BlueCross BlueShield of Arizona
An Independent Licensee of the Blue Cross and Blue Shield Association

| | |
|---|---|
| **PHARMACY COVERAGE GUIDELINES** | **ORIGINAL EFFECTIVE DATE: 8/02/18** |
| **SECTION: DRUGS** | **LAST REVIEW DATE: 8/02/18** |
| | **LAST CRITERIA REVISION DATE:** |
| | **ARCHIVE DATE:** |

# OLUMIANT® (baricitinib) oral tablet

**Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.**

**This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.**

**The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.**

**The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.**

**State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.**

**Pharmacy Coverage Guidelines are subject to change as new information becomes available.**

**For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.**



This Pharmacy Coverage Guideline does not apply to FEP or other states' Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. **Incomplete forms or forms without the chart notes will be returned.**

## OLUMIANT® (baricitinib) oral tablet (cont.)

**Criteria:**

- **Criteria for initial therapy:** Olumiant (baricitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Prescriber is a Rheumatologist

2. Individual is 18 years of age or older

3. A confirmed diagnosis of rheumatoid arthritis identified by **ONE** of the following:
   - Clinical Disease Activity Index (CDAI) score greater than 10
   - Disease Activity Score 28 (DAS28) of greater than 3.2
   - Patient Activity Scale (PAS) of greater than 3.7
   - Patient Activity Scale II (PASII) of greater than 3.7
   - Routine Assessment of Patient Index Data 3 (RAPID-3) score greater than 2
   - Simplified Disease Activity Index (SDAI) score greater than 11

4. Individual has failure (used for ≥ 3 consecutive months), contraindication or intolerance to **methotrexate** and **ONE or more** of the following:
   - Leflunomide
   - Sulfasalazine
   - Tumor necrosis factor-alpha inhibitor (TNF-inhibitor like Enbrel, etc.)

5. For **non-preferred agents** for rheumatoid arthritis, individual has failure (used for ≥ 3 consecutive months), contraindication or intolerance to **TWO** of the following preferred agents:
   - Cimzia
   - Humira
   - Otezla
   - Remicade
   - Simponi
   - Stelara

6. **ALL** of the following baseline tests have been completed before initiation of treatment with continued monitoring as clinically appropriate:
   - Latent tuberculosis test, if positive treatment for tuberculosis is started prior to Olumiant
   - Hemoglobin is > 8 g/dL
   - Absolute lymphocyte count is ≥ 500 cells/$mm^3$
   - Absolute neutrophil count is ≥ 1,000 cells/$mm^3$
   - Liver function tests
   - Lipid panel

7. Will not be used in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine

8. Will not be used with live vaccines

## OLUMIANT® (baricitinib) oral tablet (cont.)

9. No evidence of active serious infections, including clinically important localized infections or sepsis when initiating or continuing therapy

10. Will not be used in patients with severe hepatic impairment

11. Will not be used in patients with moderate or severe renal impairment (estimated GFR of < 60 mL/min/1.73 $m^2$)

12. Woman patient who is breast feeding an infant or child should stop breast feeding during therapy

**Initial approval duration**: 6 months, 30 tablets per month

- **Criteria for continuation of coverage (renewal request):** Olumiant (baricitinib) is considered ***medically necessary*** and will be approved when **ALL** of the following criteria are met:

1. Individual continues to be seen by a Rheumatologist

2. Individual's condition responded while on therapy
   - Response is defined as at least a 20% improvement in TWO of the following:
     - ACR 20
     - Number of tender joints
     - Number of swollen joints
     - Pain

3. Individual has been adherent with the medication

4. Individual has not developed any significant level 4 adverse drug effects that may exclude continued use
   - Significant adverse effect such as:
     - Thrombosis: DVT, PE, or arterial
     - Gastrointestinal perforation
     - Liver toxicity

5. There are no significant interacting drugs

**Renewal duration**: 12 months, 30 tablets per month

**Description:**
Olumiant (baricitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more TNF antagonist therapies. May be used as monotherapy or in combination with methotrexate or other non-biologic Disease Modifying Anti-rheumatic Drugs (DMARDs). Use of Olumiant in combination with other JAK inhibitors, biologic DMARDs, or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

## OLUMIANT® (baricitinib) oral tablet (cont.)

**Definitions:**

**Rheumatoid Arthritis Disease Activity Measurement Instruments**:

| Instrument | Threshold of Disease Activity |
|---|---|
| Clinical Disease Activity Index (CDAI) | Range: 0 to 76<br>Remission: ≤ 2.8<br>Low activity: >2.8 to ≤ 10<br>Moderate activity: >10 to ≤ 22<br>High activity: >22 |
| Disease Activity Score 28 (DAS28) | Range: 0.5 to 9<br>Remission: < 2.6<br>Low activity: > 2.6 to ≤ 3.2<br>Moderate activity: > 3.2 to ≤ 5.1<br>High activity: > 5.1 |
| Patient Activity Scale (PAS)<br>Patient Activity Scale II (PASII) | Range 0 to 10<br>Remission: 0 to 0.25<br>Low activity: >0.25 to 3.7<br>Moderate activity: > 3.7 to < 8.0<br>High activity: ≥ 8.0 |
| Routine Assessment of Patient Index Data 3 (RAPID-3) | Range: 0 to 10<br>Remission: 0 to 1.0<br>Low activity: > 1.0 to 2.0<br>Moderate activity: > 2.0 to 4.0<br>High activity: > 4.0 to 10 |
| Simplified Disease Activity Index (SDAI) | Range: 0 to 90<br>Remission: ≤ 3.3<br>Low activity: > 3.3 to ≤ 11.0<br>Moderate activity: > 11.0 to ≤ 26<br>High activity: > 26 |

**Rheumatoid Arthritis Preferred and Non-preferred Agents**:

| Disease State | Preferred agents | Non-Preferred agents | |
|---|---|---|---|
| Rheumatoid Arthritis (RA) | **Cimzia**<br>**Humira**<br>**Remicade**<br>**Simponi** | Actemra | (QSE) |
| | | Enbrel | (QSE) |
| | | Kevzara | (DSE) |
| | | Kineret | (QSE) |
| | | Orencia | (QSE) |
| | | Rituxan | (QSE) |
| | | Olumiant | (DSE) |
| | | Xeljanz | (DSE) |
| | | Xeljanz XR | (DSE) |

**DSE:** Double Step Edit. Individual has failure, contraindication or intolerance to at least **TWO** preferred agents with a specific duration.

**QSE:** Quadruple Step Edit. Individual has failure, contraindication or intolerance to at least **FOUR** preferred agents with a specific duration.

## OLUMIANT® (baricitinib) oral tablet (cont.)

**Resources:**

Olumiant (baricitinib) product information accessed 07-24-18 at DailyMed: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=866e9f35-9035-4581-a4b1-75a621ab55cf

"Small Molecules and Biologics Chart AP94", BCBSAZ Administrative Procedure Guideline when preferred TNF medications are otherwise contraindicated or not labeled for the indication being prescribed.

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

**Fax completed prior authorization request form to 602-864-3126** or email to pharmacyprecert@azblue.com.
Call 866-325-1794 to check the status of a request.
All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.**
Pharmacy Coverage Guidelines are available at www.azblue.com/pharmacy.

# Pharmacy Prior Authorization Request Form

**Do not copy for future use. Forms are updated frequently.**
**REQUIRED: Office notes, labs, and medical testing relevant to the request that show medical justification are required.**

## Member Information

| Member Name (first & last): | Date of Birth: | Gender: | BCBSAZ ID#: |
|---|---|---|---|
| Address: | City: | State: | Zip Code: |

## Prescribing Provider Information

| Provider Name (first & last): | Specialty: | NPI#: | DEA#: |
|---|---|---|---|
| Office Address: | City: | State: | Zip Code: |
| Office Contact: | Office Phone: | Office Fax: | |

## Dispensing Pharmacy Information

| Pharmacy Name: | Pharmacy Phone: | Pharmacy Fax: |
|---|---|---|

## Requested Medication Information

| Medication Name: | Strength: | Dosage Form: |
|---|---|---|
| Directions for Use: | Quantity: / Refills: | Duration of Therapy/Use: |

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _____ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis? Please specify below.**

   **ICD-10 Code:** _____ **Diagnosis Description:** _____

2. ☐ Yes ☐ No **Was this medication started on a recent hospital discharge or emergency room visit?**

3. ☐ Yes ☐ No **There is absence of ALL contraindications.**

4. **What medication(s) has the individual tried and failed for this diagnosis? Please specify below.**
Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

| Medication Name, Strength, Frequency | Dates started and stopped or Approximate Duration | Describe response, reason for failure, or allergy |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

5. **Are there any supporting labs or test results? Please specify below.**

| Date | Test | Value |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

BlueCross BlueShield of Arizona

An Independent Licensee of the Blue Cross and Blue Shield Association

# Pharmacy Prior Authorization Request Form

**6. Is there any additional information the prescribing provider feels is important to this review? Please specify below.**
For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

**Signature affirms that information given on this form is true and accurate and reflects office notes**

Prescribing Provider's Signature: Date:

**Please note**: Some medications may require completion of a drug-specific request form.

**Incomplete forms or forms without the chart notes will be returned.**

Office notes, labs, and medical testing relevant to the request that show medical justification are required.