

Notice to 340B Covered Entities Regarding GAMMAKED™ [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified]

August 2019

Kedron Biopharma wishes to inform 340B covered entities regarding how they may acquire GAMMAKED™ [Immune Globulin Injection (Human), 10% Caprylate/Chromatography Purified] at the 340B ceiling price. GAMMAKED is marketed under the following NDCs: 76125-900-01; 76125-900-25; 76125-900-50; 76125-900-10; 76125-900-20.

GAMMAKED is approved to treat chronic inflammatory demyelinating polyneuropathy in adults to improve neuromuscular disability and impairment and for maintenance therapy to prevent relapse, primary humoral immunodeficiency in patients 2 years of age and older, and idiopathic thrombocytopenic purpura (“ITP”) in adults and children to raise platelet counts to prevent bleeding or to allow a patient with ITP to undergo surgery.

To address the imbalance between GAMMAKED supply and demand, Kedron has developed a defined distribution network for the product. Kedron allocates a specified portion of its supply of GAMMAKED through specialty distributors to certain specialty pharmacies, home infusion providers, and clinics, to help patients who have initiated therapy maintain access to the product. Covered entities may access GAMMAKED at the 340B price through contract pharmacy arrangements with these entities. Kedron also offers unallocated GAMMAKED for sale on the open market when supply of the product permits doing so. This unallocated supply is available for 340B covered entity and commercial customer purchase through our distributors.

Covered entities interested in purchasing GAMMAKED may contact 340BProgram@kedrion.com for more information on the distributors and pharmacies that carry the product.