Ilumya™ (tildrakizumab-asmn)

Last Review Date: 10/31/2019  Number: MG.MM.PH.114

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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 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 (i.e. head and neck, palms, soles or genitalia); **AND**
- Patient has not responded adequately (or is not a candidate) to a 3-month minimum trial of topical agents (i.e. Anthralin, Coal Tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues); **AND**
- Patient has not responded adequately (or is not a candidate) to a 3-month minimum trial of at least 1 systemic agent (i.e. immunosuppressives, retinoic acid derivatives, and/or methotrexate); **AND**
- Patient has not responded adequately (or is not a candidate) to a 3-month minimum trial of phototherapy (i.e. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol); **AND**
- Patient has a documented failure, or intolerance to, **TWO** of the following:
  - Cosentyx
  - Humira
  - Otezla
  - Skyrizi
  - Stelara SC
  - Tremfya

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, and 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)].
Applicable Procedure Codes

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<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>J3245</td>
<td>Injection, tildrakizumab-asmn, 1 mg</td>
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<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
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Applicable Diagnosis Codes

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>L40.0</td>
<td>Psoriasis vulgaris</td>
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Revision History

<table>
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<th>Date</th>
<th>Changes</th>
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| 10/31/2019 | 1. Removed criteria - “Patient’s baseline disease severity has been assessed by a physician utilizing an objective measure; AND”  
2. Added examples for “Incapacitation due to plaque location” - (i.e. head and neck, palms, soles or genitalia)  
3. Added examples of medications patient has to try and fail  
   a. For topical agents added: (i.e. Anthralin, Coal Tar preparations, corticosteroids, emollients, immunosuppressives, keratolytics, retinoic acid derivatives, and/or Vitamin D analogues)  
   b. For systemic agents added: (i.e. immunosuppressives, retinoic acid derivatives, and/or methotrexate)  
   c. For phototherapy added: (i.e. Psoralens with UVA light (PUVA) OR UVB with coal tar or dithranol)  
4. Continuation criteria- removed portion that includes a different scoring tool than initiation criteria  
5. Added J3245 injection, tildrakizumab-asmn, 1mg |
| 7/19/2019  | Added Skyrizi and Tremfya to preferred options                      |

References

