## Biologicals for RA, Psoriasis, or Crohn’s Disease

**Goal(s):**
- Cover biologicals according to OHP list guidelines.
- Promote use that is consistent with National Guidelines and medical evidence.
- Promote use of high value products.

**Length of Authorization:**
Up to 12 months

**Requires PA:**
- Non-preferred drugs

**Covered Alternatives:**
Preferred alternatives listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Trade Name</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abatacept</td>
<td>Orencia</td>
<td>RA, juvenile RA, juvenile idiopathic arthritis</td>
</tr>
<tr>
<td>Adalimumab</td>
<td>Humira</td>
<td>RA, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, Crohn’s disease, plaque psoriasis, ulcerative colitis</td>
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<tr>
<td>Anakinra</td>
<td>Kineret</td>
<td>RA</td>
</tr>
<tr>
<td>Apremilast</td>
<td>Otezla</td>
<td>Psoriatic arthritis, plaque psoriasis</td>
</tr>
<tr>
<td>Certolizumab</td>
<td>Cimzia</td>
<td>RA, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis</td>
</tr>
<tr>
<td>Etanercept</td>
<td>Enbrel</td>
<td>RA, psoriatic arthritis, ankylosing spondylitis, juvenile idiopathic arthritis, plaque psoriasis</td>
</tr>
<tr>
<td>Golimumab</td>
<td>Simponi</td>
<td>RA, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis</td>
</tr>
<tr>
<td>Infliximab*</td>
<td>Remicade</td>
<td>RA, Crohn’s disease, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, plaque psoriasis</td>
</tr>
<tr>
<td>Natalizumab*</td>
<td>Tysabri</td>
<td>Crohn’s disease, multiple sclerosis</td>
</tr>
<tr>
<td>Rituximab*</td>
<td>Rituxan</td>
<td>RA, CLL, Wegener granulomatosis, Microscopic polyangiitis, non-Hodgkin lymphoma</td>
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<tr>
<td>Secukinumab</td>
<td>Cosentyx</td>
<td>Plaque psoriasis</td>
</tr>
<tr>
<td>Tocilizumab*</td>
<td>Actemra</td>
<td>RA, juvenile idiopathic arthritis</td>
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<tr>
<td>Tofacitinib</td>
<td>Xeljanz</td>
<td>RA</td>
</tr>
<tr>
<td>Ustekinumab</td>
<td>Stelara</td>
<td>Plaque psoriasis, psoriatic arthritis</td>
</tr>
<tr>
<td>Vedolizumab</td>
<td>Entyvio</td>
<td>Ulcerative colitis, Crohn’s disease</td>
</tr>
</tbody>
</table>

Abbreviations: CLL: chronic lymphocytic leukemia; RA: rheumatoid arthritis
* Must be billed via HCPC J-code and payment requires trial of preferred self-administered drug first.

## Approval Criteria

<table>
<thead>
<tr>
<th>1. What diagnosis is being treated?</th>
<th>Record ICD9 code.</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Is the diagnosis covered by OHP?</td>
<td><strong>Yes:</strong> Go to #3</td>
</tr>
<tr>
<td>3. Will the provider change to a preferred product?</td>
<td><strong>Yes:</strong> Inform provider of preferred alternatives.</td>
</tr>
</tbody>
</table>
| **Approval Criteria** | **Yes:** Go to #5 | **No:** Go to #7.  
* Note: Seborrheic dermatitis (690.XX), keroderma (701.1-701.3) or other hypertrophic and atrophic conditions of skin (701.8, 701.9) are not covered by OHP? |
|---|---|---|
| 4. Is the diagnosis chronic plaque psoriasis (ICD-9: 696.1-696.2, 696.8) and the product requested FDA approved for psoriasis (see table above)?  
* Moderate/Severe psoriasis treatments are covered by the OHP | | |
| 5. Is the Psoriasis Moderate/Severe? Defined as functional impairment and one or more of the following:  
- At least 10% body surface area involved or with functional impairment?  
- Hand, foot or mucous membrane involvement | **Yes:** Go to #6 | **No:** Pass to RPh; deny, not covered by the OHP. |
| 6. Has the patient tried and not had an adequate response to standard systemic therapies or has a contraindication to ALL of the following:  
- High-potency topical corticosteroids: betamethasone dipropionate, clobetasol, fluocinonide  
- At least one other topical agent: calcipotriene, tazarotene, anthralin  
- At least one other systemic therapy: cyclosporine, methotrexate or acitretin | **Yes:** Approve for length of treatment; maximum 1 year. | **No:** Pass to RPh; deny for medical appropriateness. |
| 7. Is the diagnosis ankylosing spondylitis (ICD-9 720) and the product requested is FDA approved for ankylosing spondylitis? | **Yes:** Approve treatment for up to 1 year. | **No:** Go to #8 |
| 8. Is the diagnosis rheumatoid arthritis (ICD-9 714.xx) or psoriatic arthropathy (ICD-9 696.0) and the product requested FDA approved for rheumatoid arthritis (see table above)? | **Yes:** Go to #9 | **No:** Go to #12 |
| 9. Has the patient had a trial and inadequate response to methotrexate or other first line DMARDs (leflunomide, sulfasalazine, hydroxychloroquine, penicillamine) and a disease duration of ≥6 months?  
**OR**  
An intolerance or contraindication to oral DMARDs? | **Yes:** Go to #10 | **No:** Pass to RPh; deny for medical appropriateness. |
## Approval Criteria

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<thead>
<tr>
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<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>10. Is the request for tofacitinib?</td>
<td>Yes: Go to #11</td>
<td>No: Approve treatment for up to 1 year.</td>
</tr>
<tr>
<td>11. Has the patient had a trial and inadequate response or intolerance to 1 or more biologic TIM (Humira, Enbrel, Cimzia, Simponi, Orencia)?</td>
<td>Yes: Approve treatment for up to 1 year.</td>
<td>No: Pass to RPh; deny for medical appropriateness.</td>
</tr>
<tr>
<td>12. Is the diagnosis Crohn’s disease (ICD-9 555) or ulcerative colitis (ICD-9 556.0-556.9) and the product requested FDA approved for the indication (see table above)?</td>
<td>Yes: Go to #13</td>
<td>No: Pass to RPh; deny for medical appropriateness.</td>
</tr>
<tr>
<td>13. Has the patient had a trial and inadequate response to conventional therapy including immunosuppressive therapy (mercaptopurine, azathioprine) and/or corticosteroid treatments? OR Has an intolerance or contraindication to conventional therapy?</td>
<td>Yes: Approve treatment for up to 1 year.</td>
<td>No: Pass to RPh; deny for medical appropriateness.</td>
</tr>
</tbody>
</table>

*P&T/DUR Review: 7/15; 9/14; 8/12
Implementation: 8/15; 9/27/14; 2/21/13*