Privigen® (immune globulin intravenous [human], 10%) – New indication, new warning

- On September 14, 2017, CSL Behring announced the FDA approval of Privigen (immune globulin intravenous [human], 10%) for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.
    - Privigen maintenance therapy in CIDP has not been studied for periods longer than 6 months. After responding during an initial treatment period, not all patients require indefinite maintenance therapy with Privigen in order to remain free of CIDP symptoms. Individualize the duration of any treatment beyond 6 months based upon the patient's response and demonstrated need for continued therapy.
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- Privigen is also approved as replacement therapy for primary humoral immunodeficiency, and for the treatment of patients ≥ 15 years of age with chronic immune thrombocytopenic purpura to raise platelet counts.

- CIDP is a rare autoimmune disorder that affects the peripheral nerves and may cause permanent nerve damage. CIDP effects can worsen over time, leading to significant activity limitations and a decreased quality of life. In the U.S., it is estimated that the incidence of CIDP is up to two patients per 100,000 people each year, with a prevalence of 40,000 people affected.

- The FDA approval was based on results from two clinical studies (PATH and PRIMA) that focused on the use of immunoglobulin (IG) therapy for treating CIDP. Response was measured by the patient's adjusted score on the Inflammatory Neuropathy Cause and Treatment (INCAT) scale, which measures the ability to walk and perform tasks.
    - In PATH, 207 patients receiving Privigen were studied for up to 13 weeks, and the response rate was 73%.
    - In PRIMA (n = 28), 61% of patients responded to Privigen over 25 weeks.
    - The overall median time to first adjusted INCAT response in PRIMA was 7.5 weeks [18 weeks in IG intravenous (IGIV)-untreated and 3 weeks in IGIV-pretreated]. The median time to first adjusted INCAT response in PATH (all IGIV-pretreated) was 3.7 weeks (95% CI: 3.4, 5.9).

- Privigen carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.

- The *Warnings and Precautions* section was also updated with information regarding hypertension (HTN). Elevations of systolic blood pressure to ≥ 180 mmHg and/or of diastolic blood pressure to > 120 mm Hg (hypertensive urgency) have been observed during and/or shortly following infusion of Privigen.
    - These blood pressure elevations were resolved or significantly improved within hours with either observation alone or changes in oral antihypertensive therapy.
    - Such elevations were reported more often among patients with a history of HTN. Patients should be checked for a history of HTN and current antihypertensive medication use. Blood pressure should be monitored prior to, during, and following Privigen infusion.

- The most common adverse reactions (> 5%) with Privigen use for CIDP were headache, asthenia, HTN, 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.

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- The recommended initial loading dose of Privigen for CIDP is 2 g/kg (20 mL/kg) given as an IV infusion in divided doses over two to five consecutive days. Privigen may be administered as a maintenance infusion of 1 g/kg (10 mL/kg) administered in a single infusion given in one day or divided into two doses given on two consecutive days, every 3 weeks. Maintenance therapy beyond 6 months has not been studied.

    — Refer to the Privigen drug label for infusion rates and the doses for all other indications.

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