UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

<table>
<thead>
<tr>
<th>Program Number</th>
<th>2019 P 3109-3</th>
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<tbody>
<tr>
<td>Program</td>
<td>Step Therapy</td>
</tr>
<tr>
<td>Medications</td>
<td>Ilumya™ (tildrakizumab-asmn)*</td>
</tr>
<tr>
<td></td>
<td>*Ilumya is excluded from coverage for the majority of our benefits</td>
</tr>
<tr>
<td>P&amp;T Approval Date</td>
<td>5/2018, 2/2019, 9/2019</td>
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<tr>
<td>Effective Date</td>
<td>1/1/2020: Oxford only: N/A</td>
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1. **Background:**
   Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try three preferred self-administered injectable products before providing coverage for Ilumya™. Infused medications for any of the conditions referenced in this document are not part of the criteria.

Ilumya (tildrakizumab) is an interleukin-23 antagonist indicated for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Humira® (adalimumab) is also indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis, or for reducing signs and symptoms in adult patients with active ankylosing spondylitis.

Stelara® (ustekinumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active psoriatic arthritis.

Cosentyx® (secukinumab) is indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy. It is also indicated for the treatment of adult patients with active psoriatic arthritis or for treatment of adults with active ankylosing spondylitis.

Tremfya® (guselkumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

Cimzia® (certolizumab) is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy or for treatment of adult patients with active psoriatic arthritis.
Skyrizi™ (risankizumab) is indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Members will be required to meet the coverage criteria below.

2. **Coverage Criteria**:  

A. **Plaque Psoriasis**

1. **Ilumya** will be approved based on **both** of the following criteria:

   a. History of failure, contraindication, or intolerance to **two** of the following preferred biologic products (document drug, date, and duration of trial):
   
   (1) Humira (adalimumab)  
   (2) Stelara (ustekinumab)  
   (3) Tremfya (guselkumab)  
   (4) Cimzia (certolizumab)  
   (5) Skyrizi (risankizumab)

   -AND-  

   b. History of failure, contraindication, or intolerance to Cosentyx (secukinumab) (document drug, date, and duration of trial).

Authorization will be issued for 12 months.

*a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules**:

   - Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
   - *Ilumya is excluded from coverage for the majority of our benefits
   - Medical Necessity, Supply limits and/or Notification may be in place.

4. **References**:


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<thead>
<tr>
<th>Program</th>
<th>Step Therapy - Ilumya (tildrakizumab)</th>
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<tbody>
<tr>
<td></td>
<td><strong>Change Control</strong></td>
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<tr>
<td>5/2018</td>
<td>New program.</td>
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<tr>
<td>2/2019</td>
<td>Annual review. Updated background and criteria adding Cimzia to list of preferred products for the treatment of plaque psoriasis. Updated references.</td>
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<tr>
<td>9/2019</td>
<td>Updated background and criteria adding Skyrizi as preferred medication. Added coverage exclusion statement. Updated references.</td>
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