

Increased Dosage Recommended for Intramuscular Immune Globulin for Hepatitis A Pre- and Post-Exposure Prophylaxis, July 20, 2017

This health alert informs providers that Grifols Therapeutics, the manufacturer of GamaSTAN® S/D, the only formulation of human intramuscular (IM) immune globulin (IG) in the United States, has increased the recommended dosage for their product for the pre- and post-exposure prophylaxis of hepatitis A virus (HAV).

Providers are requested to use the increased dosage immediately for patients recommended to receive intramuscular (IM) IG needing GamaSTAN® S/D for post-exposure prophylaxis after exposure to hepatitis A or for pre-exposure prophylaxis prior to travel to countries with high or intermediate [endemic transmission of hepatitis A](#).

Situation

On July 7, 2017, Grifols Therapeutics increased the recommended dosages of its product (GamaSTAN® S/D) for pre- and post-exposure prophylaxis of hepatitis A virus (HAV) infection.

The newly recommended dose for HAV post-exposure prophylaxis is 0.1 mL/kg, which 5 times greater than the previously recommended dose.

The doses for pre-exposure prophylaxis for travel were also increased:

0.1 mL/kg for stays up to one month, 0.2 mL/kg for stays up to two months, and repeated boosters of 0.2 mL/kg every two months for stays beyond two months.

The dosages were changed based on reportedly lower concentrations of anti-HAV antibodies in the product due to decreasing prevalence of previous HAV infection among plasma donors. The provider letter from Grifols Therapeutics that outlines these changes is available [here](#).

California Department of Public Health (CDPH) guidance on the management of pre- and post-exposure prophylaxis of HAV ([CDPH HAV PEP Quicksheet](#) and [CDPH HAV PEP Administration](#)) has been updated to reflect these changes.

San Diego County is currently experiencing a large HAV outbreak. As of July 17, 2017, 251 cases have been reported, including 5 deaths. Detailed recommendations for the outbreak may be found at the [County Hepatitis A website](#), which has weekly updates on the case count and copies of all health alerts regarding HAV. Santa Cruz County is also experiencing an HAV outbreak with at least 27 cases. In both counties, most of the infected persons have been homeless and/or users of illicit drugs.

Recommendation

Providers should immediately use the increased immune globulin dosage when indicated for HAV post-exposure prophylaxis.

Susceptible people exposed to HAV should receive a dose of single-antigen HAV vaccine and/or intramuscular (IM) immune globulin (IG) (**0.1 mL/kg**) as soon as possible within 2 weeks of last exposure. The following table adapted from CDPH guidance may be utilized to determine which products to use to prevent HAV in exposed persons:

| Age/years | <1† | 1-40 | 41-59 | 60-74† | 75+ |
|-----------|---------|-------------------|---------|--------------|--------------|
| Healthy | IG only | Vaccine preferred | Vaccine | IG + vaccine | IG + vaccine |
| Other‡ | IG | IG | IG | IG | IG |

†When IG is unavailable or in short supply, single-antigen HAV vaccine may be used for PEP in healthy people 60-74 years of age and in infants >6 months of age.

‡Other medical conditions are defined at:

https://archive.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf

Persons administered IG for whom HAV vaccine is also recommended for other reasons (including ongoing exposure during the current outbreak) should receive a dose of hepatitis A vaccine simultaneously with IG.

Persons who were exposed less than 2 weeks ago and who have recently received a dose of IM IG less than 0.1 mL/kg may receive an additional dose for a total of 0.1 mL/kg.

Providers with questions about IM IG dosing or HAV may contact the CDPH Immunization Branch Vaccine Preventable Diseases Epidemiology Section at 510-620-3737.

Thank you for your efforts to prevent and control hepatitis A infection in California.