

## FORMULARY EXCEPTION POLICY

**POLICY:** Inflammatory Conditions – Ilumya™ (tildrakizumab-asmn for subcutaneous injection – Sun Pharmaceuticals/Merck)

**DATE REVIEWED:** 06/14/2019

---

**Documentation Required:** The prescriber must provide written documentation supporting the trials of Formulary products, 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. Plaque Psoriasis.

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

- i. The patient is an adult  $\geq 18$  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 (e.g., methotrexate [MTX], cyclosporine, acitretin tablets, or psoralen plus ultraviolet A light [PUVA]) for at least 3 months, unless intolerant.  
NOTE: 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 [e.g., Enbrel], a certolizumab pegol product [Cimzia], Cosentyx [secukinumab for SC injection], an adalimumab product [e.g., Humira], an infliximab product [e.g., Inflectra, Remicade, Renflexis], Siliq [brodalumab SC injection], Skyrizi (risankizumab), Stelara [ustekinumab for SC injection], Taltz [ixekizumab 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. Ilumya is prescribed by or in consultation with a dermatologist; AND
- iv. The patient has tried TWO 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 Ilumya. 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 Ilumya; AND
- ii. The patient meets ONE of the following conditions (a or b):
  - a) The patient has been established on Ilumya for at least 90 days and prescription claims history indicates at least a 90-day supply of Ilumya 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 Ilumya for at least 90 days AND the patient has been receiving Ilumya via paid claims (e.g., patient has not been receiving samples or coupons or other types of waivers in order to obtain access to Ilumya); OR

- b) The patient has tried TWO 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.

- 2. **Conditions Not Recommended for Coverage.** Patients who meet any of the following criteria (A or B) do not qualify for treatment with Ilumya:
  - 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 Ilumya; OR
  - B) Other circumstances not listed in criterion 1 (above).