients with known hypersensitivity to sarilumab or any of the inactive ingredients

Precautions/Warnings

- **Serious Infections**: Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents including sarilumab for RA. The most frequently observed serious infections with sarilumab included pneumonia and cellulitis. Avoid sarilumab use in patients with an active infection, including localized infections.
    - **Tuberculosis**: Evaluate patients for TB risk factors and test for latent infection prior to initiating treatment. Treat patients with latent TB with standard antimycobacterial therapy before initiating sarilumab
    - **Viral Reactivation:** Viral reactivation has been reported with immunosuppressive biologic therapies. Cases of herpes zoster were observed in clinical studies with sarilumab. The risk of Hepatitis B reactivation with is unknown since patients who were at risk for reactivation were excluded.
- **Laboratory Abnormalities**
    - **Neutropenia:** Treatment with sarilumab was associated with a higher incidence of decrease in absolute neutrophil count (ANC). Assess neutrophil count prior to initiation of therapy and monitor neutrophil count 4 to 8 weeks after start of therapy and every 3 months thereafter. Adjust the dose as needed based on ANC results.
    - **Thrombocytopenia**: Treatment with sarilumab was associated with a reduction in platelet counts in clinical studies. Assess platelet count prior to initiation of therapy and monitor platelets 4 to 8 weeks after start of therapy and every 3 months thereafter. Adjust the dose as needed based on platelet counts.
    - **Elevated Liver Enzymes**: Treatment with sarilumab was associated with a higher incidence of transaminase elevations. These elevations were transient and did not result in any clinically evident hepatic injury in clinical studies. Increased frequency and magnitude of these elevations were observed when potentially hepatotoxic drugs (e.g., MTX) were used in combination. Assess ALT/AST levels prior to initiation of treatment and monitor ALT and AST levels 4 to 8 weeks after start of therapy and every 3 months thereafter. Adjust the dose as needed based on transaminase elevations.
    - **Lipid Abnormalities**: Treatment with sarilumab was associated with increases in lipid parameters such as LDL-C, HDL-C, and/or triglycerides. Assess lipid parameters approximately 4 to 8 weeks following initiation of treatment, then at approximately 6-month intervals. Manage patients according to clinical guidelines for the management of hyperlipidemia.
- **Gastrointestinal (GI) Perforation**: Gastrointestinal perforations have been reported in clinical studies. Risk may be increased with concurrent diverticulitis or concomitant use of NSAIDs or corticosteroids. Promptly evaluate acute abdominal signs or symptoms.
- I**mmunosuppression**: Treatment with immunosuppressants may result in an increased risk of malignancies. The impact of treatment with sarilumab on the development of malignancies is not known but malignancies were reported in clinical studies.
- **Hypersensitivity reactions**: Hypersensitivity reactions have been reported in association with sarilumab. Injection site rash, rash, and urticaria were the most frequent hypersensitivity reactions.

- **Active Hepatic Disease and Hepatic Impairment**: Treatment with sarilumab is not recommended in patients with active hepatic disease or hepatic impairment, as treatment was associated with transaminase elevations.
- **Live vaccines**: Avoid concurrent use of live vaccines during treatment with sarilumab due to the risk of infection. Follow vaccination guidelines.

BILLING/CODING INFORMATION:

HCPCS Coding

J3590	Unclassified biologics

ICD-10 Diagnosis Codes That Support Medical Necessity

M05.00 – M05.09	Felty's syndrome
M05.10 – M05.19	Rheumatoid lung disease with rheumatoid arthritis
M05.20 – M05.29	Rheumatoid vasculitis with rheumatoid arthritis
M05.30 – M05.39	Rheumatoid heart disease with rheumatoid arthritis
M05.40 – M05.49	Rheumatoid myopathy with rheumatoid arthritis
M05.50 – M05.59	Rheumatoid polyneuropathy with rheumatoid arthritis
M05.60 – M05.69	Rheumatoid arthritis with involvement of other organs and systems
M05.70 – M05.7A	Rheumatoid arthritis with rheumatoid factor without organ or systems involvement
M05.80 – M05.8A	Other rheumatoid arthritis with rheumatoid factor
M05.9	Rheumatoid arthritis with rheumatoid factor, unspecified
M05.A	Abnormal rheumatoid factor and anti-citrullinated protein antibody with rheumatoid arthritis
M06.00 – M06.0A	Rheumatoid arthritis without rheumatoid factor
M06.20 – M06.29	Rheumatoid bursitis
M06.30 – M06.39	Rheumatoid nodule
M06.80 – M06.8A	Other specified rheumatoid arthritis
M06.9	Rheumatoid arthritis, unspecified
M08.09	Unspecified juvenile rheumatoid arthritis, multiple sites
M08.3	Juvenile rheumatoid polyarthritis (seronegative)
M08.89	Other juvenile arthritis, multiple sites
M35.3	Polymyalgia rheumatica

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Part D: BCBSF has delegated to Prime Therapeutics authority to make coverage determinations for the Medicare Part D services referenced in this guideline.

Medicare Advantage: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of guideline creation.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

DMARDs: An acronym for disease-modifying antirheumatic drug. These are drugs that modify the rheumatic disease processes, and slow or inhibit structural damage to cartilage and bone. These drugs are unlike symptomatic treatments such as NSAIDs that do not alter disease progression. DMARDs can be further subcategorized. With the release of biologic agents (e.g., anti-TNF drugs), DMARDs were divided into either: (1) conventional, traditional, synthetic, or non-biological DMARDs; or as (2) biological DMARDs. However, with the release of newer targeted non-biologic drugs and biosimilars, DMARDs are now best categorized as: (1) conventional synthetic DMARDs (csDMARD) (e.g., MTX, sulfasalazine), (2) targeted synthetic DMARDs (tsDMARD) (e.g., apremilast, baricitinib, tofacitinib), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD (boDMARD).

Interleukin-6 (IL-6): a protein that in humans is encoded by the IL6 gene. It acts as both a pro-inflammatory and anti-inflammatory cytokine. It is secreted by T cells and macrophages to stimulate immune response to trauma, especially burns or other tissue damage leading to inflammation.

Rheumatoid arthritis: usually occurs between ages 20 and 50. Inflammation begins in a joint, usually those of the fingers and hands, resulting in pain, swelling, redness, and eventually joint deformity. It is considered an autoimmune disease, which can affect the entire body, causing fatigue, weight loss, weakness, fever, and loss of appetite. It affects each person differently, with symptoms ranging from mild to debilitating. In many cases, it is difficult to control. In about one in six cases, rheumatoid arthritis becomes severely debilitating and can shorten the life of the person affected.

RELATED GUIDELINES:

Abatacept (Orencia), 09-J0000-67
Adalimumab Products, 09-J0000-46
Anakinra (Kineret), 09-J0000-45
Baricitinib (Olumiant), 09-J3000-10
Certolizumab Pegol (Cimzia), 09-J0000-77
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Infliximab Products, 09-J0000-39
Rituximab Products, 09-J0000-59
Tocilizumab Products (Actemra, Tofidence, Tyenne), 09-J1000-21

Tofacitinib (Xeljanz, Xeljanz XR) Oral Solution, Tablet, and Extended-Release Tablet, 09-J1000-86
Upadacitinib (Rinvoq), 09-J3000-51

OTHER:

NOTE: The list of biologic immunomodulator agents not permitted as concomitant therapy can be found at Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.

Table 2:

DMARD Generic Name	DMARD Brand Name
Auranofin (oral gold)	Ridaura
Azathioprine	Imuran
Cyclosporine	Neoral, Sandimmune
Hydroxychloroquine	Plaquenil
Leflunomide	Arava
Methotrexate	Rheumatrex, Trexall
Sulfasalazine	Azulfidine, Azulfidine EN-Tabs

Table 3: Grading of Severity of Rheumatoid Arthritis

Severity	Criteria
Mild	Joint pain Inflammation of at least 3 joints No inflammation in tissues other than the joints Usually, a negative result on a rheumatoid factor test An elevated erythrocyte sedimentation rate (ESR) or C reactive protein (CRP) level No evidence of bone or cartilage damage on x-rays
Moderate	Between 6 and 20 inflamed joints Usually no inflammation in tissues other than the joints An elevated ESR or CRP levels A positive rheumatoid factor test or anti-cyclic citrullinated peptide (anti-CCP) antibodies Evidence of inflammation but no evidence of bone damage on x-rays
Severe	More than 20 persistently inflamed joints or a rapid loss of functional abilities Elevated ESR or CRP levels Anemia related to chronic illness Low blood albumin level A positive rheumatoid factor test, often with a high level Evidence of bone and cartilage damage on x-ray Inflammation in tissues other than joints

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Pharmacy Policy Committee on 11/12/25.

GUIDELINE UPDATE INFORMATION:

09/15/17	New Medical Coverage Guideline.
01/01/18	Revision to guideline consisting of updating the preferred self-administered biologic products according to indication for use. Tofacitinib (Xeljanz, Xeljanz XR) added as prerequisite therapy for rheumatoid arthritis indication.
07/01/18	Revision to guideline consisting of updating the position statement.
10/15/18	Review and revision to guideline consisting of updating the position statement, definitions, related guidelines, and references.
10/15/19	Review and revision to guideline consisting of updating the position statement, billing/coding, and references.
01/01/20	Revision to guideline consisting of updating the position statement due to changes in preferred and non-preferred products.
07/01/20	Revision to guideline consisting of updating the description, position statement, dosage/administration, and other section.
01/01/21	Review and revision to guideline consisting of updating the position statement and references.

03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
09/15/21	Update to Table 1 in Position Statement.
11/15/21	Revision to guideline consisting of updating the position statement.
01/01/22	Review and revision to guideline consisting of updating the description, position statement, related guidelines, other section, and references.
02/15/22	Update to Table 1 in Position Statement.
03/15/22	Revision to guideline consisting of updating the position statement and other sections.
05/15/22	Update to Table 1 in Position Statement.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Update to Table 1 in Position Statement.
01/01/23	Review and revision to guideline consisting of updating the position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
4/15/23	Revision to guideline consisting of updating the position statement and other section.
05/15/23	Revision to guidelines consisting of updates to the description, position statement, dosage/administration, billing/coding, and references based on the new FDA-approved indication for the treatment of polymyalgia rheumatica.
07/01/23	Revision to guideline consisting of updating the position statement and other section.Amjevita and Hadlima added as Step 1a agents. Humira biosimilar products added to list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
01/01/24	Review and revision to guideline consisting of updating the position statement, other section, and references. Amjevita low-concentration [10 mg/0.2 mL, 20 mg/0.4 mL, and 40 mg/0.8 mL concentrations only] clarified as the preferred prerequisite product. Update to Table 1 in Position Statement. New drugs were added to the list of drugs that are not permitted for use in combination.
07/01/24	Revision to guideline consisting of updating the description, position statement, related guidelines, and other section. Amjevita low-concentration removed as a required prerequisite agent. Updates to the positioning of agents in Table 1. Removal of latent TB testing requirement. New drugs added to the list of Biologic Immunomodulator Agents Not Permitted as Concomitant Therapy.
08/15/24	Revision to guidelines consisting of updates to the description, position statement, dosage/administration, billing/coding, and references based on the new FDA-approved indication for the treatment of active PJIA in patients who weigh 63 kg or greater.
10/01/24	Revision to guideline consisting of updating the position statement. Updates to Table 1. Simlandi added among the required prerequisite agents for Kevzara for RA and PJIA.
01/01/25	Review and revision to guideline consisting of updating the description (NCCN info), position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for PJIA and RA. Update to original Table 1 which is now a link out from the Position Statement. Table titles updated. Revised wording regarding maximum dosage exceptions. New drugs were added to the list of drugs that are not permitted for use in combination.
10/01/25	Revision: Added ICD-10 code M05.A. Updated ICD-10 code ranges for RA.

01/01/26	Review and revision to guideline consisting of updating the description, position statement, and references.