Drug Class Prior Authorization Criteria
Rheumatic and Inflammatory Diseases

Line of Business: Medicaid
P & T Approval Date: August 21, 2019  Effective Date: October 1, 2019

These criteria have been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the IEHP Pharmacy and Therapeutics Subcommittee.

Drugs Requiring Prior Authorization Review: Enbrel (etanercept), Humira (adalimumab), Otezla (apremilast)

<table>
<thead>
<tr>
<th>Medication</th>
<th>Ankylosing spondylitis</th>
<th>Crohn’s disease</th>
<th>Hidradenitis suppurativa</th>
<th>Plaque psoriasis</th>
<th>Psoriatic arthritis</th>
<th>Rheumatoid arthritis</th>
<th>Ulcerative colitis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enbrel (etanercept)</td>
<td>x</td>
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<tr>
<td>Humira (adalimumab)</td>
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<tr>
<td>Otezla (apremilast)</td>
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</tbody>
</table>

- x = indicates that there is a PA criteria on the medication for the indication

CRITERIA:

ENBREL (ETANERCEPT)

Covered Uses: Ankylosing spondylitis

Excluding Criteria: N/A

Required Medical Information: Must meet the following requirement:
  a. Failure or clinically significant adverse effects to at least one-month treatment course of NSAID therapy at maximal recommended dose or maximally tolerated dose

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
  a. Documentation of meeting therapeutic goal (e.g. disease stability,
improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Plaque psoriasis

Excluding Criteria: N/A

Required Medical Information: Must meet all of the following requirements:

a. Must meet “1” of the following requirements:
   i. Documented psoriasis involvement of at least 10% of the body surface area
   ii. Documented psoriasis involvement of the face, ears, hands, feet or genitalia
   iii. Documented significant functional disability (i.e. unable to do daily activities)

b. Trial and failure of at least one non-biologic DMARD (e.g. methotrexate, cyclosporine, azathioprine, etc.)

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)

b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Psoriatic arthritis

Exclusion Criteria: N/A

Required Medical Information: Must meet the following requirement:

a. Failure or clinically significant adverse effects to at least one non-biologic DMARD (e.g. methotrexate, leflunomide, sulfasalazine, etc.)

Age Restrictions: N/A
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Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
   a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
   b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Rheumatoid arthritis

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:
   a. Failure or clinically significant adverse effects to at least one non-biologic DMARD: methotrexate, hydroxychloroquine, leflunomide or sulfasalazine

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
   a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
   b. Requested dosage and administration are consistent with the FDA recommendations

HUMIRA (ADALIMUMAB)

Covered Uses: Ankylosing spondylitis

Exclusion Criteria: N/A

Required Medical Information: Must meet the following requirement:
   a. Failure or clinically significant adverse effects to at least one-month
<table>
<thead>
<tr>
<th><strong>Drug Class Prior Authorization Criteria</strong></th>
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</thead>
<tbody>
<tr>
<td><strong>Rheumatic and Inflammatory Diseases</strong></td>
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<tr>
<td>treatment course of NSAID therapy at maximal recommended dose or maximally tolerated dose</td>
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<tr>
<td><strong>Age Restrictions:</strong></td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions:</strong></td>
<td>Rheumatologist</td>
</tr>
</tbody>
</table>
| **Other Criteria:** | Reauthorization Criteria: Must meet all of the following requirements:  
  a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)  
  b. Requested dosage and administration are consistent with the FDA recommendations |
| **Covered Uses:** | Crohn’s disease |
| **Exclusion Criteria:** | CCS eligible |
| **Required Medical Information:** | Must meet all of the following requirements:  
  a. Must meet “1” of the following requirements:  
     i. Failure or clinically significant adverse effects to an adequate course of corticosteroids (e.g. oral budesonide 9 mg/day, prednisone 40-60 mg daily)  
     ii. Documentation that patient has been unable to taper corticosteroid therapy without experiencing worsening of disease  
  b. Treatment with at least a two-month course of DMARD (e.g. azathioprine, mercaptopurine or methotrexate) was not effective or not tolerated, unless all are contraindicated. |
| **Age Restrictions:** | N/A |
| **Prescriber Restrictions:** | Gastroenterologist |
| **Other Criteria:** | Reauthorization Criteria: Must meet all of the following requirements:  
  a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)  
  b. Requested dosage and administration are consistent with the FDA recommendations |
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Covered Uses: Hidradenitis suppurativa

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet “1” of the following requirements:
   a. Diagnosis of severe hidradenitis suppurativa (e.g. Hurley Stage III)
   b. Diagnosis of moderate hidradenitis suppurativa (e.g. Hurley Stage II); and Failure or clinically significant adverse effects to 12-weeks of antibiotic therapy: clindamycin, doxycycline, minocycline or tetracycline

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
   a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
   b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Plaque psoriasis

Exclusion Criteria: N/A

Required Medical Information: Must meet all of the following requirements:
   a. Must meet “1” of the following requirements:
      i. Documented psoriasis involvement of at least 10% of the body surface area
      ii. Documented psoriasis involvement of the face, ears, hands, feet or genitalia
      iii. Documented significant functional disability (i.e. unable to do daily activities)
   b. Trial and failure of at least one non-biologic DMARD (e.g. methotrexate, cyclosporine, azathioprine, etc.)

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist
Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)

b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Psoriatic arthritis

Exclusion Criteria: N/A

Required Medical Information: Must meet the following requirement:

a. Failure or clinically significant adverse effects to at least one non-biologic DMARD (e.g. methotrexate, leflunomide, sulfasalazine, etc.)

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Covered Uses: Rheumatoid arthritis

Exclusion Criteria: CCS eligible

Required Medical Information: Must meet the following requirement:

a. Failure or clinically significant adverse effects to at least one non-biologic DMARD: methotrexate, hydroxychloroquine, leflunomide or sulfasalazine

Age Restrictions: N/A

Prescriber Restrictions: Rheumatologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:

a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)

b. Requested dosage and administration are consistent with the FDA recommendations
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a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

Covered Uses: Ulcerative colitis
Exclusion Criteria: CCS eligible

Required Medical Information: Must meet all of the following requirements:
a. Failure or clinically significant adverse effects to “2” of the following:
   i. An adequate course of corticosteroids (e.g. oral budesonide 9 mg/day, prednisone 40-60 mg daily or budesonide rectal for 7-14 days)
   ii. At least one aminosalicylate: mesalamine, balsalazide, sulfasalazine
   iii. Treatment with at least a two-month course of DMARD (e.g. azathioprine, mercaptopurine, methotrexate) was not effective or not tolerated, unless all are contraindicated

Age Restrictions: N/A
Prescriber Restrictions: Gastroenterologist

Other Criteria: Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

OTEZLA (APREMILAST)

Covered Uses: Plaque psoriasis
Psoriatic arthritis
Exclusion Criteria: N/A
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Required Medical Information:
Must meet the following requirement:
a. Must meet “1” of the following requirements:
   i. Failure or clinically significant adverse effects to one of the preferred biologic therapies: **Enbrel** or **Humira**

Age Restrictions: N/A

Prescriber Restrictions: Dermatologist, Rheumatologist

Other Criteria:
Reauthorization Criteria: Must meet all of the following requirements:
a. Documentation of meeting therapeutic goal (e.g. disease stability, improvement in daily activities and/or reduction in frequency of disease attacks)
b. Requested dosage and administration are consistent with the FDA recommendations

<table>
<thead>
<tr>
<th>Change Control</th>
<th>Date</th>
<th>Change</th>
<th>Author</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>08/21/2019</td>
<td>- Added an indication table on page 1 for overview purpose</td>
<td>SV</td>
</tr>
<tr>
<td></td>
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<td>- Retired PA criteria for non-preferred agents:</td>
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<td>- Retired PA criteria for low volume utilization</td>
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<td>o <strong>Humira</strong>: NIU (non-infectious uveitis) criteria retired</td>
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<td>- Created PA criteria for high PA volume indication:</td>
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<tr>
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<td>o <strong>Humira</strong>: HS (hidradenitis suppurativa) criteria added</td>
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<td>05/15/2019</td>
<td>- Revise <strong>Xeljanz</strong> criteria: remove trial and failure requirement through <strong>Humira</strong>, <strong>Simponi</strong> and <strong>Renflexis</strong> per new updated 2019 ACG guidelines</td>
<td>ND</td>
</tr>
<tr>
<td></td>
<td>08/17/2018</td>
<td>- Post P&amp;T changes: Remove <strong>Inflectra</strong> and <strong>Remicade</strong> from document; <strong>Renflexis</strong> is the preferred infliximab agent</td>
<td>HC</td>
</tr>
<tr>
<td></td>
<td>08/06/2018</td>
<td>- Added double lines to all drug names for consistency</td>
<td>IK</td>
</tr>
<tr>
<td></td>
<td>07/15/2018</td>
<td>- Added new FDA indication of plaque psoriasis to <strong>Cimzia</strong></td>
<td>HC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Added new FDA indication of ulcerative colitis to <strong>Xeljanz</strong></td>
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### Drug Class Prior Authorization Criteria
**Rheumatic and Inflammatory Diseases**

<table>
<thead>
<tr>
<th>Date</th>
<th>Notes</th>
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<tbody>
<tr>
<td>07/11/2018</td>
<td>Reformatted document</td>
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</tbody>
</table>

- **Remicade**: Documented intolerance or contraindication to an inactive ingredient in **Renflexis** and **Inflectra**
- **Inflectra**: Documented intolerance or contraindication to an inactive ingredient in **Renflexis**
- Remove **Ilaris** criteria due to rare indications