



FORMULARY EXCEPTION POLICY

POLICY: Inflammatory Conditions – Simponi® (golimumab for subcutaneous injection – Janssen Biotech, Inc.)

DATE REVIEWED: 01/01/2019

Continuation of Therapy: Approval for a patient continuing therapy with Simponi SC 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 Simponi SC 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 Simponi SC for at least 90 days, AND that the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC).

Documentation Required: For rheumatoid arthritis (RA), ankylosing spondylitis (AS), and psoriatic arthritis (PsA), 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 Simponi SC for RA, AS, or PsA; a trial of one formulary product is required for ulcerative colitis. When this requirement is not met, the Formulary products will be offered for review.

CRITERIA

1. Ankylosing Spondylitis (AS).

A) Initial Therapy. Approve for 3 months if the patient meets BOTH of the following conditions (i and ii):

- i. Simponi SC is prescribed by or in consultation with a rheumatologist; AND
- ii. The patient has tried TWO of Cosentyx, Enbrel, and Humira **[documentation required]**.

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

B) Patients Currently Receiving Simponi (SC or Aria). 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., decreased pain or stiffness, improved function or activities of daily living), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria); AND
- ii. The patient meets ONE of the following conditions (a, b, or c):
 - a) The patient has been established on Simponi SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi SC 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 Simponi SC for at least 90 days AND the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC); OR

b) According to the prescribing physician, the patient has been established on Simponi Aria for at least 90 days; OR

c) The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required].

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

2. Psoriatic Arthritis (PsA).

A) Initial Therapy. Approve for 3 months if the patient meets BOTH of the following conditions (i and ii):

- i. Simponi SC is prescribed by or in consultation with a rheumatologist or a dermatologist; AND
- ii. The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara, and Xeljanz/XR [documentation required].

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

B) Patients Currently Receiving Simponi (SC or Aria). 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; improvements in acute phase reactants [for example, CRP]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria); AND

ii. The patient meets ONE of the following conditions (a, b, or c):

a) The patient has been established on Simponi SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi SC 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 Simponi SC for at least 90 days AND the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC); OR

b) According to the prescribing physician, the patient has been established on Simponi Aria for at least 90 days; OR

c) The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, or Xeljanz/XR [documentation required].

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

4. 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 tried ONE conventional synthetic disease-modifying antirheumatic drug (DMARD) for at least 3 months (e.g., methotrexate [oral or injectable], leflunomide, hydroxychloroquine, and sulfasalazine).

NOTE: An exception to the requirement for a trial of one conventional synthetic DMARD can be made if the patient has already has a 3-month trial at least one biologic DMARD (e.g., Cimzia [certolizumab pegol SC injection], an etanercept product [e.g., Enbrel], an adalimumab product [e.g., Humira], an infliximab product [e.g., Inflectra, Remicade, Renflexis], Simponi Aria [golimumab IV infusion], Actemra [tocilizumab SC injection, tocilizumab IV infusion], Kevzara [sarilumab SC injection], Kineret [anakinra SC injection], Orencia [abatacept IV infusion, abatacept SC injection], and a rituximab product [e.g., Rituxan]. These patients who have already tried a biologic for RA are not required to “step back” and try a conventional synthetic DMARD; AND

- ii. Simponi SC is prescribed by or in consultation with a rheumatologist; AND

- iii. The patient has tried TWO of Actemra SC, Enbrel, Humira, and 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.

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 Simponi (SC or Aria). 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 Simponi SC or Aria; AND

- ii. The patient meets ONE of the following conditions (a, b, or c):

- a) The patient has been established on Simponi SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi SC 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 Simponi SC for at least 90 days AND the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC); OR

- b) According to the prescribing physician, the patient has been established on Simponi Aria for at least 90 days; OR

- c) The patient has tried TWO of Actemra SC, Enbrel, Humira, and Xeljanz/XR [documentation required]. Note: Trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as a trial of ONE product.

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.

5. Ulcerative Colitis (UC) in an Adult.

- A) Initial Therapy. Approve for 3 months if the patient meets ALL of the following conditions (i, ii, and iii):

- i. The patient meets ONE of the following conditions (a or b):

- a) Patient has had a 2-month trial of one conventional systemic agent (e.g., 6-mercaptopurine, azathioprine, cyclosporine, tacrolimus, or a corticosteroid such as prednisone or methylprednisolone) or was intolerant to one of these agents for ulcerative colitis.
NOTE: An exception to this criterion can be made if the patient has already tried a biologic (e.g., an adalimumab product [e.g., Humira], or an infliximab product [e.g., Remicade, Inflectra, Renflexis], Entyvio® [vedolizumab for IV infusion]). These patients who have already received a biologic are not required to “step back” and try another agent]; OR
- b) The patient has pouchitis AND has tried therapy with an antibiotic (e.g., metronidazole, ciprofloxacin), probiotic, corticosteroid enema [for example, Cortenema® {hydrocortisone enema, generics}], or Rowasa® (mesalamine) enema; AND
- ii. Simponi SC is prescribed by or in consultation with a gastroenterologist; AND
- iii. The patient has tried Humira or Xeljanz.
NOTE: If the patient has met criterion i and ii but criterion iii is not met, offer to review for the Formulary product (Humira or Xeljanz) using the appropriate *ESI Inflammatory Conditions* criteria.
- B) Patients Currently Receiving Simponi (SC or Aria). 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., decreased stool frequency or rectal bleeding), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Simponi (SC or Aria); AND
 - ii. The patient meets ONE of the following conditions (a, b, or c):
 - a) The patient has been established on Simponi SC for at least 90 days and prescription claims history indicates at least a 90-day supply of Simponi SC 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 Simponi SC for at least 90 days AND the patient has been receiving Simponi SC via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Simponi SC); OR
 - b) According to the prescribing physician, the patient has been established on Simponi Aria for at least 90 days; OR
 - c) The patient has tried Humira or Xeljanz.
- NOTE: If the patient has met criterion i but criterion ii is not met, offer to review for the Formulary product (Humira or Xeljanz) using the appropriate *ESI Inflammatory Conditions* criteria.
- 6. **Spondyloarthritis (SpA), Subtypes Other than Ankylosing Spondylitis or Psoriatic Arthritis** (e.g., undifferentiated arthritis, non-radiographic axial SpA, Reactive Arthritis [Reiter’s disease]) [NOTE: For AS or PsA, refer to the respective criteria under FDA-approved indications]. Approve for 1 year if BOTH of the following conditions are met (A and B):
 - A) The patient meets one of the following conditions (i or ii):
 - i. The patient has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least ONE conventional synthetic DMARD (e.g., methotrexate [MTX], leflunomide, sulfasalazine) has been tried; OR
 - ii. The patient has axial spondyloarthritis; AND
 - B) Simponi SC is prescribed by or in consultation with a rheumatologist.
- 7. **Patient has been Established on Simponi SC for ≥ 90 days.** For conditions that do not have criteria for Patients Currently Receiving Simponi Aria or SC but are indications or conditions addressed as an approval in the section, approve Simponi SC for 1 year, if the patient is currently taking Simponi SC

for ≥ 90 days. (In the professional opinion of specialist physicians reviewing the data, we have adopted these criteria.)

8. Conditions Not Recommended for Coverage. Patients who meet any of the following criteria do not qualify for treatment with Simponi SC:

- A)** Concurrent Use with a Biologic or with a Targeted Synthetic Disease-Modifying Antirheumatic Drug (DMARD). Note: This does NOT exclude the use of conventional synthetic DMARDs (e.g., MTX, leflunomide, hydroxychloroquine, and sulfasalazine) in combination with Simponi SC; OR
- B)** Plaque Psoriasis without Psoriatic Arthritis; OR
- C)** Other circumstances not listed in criterion 1 through 7 (above).