09-J3000-10

Original Effective Date: 09/15/18

Reviewed: 11/12/25

Revised: 07/01/26

Subject: Baricitinib (Olumiant ®) Tablet

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DESCRIPTION:

Baricitinib (Olumiant) is an oral Janus kinase (JAK) inhibitor initially approved by the US Food and Drug Administration (FDA) in May 2018 for “treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies”. Many mediators in autoimmune inflammation (e.g., interleukins 2, 6, 12, 15, and 23; interferons; and granulocyte–macrophage colony-stimulating factor [GM-CSF]) signal through the JAK family (JAK1, JAK2, JAK3, and tyrosine kinase 2 [Tyk2]). Baricitinib is the second JAK inhibitor to be approved by the FDA for the treatment of RA; the first being tofacitinib (Xeljanz) in November 2012. Tofacitinib has the greatest affinity for JAK3, but it is considered a pan-JAK inhibitor (inhibitory activity at all but JAK3>JAK1>JAK2). Baricitinib is a potent JAK1 and JAK2 inhibitor with minimal activity on JAK3. Other JAK inhibitors are development, and each has a unique inhibitory profile among the various JAK proteins. The clinical significance of the different JAK affinity profiles among the various JAK inhibitors has yet to be determined. In November 2020, the FDA issued an emergency use authorization (EUA) for the unapproved use of baricitinib, in combination with remdesivir, for treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). In July 2021, the EUA was revised to no longer require baricitinib to be used in combination with remdesivir. Then in May 2022, the FDA approved a new indication for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO, making Olumiant the first immunomodulatory treatment for COVID-19 to receive FDA approval. Olumiant remains under EUA status for hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. In June 2022, the FDA approved a new indication for treatment of adult patients with severe alopecia areata. Baricitinib is the first systemic therapy to be approved by the FDA for the treatment of alopecia areata. In December 2021, based on the results of a post-marketing safety study of tofacitinib (Xeljanz) showing increased risk of all-cause mortality, major adverse cardiovascular events, and cancer as compared to TNF blockers in certain RA patients, the FDA modified baricitinib’s RA indication to require an inadequate response or intolerance to one or more TNF blockers. The Boxed Warning was also updated to include this additional safety information.

RHEUMATOID DISORDERS

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.

DERMATOLOGICAL DISORDERS

Alopecia Areata

Alopecia areata (AA) is a chronic autoimmune disease characterized by non-scarring hair loss of the scalp. The most common pattern of presentation of hair loss is the patch subtype, with circular patches seen on the scalp or beard areas. Hair loss may also affect other parts of the body, including the eyebrows, eyelashes, beard, and axillary. AA may also affect the nails and cause nail pitting, or in severe cases cause trachyonychia. During early stages of the disease spontaneous hair regrowth is common, but this becomes more rare as the hair loss becomes more extensive. Patients may have a decreased quality-of-life or psychological burden associated with the disease. Patients with AA tend to have a higher risk of both depression and anxiety.

AA is diagnosed based off of clinical presentation and patient history, but sometimes a biopsy is required. Active AA can be assessed with a pull test. A pull test involves firmly pulling 50 to 60 hairs close to the scalp, and a positive test is defined as greater than 10% of hairs being pulled out. Severity of the disease is a strong predictor of long-term outcomes of the disease and can assist in guiding treatment. The Severity of Alopecia Tool (SALT) involves splitting the scalp into four quadrants and determining the percentage of scalp area devoid of terminal hairs to provide a total affected area. One limitation of SALT is it does not account for hair loss of facial hair (eyelashes, eyebrows, beard) or body hair. Severity of AA has been defined as follows:

- Mild AA: 20% or less scalp hair loss
- Moderate AA: 21%-49% scalp hair loss
- Severe AA: 50%-100% scalp hair loss

Pharmacologic treatment of AA includes topical/intralesional/systemic corticosteroids, systemic immunosuppressants (e.g., cyclosporine, azathioprine, methotrexate), and minoxidil, with the use of each intervention dependent on the severity of the disease and the area of the body affected. Janus kinase (JAK) inhibitors have been shown to be effective in adults and young people with severe AA and are strongly recommended for these patients.

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 baricitinib (Olumiant) **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 baricitinib (starting on samples is not approvable) within the past 90 days
    b. The prescriber states the member has been treated with baricitinib (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. Baricitinib 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") [does **NOT** apply to COVID-19 treatment]:
            I. The member's age is within FDA labeling for the requested indication for baricitinib
            II. The prescriber has provided information in support of using baricitinib 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., dermatologist for AA, rheumatologist for RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis [does **NOT** apply to COVID-19 treatment]
3. Member does **NOT** have any FDA labeled contraindications to baricitinib
4. Member will **NOT** be using baricitinib in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Opzelura (ruxolitinib), 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)] [does **NOT** apply to COVID-19 treatment]
5. **ANY** of the following ("a", "b", "c", "d", "e", or "f"):
    a. For RA - the dosage does not exceed 2 mg once daily
        - QL: 1 mg tablet – 1 tablet/day
        - QL: 2 mg tablet – 1 tablet/day
    b. For AA - the dosage does not exceed 4 mg once daily
        - QL: 1 mg tablet – 1 tablet/day
        - QL: 2 mg tablet – 1 tablet/day
        - QL: 4 mg tablet – 1 tablet/day

c. For COVID-19 - the dosage does not exceed the following:

- Adults and pediatric patients 9 years of age and older - 4 mg once daily for 14 days or until hospital discharge, whichever comes first
- Pediatric patients 2 years to less than 9 years of age - 2 mg once daily for 14 days or until hospital discharge, whichever comes first

d. 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)

e. 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)

f. 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 (except COVID-19 treatment which is limited to no more than 14 days)

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 agents (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 (excluding samples) indicates use of another biologic immunomodulator agent **OR** a systemic targeted synthetic small molecule drug (e.g., oral JAK inhibitor) 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 patient, **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)
Alopecia areata (AA)	**BOTH** of the following: 1. Member has a diagnosis of severe alopecia areata **AND** 2. Member has at least 50% scalp hair loss that has lasted 6 months or more
Coronavirus disease 2019 (COVID-19)	**ALL** of the following: 1. Baricitinib will be used for the treatment of suspected or laboratory-confirmed COVID-19 **AND** 2. Member is hospitalized **AND** 3. Member is requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) **AND** 4. Member is 2 years of age or older
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 baricitinib (Olumiant) **meets the definition of medical necessity** when **ALL** of the following are met ("1" to "6"):

1. An authorization or reauthorization for baricitinib has been previously approved by Florida Blue (except for COVID-19 indication – see initiation criteria)

   [Note: members not previously approved for the requested agent will require initial evaluation review]

2. Member has had clinical benefit with baricitinib therapy
3. The prescriber is a specialist in the area of the member's diagnosis (e.g., dermatologist for AA, rheumatologist for RA) or the prescriber has consulted with a specialist in the area of the member's diagnosis
4. Member does **NOT** have any FDA labeled contraindications to baricitinib
5. Member will **NOT** be using baricitinib in combination with another biologic immunomodulator agent (full list in "Other" section); Janus kinase (JAK) inhibitor [Cibinqo (abrocitinib), Leqselvi (deuruxolitinib), Litfulo (ritlecitinib), Opzelura (ruxolitinib)], 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)]
6. **ANY** of the following ("a", "b", "c", "d". or "e"):
    a. For RA - the dosage does not exceed 2 mg once daily
        - QL: 1 mg tablet – 1 tablet/day
        - QL: 2 mg tablet – 1 tablet/day
    b. For AA - the dosage does not exceed 4 mg once daily
        - QL: 1 mg tablet – 1 tablet/day
        - QL: 2 mg tablet – 1 tablet/day
        - QL: 4 mg tablet – 1 tablet/day
    c. 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)
    d. 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)

e. 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 adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies
  - Limitation of Use (per product labeling): Use of baricitinib in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.
  - The recommended dosage is 2 mg once daily. Baricitinib may be used as monotherapy or in combination with methotrexate or other DMARDs. Baricitinib is given orally with or without food.
  - Initiation is not recommended in patients with an absolute lymphocyte count (ALC) less than 500 cells/mm^3, absolute neutrophil count (ANC) less than 1,000 cells/mm^3, or hemoglobin (Hg) level less than 8 g/dL. Also, prior to initiating baricitinib, test patients for latent tuberculosis (TB). If positive, consider treating for TB prior to baricitinib use.
- Treatment of adult patients with severe alopecia areata
  - Limitation of Use (per product labeling): Not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.
  - The recommended dosage is 2 mg once daily orally. Increase to 4 mg once daily if the response to treatment is not adequate. For patients with nearly complete or complete scalp hair loss, with or without substantial eyelash or eyebrow hair loss, consider treating with 4 mg once daily. Once patients achieve an adequate response to treatment with 4 mg, decrease the dosage to 2 mg once daily.
  - Initiation is not recommended in patients with an absolute lymphocyte count (ALC) less than 500 cells/mm^3, absolute neutrophil count (ANC) less than 1,000 cells/mm^3, or hemoglobin (Hg) level

less than 8 g/dL. Also, prior to initiating baricitinib, test patients for latent tuberculosis (TB). If positive, consider treating for TB prior to baricitinib use.

- Treatment of coronavirus disease 2019 (COVID-19) in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)
    - The recommended dosage for adults is 4 mg once daily orally, with or without food, for 14 days or until hospital discharge, whichever occurs first. An alternative administration for patients unable to swallow tablets [oral dispersion, gastrostomy tube (G tube), nasogastric tube (NG tube) or orogastric tube (OG tube)] may be used. Refer to the product labeling for instruction on preparation.
    - Initiation is not recommended in patients with an ALC less than 200 cells/mm^3 or ANC less than 500 cells/mm^3.

Dose Adjustments

- Adverse effects:
    - Serious infection
        - RA and AA - hold treatment until the infection is controlled
        - COVID-19 - the risks and benefits of treatment in patients with other concurrent infections should be considered
    - ALC less than 500 (RA and AA) or 200 (COVID-19) - interrupt therapy until ALC ≥500 (RA) or ≥200 (COVID-19)
    - ANC less than 1,000 (RA and AA) or 500 (COVID-19) - interrupt therapy until ALC ≥1,000 (RA) or ≥500 (COVID-19)
    - Hg <8 (RA and AA only) - interrupt therapy until Hg ≥8
- Hepatic impairment: no dosage adjustment is recommended for mild or moderate hepatic impairment. Baricitinib is not recommended in RA and AA patients with severe hepatic impairment. It is not known if dosage adjustment is needed in patients with COVID-19 and severe hepatic impairment. Olumiant should only be used in patients with COVID-19 and severe hepatic impairment if the potential benefit outweighs the potential risk.
- Renal impairment:
    - RA - the recommended dose in patients with moderate renal impairment (estimated glomerular filtration rate (GFR) between 30 and 60 mL/min/1.73 m^2) is 1 mg once daily. Baricitinib is not recommended in patients with severe renal impairment (an eGFR of less than 30 mL/minute/1.73m^2).
    - AA - the recommended dose in patients with moderate renal impairment (estimated glomerular filtration rate (GFR) between 30 and 60 mL/min/1.73 m^2) is 1 mg once daily (if the original recommended dosage is 2 mg) or 2 mg once daily (if the original recommended dosage is 4 mg). Baricitinib is not recommended in patients with severe renal impairment (an eGFR of less than 30 mL/minute/1.73m^2).

- COVID-19 - the recommended dose in patients with moderate renal impairment (eGFR between 30 and 60 mL/min/1.73 m^2) is 2 mg once daily, and in patient with severe renal impairment (an eGFR of less than 30 mL/minute/1.73m^2).is 1 mg once daily. Baricitinib is not recommended in patients with who are on dialysis, have end-stage renal disease (ESRD), or acute kidney injury (eGFR <15 mL/min/1.73m^2).

- Drug Interactions:
  - Patients taking strong Organic Anion Transporter 3 (OAT3) inhibitors, such as probenecid - If the recommended dosage is 4 mg once daily, reduce to 2 mg once daily. If the recommended dosage is 2 mg once daily, reduce dose to 1 mg once daily. If the recommended dosage is 1 mg once daily, consider discontinuing probenecid.

Drug Availability

- 1 mg film-coated, immediate-release tablet
- 2 mg film-coated, immediate-release tablet
- 4 mg film-coated, immediate-release tablet

PRECAUTIONS:

Boxed Warning

WARNING: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, AND THROMBOSIS

- SERIOUS INFECTIONS
  - Patients treated with Olumiant are at risk for developing serious infections that may lead to hospitalization or death. Most patients with rheumatoid arthritis who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.
  - If a serious infection develops, interrupt Olumiant until the infection is controlled.
  - Reported infections include:
    - Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Olumiant should not be given to patients with active tuberculosis. Patients, except those with COVID-19, should be tested for latent tuberculosis before initiating Olumiant and during therapy. If positive, start treatment for latent infection prior to Olumiant use.
    - Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.
    - Bacterial, viral, and other infections due to opportunistic pathogens.
  - The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

- Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with Olumiant including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

- MORTALITY
  - In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular risk factor comparing another Janus kinase (JAK) inhibitor to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden cardiovascular death, was observed with the JAK inhibitor.
- MALIGNANCIES
  - Lymphoma and other malignancies have been observed in patients treated with Olumiant. In RA patients treated with another JAK inhibitor, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.
- MAJOR ADVERSE CARDIOVASCULAR EVENTS
  - In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), was observed when compared with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue Olumiant in patients that have experienced a myocardial infarction or stroke.
- THROMBOSIS
  - Thrombosis, including deep venous thrombosis and pulmonary embolism, has been observed at an increased incidence in patients treated with Olumiant compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. In RA patients 50 years of age and older with at least one cardiovascular risk factor treated with another JAK inhibitor, a higher rate of thrombosis was observed when compared with TNF blockers. Avoid Olumiant in patients at risk. Patients with symptoms of thrombosis should discontinue Olumiant and be promptly evaluated.

Contraindications

- None

Precautions/Warnings

- **Serious Infections** – see Boxed Warning
- **Mortality** – see Boxed Warning
- **Malignancy and Lymphoproliferative Disorders** – see Boxed Warning
- **Major Adverse Cardiovascular Events** – See Boxed Warning

- **Thrombosis** – see Boxed Warning
- **Gastrointestinal Perforations** - Events of gastrointestinal perforation have been reported in clinical studies with baricitinib, although the role of JAK inhibition in these events is not known. Baricitinib should be used with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Patients presenting with new onset abdominal symptoms should be evaluated promptly for early identification of gastrointestinal perforation.

- **Laboratory Abnormalities**
  - Neutropenia - Treatment with baricitinib was associated with an increased incidence of neutropenia compared to placebo. In patients with RA or AA, avoid initiation or interrupt treatment in patients with an ANC less than 1,000 cells/mm^3. In patients with COVID-19, there is limited information regarding use in patients with ANC less than 1000 cells/mm^3. Avoid initiation or interrupt treatment in patients with COVID-19 and an ANC less than 500 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.
  - Lymphopenia - ALC less than 500 cells/mm^3 were reported in clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with baricitinib, but not placebo. In patients with RA or AA, avoid initiation or interrupt treatment in patients with an ALC less than 500 cells/mm^3. In patients with COVID-19, there is limited information regarding use in patients with ALC less than 200 cells/mm^3. Avoid initiation or interrupt treatment in patients with COVID-19 and an ANC less than 200 cells/mm^3. Evaluate at baseline and thereafter according to routine patient management.
  - Anemia - Decreases in hemoglobin levels to less than 8 g/dL were reported in clinical trials. In patients with RA or AA, avoid initiation or interrupt treatment in patients with hemoglobin less than 8 g/dL. In patients with COVID-19, there is limited information regarding use in patients with hemoglobin less than 8 g/dL. Evaluate at baseline and thereafter according to routine patient management.
  - Liver Enzyme Elevations - Treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases to greater than or equal to 5x and greater than or equal to 10x ULN were observed for both ALT and AST in patients in clinical trials. Evaluate at baseline and thereafter according to routine patient management. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt baricitinib until this diagnosis is excluded.
  - Lipid Elevations - Treatment with baricitinib was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein (LDL) cholesterol, and high-density lipoprotein (HDL) cholesterol. Assessment of lipid parameters should be performed approximately 12 weeks following initiation. Manage patients according to clinical guidelines for the management of hyperlipidemia.
- **Vaccinations** - Avoid use of live vaccines with baricitinib. Update immunizations in agreement with current immunization guidelines prior to initiating baricitinib therapy.

- **Hypersensitivity** - Reactions such as angioedema, urticaria, and rash that may reflect drug hypersensitivity have been observed in patients receiving baricitinib, including serious reactions. If a serious hypersensitivity reaction occurs, promptly discontinue baricitinib while evaluating the potential causes of the reaction.

BILLING/CODING INFORMATION:

HCPCS Coding

J8499	Prescription drug, oral, non-chemotherapeutic, Not Otherwise Specified

ICD-10 Diagnosis Codes That Support Medical Necessity

L63.0 – L63.9	Alopecia areata
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
U07.1	COVID-19

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 drugs. 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., tofacitinib, apremilast), and (3) biological DMARDs (bDMARD), which can be either a biosimilar DMARD (bsDMARD) or biological originator DMARD

Rheumatoid arthritis: usually strikes 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
Certolizumab Pegol (Cimzia), 09-J0000-77
Etanercept (Enbrel), 09-J0000-38
Golimumab (Simponi, Simponi Aria), 09-J1000-11
Infliximab Products, 09-J0000-39
Ritlecitinib (Litfulo), 09-J4000-57
Rituximab Products), 09-J0000-59
Sarilumab (Kevzara), 09-J2000-87
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

REFERENCES:

1. Clinical Pharmacology powered by ClinicalKey [Internet]. Tampa, FL: Elsevier; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed 10/29/25.
2. Dougados M, van der Heijde D, Chen YC, et al: Baricitinib in patients with inadequate response or intolerance to conventional synthetic DMARDs: results from the RA-BUILD study. Ann Rheum Dis 2017; 76(1):88-95.
3. Egeberg A, Linsell L, Johansson E, et al. Treatments for Moderate-to-Severe Alopecia Areata: A Systematic Narrative Review. Dermatology and Therapy. 2023;13(12):2951-2991.
4. Fleischmann R, Takeuchi T, Schiff M, et al. Efficacy and safety of long-term baricitinib with and without methotrexate for the treatment of rheumatoid arthritis: experience with baricitinib monotherapy continuation or after switching from methotrexate monotherapy or baricitinib plus methotrexate. Arthritis Care Res (Hoboken). 2019 Jun 24. [Epub ahead of print].
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2021 Jul;73(7):924-939.
6. Genovese MC, Kremer J, Zamani O, et al: Baricitinib in patients with refractory rheumatoid arthritis. N Engl J Med 2016; 374(13):1243-1252.
7. Gilhar A, Etzioni A, Paus R. Alopecia areata. N Engl J Med. 2012 Apr 19;366(16):1515-25.
8. Graudal N, Hubeck-Graudal T, Tarp S, et al. Effect of combination therapy on joint destruction in rheumatoid arthritis: a network meta-analysis of randomized controlled trials. PLoS One. 2014 Sep 22;9(9):e106408.
9. Harries MJ, Ascott A, Asfour L, et al. British Association of Dermatologists living guideline for managing people with alopecia areata 2024. Br J Dermatol. 2025 Jan 24;192(2):190-205.
10. Kalil AC, Patterson TF, Mehta AK, et al.; ACTT-2 Study Group Members. Baricitinib plus Remdesivir for Hospitalized Adults with Covid-19. N Engl J Med. 2021 Mar 4;384(9):795-807. Epub 2020 Dec 11.
11. Karlsson JA, Neovius M, Nilsson JA, et al. Addition of infliximab compared with addition of sulfasalazine and hydroxychloroquine to methotrexate in early rheumatoid arthritis: 2-year quality-of-life results of the randomised, controlled, SWEFOT trial. Ann Rheum Dis. 2013 Dec;72(12):1927-33.
12. King BA, Mesinkovska NA, Craiglow B, et al. Development of the alopecia areata scale for clinical use: Results of an academic-industry collaborative effort. J Am Acad Dermatol. 2022 Feb;86(2):359-364.

13. King B, Ohyama M, Kwon O, et al.; BRAVE-AA Investigators. Two Phase 3 Trials of Baricitinib for Alopecia Areata. N Engl J Med. 2022 May 5;386(18):1687-1699. Epub 2022 Mar 26.
14. Kunwar S, Collins CE, and Constantinescu F. Baricitinib, a Janus kinase inhibitor, in the treatment of rheumatoid arthritis: a systematic literature review and meta-analysis of randomized controlled trials. Clin Rheumatol. 2018 Jul 13. [Epub ahead of print].
15. Krause ML, Amin A, and Makol A. Use of DMARDs and biologics during pregnancy and lactation in rheumatoid arthritis: what the rheumatologist needs to know. Ther Adv Musculoskelet Dis. 2014 Oct; 6(5): 169–184.
16. Marconi VC, Ramanan AV, de Bono S, et al.; COV-BARRIER Study Group. Efficacy and safety of baricitinib for the treatment of hospitalised adults with COVID-19 (COV-BARRIER): a randomised, double-blind, parallel-group, placebo-controlled phase 3 trial. Lancet Respir Med. 2021 Dec;9(12):1407-1418. Epub 2021 Sep 1. Erratum in: Lancet Respir Med. 2021 Oct;9(10): e102.
17. Micromedex Healthcare Series [Internet Database]. Greenwood Village, Colo: Thomson Healthcare. Updated periodically. Accessed 10/29/25.
18. Messenger AG, McKillop J, Farrant P, et al. British Association of Dermatologists' guidelines for the management of alopecia areata 2012. Br J Dermatol 2012; 166:916.
19. Olumiant (baricitinib tablet) [package insert]. Indianapolis, IN: Eli Lilly and Company; June 2022.
20. Rahimi R, Nikfar S, Rezaie A, et al. Pregnancy outcome in women with inflammatory bowel disease following exposure to 5-aminosalicylic acid drugs: a meta-analysis. Reprod. Toxicol; 2008:25,271–275.
21. Scott DL, Ibrahim F, Farewell V, et al. Tumour necrosis factor inhibitors versus combination intensive therapy with conventional disease modifying anti-rheumatic drugs in established rheumatoid arthritis: TACIT non-inferiority randomised controlled trial. BMJ. 2015 Mar 13;350:h1046.
22. Sibbald C. Alopecia Areata: An Updated Review for 2023. J Cutan Med Surg. 2023 May-Jun;27(3):241-259.
23. Smolen JS, Landewé RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. Ann Rheum Dis. 2023 Jan;82(1):3-18. Epub 2022 Nov 10. Erratum in: Ann Rheum Dis. 2023 Mar;82(3):e76.
24. Strazzulla LC, Wang EHC, Avila L, et al. Alopecia areata: Disease characteristics, clinical evaluation, and new perspectives on pathogenesis. J Am Acad Dermatol. 2018 Jan;78(1):1-12.
25. Taylor PC, Keystone EC, van der Heijde D, et al. Baricitinib versus Placebo or Adalimumab in Rheumatoid Arthritis. N Engl J Med. 2017 Feb 16;376(7):652-662.
26. van der Heijde D, Dougados M, Chen YC, et al. Effects of baricitinib on radiographic progression of structural joint damage at 1 year in patients with rheumatoid arthritis and an inadequate response to conventional synthetic disease-modifying antirheumatic drugs. RMD Open. 2018 May 8;4(1): e000662.
27. van Vollenhoven RF, Geborek P, Forslind K, et al. Conventional combination treatment versus biological treatment in methotrexate-refractory early rheumatoid arthritis: 2-year follow-up of the randomised, non-blinded, parallel-group Swefot trial. Lancet. 2012 May 5;379(9827):1712-20.
28. Wallace DJ, Furie RA, Tanaka Y, et al. Baricitinib for systemic lupus erythematosus: a double-blind, randomised, placebo-controlled, phase 2 trial. Lancet. 2018 Jul 21;392(10143):222-231.
29. Wright TB and Punaro M. Paediatric systemic lupus erythematosus: insights from translational research. Rheumatology (Oxford). 2017 Apr 1;56(suppl_1): i24-i31.

COMMITTEE APPROVAL:

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

GUIDELINE UPDATE INFORMATION:

09/15/18	New Medical Coverage Guideline.
10/15/19	Review and revision to guideline consisting of updating the position statement, billing/coding, other section, 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 references.
01/01/21	Review and revision to guideline consisting of updating the description, position statement, precautions, and references.
03/15/21	Revision to guideline consisting of updating Table 1 in the position statement.
09/15/21	Revision to guideline consisting of updating the description, position statement. other section, and references.
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, dosage/administration, precautions, other section, related guidelines, 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.
06/15/22	Revision to guideline consisting of updating the position statement and other sections.
07/15/22	Update to Table 1 in Position Statement.
09/15/22	Review and revision to guideline consisting of updating the description, position statement, dosage/administration, precautions, billing/coding, and references.
01/01/23	Review and revision to guideline consisting of updating the description section, position statement, other section, and references. New drugs were added to the list of drugs that are not permitted for use in combination.
04/15/23	Revision to guideline consisting of updating the position statement and other section.
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 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.
10/01/24	Revision to guideline consisting of updating the position statement. Updates to Table 1. Simlandi added among the required prerequisite agents for Olumiant for RA.
01/01/25	Review and revision to guideline consisting of updating the position statement, other section, and references. Adalimumab-aaty and Adalimumab-adaz added among the prerequisite therapies for 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.
07/01/26	Revision: Modified the prerequisite requirement that bypasses the conventional agent step to exclude sample use and include systemic targeted synthetic small molecule drugs as an option.