OREGON HEALTH AUTHORITY
IMMUNIZATION PROGRAM

HyperTET®1 Tetanus Immune Globulin (TIG)

Reviewed July 16, 2017

No changes from the previous version.

I. OREGON IMMUNIZATION MODEL STANDING ORDER:
1. Check the ALERT Immunization Information System (IIS) to determine client’s tetanus immunization history.

2. Screen clients for contraindications to tetanus vaccine and tetanus immune globulin.

3. Provide a current Vaccine Information Statement (VIS) and tetanus immune globulin patient information sheet. Answer any questions.

4. Record all required data elements in the client’s permanent health record.

5. See warning on page 2.

6. Give HyperTET® IM for adult and pediatric patients in the limb opposite the vaccination site. See table on page 2 for dosing amounts. Aspirate to check for blood return.1 See package insert for directions.

7. Give tetanus containing vaccine in the limb opposite the TIG site as indicated. See DT and DTaP/Combo standing orders for specifics.

8. Observe client for 15 minutes after vaccination to decrease the risk for injury should they faint.

_________________________________________________________
Signature Health Officer or Medical Provider Date

_________________________________________________________
Signature Health Officer or Medical Provider Date

This order expires July 31, 2018
Warning

HyperTET is made from human plasma. Products made from human plasma may contain infectious agents, such as viruses, and, theoretically, the Creutzfeldt–Jakob Disease (CJD) agent that can cause disease. The risk that such products will transmit an infectious agent has been reduced by screening plasma donors for prior exposure to certain viruses, by testing for the presence of certain current virus infections, and by inactivating and/or removing certain viruses. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Individuals who receive infusions of blood or plasma products may develop signs and/or symptoms of some viral infections, particularly hepatitis C. ALL infections thought by a physician possibly to have been transmitted by this product should be reported by the physician or other healthcare provider to Grifols Therapeutics Inc. [1-800-520-2807].

The physician should discuss the risks and benefits of this product with the patient, before prescribing or administering it to the patient.

1. HyperTET® should be given with caution to patients with a history of prior systemic allergic reactions following the administration of human immunoglobulin preparations.

2. In patients who have severe thrombocytopenia or any coagulation disorder that would contraindicate intramuscular injections, HyperTET® should be given only if the expected benefits outweigh the risks.

3. Recommended intervals between administration of tetanus immune globulin preparations and measles- or varicella-containing vaccine:*2

<table>
<thead>
<tr>
<th>Immune globulin</th>
<th>Dose</th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HyperTET®</td>
<td>250 units (10 mg IgG/kg) IM*</td>
<td>3 months</td>
</tr>
</tbody>
</table>

*See dosing table section II. Does not apply to Zoster vaccine. For complete table, see MMR or Varicella standing orders.

Revised 03-2017
II. TETANUS IMMUNE GLOBULIN (HyperTET®) SCHEDULE\(^1\)*

Post-exposure only, not for active tetanus disease

<table>
<thead>
<tr>
<th>Recommended Age</th>
<th>DOSE(^0)</th>
<th>Route</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;7 years(^1, 2)</td>
<td>4 units/kg or 250 units</td>
<td>IM</td>
<td>Vastus Lateralis (thigh) Deltoid (arm)</td>
</tr>
<tr>
<td>&gt;7 years(^1)</td>
<td>250 units</td>
<td>IM</td>
<td>Limb opposite from where the tetanus vaccine is given</td>
</tr>
<tr>
<td>Diabetics(^3)</td>
<td>250–500 units</td>
<td>IM</td>
<td></td>
</tr>
<tr>
<td>≥60 years(^5)</td>
<td>250–500 units</td>
<td>IM</td>
<td></td>
</tr>
</tbody>
</table>

* Where tetanus immunization is contraindicated, use HyperTET® for individuals who have a wound that is neither clean nor minor.\(^1\)

\(^0\) The dosage should be adjusted according to the severity of the infection.\(^1\) (Dose calculator available)\(^2\)

\(^3\) Diabetics are at increased risk for tetanus. Reported tetanus is about 3 times more common and fatalities are about 4 times more common in diabetics.\(^3\)

**ACCEPTABLE VOLUME** for a single dose of immune globulin (IG) to inject into either the deltoid or vastus lateralis muscle of a normal-weight adult.\(^4\)

Deltoid:
- Average 0.5 mL
- Range 0.5–2 mL

Vastus Lateralis:
- Average 1–4 mL
- Range 1–5 mL

Infants and toddlers would fall at the lower end of the range, whereas adolescents and adults would generally fall on the higher end of the range.

Revised 03-2017
### III.A. RECOMMENDATIONS FOR USE OF TETANUS IMMUNE GLOBULIN AND VACCINE

#### Tetanus Prophylaxis in Wound Management

<table>
<thead>
<tr>
<th>History of Tetanus Immunization</th>
<th>Clean, Minor Wounds</th>
<th>All Other Wounds*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tetanus containing vaccine◊</td>
<td>TIG</td>
</tr>
<tr>
<td>Uncertain or &lt;3 doses</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>3 or more doses</td>
<td>No§</td>
<td>No</td>
</tr>
</tbody>
</table>

*Such as, but not limited to, wounds contaminated with dirt, feces, soil, and saliva; puncture wounds; wounds from crushing, tears, burns, and frostbite.

◊Age–appropriate formulation. See DT standing order.

§Yes, if ≥10 years since last dose.

†Yes, if ≥5 years since last dose.

Adapted from CDC "Pink Book," "Epidemiology and Prevention of Vaccine-Preventable Diseases, Tetanus" (available at [https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html](https://www.cdc.gov/vaccines/pubs/pinkbook/tetanus.html) and MMWR 2006, 55(RR-17).
IV. CONTRAINDICATIONS to HyperTET®

None known

V. A. WARNINGS

See page 2.

V. B. PRECAUTIONS

1. Do not give intravenously.

2. The gluteal region should not be used because of the risk of sciatic nerve injury.

3. Live Vaccines

   Ty21a typhoid, yellow fever, LAIV, zoster, and rotavirus vaccines may be administered at any time before, concurrent with, or after administration of any immune globulin, hyperimmune globulin, or intravenous immune globulin (IGIV). Blood (e.g., whole blood, packed red blood cells, and plasma) and other antibody-containing blood products (e.g., immune globulin, hyperimmune globulin, and IGIV) can inhibit the immune response to measles, mumps, rubella and varicella vaccines for ≥3 months. See appendix A on page 10 for specifics.

VI. SIDE EFFECTS AND ADVERSE EVENTS

1. Slight soreness at the injection site.

2. Slight temperature elevation may be noted at times.

3. Sensitization to repeated injections of human immunoglobulin is extremely rare.

4. In the course of routine injections of large numbers of persons with immunoglobulin there have been a few isolated occurrences of angioneurotic edema, nephrotic syndrome, and anaphylactic shock after injection.
VII. OTHER CONSIDERATIONS

1. **Adverse Events**: epinephrine hydrochloride solution (1:1,000) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.  

2. **Military Personnel**: If an adult has a record of military service and does not have records available, providers can assume that the person has received all vaccines recommended by the military at the time of service entry. Serologic testing might be helpful in clarifying immune status if questions remain because at different times and depending on military assignments, there might be interservice and individual differences.  

3. **Immunocompromised**: individuals with altered immunocompetence may have reduced immune responses.  

4. **Nursing Mothers**: All classes of immunoglobulins can be detected in [breast] milk. Immunoglobulins from the mother help to support the infant’s health.  

VIII. STORAGE AND HANDLING

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 971-673-4VFC (4823).  

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Temp</th>
<th>Storage Issues</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>HyperTET® 1</td>
<td>Store at 2°–8°C (36°F–46°F)</td>
<td>Do not use if IG has been frozen. Report to health educator.</td>
<td>No natural rubber latex Available in 250–unit single use syringe without preservative</td>
</tr>
</tbody>
</table>
IX. ADVERSE EVENTS REPORTING

Public providers are to complete the Vaccine Adverse Events Reporting System (VAERS) report online at https://vaers.hhs.gov/reportevent.html

1. Save a copy of the report number for your records
2. Send copies of the report and VAERS ID number to the Oregon Immunization Program Vaccine Safety Coordinator via confidential email at ORVAERS.Reports@state.or.us or fax (971-673-0278).

Private providers are to report events directly to VAERS and can read about options on how to do so at https://vaers.hhs.gov/reportevent.html.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 971.673.0300 and 711 for TTY. For other questions, consult with the vaccine recipient’s primary health care provider or a consulting physician.

Electronic copy of this standing order is available at: http://1.usa.gov/OregonStandingOrders
References


