



## FORMULARY EXCEPTION POLICY

**POLICY:** Inflammatory Conditions – Taltz® (ixekizumab for subcutaneous injection – Eli Lilly and Company)

**DATE REVIEWED:** 10/14/2019

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**Documentation 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.

### CRITERIA

#### 1. Ankylosing Spondylitis.

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

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

Note: A trial of Cimzia, an infliximab product, or Simponi (Aria or SC) also counts [documentation required]. 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) Patient is Currently Receiving Taltz. Approve for 1 year if the patient meets BOTH of the following (i and ii):

- i. The patient has had a response, as determined by the prescriber.  
Note: Examples of a response to therapy include decreased pain or stiffness, improved function or activities of daily living. The patient may not have a full response, but there should have been a recent or past response to Taltz; AND

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

a) The patient has been established on Taltz for at least 90 days and prescription claims history indicates at least a 90-day supply of Taltz 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 Taltz for at least 90 days AND the patient has been receiving Taltz via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Taltz); AND meets at least ONE of the following [(1), (2), or (3)]:

- (1) According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Siliq; OR
- (2) The patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic; OR
- (3) The patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated.

Note: Examples of systemic agents taken for rheumatic conditions include methotrexate, sulfasalazine, and leflunomide. For patients who have not tried the Formulary Products, Cosentyx is approved for patients who meet criterion iia but do not meet iia (1), (2), or (3); OR

- b) The patient has tried TWO of Cosentyx, Enbrel, and Humira [documentation required].  
Note: A trial of Cimzia, an infliximab product, 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 (Cosentyx, Enbrel, or Humira) using the appropriate *ESI Inflammatory Conditions* criteria.

2. **Plaque Psoriasis. Initial Therapy.** Approve for 3 months if the patient meets ALL of the following criteria (i, ii, iii, and iv):

i. The patient is  $\geq 18$  years of age; AND

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

- a) The patient has tried at least one traditional systemic agent for psoriasis.

Note: Examples of traditional systemic agents for psoriasis include methotrexate (MTX), cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light (PUVA). An exception to the requirement for a trial of one traditional systemic agent for psoriasis can be made if the patient has already had a 3-month trial or previous intolerance to at least one biologic (e.g., an etanercept product, a certolizumab pegol product [Cimzia], Cosentyx [secukinumab SC injection], an adalimumab product, Ilumya [tildrakizumab-asmn SC injection], an infliximab product, Siliq [brodalumab SC injection], Skyrizi (risankizumab-rzaa SC injection), Stelara [ustekinumab SC injection], or Tremfya [guselkumab SC injection]). These patients who have already tried a biologic for psoriasis are not required to “step back” and try a traditional systemic agent for psoriasis); OR

- b) The patient has a contraindication to methotrexate (MTX), as determined by the prescribing physician; AND

iii. Taltz is prescribed by or in consultation with a dermatologist; AND

iv. The patient has tried THREE of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required].

Note: If the patient has met criterion i, ii, and iii but criterion iv is not met, offer to review for a Formulary product (Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya) using the appropriate *ESI Inflammatory Conditions* criteria.

- B) **Patient is Currently Receiving Taltz.** Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

i. The patient has responded, as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Taltz; AND

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

- a) The patient has been established on Taltz for at least 90 days and prescription claims history indicates at least a 90-day supply of Taltz 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 Taltz for at least 90 days AND the patient has been receiving Taltz via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Taltz); AND meets at least ONE of the following [(1), (2), (3), or (4)]:

(1) According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Siliq; OR

- (2) The patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic; OR
- (3) The patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated; OR
- (4) The patient is taking the requested agent in combination with phototherapy.

Note: Examples include narrowband ultraviolet B [NB-UVB] phototherapy. For patients who have not tried the Formulary Products, Cosentyx is approved for patients who meet criterion iia but do not meet iia (1), (2), (3), or (4); OR

- b) The patient has tried THREE of Cosentyx, Humira, Otezla, Skyrizi, Stelara SC, or Tremfya [documentation required].

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

**3. Psoriatic Arthritis (PsA).** Approve Taltz for the duration noted if the patient meets ONE of the following conditions (A or B):

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

- i. Taltz is prescribed by or in consultation with a rheumatologist or a dermatologist; AND
- ii. The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as ONE product.

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, and Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.

- B) Patient is Currently Receiving Taltz: Approve for 1 year if the patient meets BOTH of the following conditions (i and ii):

- i. The patient has responded (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, C-reactive protein]), as determined by the prescriber. The patient may not have a full response, but there should have been a recent or past response to Taltz; AND
- ii. The patient meets ONE of the following conditions (a or b):

- a) The patient has been established on Taltz for at least 90 days and prescription claims history indicates at least a 90-day supply of Taltz 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 Taltz for at least 90 days AND the patient has been receiving Taltz via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Taltz); AND meets at least ONE of the following [(1), (2), or (3)]:

- (1) According to the prescriber, the patient has previously experienced a sub-therapeutic response or intolerance to Cosentyx or Siliq; OR
- (2) The patient has previously tried at least one biologic for the current condition, and according to the prescriber, the patient demonstrated inadequate efficacy to that biologic; OR
- (3) The patient is currently using the requested biologic concomitantly with a traditional systemic agent for the condition being treated.

Note: Examples of systemic agents taken for rheumatic conditions include methotrexate, sulfasalazine, and leflunomide. For patients who have not tried the Formulary Products, Cosentyx is approved for patients who meet criterion 1Bii but do not meet 1Bii(1), (2), or (3); OR

- b) The patient has tried TWO of Cosentyx, Enbrel, Humira, Stelara SC, and Xeljanz/XR [documentation required]. Note: A trial of either or both Xeljanz products (Xeljanz and Xeljanz XR) collectively counts as **ONE** product.

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, and Xeljanz/XR) using the appropriate *ESI Inflammatory Conditions* criteria.

- 4. Conditions Not Recommended for Coverage.** Patients who meet any of the following criteria (A, B, C, or D) do not qualify for treatment with Taltz:
- 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 Taltz; OR
  - B) Inflammatory Bowel Disease (i.e., Crohn’s Disease [CD], Ulcerative Colitis [UC]); OR
  - C) Patients < 18 Years of Age; OR
  - D) Other circumstances not listed in criterion 1 or 2 (above).