Ilumya™ (tildrakizumab-asmn)

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Definition

Ilumya (tildrakizumab-asmn) is a humanized IgG1/k monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor. IL-23 is a naturally occurring cytokine that is involved in inflammatory and immune responses. Ilumya inhibits the release of pro-inflammatory cytokines and chemokines.

Ilumya (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Dosing

Max dose (per dose and over time):

- Loading:
  - 100 mg at week 0 and 4
- Maintenance:
  - 100 mg every 12 weeks

Guideline

Ilumya (tildrakizumab-asmn) is considered medically necessary for the following diagnosis when subsequent criteria are met:

Plaque Psoriasis:

- Patient is 18 years of age or older; **AND**
- Patient has been evaluated and screened for the presence of latent TB infection prior to initiating treatment; **AND**
- Patient does not have a clinically important active infection; **AND**
- Patient will not receive live vaccines during therapy; **AND**
- Patient will not concurrently receive treatment with another TNF-inhibitor, biologic response modifier or other non-biologic immunomodulating agent; **AND**
- Patient's baseline disease severity has been assessed by a physician utilizing an objective measure; **AND**
- Patient has had moderate to severe plaque psoriasis for at least 6 months and at least one of the following:
    - Involvement of at least 10% of body surface area (BSA); **OR**
    - Psoriasis Area and Severity Index (PASI) score of 10 or greater; **OR**
    - Incapacitation due to plaque location; **AND**
- Patient has not responded adequately (or is not a candidate) to a 3 month minimum trial of topical agents; **AND**
- Patient has not responded adequately (or is not a candidate) to a 3 month minimum trial of at least 1 systemic agent; **AND**
- Patient has not responded adequately (or is not a candidate) to a 3 month minimum trial of phototherapy
- Patient has a documented failure, or intolerance to, **TWO** of the following:
    - Cosentyx
    - Humira
    - Otezla
    - Stelara SC

Coverage for Ilumya (tildrakizumab-asmn) may be renewed for the following diagnosis when the subsequent criteria are met:

Plaque Psoriasis:

- Patient continues to meet the initial approval criteria above; **AND**
- Absence of unacceptable toxicity from the drug; **AND**
- Patient will receive ongoing monitoring for presence of TB or other active infections: **AND**
- Patient has responded to treatment as indicated by at least one of the following:
    - Improvement in signs and symptoms compared to baseline such as redness, thickness scaliness; **OR**
    - Reduction in the amount of surface area involved; **OR**
    - Improvement on a disease activity scoring tool [e.g. a 75% reduction in the PASI score from when treatment started (PASI 75) or a 50% reduction in the PASI score (PASI 50) and a four point reduction in the DLQI from when treatment started].

Revision History

1/7/2019	Removed JCode J3590, Added JCode J3245. Updated Medical Policy Number

Applicable Procedure Codes

J3245	Injection, tildrakizumab-asmn, 1 mg: 1 billable unit = 1 mg

Applicable Diagnosis Codes

L40.0	Psoriasis vulgaris

References

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6. Armstrong AW, Siegel MP, Bagel J, et al. From the Medical Board of the National Psoriasis Foundation: Treatment targets for plaque psoriasis. J Am Acad Dermatol. 2017 Feb; 76(2):290-298. Doi: 10.1016/j.jaad.2018.10.017