## MP 5.01.93- Specialty Drugs: Drug-Specific Criteria

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Medically Necessary (if all the following criteria apply):</th>
<th>Contraindications/Exclusions:</th>
<th>Step Therapy Required:</th>
<th>Additional Required Clinical Criteria:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Abatacept (Orencia)</td>
<td>• Moderate to Severe Active Adult RA 1. Rheumatologist confirmed</td>
<td>• Not to be used in combination with another biologic DMARD</td>
<td>• Prior treatment with non-biologic Disease-Modifying Antirheumatic Drug (DMARD) and treatment failure due to ≥ 1 of the following: 1. Significant intolerance 2. Allergic response 3. Continued symptoms after 3 months of treatment</td>
<td>• Negative TB test or TB Treatment • Risks of serious infection and cancer discussed with patient or caregiver</td>
<td>1, 2, 7, 11, 13, 14, 18, 24, 31, 44, 48, 49, 51, 53, 55, 57</td>
</tr>
<tr>
<td>Codes: HCPCS J0129</td>
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<tr>
<td></td>
<td>• Moderate to Severe Active Juvenile Idiopathic Arthritis 1. Rheumatologist Confirmed 2. Over 6 years of age 3. Polyarthritis (≥ 5)</td>
<td>• Not to be used in combination with another biologic DMARD</td>
<td>• Prior treatment with a biologic DMARD (i.e., a TNF alpha antagonist) and treatment failure due to ≥ 1 of the following:</td>
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</tbody>
</table>

Notes:
- **Medically Necessary**: If all the following criteria apply.
- **Contraindications/Exclusions**: Not to be used in combination with another biologic DMARD.
- **Step Therapy Required**: Prior treatment with non-biologic Disease-Modifying Antirheumatic Drug (DMARD) and treatment failure due to ≥ 1 of the following:
  - Significant intolerance
  - Allergic response
  - Continued symptoms after 3 months of treatment
- **Additional Required Clinical Criteria**: Negative TB test or TB Treatment, Risks of serious infection and cancer discussed with patient or caregiver.
- **References**: 1, 2, 7, 11, 13, 14, 18, 24, 31, 44, 48, 49, 51, 53, 55, 57.


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<tr>
<td>Alpha 1 - Proteinase inhibitor (Prolastin-C)</td>
<td>1. Significant intolerance 2. Allergic response 3. Continued symptoms after 6 weeks of treatment</td>
<td>IgA deficiency with antibodies against IgA due to the risk of developing hypersensitivity and anaphylactic reactions.</td>
<td></td>
<td></td>
<td>5, 6, 10, 12, 40</td>
</tr>
</tbody>
</table>

- **Codes:** HCPCS J0256, J0257

- **Contraindications:**
  - Congenital alpha 1-antitrypsin deficiency (AATD) and Emphysema
    1. Confirmed by Pulmonologist

- **References:**
  - Alpha 1-antitrypsin (AAT) < 11 uM/L
  - FEV1 ≥ 30% and ≤ 65%
  - Nonsmoker/ smoking cessation

| Denosumab (Prolia) | Osteoporosis in post-menopausal women | Osteoporosis in men | Combination therapy  
|---------------------|-------------------------------------|---------------------|---------------------------------------------------------|-----------------------------------------------------------|

- **Codes:** HCPCS J0897

- **Osteoporosis in post-menopausal women:**
  - Combination therapy
  - Pregnancy
  - Under 18 years of age
  - Treatment with zoledronic acid within the past

- **Osteoporosis in men:**
  - Combination therapy
  - Failed oral bisphosphonates
  - If oral bisphosphonates are not tolerated, IV | Osteoporotic (defined by T-score below -2.5) by dual x-ray absorptiometry (DXA), or low impact fracture
  - Normal phosphorus and magnesium levels
  - Planned supplementation with calcium and Vitamin-D | 4, 20, 21, 56, 59
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<td><strong>Golimumab (Simponi Aria)</strong>&lt;br&gt;<strong>Codes:</strong> HCPCS J1602</td>
<td>● Rheumatoid Arthritis (RA)&lt;br&gt;1. Rheumatologist Confirmed; with&lt;br&gt;2. Ongoing disease activity (in a commonly used scoring system)&lt;br&gt;3. Age ≥ 18 years</td>
<td>year&lt;br&gt;● Hypocalcemia</td>
<td>● Prior treatment with non-biologic Disease-Modifying Antirheumatic Drug (DMARD) and treatment failure due to ≥ 1 of the following:&lt;br&gt;1. Significant intolerance&lt;br&gt;2. Allergic response&lt;br&gt;3. Continued symptoms after 3 months of treatment</td>
<td>● TB testing negative or TB treated&lt;br&gt;● Risks of serious infection and cancer discussed with patient or caregiver&lt;br&gt;● May be combined with Methotrexate</td>
<td>1, 2, 22, 33, 29, 42, 44, 45, 48, 51</td>
</tr>
<tr>
<td><strong>Natalizumab (Tysabri)</strong></td>
<td>● Relapsing Remitting Multiple Sclerosis (RRMS)&lt;br&gt;● Combination drug therapy for MS</td>
<td></td>
<td>● Previous treatment with ≥ 1 MS disease</td>
<td>● Risk of progressive multifocal leukoencephalopathy (PML) discussed with patient or caregiver</td>
<td>8, 15, 19, 23, 27, 38</td>
</tr>
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<td>Drug Name</td>
<td>Medically Necessary (if all the following criteria apply):</td>
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<tr>
<td>Codes: HCPCS J2323</td>
<td>1. Confirmed by a Neurologist 2. Over 18 years of age</td>
<td>modifying drugs (biologic or glatiramer acetate) <strong>with</strong> treatment failure, due to one of the following: 1. Significant intolerance 2. Allergic response 3. Progression of disability or worsening neurologic function 4. Significant relapse or new MRI lesions after therapy ≥ 6 months</td>
<td>• Negative JC virus testing • Enrollment in TOUCH Prescribing Program</td>
<td></td>
<td>54, 58</td>
</tr>
<tr>
<td>• Inflammatory Bowel Disease [i.e., Crohn's Disease (CD)]</td>
<td>1. Moderate to severe</td>
<td>• Previous treatment with biologics <strong>with</strong> treatment failure, due to</td>
<td>• Risk of progressive multifocal leukoencephalopathy (PML) discussed with patient or caregiver • Negative JC virus testing • Enrollment in TOUCH Prescribing</td>
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<tr>
<td>Romiplostin (Nplate)</td>
<td>disease confirmed by a Gastroenterologist 2. Over age 18</td>
<td></td>
<td>one of the following: 1. Significant intolerance 2. Allergic response 3. Continued symptoms or findings ≥ 2 months</td>
<td>Program</td>
<td></td>
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<tr>
<td>Codes: HCPCS J2796</td>
<td>Immune Thrombocytopenia (ITP) 1. Confirmed by a specialist 2. Maintenance therapy for platelet count &lt; 30 x10 (9)/L 3. Over age 18</td>
<td>Bleeding episode (urgent)</td>
<td>Prior therapy with: Corticosteroid and/or immune globulin with treatment failure, due to one of the following: 1. Significant intolerance 2. Continued platelet count &lt; 30 x10 (9)/L 3. Allergic response</td>
<td>Risk of thrombosis discussed with patient or caregiver</td>
<td>3, 25, 34, 39, 60</td>
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<tr>
<td>Taliglucerase</td>
<td>Type 1 Gaucher</td>
<td>Age ≤ 18 and ≥</td>
<td>With ≥ one of the following:</td>
<td>28, 33,</td>
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<td>Codes: HCPCS J3060</td>
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<td></td>
<td>• Type 2 Gaucher Disease  • Type 3 Gaucher disease</td>
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<tr>
<td>Tocilizumab (Actemra)</td>
<td>Moderate to Severe Active Rheumatoid Arthritis (RA)</td>
<td>Tried and/or failed ≥ 1 Disease-Modifying Antirheumatic Drug (DMARD) with treatment failure due to: 1. Significant intolerance 2. Allergic response 3. Continued symptoms after 3 months of treatment</td>
<td>Negative TB test or TB Treatment  • Risks of serious infection and cancer discussed with patient or caregiver</td>
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<td>1, 2, 7, 14, 17, 24, 32, 42, 44, 48, 49, 51, 53, 55</td>
</tr>
<tr>
<td>Codes: HCPCS J3262</td>
<td>1. Confirmed by Rheumatologist 2. Over 18 years of age</td>
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<td></td>
<td>• ≤ 2 years of age</td>
<td>• Previously treated for JIA (e.g. NSAIDs, corticosteroids, or</td>
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<td></td>
<td>• Juvenile Idiopathic Arthritis (Systemic, Polyarticular)</td>
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| Vedolizumab (Entyvio) | 2. Moderate to high disease activity  
3. Active in ≥ 5 joints | Perianal fistulizing disease | methotrexate) | Biologic therapy failure due to:  
1. Significant intolerance or side effects  
2. Allergic response  
3. Continued symptoms or findings ≥ 2 months | 16, 38, 46, 52, 54 |
|          | [Codes: HCPCS C9026] |                               |                        |                                         |             |
| Velaglucerase Alfa (VPRIV) | • Moderate to Severe Inflammatory Bowel Disease (i.e., Crohn’s Disease, ulcerative colitis)  
1. Gastroenterologist Confirmed  
2. Age ≥ 18 | Previous treatment with biologics with treatment failure, due to one of the following:  
1. Significant intolerance  
2. Allergic response  
3. Continued symptoms or findings ≥ 6 weeks |                        | With ≥ one of the following:  
1. Anemia  
2. Thrombocytopenia  
3. Splenomegaly  
4. Hepatomegaly  
5. Bone disease | 28, 36, 47, 61 |
|          | [Codes: HCPCS J3385] |                               |                        |                                         |             |
| Zoledronic | • Osteoporosis or Current | • Tried and/or |                        | Osteopenic (T-score -1.0 to -2.5) or | 9, 21, |
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<tr>
<td>Acid (Reclast)</td>
<td>Osteopenia treatment in post-menopausal women</td>
<td>treatment with similar medication (e.g., Zometa, Xgeva, or Prolia)</td>
<td>failed oral bisphosphate</td>
<td>osteoporotic (T-score below -2.5) by dual x-ray absorptiometry (DXA), or low impact fracture</td>
<td>26, 35, 41, 43, 56, 59</td>
</tr>
<tr>
<td></td>
<td>• Osteoporosis in men</td>
<td>• Pregnancy</td>
<td>by oral bisphosphonates</td>
<td>• Patients with creatinine clearance of &lt;35mL/min and in those with evidence of acute renal impairment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Paget’s Disease</td>
<td>• Under 18 years of age</td>
<td>• Treatment with zoledronic acid within the past year</td>
<td>• Renal function evaluated and no evidence of renal impairment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1. With consistent radiographic findings</td>
<td>• Hypocalcemia</td>
<td>• Normal phosphorus and magnesium levels</td>
<td>• Glucocorticoid-induced osteoporosis (GIO) or treatment with glucocorticoids for more than 3 months</td>
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<tr>
<td></td>
<td>2. Elevated serum alkaline phosphatase</td>
<td></td>
<td>• Planned supplementation with calcium and Vitamin D</td>
<td>• Osteoporosis treatment (post-menopausal females, males) and GIO treatment: 5 mg once a year</td>
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<tr>
<td></td>
<td>Glucocorticoid-induced osteoporosis (GIO)</td>
<td></td>
<td>• Osteoporosis prevention (post-menopausal women) treatment: 5 mg once every 2 years</td>
<td>• Paget’s disease treatment: a single 5 mg infusion</td>
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<tr>
<td></td>
<td>or treatment with glucocorticoids for more than 3 months</td>
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</tbody>
</table>

### References


37. Pfizer Labs. Elelyso (Taliglucerase alfa) prescribing information. New York NY; Pfizer Labs; 2012. Available form:


