### Systemic Immunomodulators

<table>
<thead>
<tr>
<th>Brand Names</th>
<th>Generic Names</th>
<th>Dosage Strengths</th>
<th>Dosage Form</th>
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<tbody>
<tr>
<td>Actemra®</td>
<td>tocilizumab</td>
<td>80mg/4ml, 200mg/10ml, 400mg/20ml</td>
<td>Single use vial</td>
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<tr>
<td>Arava®</td>
<td>leflunomide</td>
<td>10mg, 20mg, 100mg</td>
<td>Capsules</td>
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<tr>
<td>Arcalyst®</td>
<td>rilonacept</td>
<td>220mg</td>
<td>Single use vial</td>
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<tr>
<td>Cimzia®</td>
<td>certolizumab</td>
<td>200mg</td>
<td>Powder for SC injection</td>
</tr>
<tr>
<td>Cosentyx®</td>
<td>secukinumab</td>
<td>150mg/ml, 150mg</td>
<td>Single use senoready® pen, single use prefilled syringe, single use vial (HCP admin only)</td>
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<tr>
<td>Enbrel®</td>
<td>etanercept</td>
<td>25mg, 50mg/ml</td>
<td>SC syringe</td>
</tr>
<tr>
<td>Entyvio®</td>
<td>vedolizumab</td>
<td>300mg/20ml</td>
<td>Single use vial</td>
</tr>
<tr>
<td>Humira®</td>
<td>adalimumab</td>
<td>40mg/0.8ml, 20mg/0.4ml</td>
<td>SC syringe</td>
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<tr>
<td>Ilaris®</td>
<td>canakinumab</td>
<td>180 mg reconstituted to 150 mg/ml</td>
<td>Single use vial</td>
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<tr>
<td>Kineret®</td>
<td>anakinra</td>
<td>100mg/0.67ml</td>
<td>SC syringe</td>
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<td>Orencia®</td>
<td>abatacept</td>
<td>250 mg</td>
<td>Powder for injection</td>
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<td>Otezla®</td>
<td>apremilast</td>
<td>30mg, two starter pack</td>
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<td>Remicade®</td>
<td>infliximab</td>
<td>100 mg/20 ml</td>
<td>Single use vial</td>
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<td>Simponi® /Simponi Aria®</td>
<td>golimumab</td>
<td>50mg/0.5ml, 50mg/4ml</td>
<td>Single dose prefilled syringe, Smartject autoinjector</td>
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<td>Stelara®</td>
<td>ustekinumab</td>
<td>45mg/0.5ml, 90mg/1ml</td>
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<td>Taltz®</td>
<td>Ixekizumab</td>
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<td>Prefilled syringe, Prefilled auto-injector</td>
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<td>Xeljanz®/XR</td>
<td>tofacitinib</td>
<td>5mg tablet, 11mg tablet (XR)</td>
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### Indications:

**Actemra® (tocilizumab)**
- Reduction in signs and symptoms of active Rheumatoid Arthritis (RA) in adult patients
- Juvenile Idiopathic Arthritis (JIA) in patients 2 years and older

**Arava® (leflunomide)**
- Reduction in signs and symptoms of active Rheumatoid Arthritis (RA) in adult patients

**Arcalyst® (rilonacept)**
- Cryopyrin-Associated Periodic Syndromes (CAPS) in patients ≥ 12 years of age

**Cimzia® (certolizumab)**
- Ankylosing spondylitis
- Moderately to severely active Crohn’s Disease in adult patients
- Moderately to severely active RA in combination with methotrexate
- Psoriatic arthritis
SYSTEMIC IMMUNOMODULATORS
(cont.)

**Cosentyx** *(secukinumab)*
- Moderate to severe Plaque psoriasis
- Ankylosing spondylitis
- Psoriatic arthritis

**Enbrel** *(etanercept)*
- Moderately to severely active RA
- Juvenile Idiopathic Arthritis (JIA) in patients 2 years and older (previously listed as Juvenile Rheumatoid Arthritis (JRA))
- Psoriatic arthritis
- Ankylosing spondylitis
- Moderate to severe chronic plaque psoriasis

**Entyvio** *(vedolizumab)*
- Moderately to severely active Crohn’s Disease in adult patients
- Moderately to severely active Ulcerative Colitis in adult patients

**Humira** *(adalimumab)*
- Reduction in signs and symptoms of active RA in adult patients
- Moderate to severe chronic plaque psoriasis
- Juvenile Idiopathic Arthritis (JIA) in patients 2 years and older (previously listed as Juvenile Rheumatoid Arthritis (JRA))
- Psoriatic arthritis
- Ankylosing spondylitis
- Moderately to severely active Crohn’s Disease in patients 6 years and older
- Moderately to severely active Ulcerative Colitis
- Hidradenitis Suppurativa
- Uveitis

**Ilaris** *(canakinumab)*
- Juvenile Idiopathic Arthritis (JIA) in patients 2 years and older
- Cryopyrin-Associated Periodic Syndromes (CAPS) in patients 4 years and older including:
  - Familial Cold Autoinflammatory Syndrome (FCAS)
  - Muckle-Wells Syndrome (MWS)
- Tumor Necrosis Factor Receptor Associated Periodic Syndrome (TRAPS) in adult and pediatric patients
- Hyperimmunoglobulin D Syndrome (HIDS)/Mevalonate Kinase Deficiency (MKD) in adult and pediatric patients
- Familial Mediterranean Fever (FMF) in adult and pediatric patients

**Kineret** *(anakinra)*
- Moderately to severely active RA
- Cryopyrin-Associated Periodic Syndromes (CAPS)

**Orencia** *(abatacept)*
- Moderately to severely active RA
- Juvenile Idiopathic Arthritis (JIA) in patients 6 years and older (previously listed as Juvenile Rheumatoid Arthritis (JRA))

**Otezla** *(apremilast)*
- Psoriatic arthritis
- Plaque psoriasis
SYSTEMIC IMMUNOMODULATORS
(cont.)

**Remicade® (infliximab)**
- Moderately to severely active RA in adult patients in combination with methotrexate
- Psoriatic arthritis
- Ankylosing spondylitis
- Plaque psoriasis
- Moderately to severely active Crohn’s Disease in patients 6 years and older
- Moderately to severely active Ulcerative Colitis in patients 6 years and older

**Simponi ® (golimumab)**
- Moderately to severely active Rheumatoid Arthritis (RA) in adults, in combination with methotrexate
- Active Psoriatic Arthritis (PsA) in adults, alone or in combination with methotrexate
- Active Ankylosing Spondylitis in adults (AS)
- Moderately to severely active Ulcerative Colitis

**Simponi Aria® (golimumab)**
- Moderately to severely active Rheumatoid Arthritis (RA) in adults, in combination with methotrexate

**Stelara ® (ustekinumab)**
- Moderate to severe Plaque psoriasis
- Psoriatic arthritis
- Moderately to severely active Crohn’s Disease who have
  - failed or were intolerant to treatment with immunomodulators or corticosteroids, but never failed a tumor necrosis factor (TNF) blocker or
  - failed or were intolerant to treatment with one or more TNF blockers

**Taltz® (ixekizumab)**
- Moderate to severe Plaque psoriasis

**Xeljanz® /XR (tofacitinib)**
- Moderately to severely active Rheumatoid Arthritis (RA) in adults alone or in combination with methotrexate or other DMARDs

**Length of authorization:**
- Initial 3 months for Crohn’s or Ulcerative Colitis
- 1 year for all other indications
- Renewal 1 year dependent upon medical records supporting response to therapy and review of RX history

**Criteria for Approval:**
A. Prior approval will only be granted for the approved FDA indications listed above, AND
B. Must be prescribed by a rheumatologist, gastroenterologist or dermatologist based on the approved FDA indication

**Rheumatoid Arthritis:**
1. Trial and failure of, contraindication, or adverse reaction to methotrexate and at least one other DMARD (sulfasalazine, hydroxychloroquine, minocycline)

**Moderately to severely active Crohn’s Disease (all of the following must be met):**
1. Trial and failure of a compliant regimen of oral corticosteroids (moderate to severe CD) unless contraindicated or intravenous corticosteroids (severe and fulminant CD or failure to respond to oral corticosteroids)
SYSTEMIC IMMUNOMODULATORS
(cont.)

Moderately to severely active ulcerative colitis (all of the following must be met):
1. Trial and failure of a compliant regimen of oral or rectal aminosalicylates (i.e., sulfasalazine or mesalamine) for two consecutive months, AND
2. Trial and failure of a compliant regimen of oral corticosteroids (for moderate to severe CD) unless contraindicated, or intravenous corticosteroids (for severe and fulminant CD or failure to respond to oral corticosteroids), AND
3. Trial and failure of a compliant regimen of azathioprine or mercaptopurine for three consecutive months

Moderate to severe chronic plaque psoriasis:
1. Must have a previous failure on a topical psoriasis agent

Ankylosing Spondylitis
1. Trial and failure required with an NSAID

Psoriatic Arthritis
1. Trial and failure required with methotrexate first or in combination with methotrexate if appropriate

Criteria for Denial:
1. Moderate to severe heart failure (New York Heart Association [NYHA] Functional Class III/IV)
2. Live vaccines should not be given concurrently
3. Presence of active infections
4. Current or recent malignancy
5. Concomitant treatment with azathioprine or 6-mercaptopurine due to increased risk of fatal hepatosplenic T-cell lymphomas (for Remicade® request only)
6. Pregnancy (for Arava® request only)
7. Concomitant use of Kineret® or Orencia® with Remicade®, Cimzia®, Humira®, or Enbrel®
8. Concurrent diagnosis of irritable bowel syndrome (for Cosentyx® only)

Non-Preferred drugs on the Preferred Drug List (PDL) require additional Prior Approval (PA).

References:
5. Ilaris [package insert]. East Hanover, NJ; Novartis; October 2014.


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<td>New</td>
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