Ilumya™ (tildrakizumab-asmn)

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 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**

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>1/7/2019</td>
<td>Removed JCode J3590, Added JCode J3245. Updated Medical Policy Number</td>
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**Applicable Procedure Codes**

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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J3245</td>
<td>Injection, tildrakizumab-asmn, 1 mg: 1 billable unit = 1 mg</td>
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Applicable Diagnosis Codes

| L40.0 | Psoriasis vulgaris |

References

1. Ilumya [package insert]. Whitehouse Station, NJ; MSD-Sun Pharmaceuticals; March 2018. Accessed June 2018