Coding Information for Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Diagnosis and ICD-10-CM billing codes for IVlg therapy
Privigen Coding Information

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 codes 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®, HCPCS, and ICD-10-CM codes provided are based on AMA or CMS guidelines. The billing party is solely responsible for coding of services (eg, 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 Codes [for claims with a date of service on or after October 1, 2015]
The following ICD-10-CM codes may be used to identify patient medical conditions typically associated with Privigen use.

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

Most insurers cover Privigen for the medically necessary treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). Medicaid coverage varies by state, and coverage by other payers varies by plan and by contract.

Medicare coverage and billing requirements are dependent in part on where the patient is treated. Medicare Part B covers treatment for CIDP in a clinical setting. Treatment in the home may be eligible for coverage under Medicare Part D.

CPT® and HCPCS Codes
(Healthcare Common Procedural Coding System)

<table>
<thead>
<tr>
<th>CPT®/HCPCS Code1,2,3</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>S9338*</td>
<td>Home infusion therapy, immunotherapy, administrative services, professional pharmacy services, care coordination, and all necessary supplies and equipment (drugs and nursing visits coded separately)</td>
</tr>
<tr>
<td>J1459</td>
<td>Injection, immune globulin (Privigen), intravenous, non-lyophilized (eg, liquid), 500 mg</td>
</tr>
<tr>
<td>96365</td>
<td>Intravenous infusion, for therapy and prophylaxis or diagnosis (specify substance or drug), initial, up to 1 hour</td>
</tr>
<tr>
<td>96366</td>
<td>Each additional hour (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

Privigen Vial Sizes
Ready-to-Use Privigen Vial Sizes

<table>
<thead>
<tr>
<th>Protein</th>
<th>Fill Size</th>
<th>NDC Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 g</td>
<td>50 mL</td>
<td>44206-0436-05</td>
</tr>
<tr>
<td>10 g</td>
<td>100 mL</td>
<td>44206-0437-10</td>
</tr>
<tr>
<td>20 g</td>
<td>200 mL</td>
<td>44206-0438-20</td>
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<tr>
<td>40 g</td>
<td>400 mL</td>
<td>44206-0439-40</td>
</tr>
</tbody>
</table>

CPT=Current Procedural Terminology
*S-codes are HCPCS codes used by some private health plans for billing and reimbursement. Medicaid plans may use S-codes as well, but Medicare does not use them.*
†11-digit number for billing purposes.

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
Please see full Important Safety Information on back and enclosed full prescribing information for Privigen, including boxed warning.

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 J1459 for Privigen
- Include CPT codes for infusion:
  96365, infusions first hour
  96366, infusion each additional hour

C  | Field 24D (Shaded Area)
For Medicaid claims, and for Medicare 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 Privigen is reported in 24D. The various Medicaid plans and Medicare 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 (e.g., N499999999999). This is typically followed by the NDC unit of measure (F2 [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 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 letter from Field 21 should be entered in Field 24E for each HCPCS code reported in Field 24D.

E  | Field 24G (Days or Units)
Enter the total number of 500-mg billing units.
For example, if 40 grams are dispensed, the number of billing units would equal 80.
Important Safety Information

Privigen is indicated for the treatment of:
- Primary humoral immunodeficiency (PI)
- Chronic immune thrombocytopenic purpura (ITP) in patients age 15 years and older
- Chronic inflammatory demyelinating polyneuropathy (CIDP) in adults
  - Limitation of use: maintenance therapy in CIDP has not been studied for periods longer than 6 months. Individualize duration of treatment beyond 6 months based on patient response.

WARNING: THROMBOSIS, RENAL DYSFUNCTION AND ACUTE RENAL FAILURE

- Thrombosis may occur with immune globulin products, including Privigen. 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.
- Renal dysfunction, acute renal failure, osmotic nephrosis, and death may occur with immune globulin intravenous (IGIV) products in predisposed patients. Renal dysfunction and acute renal failure occur more commonly in patients receiving IGIV products that contain sucrose. Privigen does not contain sucrose.
- For patients at risk of thrombosis, renal dysfunction or renal failure, administer Privigen 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.

See full prescribing information for complete boxed warning.

Privigen is contraindicated in patients with history of anaphylactic or severe systemic reaction to human immune globulin, in patients with hyperprolinemia, and in IgA-deficient patients with antibodies to IgA and a history of hypersensitivity.

In patients at risk of developing acute renal failure, monitor urine output and renal function, including blood urea nitrogen and serum creatinine. Hyperproteinemia, increased serum viscosity, or hypotension can occur with Privigen. Infrequently, aseptic meningitis syndrome (AMS) may occur—especially with high doses or rapid infusion.

Hemolysis, either intravascular or due to enhanced red blood cell sequestration, may occur. Risk factors include non-O blood group and high doses. Closely monitor patients for hemolysis and hemolytic anemia.

During and shortly following Privigen infusion, elevations of systolic and diastolic blood pressure (including cases of hypertensive urgency) have been observed. These elevations resolved or significantly improved within hours with oral anti-hypertensive therapy or observation alone. Check patients for a history of hypertension and monitor blood pressure during this period.

Consider relative risks and benefits before prescribing high-dose regimen for chronic ITP and CIDP in patients at increased risk of thrombosis, hemolysis, acute kidney injury or volume overload. Monitor patients for pulmonary adverse reactions (transfusion-related acute lung injury [TRALI]).

Privigen is derived from human plasma. 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.

In clinical studies of patients with PI, the most common adverse reactions to Privigen, observed in >5% of subjects, were headache, fatigue, nausea, chills, vomiting, back pain, pain, elevated body temperature, abdominal pain, diarrhea, cough, stomach discomfort, chest pain, joint swelling/effusion, influenza-like illness, pharyngolaryngeal pain, urticaria, and dizziness. Serious adverse reactions were hypersensitivity, chills, fatigue, dizziness, and increased body temperature.

In clinical studies of patients being treated for chronic ITP, the most common adverse reactions, seen in >5% of subjects, were laboratory findings consistent with hemolysis, headache, elevated body temperature, anemia, nausea, and vomiting. A serious adverse reaction was aseptic meningitis syndrome.

In clinical studies of patients being treated for CIDP, the most common reactions, observed in >5% of subjects, were headache, asthenia, hypertension, nausea, pain in extremity, hemolysis, influenza-like illness, leukopenia, and rash. Serious adverse reactions were hemolysis, exacerbation of CIDP, acute rash, increased diastolic blood pressure, hypersensitivity, pulmonary embolism, respiratory failure, and migraine.

Treatment with Privigen might interfere with a patient’s response to live virus vaccines and could lead to misinterpretation of serologic testing. In patients over 65 and those at risk of renal insufficiency, do not exceed recommended dose and infuse at the minimum rate practicable.

Please see enclosed full prescribing information for Privigen, including boxed warning.

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.