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Requested service	Required clinical criteria and information
Adagen® (pegademase bovine)  J2504	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of adenosine deaminase (ADA) deficiency in a member with severe combined immunodeficiency disease (SCID)</li> <li>• Evidence that the member failed bone marrow transplantation or is not a suitable candidate</li> <li>• Clinical documentation supporting the diagnosis</li> <li>• Any additional pertinent medical information</li> </ul>
Aldurazyme® (laronidase)  J1931	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of one of the following: Hurler mucopolysaccharidosis (MPS) I with moderate to severe symptoms or Hurler-Scheie MPS I with moderate to severe symptoms</li> <li>• Clinical documentation supporting the diagnosis such as serum assays showing enzyme deficiency of alpha-L-iduronidase and urinary glycosaminoglycans (GAGs), dermatan sulfate or heparan sulfate</li> <li>• Any additional pertinent medical information</li> </ul>
Aralast NP (alpha-1 proteinase inhibitor)  J0256	Please submit the following: <ul style="list-style-type: none"> <li>• Evidence that member is 18 years of age or older</li> <li>• Clinical documentation supporting congenital deficiency of alpha<sub>1</sub>-proteinase inhibitor such as serum levels of alpha-1 antitrypsin</li> <li>• Diagnosis of symptomatic emphysema</li> <li>• Any additional pertinent medical information</li> </ul>

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<p>Aranesp® (darbepoetin alfa)</p> <p>J0881</p>	<p>Please submit the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Clinical documentation supporting the diagnosis</li> <li>• Location at which the requested drug will be administered (e.g., clinic, home, office)</li> <li>• Any additional pertinent medical information</li> </ul>
<p>Beleodaq® (belinostat)</p> <p>J9032</p>	<p>Please submit the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis of relapsed or refractory peripheral T-cell lymphoma (PTCL)</li> <li>• Evidence of intolerance to or progression of disease on at least one prior therapy</li> <li>• Names of medications previously used to treat this condition, including dosage, dates of therapy, and response to treatment</li> <li>• Any additional pertinent clinical information</li> </ul>
<p>Boniva® (ibandronate)</p> <p>J1740</p>	<p>Please submit the following:</p> <ul style="list-style-type: none"> <li>• Diagnostic evidence of osteoporosis</li> <li>• Previous treatments and interventions to improve bone mineral density</li> <li>• Any additional pertinent medical information</li> </ul>
<p>Botox® (botulinum toxin type A) injections</p> <p>J0585</p>	<p>Please submit the following:</p> <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Previous treatment</li> <li>• Response to previous treatment</li> </ul>

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Requested service	Required clinical criteria and information
Cerezyme <sup>®</sup> (imiglucerase)  J1786	Please submit the following: <ul style="list-style-type: none"> <li>• Clinical documentation supporting a confirmed diagnosis of Type 1 Gaucher disease such as:               <ul style="list-style-type: none"> <li>◦ Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts <math>\leq 30</math> percent normal activity</li> <li>◦ Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene</li> </ul> </li> <li>• Evidence that symptomatic manifestations of the disease are present, such as anemia, thrombocytopenia, bone disease, hepatomegaly, or splenomegaly</li> <li>• Any additional pertinent medical information</li> </ul>
Cyramza <sup>®</sup> (ramucirumab)  J9308	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Any pertinent lab results or genetic testing to confirm diagnosis</li> <li>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation</li> <li>• Dosage of drug and frequency of administration</li> </ul>
Dysport <sup>®</sup> (abobotulinumtoxin A)  J0586	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Previous treatment</li> <li>• Response to previous treatment</li> </ul>
Elaprase <sup>®</sup> (idursulfase)  J1743	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of Hunter syndrome (MPS II)</li> <li>• Clinical documentation supporting the diagnosis such as deficiency of iduronate sulfatase and urine GAGs, dermatan sulfate or heparan sulfate</li> <li>• Any additional pertinent medical information</li> </ul>

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Eleyso™ (taliglucerase alfa)  J3060	Please submit the following: <ul style="list-style-type: none"> <li>• Clinical documentation supporting a diagnosis of Type 1 Gaucher disease such as:               <ul style="list-style-type: none"> <li>○ Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts ≤30 percent of normal activity</li> <li>○ Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene</li> </ul> </li> <li>• Any additional pertinent medical information</li> </ul>
Epogen® (epoetin alfa)  J0885	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Clinical documentation supporting the diagnosis</li> <li>• Location at which the requested drug will be administered (e.g., clinic, home, office)</li> <li>• Any additional pertinent medical information</li> </ul>
Euflexxa® (1% sodium hyaluronate)  J7323	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>
Eylea® (afibercept injection)  J0178	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Dosage of and frequency of administration</li> <li>• Any additional pertinent medical information</li> </ul>

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Fabrazyme® (agalsidase beta)  J0180	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of Fabry disease</li> <li>• Clinical documentation showing other conditions, such as cardioembolic stroke or dissection syndromes, have been ruled out</li> <li>• Clinical documentation supporting the diagnosis such as deficient activity of α-galactosidase and molecular testing for GLA mutation</li> <li>• Any additional pertinent medical information</li> </ul>
Flolan® (epoprostenol sodium)  J1325	Please submit the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Clinical documentation supporting a diagnosis of pulmonary hypertension therapy (PAH) (WHO Group I)</li> <li><input type="checkbox"/> Place of patient residence (e.g., home, long-term care facility, skilled nursing facility)</li> <li><input type="checkbox"/> Whether the drug will be administered with durable medical equipment (e.g., nebulizer or infusion pump)</li> <li><input type="checkbox"/> Any additional pertinent medical information</li> </ul>
Gel-One® (cross-linked hyaluronate)  J7326	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>
Gel-Syn™ (hyaluronic acid)  J7328	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>

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GenVisc® 850 (sodium hyaluronate)  Q9980	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>
Glassia® (alpha 1- proteinase inhibitor)  J0257	Please submit the following: <ul style="list-style-type: none"> <li>• Evidence that member is 18 years of age or older</li> <li>• Clinical documentation supporting congenital deficiency of alpha1-proteinase inhibitor such as serum levels of alpha-1 antitrypsin</li> <li>• Diagnosis of symptomatic emphysema</li> <li>• Any additional pertinent medical information</li> </ul>
Hyalgan® (sodium hyaluronate)  J7321	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>
Immune globulin (intravenous and subcutaneous)  J1459, J1556, J1557, J1559, J1561, J1566, J1568, J1569, J1572, J1575	Please submit the following: <ul style="list-style-type: none"> <li>• Clinical documentation supporting the diagnosis immune globulin will be used to treat such as disease-associated symptoms and any pertinent laboratory results or testing used to confirm diagnosis</li> <li>• Names of medications previously used to treat this condition, including regimens, dates of therapy, and response to treatment</li> <li>• Any additional pertinent medical information</li> </ul>



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Keytruda® (pembrolizu- mab)  J9271	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Names of medications previously used to treat the condition, including dosage, dates of therapy, and response to treatment</li> <li>• Any additional pertinent medical information, including genetic testing if applicable</li> </ul>
Lucentis® (ranibizumab injection)  J2778	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Dosage and frequency of administration</li> <li>• Any additional pertinent medical information</li> </ul>
Lumizyme® (alglucosidase alfa)  J0221	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of Pompe disease</li> <li>• Evidence that all other possible conditions have been ruled out</li> <li>• Clinical documentation supporting the diagnosis such as absence of acid alpha glucosidase (GAA) activity, through GAA mutation testing or GAA activity testing in fibroblasts or muscle; screening tests including chest X-ray, electrocardiogram (ECG), electromyogram (EMG) AND/OR creatine kinase (CK), among other laboratory tests</li> <li>• Any additional pertinent medical information</li> </ul>
Monovisc® (cross-linked sodium hyaluronate)  J7327	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>

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Myobloc® (rima- botulinumtoxin B)  J0587	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Previous treatment</li> <li>• Response to previous treatment</li> </ul>
Myozyme® (alglucosidase alfa)  J0220	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of infantile-onset Pompe disease</li> <li>• Evidence that all other possible conditions have been ruled out</li> <li>• Clinical documentation supporting the diagnosis such as absence of acid alpha glucosidase (GAA) activity, through GAA mutation testing or GAA activity testing in fibroblasts or muscle; screening tests including chest X-ray, electrocardiogram (ECG), electromyogram (EMG), AND/OR creatine kinase (CK), among other laboratory tests</li> <li>• Any additional pertinent medical information</li> </ul>
Naglazyme® (galsulfase)  J1458	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of mucopolysaccharidosis (MPS) syndrome VI</li> <li>• Clinical documentation supporting the diagnosis such as enzyme deficiency of N- acetylgalactosamine-6-sulfate and urinary GAG - dermatan sulfate</li> <li>• Any additional pertinent medical information</li> </ul>
Neulasta® (pegfilgrastim)  J2505	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Clinical documentation supporting the diagnosis</li> <li>• Location at which the requested drug will be administered (clinic, home, office)</li> <li>• Any additional pertinent medical information</li> </ul>



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Opdivo® (nivolumab)  J9299	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Names of medications previously used to treat the condition, including dosage, dates of therapy, and response to treatment</li> <li>• Any additional pertinent medical information, including genetic testing if applicable</li> </ul>
Procrit® (epoetin alfa)  J0885	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Clinical documentation supporting the diagnosis</li> <li>• Location at which the requested drug will be administered (e.g., clinic, home, office)</li> <li>• Any additional pertinent medical information</li> </ul>
Prolastin-C® (alpha-1 proteinase inhibitor)  J0256	Please submit the following: <ul style="list-style-type: none"> <li>• Evidence that member is 18 years of age or older</li> <li>• Clinical documentation supporting congenital deficiency of Alpha1-Proteinase inhibitor such as serum levels of alpha-1 antitrypsin</li> <li>• Diagnosis of symptomatic emphysema</li> <li>• Any additional pertinent medical information</li> </ul>
Prolia® (denosumab)  J0897	Please submit the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Diagnosis</li> <li><input type="checkbox"/> Any pertinent laboratory results or testing to confirm diagnosis such as a DEXA scan</li> <li><input type="checkbox"/> Dosage and frequency of administration</li> <li><input type="checkbox"/> Any additional pertinent medical information</li> </ul>

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Reclast <sup>®</sup> (zoledronic acid)  J3489	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnostic evidence of osteoporosis</li> <li>• Previous treatments and interventions to improve bone mineral density</li> <li>• Any additional pertinent medical information</li> </ul>
Remicade <sup>®</sup> (infliximab)  J1745	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Any pertinent lab results or clinical documentation supporting the diagnosis</li> <li>• Names of medications previously used to treat this condition, including dates of therapy and reason for discontinuation</li> <li>• Dosage of drug and frequency of administration</li> </ul>
Remodulin <sup>®</sup> (treprostinil)  J3285	Please submit the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Clinical documentation supporting a diagnosis of pulmonary hypertension therapy (PAH) (WHO Group I)</li> <li><input type="checkbox"/> Place of patient residence (e.g., home, long-term care facility, skilled nursing facility)</li> <li><input type="checkbox"/> Whether the drug will be administered with durable medical equipment (e.g., nebulizer or infusion pump)</li> <li><input type="checkbox"/> Any additional pertinent medical information</li> </ul>
Supartz FX <sup>™</sup> (sodium hyaluronate)  J7321	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>

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Requested service	Required clinical criteria and information
Synvisc® Synvisc- One® (hylan G-F 20)  J7325	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of osteoarthritis of the knee supported by radiological evidence</li> <li>• Documentation that conservative nonpharmacologic therapy and simple analgesics, e.g., acetaminophen have been ineffective</li> <li>• Any additional pertinent medical information</li> </ul>
Tyvaso® (treprosti nil)  J7686	Please submit the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Clinical documentation supporting a diagnosis of pulmonary hypertension therapy (PAH) (WHO Group I)</li> <li><input type="checkbox"/> Place of patient residence (e.g., home, long-term care facility, skilled nursing facility)</li> <li><input type="checkbox"/> Whether the drug will be administered with durable medical equipment (e.g., nebulizer or infusion pump)</li> <li><input type="checkbox"/> Any additional pertinent medical information</li> </ul>
Veletri® (epo- prosten ol)  J1325	Please submit the following: <ul style="list-style-type: none"> <li><input type="checkbox"/> Clinical documentation supporting a diagnosis of pulmonary hypertension therapy (PAH) (WHO Group I)</li> <li><input type="checkbox"/> Place of patient residence (e.g., home, long-term care facility, skilled nursing facility)</li> <li><input type="checkbox"/> Whether the drug will be administered with durable medical equipment (e.g., nebulizer or infusion pump)</li> <li><input type="checkbox"/> Any additional pertinent medical information</li> </ul>
Vimizim® (elosulfase alfa)  J1322	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis of mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome)</li> <li>• Clinical documentation supporting the diagnosis such as clinical examination, skeletal radiographs, urinary GAG, and enzymatic activity of GALNS in blood cells or fibroblasts</li> <li>• Any additional pertinent medical information</li> </ul>

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VPRIV <sup>®</sup> (velaglucerase alfa)  J3385	Please submit the following: <ul style="list-style-type: none"> <li>• Clinical documentation supporting the diagnosis of Type 1 Gaucher disease such as:               <ul style="list-style-type: none"> <li>○ Biochemical assay of glucocerebrosidase activity in WBCs or skin fibroblasts ≤30 percent of normal activity</li> <li>○ Genotyping revealing two pathogenic mutations of the glucocerebrosidase gene</li> </ul> </li> <li>• Any additional pertinent medical information</li> </ul>
Xeomin <sup>®</sup> (incobotulinumtoxinA)  J0588	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Previous treatment</li> <li>• Response to previous treatment</li> </ul>
Xgeva <sup>™</sup> (denosumab)  J0897	Please submit the following: <ul style="list-style-type: none"> <li>• Diagnosis</li> <li>• Any pertinent laboratory results or testing to confirm diagnosis</li> <li>• Dosage and frequency of administration</li> <li>• Any additional pertinent medical information</li> </ul>
Xiaflex <sup>®</sup> (collagenase clostridium histolyticum)  J0775	Please submit the following: <ul style="list-style-type: none"> <li>• Evidence that member is 18 years of age or older</li> <li>• Diagnosis of Dupuytren's contracture with a palpable cord or Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy</li> <li>• Any additional pertinent medical information</li> </ul>

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Zemaira® (alpha-1 proteinase inhibitor)  J0256	Please submit the following: <ul style="list-style-type: none"> <li>• Evidence that member is 18 years of age or older</li> <li>• Clinical documentation supporting congenital deficiency of alpha1-proteinase inhibitor such as serum levels of alpha-1 antitrypsin</li> <li>• Diagnosis of symptomatic emphysema</li> <li>• Any additional pertinent medical information</li> </ul>



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and Blue Shield Association

### Multi-language Interpreter Services

**Spanish:** ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-888-488-9850 (TTY: 711).

**Vietnamese:** CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-888-488-9850 (TTY: 711).

**Chinese:** 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-888-488-9850 (TTY: 711)。

**Arabic:** ملحوظة: إذا كنت تتحدث العربية، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-888-488-9850 (رقم هاتف الصم والبكم: 711).

**Karen:** ဟံသုဉ်ဟံသး- နမ့ကတိၤ ကညိ ကျိအသိ, နမၤန့ ကျိအတၢ်မၤတၢ်လၢ တလၢဂ်ဘျုးလၢဂ်စ့ၤ နိတမံၤဘျုးသ့န့ၣ်လီၤ. ကိ: 1-888-488-9850 (TTY: 711)

**French:** ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-888-488-9850 (ATS: 711).

**Cushite:** XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1-888-488-9850 (TTY: 711).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-888-488-9850 (TTY: 711).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-888-488-9850 (TTY: 711) 번으로 전화해 주십시오.

**Nepali:** ध्यान दिनुहोस्: यदि तपाईंले नेपाली बोल्नुहुन्छ भने, तपाईंको लागि भाषा सहायता सेवाहरू नि:शुल्क उपलब्ध छन्। 1-888-488-9850 (TTY: 711) मा फोन गर्नुहोस्।



**Russian:** ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-888-488-9850 (телетайп: 711).

**Laotian:** ໂບດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທ 1-888-488-9850 (TTY: 711).

**Kurdish:** ناگاداری: ئه‌گهر به زمانى كوردى قهسه، دهكهیت خزمهتگوزاریهكانى یارمهتی، زمان بهخۆرایى بو تو بهردهسته. پهپهندی به 1-888-488-9850 (TTY: 711) بکه.

**Persian:** توجه: اگر به زبان فارسی صحبت می‌کنید، خدمات و کمک‌های زبانی رایگان برای شما موجود است. برای کسب اطلاعات بیشتر، با شماره 1-888-488-9850 (TTY: 711) تماس بگیرید.

**Japanese:** 注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。1-888-488-9850（TTY: 711）まで、お電話にてご連絡ください。