

FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Olumiant® (baricitinib tablets – Lilly)

DATE REVIEWED: 04/19/2019

Continuation of Therapy: Approval for a patient continuing therapy with Olumiant must be supported with verification, noted in the criteria as either [verification in prescription claims history required] or, if not available, [verification by prescribing physician required].

- If the patient has at least 130 days of prescription claims history on file, claims history must support that the patient has received Olumiant for 90 days within a 130-day look-back period; OR
- When 130 days of the patient’s prescription claim history file is unavailable for verification, the prescriber must verify that the patient has been receiving Olumiant for at least 90 days, AND that the patient has been receiving Olumiant via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Olumiant).

Documentation Required: For rheumatoid arthritis (RA), a trial of two Formulary products is required. The prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals are provided for the duration noted below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Formulary Products: Unless exception criteria are met, a trial of two Formulary products is required prior to approval of Olumiant for RA. When this requirement is not met, the Formulary products will be offered for review.

CRITERIA

1. Rheumatoid Arthritis (RA).

A) Initial Therapy: Approve for 3 months if the patient meets the following criteria (i, ii, and iii):

- i. The patient has had a 3-month trial of at least ONE tumor necrosis factor inhibitor (TNFi) for this condition, unless intolerant.

NOTE: Examples of TNFis include an adalimumab product [e.g., Humira], Cimzia [certolizumab SC injection], an etanercept product [e.g., Enbrel, Erelzi], an infliximab product [e.g., Remicade, Inflectra, Renflexis], Simponi SC [golimumab SC injection], or Simponi Aria [golimumab IV infusion]). Conventional synthetic DMARDs such as methotrexate [MTX], leflunomide, hydroxychloroquine, and sulfasalazine do not count; AND

- ii. Olumiant is prescribed by or in consultation with a rheumatologist; AND
- iii. The patient has tried TWO of Actemra SC, Enbrel, Humira, or Xeljanz/XR [documentation required]. Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of ONE product. A trial of Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Orencia IV or SC, or Simponi (Aria or SC) also counts [documentation required].

NOTE: If the patient has met criterion i and ii but criterion iii is not met, offer to review for a Formulary product (Actemra SC, Enbrel, Humira, or Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.

- B) Patients Currently Receiving Olumiant:** Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):
- i.** The patient has had a response (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints or tendon sheaths; improved laboratory values; reduced dosage of corticosteroids), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Olumiant; **AND**
 - ii.** The patient meets ONE of the following conditions (a or b):
 - a)** The patient has been established on Olumiant for at least 90 days and prescription claims history indicates at least a 90-day supply of Olumiant was dispensed within the past 130 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required]. **Note:** In cases when 130 days of the patient's prescription claim history file is unavailable to be verified, an exception to this requirement is allowed if the prescriber has verified that the patient has been receiving Olumiant for at least 90 days **AND** the patient has been receiving Olumiant via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Olumiant); **OR**
 - b)** The patient has tried TWO of Actemra SC, Enbrel, Humira, or Xeljanz/XR [documentation required]. **Note:** A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of **ONE** product. A trial Actemra IV, Cimzia, an infliximab product (e.g., Inflectra, Remicade, Renflexis), Kevzara, Orencia IV or SC, or Simponi (Aria or SC) also counts [documentation required].

NOTE: If the patient has met criterion i but criterion ii is not met, offer to review for a Formulary product (Actemra SC, Enbrel, Humira, or Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.