CRITERIA FOR PRIOR AUTHORIZATION

Psoriatic Arthritis Agents

BILLING CODE TYPE
For drug coverage and provider type information, see the KMAP Reference Codes webpage.

MANUAL GUIDELINES
Prior authorization will be required for all current and future dose forms available. All medication-specific criteria, including drug-specific indication, age, and dose for each agent is defined in Table 1 below.

Abatacept (Orencia®)
Adalimumab (Humira®, Abrilada™, Amjevita™, Cyltezo®, Hadlima™, Hulio®, Hyrimoz®, Idacio®, Yuflyma®, Yusimry™, Humira®, Amjevita™)
Apremilast (Otezla®)
Certolizumab (Cimzia®)
Etanercept (Enbrel®)
Golimumab (Simponi®, Simponi Aria®)
Guselkumab (Tremfya®)
Infliximab (Remicade®, Avsola®, Renflexis®, Inflectra®)
Ixekizumab (Taltz®)
Risankizumab (Skyrizi®)
Secukinumab (Cosentyx®)
Tofacitinib (Xeljanz®, Xeljanz XR®)
Upadacitinib (Rinvoq®)
Ustekinumab (Stelara®)

GENERAL CRITERIA FOR INITIAL PRIOR AUTHORIZATION: (must meet all of the following)
- Must be approved for the indication, age, weight (if applicable), and not exceed dosing limits listed in Table 1.
- Must be prescribed by or in consultation with a dermatologist or rheumatologist.²
- Patient must have had an adequate trial (at least 90 consecutive days) of or contraindication to methotrexate. If the patient has a contraindication to methotrexate, the patient must have an adequate trial of at least one other conventional therapy or contraindication to all conventional therapies listed in Table 2.²,3,5,10,13,14,15,16
- For all agents listed, the preferred PDL drug, if applicable, which covers this indication, is required unless the patient meets the non-preferred PDL PA criteria.
- Prescriber must provide the baseline of ONE of the following criteria:
  o Number of swollen joint(s)
  o Number of tender joint(s)
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

Table 1. FDA-approved age and dosing limits of Psoriatic Arthritis (PsA) Agents.³⁻²⁴

<table>
<thead>
<tr>
<th>Medication</th>
<th>Indication(s)</th>
<th>Age</th>
<th>Dosing Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guselkumab (Tremfya®)</td>
<td>PsA</td>
<td>≥18 years</td>
<td>100 mg SC at weeks 0, 4, and every 8 weeks thereafter.</td>
</tr>
<tr>
<td>Risankizumab (Skyrizi®)</td>
<td>PsA</td>
<td>≥18 years</td>
<td>150 mg SC at weeks 0, 4 and every 12 weeks thereafter.</td>
</tr>
</tbody>
</table>
### PA Criteria

| Ustekinumab (Stelara®) | PsA | ≥ 6 years | 45 mg initially SC at weeks 0 and 4, followed by 45 mg every 12 weeks thereafter.  
Coexistent moderate to severe plaque psoriasis and weight more than 100 kg: 90 mg SC initially and 4 weeks later, and then 90 mg every 12 weeks thereafter. |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interleukin-17a Inhibitors</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Secukinumab (Cosentyx®) | PsA | ≥ 2 years | Adult patients:  
• 150 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then up to 300 mg every 4 weeks.  
• With coexistent moderate to severe plaque psoriasis: 300 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then 300 mg every 4 weeks.  
Pediatric patients 2 years and older:  
• Weighting > 15 kg and < 50 kg: 75 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then 75 mg every 4 weeks.  
• Weighting ≥ 50 kg: 150 mg SC once weekly at weeks 0, 1, 2, 3, and 4; then 150 mg every 4 weeks. |
| Ixekizumab (Taltz®) | PsA | ≥ 18 years | 160 mg administered SC at week 0, followed by 80 mg every 4 weeks.  
Coexistent moderate to severe plaque psoriasis: 160 mg SC at week 0; then 80 mg at weeks 2, 4, 6, 8, 10 and 12; then 80 mg every 4 weeks. |
| **Janus Associated Kinase Inhibitors** |
| Tofacitinib (Xeljanz®) | PsA | ≥ 18 years | 5 mg orally twice daily. |
| Tofacitinib (Xeljanz XR®) | PsA | ≥ 18 years | 11 mg orally once daily. |
| Upadacitinib (Rinvoq®) | PsA | ≥ 18 years | 15 mg orally once daily. |
| **Phosphodiesterase-4 Enzyme Inhibitor** |
| Apremilast (Otezla®) | PsA | ≥ 18 years | 30 mg orally twice daily. |
| **Selective T-Cell Costimulation Blockers** |
| Abatacept (Orencia®) | PsA | ≥ 18 years | SC: 125 mg once weekly.  
IV: at 0, 2 and 4 weeks, then every 4 weeks thereafter.  
< 60 kg: 500 mg  
60-100 kg: 750 mg  
> 100 kg: 1,000 mg |
| **Tumor Necrosis Factor-Alpha (TNF-α) Blockers** |
| Adalimumab (Humira®, Abrilada™, Amjevita™, Cyltezo®, Hadlima™, Hulio®, Hyrimoz®, Idacio®, Yuflyma®, Yusimry™, Humira®, Amjevita™) | PsA | ≥ 18 years | 40 mg SC every other week. |
Certolizumab (Cimzia®)  | PsA  | ≥ 18 years  | 400 mg initially SC at week 0, 2, and 4 followed by 200 mg every other week or 400 mg every 4 weeks.
Etanercept (Enbrel®)* | PsA  | ≥ 18 years  | 50 mg SC once weekly.
Golimumab (Simponi®)  | PsA  | ≥ 18 years  | 50 mg initially SC monthly.
Golimumab (Simponi Aria®)  | PsA  | ≥ 2 years  | ≥18 years: 2 mg/kg IV at 0 and 4 weeks, then every 8 weeks.
           |      |       | 2 years to <18 years: 80 mg/m² IV at weeks 0 and 4, and every 8 weeks thereafter.
Infliximab (Remicade®, Renflexis®, Inflectra®, Avsola®)*  | PsA  | ≥ 18 years  | 5 mg/kg IV at 0, 2, and 6 weeks, then every 8 weeks.

SC: subcutaneous. IV: intravenous. *Biosimilars to these products are FDA-approved, but some are not currently marketed.

LENGTH OF APPROVAL (INITIAL): 12 months

CRITERIA FOR RENEWAL PRIOR AUTHORIZATION: (must meet all of the following)
- Prescriber must provide at least ONE of the following response measure(s):
  - ≥ 20% reduction in tender joint count compared to baseline
  - ≥ 20% reduction in swollen joint count compared to baseline
- Must not exceed dosing limits listed in Table 1.
- For all requested biologics or janus kinase (JAK) inhibitors, patient must not concurrently be on another biologic or JAK inhibitor listed in Table 3. After discontinuing the current biologic or JAK inhibitor, the soonest that a new biologic or JAK inhibitor will be authorized is at the next scheduled dose.

LENGTH OF APPROVAL (RENEWAL): 12 months

FOR DRUGS THAT HAVE A CURRENT PA REQUIREMENT, BUT NOT FOR THE NEWLY APPROVED INDICATIONS OR DOSAGES, FOR OTHER FDA-APPROVED INDICATIONS, AND FOR CHANGES TO AGE REQUIREMENTS NOT LISTED WITHIN THE PA CRITERIA:
- THE PA REQUEST WILL BE REVIEWED BASED UPON THE FOLLOWING PACKAGE INSERT INFORMATION: INDICATION, AGE, DOSE, AND ANY PRE-REQUISITE TREATMENT REQUIREMENTS FOR THAT INDICATION.

LENGTH OF APPROVAL (INITIAL AND RENEWAL): 12 months

Table 2. List of conventional therapy in the treatment of PsA

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Conventional Psoriatic Arthritis Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyclosporine</td>
<td>Gengraf®, Neoral®</td>
</tr>
<tr>
<td>Leflunomide</td>
<td>Arava®</td>
</tr>
<tr>
<td>Methotrexate</td>
<td>Trexall®, Rheumatrex®, Otrexup®, Rasuvo®</td>
</tr>
<tr>
<td>Sulfasalazine</td>
<td>Azulfidine®</td>
</tr>
</tbody>
</table>
Table 3. List of biologic agents/janus kinase inhibitors (agents not to be used concurrently)

<table>
<thead>
<tr>
<th>Biologic Agents/Janus Kinase Inhibitors</th>
<th>PA Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra® (tocilizumab)</td>
<td>Ilumya™ (tildrakizumab-asmn)</td>
</tr>
<tr>
<td>Adbry™ (tralokinumab)</td>
<td>Kevzara® (sarilumab)</td>
</tr>
<tr>
<td>Benlysta® (belimumab)</td>
<td>Kineret® (anakinra)</td>
</tr>
<tr>
<td>Cibinqo™ (abrocitinib)</td>
<td>Nucala® (mepolizumab)</td>
</tr>
<tr>
<td>Cimzia® (certolizumab)</td>
<td>Olumiant® (baricitinib)</td>
</tr>
<tr>
<td>Cinqair® (reslizumab)</td>
<td>Opzelura™ (ruxolitinib)</td>
</tr>
<tr>
<td>Cosentyx® (secukinumab)</td>
<td>Orensite® (abatacept)</td>
</tr>
<tr>
<td>Dupixent® (dupilumab)</td>
<td>Remicade® (infliximab) &amp; biosimilars (Avsola™, Inflectra®, Ixifi™, Renflexis®)</td>
</tr>
<tr>
<td>Enbrel® (etanercept) &amp; biosimilars (Erelzi™, Eticovo®)</td>
<td>Rinvoq™ (upadacitinib)</td>
</tr>
<tr>
<td>Entyvio® (vedolizumab)</td>
<td>Rituxan® (rituximab) &amp; biosimilars (Riabni™, Ruxience™, Truxima®)</td>
</tr>
<tr>
<td>Fasenra™ (benralizumab)</td>
<td>Rituxan Hycela™ (rituximab/hyaluronidase)</td>
</tr>
<tr>
<td>Humira® (adalimumab) &amp; biosimilars (Abrilada™, Amjevita™, Cyltezo™, Hadlima™, Hulio™, Hyrimoz™, Idacio™, Yusimry™)</td>
<td>Saphnelo™ (anifrolumab)</td>
</tr>
<tr>
<td>Ilaris® (canakinumab)</td>
<td></td>
</tr>
</tbody>
</table>

References:
4. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie Inc; February 2021.
6. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB Inc; December 2022.
10. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; October 2021.
13. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; September 2022.
14. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; [December 2021].
20. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc.; [October 2022].
27. Idacio (adalimumab-aacf) [prescribing information]. Lake Zurich, IL: Fresenius Kabi USA, LLC; December 2022.