Coding Information for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Diagnosis and ICD-10-CM billing codes for 20% subcutaneous Ig (SClg) therapy

Please see full Important Safety Information on back and enclosed full prescribing information for Hizentra, including boxed warning.
Hizentra Coding Information
Diagnosis and billing codes for 20% SClg therapy

This resource provides information from a complex and evolving medical coding system. The treating physician is solely responsible for diagnosis coding and determination of the appropriate ICD-10-CM codes1 that describe the patient’s condition and are supported by the medical record. All codes listed in this guide are for informational purposes and are not an exhaustive list. The CPT®,2 HCPCS,3 and ICD-10-CM codes provided are based on AMA or CMS guidelines. The billing party is solely responsible for coding of services (e.g., CPT coding). Because government and other third-party payer coding requirements change periodically, please verify current coding requirements directly with the payer being billed.

ICD-10-CM Diagnosis Codes1
The following ICD-10-CM codes1 may be used to identify patient medical conditions typically associated with Hizentra use.

G61 Chronic inflammatory demyelinating polyneuropathy
- G61.81 Chronic inflammatory demyelinating polyneuropathy
- Chronic inflammatory demyelinating polyneuropathy
- Chronic inflammatory demyelinating polyradiculoneuropathy
- Polyneuropathy (multiple nerve disorder)
- Polyneuropathy, chronic inflammatory demyelinating
- Polyradiculoneuropathy, chronic inflammatory demyelinating
- Polyradiculoneuropathy, inflammatory demyelinating

ICD=International Classification of Diseases
HCPCS=Healthcare Common Procedure Coding System
CPT=Current Procedural Terminology

Call us now for reimbursement support

For assistance with Prior Authorization (PA), request a PA checklist or connect with a CSL Field Reimbursement Manager from IgIQ.
1-877-355-IGIQ (4447)
Monday–Friday, 8 AM to 8 PM ET

Medicaid, and most insurers cover Hizentra for the treatment of patients with chronic inflammatory demyelinating polyneuropathy (CIDP). Coverage for Hizentra falls under Medicare Part D. Medicaid coverage policy varies by state. Coverage by other payers varies by payer and provider contract.

Prior Authorization
When a payer requires prior authorization:
- Request the approval and authorization reference code in writing
- Insert the authorization reference code into Field 23 of the CMS-1500 claim form when billing for services. Enter the authorization reference code in the equivalent field on the electronic claim form (ASC 837P, Loop 2300, Segment REF02, with the Qualifier G1 entered to Segment REF01), unless otherwise directed by the payer
- If required by the payer, attach a copy of the authorization approval letter to the paper claim form; use the payer’s designated procedure for submitting documentation with electronic claim forms

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Billing Codes
The following HCPCS codes describe supplies (including drugs) rendered by the billing provider. CMS publishes and maintains the HCPCS code set. These codes are entered to paper claim form CMS-1500 in Field 24; or, to electronic claim form ASC 837P in Loop 2400, Segment SV101-2, with the Qualifier "HC" entered to Segment SV101-1, unless otherwise directed by the payer.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J1559</td>
<td>Injection, immune globulin (Hizentra), 100 mg</td>
</tr>
</tbody>
</table>

Certain payers may require the entry of NDC information to the claim form, as directed by the payer.

<table>
<thead>
<tr>
<th>Grams Protein</th>
<th>Fill Size</th>
<th>NDC Number to Use on All Claim Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 g</td>
<td>5 mL</td>
<td>44206-0451-01</td>
</tr>
<tr>
<td>2 g</td>
<td>10 mL</td>
<td>44206-0452-02</td>
</tr>
<tr>
<td>4 g</td>
<td>20 mL</td>
<td>44206-0454-04</td>
</tr>
<tr>
<td>10 g</td>
<td>50 mL</td>
<td>44206-0455-10</td>
</tr>
</tbody>
</table>

If the billing provider performs administration services in conjunction with a patient’s infusion, the following administration codes may be used to bill for this service if the service meets the requirements of the code description.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96369</td>
<td>Subcutaneous injection for therapy or prophylaxis; initial, up to one hour, including pump setup and establishment of subcutaneous infusion site(s)</td>
</tr>
<tr>
<td>96370</td>
<td>Each additional hour</td>
</tr>
<tr>
<td>96371</td>
<td>Additional pump setup with establishment of new subcutaneous infusion site(s)</td>
</tr>
</tbody>
</table>

Billing for External Pumps and Supplies
When the billing provider furnishes an external infusion pump for patient use, the following code may be used to bill for the pump if it meets the requirements of the code description.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>E0779</td>
<td>Ambulatory infusion pump, mechanical, reusable, for infusion 8 hours or greater</td>
</tr>
<tr>
<td>E0781</td>
<td>Ambulatory infusion pump, single or multiple channels, electric or battery operated, with administrative equipment, worn by patient</td>
</tr>
<tr>
<td>E0791</td>
<td>Parenteral infusion pump, stationary, single or multichannel</td>
</tr>
</tbody>
</table>

When the billing provider furnishes supplies for the patient’s use with the external infusion pump, the following codes may be appropriate for the supplies if they meet the requirements of the code description and payer coverage policies.

<table>
<thead>
<tr>
<th>External Infusion Pump Supplies*</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>K0552</td>
<td>Supplies for external drug infusion pump, syringe-type cartridge, sterile, each</td>
</tr>
<tr>
<td>A4221</td>
<td>Supplies for maintenance of drug infusion catheter, per week</td>
</tr>
<tr>
<td>A4222</td>
<td>Infusion supplies for external drug infusion pump, per cassette or bag</td>
</tr>
</tbody>
</table>

*All 3 codes are needed to bill for infusion pump supplies.

Modifier -JB for Medicare Billing
Medicare Part D requires the addition of Modifier -JB (administered subcutaneously) to the HCPCS code for Hizentra (J1559) to confirm subcutaneous administration. Example: J1559-JB. Commercial and Medicaid plans may require the use of the JB modifier. If required, JB should also be added to the HCPCS code for the covered infusion pump (E0779) following the modifier that indicates whether the pump is being rented (RR) or purchased (NU). Example: E0779-RR-JB or E0779-NU-JB. Always check with the plan to see if the modifier code is required.
A Field 21
Enter all appropriate ICD-10-CM diagnosis codes, starting on Field 21, Line A. This field allows the entry of 1 character indicator and 12 diagnosis codes at a maximum of 7 characters in length.

B Field 24D (CPT/HCPCS)
- Enter HCPCS code J1559 for Hizentra if appropriate
- Enter HCPCS codes for pump and related supplies
  - Pump: Enter appropriate code (Medicare will cover only E0779)
  - Supplies: Enter code that best describes supplies provided (eg, K0552, A4221 or A4222)
- If the billing provider is eligible for coverage of subcutaneous infusion, enter CPT code 96369 for the establishment of infusion sites, pump setup, and the first hour of infusion. If the patient is monitored beyond the first hour, CPT code 96370 may be appropriate. Additional pump setup with establishment of new subcutaneous infusion sites is reported with CPT code 96371

C Field 24D (Shaded Area)
For Medicaid claims, and for Medicare Part D claims that will cross over to Medicaid as the secondary payer, NDC information in a specific format is required in the shaded area above the line on which Hizentra is reported in 24D. The various Medicaid plans and Medicare Part D have different reporting formats for this information. In general, the billing entity will need to supply the NDC (in HIPAA-compliant 11-digit format) preceded by the Modifier N4 (eg, N499999999999). This is typically followed by the NDC unit of measure (I2 [international unit], GR [gram], ML [milliliter], or UN [unit]) and the numeric quantity of the NDC that was dispensed.
Other payers may require similar information. Check with your payer for specific requirements related to reporting the information required in the shaded areas of Field 24.

D Field 24D (Modifier)
For Medicare Part D claims, enter Modifier -JB (administered subcutaneously) on the same line as Hizentra (ie, J1559-JB).

E Field 24E (Diagnosis Pointer)
Enter the line letter(s) from Field 21 that best describes the medical necessity for the service listed in Field 24D. For Medicare claims, only one line number from Field 21 should be entered in Field 24E for each HCPCS code reported in Field 24D.

F Field 24G (Days or Units)
- Hizentra: Enter the number of 100-mg billing units used to treat the patient. For example, if 40,000 mg are dispensed (eg, four 50-mL vials), 400 would be reported in Field 24G (40,000/100 = 400)
- Pump: Enter one billing unit
- Supplies: Enter one per unit described by the corresponding HCPCS code

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Important Safety Information

Hizentra is indicated for:

- Treatment of primary immunodeficiency (PI) in adults and pediatric patients 2 years and older.
- Maintenance therapy in adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to prevent relapse of neuromuscular disability and impairment.
  
  - Limitation of Use: Maintenance therapy in CIDP has been systematically studied for 6 months and for a further 12 months in a follow-up study. Continued maintenance beyond these periods should be individualized based on patient response and need for continued therapy.

For subcutaneous infusion only,

- WARNING: Thrombosis may occur with immune globulin products, including Hizentra. Risk factors may include: advanced age, prolonged immobilization, hypercoagulable conditions, history of venous or arterial thrombosis, use of estrogens, indwelling vascular catheters, hyperviscosity, and cardiovascular risk factors.

- For patients at risk of thrombosis, administer Hizentra at the minimum dose and infusion rate practicable. Ensure adequate hydration in patients before administration. Monitor for signs and symptoms of thrombosis and assess blood viscosity in patients at risk for hyperviscosity.

Hizentra is contraindicated in patients with a history of anaphylactic or severe systemic reaction to human immune globulin (Ig) or components of Hizentra (eg, polysorbate 80), as well as in patients with immunoglobulin A deficiency with antibodies against IgA and a history of hypersensitivity. Because Hizentra contains L-proline as stabilizer, use in patients with hyperprolinemia is contraindicated.

IgA-deficient patients with anti-IgA antibodies are at greater risk of severe hypersensitivity and anaphylactic reactions. Thrombosis may occur following treatment with Ig products, including Hizentra.

Monitor patients for aseptic meningitis syndrome (AMS), which may occur following treatment with Ig products, including Hizentra. In patients at risk of acute renal failure, monitor renal function, including blood urea nitrogen, serum creatinine and urine output. In addition, monitor patients for clinical signs of hemolysis or pulmonary adverse reactions (eg, transfusion-related acute lung injury [TRALI]).

Hizentra is derived from human blood. The risk of transmission of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent and its variant (vCJD), cannot be completely eliminated.

The most common adverse reactions (observed in ≥5% of study subjects) were local infusion-site reactions, as well as headache, diarrhea, fatigue, back pain, nausea, extremity pain, cough, upper respiratory tract infection, rash, pruritus, vomiting, upper abdominal pain, migraine, arthralgia, pain, fall, and nasopharyngitis.

The passive transfer of antibodies can interfere with response to live virus vaccines and lead to misinterpretation of serologic test results.

Please see enclosed full prescribing information for Hizentra.

To report SUSPECTED ADVERSE REACTIONS, contact the CSL Behring Pharmacovigilance Department at 1-866-915-6958 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.