Medical Policy

MP 5.01.593
Specialty Drugs

DISCLAIMER

Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

POLICY

Drug-Specific Prior Authorization Criteria
All coverage requests will be reviewed according to the criteria in the Specialty Drug Table. The drug specific criteria will be applied to the specialty drugs listed in the Specialty Drug Table located in Table 1. in the Appendix below.

POLICY GUIDELINES

Specialty Drugs—are injectable and non-injectable medications that are typically used to treat complex conditions and meet one or more of the following criteria:

- are biotech-derived or biological in nature;
- are significantly higher cost than traditional medications;
- are used in complex treatment regimens; require special delivery, storage and handling;
- require special medication-administration training for patients;
- require on-going monitoring of medication adherence, side effects, and dosage changes;
- are available through limited-distribution channels;
- and may require additional support and coordinated case management
  - all medications on the Blue Cross of Idaho (BCI) prior authorization list must go through the prior authorization process. For a list of medications that require a prior authorization, click here
  - FDA indication alone does not establish the medical necessity of a particular medication for a particular patient. We may review all coverage requests for medical necessity and in accordance with the terms of the member’s contract.

Criteria Utilized

Appropriate clinical documentation must be provided in order to review requests for coverage. Medication requests will be reviewed according to established criteria. Criteria and resources used in coverage determinations may include but not limited to:

- Eligibility for coverage according to the terms of the member contract
Medical necessity/Investigational criteria according to the member contract

- The Food and Drug Administration (FDA)
- Blue Cross Blue Shield Association Center for Clinical Effectiveness (CCE) (formerly Technology Evaluation Center [TEC] assessments)
- The Blue Cross and Blue Shield Association Medical Policy Reference Manual as adopted by BCI
- Blue Cross of Idaho Medical Policies
- McKesson/Change Health InterQual Criteria
- Criteria established by a designated pharmacy benefits manager such as the Clinical Authorization System (CAS) as adopted from CVS/Caremark
- The National Comprehensive Cancer Network (see Oncologic Drug Use below)
- NovoLogix Specialty Guidance Management Criteria
- Facts & Comparisons Compendium
- The American Hospital Formulary Service Drug Information Compendium
- Current published medical literature and peer review publications based upon scientific evidence
- Evidence-based guidelines developed by national organizations and recognized authorities
- Other criteria as adopted by the Blue Cross of Idaho Medical Policy Committee or Pharmacy and Therapeutics Committee

All requested therapies, supplies and services will be evaluated in accordance with the following criteria:

**Medically Necessary** — the Covered Services or supplies required to identify or treat an Insured’s condition, Disease, Illness or Accidental Injury and which, as recommended by the treating Physician or other Covered Provider and as determined by Blue Cross of Idaho, are:

- The most appropriate supply or level of service, considering potential benefits and harms to the Insured.
- Proven to be effective in improving health outcomes;
  - For new treatments, effectiveness is determined by scientific evidence;
  - For existing treatments, effectiveness is determined first by scientific evidence, then by professional standards, then by expert opinion.
- Not primarily for the convenience of the Insured or Covered Provider.
- Cost-effective for this condition, compared to alternative treatments, including no treatment. Cost-effectiveness does not necessarily mean lowest price.

**Investigational** — any technology (service, supply, procedure, treatment, drug, device, facility, equipment or biological product), which is in a developmental stage or has not been proven to improve health outcomes such as length of life, quality of life, and functional ability. A technology is considered investigational if, as determined by Blue Cross of Idaho, it fails to meet any one of the following criteria:

- The technology must have final approval from the appropriate government regulatory body. This applies to drugs, biological products, devices, and other products/procedures that must have approval from the U.S. Food and Drug Administration (FDA) or another federal authority before they can be marketed. Interim approval is not sufficient. The condition for which the technology is approved must be the same as that BCI is evaluating.
- The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes. The evidence should consist of current published medical literature and investigations published in peer-reviewed journals. The quality of the studies and consistency of results will be considered. The evidence should demonstrate that the technology can measure or alter physiological changes related to a Disease, injury, Illness, or condition. In
addition, there should be evidence that such measurement or alteration affects health outcomes.

- The technology must improve the net health outcome. The technology's beneficial effects on health outcomes should outweigh any harmful effects on health outcomes.
- The technology must be as beneficial as any established alternatives.
- The technology must show improvement that is attainable outside the investigational setting. Improvements must be demonstrated when used under the usual conditions of medical practice.
- *These definitions may not apply to some health plans, such as Federal Employee Program (FEP), Medicare Advantage and some self-funded group plans. Blue Cross of Idaho reserves the right to periodically update its definitions.*

For more specific information on Formulary Exception Requests, Oncologic Drug Use, and Off-Label Drug Use, please see MP 5.01.501

**REFERENCES**


**CODES**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCPCS</td>
<td>J2796</td>
<td>Injection, romiplostim, Nplate, 10 mcg</td>
</tr>
<tr>
<td></td>
<td>J3060</td>
<td>Injection, taliglucerase alfa, Elelyso, 10 units</td>
</tr>
<tr>
<td></td>
<td>J3385</td>
<td>Injection, velaglucerase alfa, VPRIV, 100 units</td>
</tr>
<tr>
<td></td>
<td>J3489</td>
<td>Injection, zoledronic acid, Reclast, 1 mg</td>
</tr>
<tr>
<td>Date</td>
<td>Action</td>
<td>Reason</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------</td>
<td>------------------------------------------------------------------------</td>
</tr>
<tr>
<td>06/15/16</td>
<td>Added to Prescription Drug section</td>
<td>New policy to address DMARD and biologic specialty drugs.</td>
</tr>
<tr>
<td>06/22/17</td>
<td>Replace policy</td>
<td>Blue Cross of Idaho annual update; no changes to policy statement.</td>
</tr>
<tr>
<td>07/26/17</td>
<td>Replace policy</td>
<td>Added Cost Effective DMARD alternatives to policy guidelines, effective 10/01/2017.</td>
</tr>
<tr>
<td>09/28/17</td>
<td>Replace policy</td>
<td>Added cost effective Alpha 1-Proteinase Inhibitors and Gaucher Disease Agents alternatives to policy guidelines, effective 12/01/2017.</td>
</tr>
<tr>
<td>12/27/17</td>
<td>Replace policy</td>
<td>Added cost-effectiveness language for Gaucher’s Disease Agents and MAB therapy for MS; Effective 03/15/2018.</td>
</tr>
<tr>
<td>04/30/18</td>
<td>Replace policy</td>
<td>Removed cost effectiveness language for: DMARD alternatives, Alpha 1-Proteinase Inhibitors, MAB therapy for MS, and Gaucher Disease Agents. Removed the following specialty drugs from the specialty drug table: Abatacept, Alpha 1-Proteinase Inhibitors, Denosumab, Golimumab, Natalizumab, Tocilizumab, and Vedolizumab. References 1-2, 4-8, 10-20, 22-24, 27, 29-32, 38, 40, 42, 44-46, 48-55, and 57-58. Remaining references renumbered in references and Specialty Drug table. Policy renumbered from 5.01.93 to 5.01.593. Changes to policy will become effective 07/01/2018.</td>
</tr>
</tbody>
</table>
### Table 1. Specialty Drugs

<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>
<th>References:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Romiplostin (Nplate)</td>
<td>• <strong>Immune Thrombocytopenia (ITP)</strong></td>
<td>• Bleeding episode (urgent)</td>
<td>• Prior therapy with: Corticosteroid and/or immune globulin <strong>with</strong> 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>1, 4, 8, 12, 18</td>
</tr>
<tr>
<td></td>
<td>1. Confirmed by a specialist</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>2. Maintenance therapy for platelet count &lt; 30 x10^9/L</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>3. Over age 18</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Taliglucerase alfa (Elelyso)</td>
<td>• <strong>Type 1 Gaucher disease</strong> (confirmed by Beta-glucosylceramidase activity or GBA gene test)</td>
<td>• Age ≤ 18 and ≥ 65</td>
<td>• <strong>With ≥ one</strong> of the following: 1. Anemia 2. Thrombocytopenia 3. Splenomegaly 4. Hepatomegaly 5. Bone disease</td>
<td>7, 10, 11, 18</td>
<td></td>
</tr>
<tr>
<td>Specialty Drugs</td>
<td>Velaglucerase Alfa (VPRIV)</td>
<td>Zoledronic Acid (Reclast)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>----------------</td>
<td>--------------------------</td>
<td>-------------------------</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type 1 Gaucher disease</strong> (confirmed by Beta-glucosylceramidase activity or GBA gene test)</td>
<td><strong>Osteoporosis or Osteopenia</strong> treatment in post-menopausal women</td>
<td><strong>Glucocorticoid-induced osteoporosis (GIO)</strong> or treatment with glucocorticoids for more than 3 months</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Age ≤ 18 and ≥ 65</strong></td>
<td><strong>Current treatment with similar medication (e.g., Zometa, Xgeva, or Prolia)</strong> Pregnancy</td>
<td><strong>Tried and/or failed oral bisphosphonates</strong> Patients with creatinine clearance of &lt;35mL/min and in those with evidence of acute renal impairment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type 2 Gaucher Disease</strong></td>
<td><strong>Under 18 years of age</strong> Treatment with zoledronic acid within the past year</td>
<td><strong>Osteopenic (T-score -1.0 to -2.5) or osteoporotic (T-score below -2.5) by dual x-ray absorptiometry (DXA), or low impact fracture</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Type 3 Gaucher disease</strong></td>
<td><strong>Hypocalcemia</strong></td>
<td><strong>Renal function evaluated and no evidence of renal impairment</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>With ≥ one of the following:</strong> 1. Anemia 2. Thrombocytopenia 3. Splenomegaly 4. Hepatomegaly 5. Bone disease</td>
<td><strong>Normal phosphorus and magnesium levels</strong></td>
<td><strong>Planned supplementation with calcium and Vitamin-D</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6, 10, 15, 19</td>
<td><strong>Osteoporosis treatment (post-menopausal females, males) and GIO treatment:</strong> 5 mg once a year</td>
<td><strong>Osteoporosis treatment (post-menopausal women) treatment:</strong> 5 mg once every two years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2, 3, 5, 9, 13, 14, 16, 17</td>
<td><strong>Paget’s disease treatment:</strong> a single 5 mg infusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>