TEXAS Department of State Health Services

Memorandum

TO: Directors, Health Service Regions
Immunization Program Managers, Health Service Regions
Directors, Local Health Departments
Immunization Program Managers, Local Health Departments

THRU: Jack C. Sims, Manager
Immunization Branch

FROM: Karen Hess, Manager
Vaccine Services Group

DATE: March 31, 2006

SUBJECT: Texas Vaccines for Children Program Updates:
Hepatitis A Vaccine - Age Revision
Hurricane Katrina Eligibility Ending
Prefilled Syringes New Trend - Pneumococcal Conjugate Vaccine (PCV7)
Implementation of Meningococcal Conjugate Vaccine (MCV4)
Measles/Mumps/Rubella/Varicella (MMRV) Vaccine

HEPATITIS A VACCINE- AGE REVISION

In October 2005, the Centers for Disease Control and Prevention (CDC) and the Advisory Committee on Immunization Practices (ACIP) revised the recommendations for the use of inactivated hepatitis A vaccines to include children 12 months of age through 18 years of age. Previously, hepatitis A vaccines were approved for use in children ages two years of age through 18 years of age.

Effective immediately, providers enrolled in the Texas Vaccines for Children (TVFC) program may begin administering the hepatitis A vaccine provided by the Texas Department of State Health Services (DSHS) to children 12 months through 18 years of age. Dosage intervals are listed below. Consult package inserts for additional information regarding hepatitis A vaccine.

Vaccine	Minimum Age (Dose 1)	Minimum interval between Dose 1 to 2
HAVRIX® (Pediatric formulation)	12 months	6 months
VAQTA® (Pediatric formulation)	12 months	6 months

HURRICANE KATRINA ELIGIBILITY ENDING

The CDC has notified state health departments that children displaced by Hurricane Katrina are no longer presumed to be eligible for the VFC. Last September, the CDC declared that children 18 years of age and younger and who were displaced by Hurricane Katrina were eligible for vaccine through the VFC.

While some children and families are still displaced by Hurricanes Katrina and Rita, TVFC providers should resume standard TVFC screening to determine eligibility (i.e., children who are uninsured, Medicaid-eligible, American Indian/Alaska Native, underinsured, or receive insurance through the Children's Health Insurance Plan).

A memo dated December 21, 2005, included a new version of the DSHS Monthly Biological Report (C-33). That memo stated that as of January 1, 2006, it was no longer necessary to document doses administered to individuals displaced by Hurricane Katrina in separate columns.

PNEUMOCOCCAL CONJUGATE VACCINE (PCV7) IN PREFILLED SYRINGES AND NEW MARKET TREND FOR VACCINES

This notice is to inform providers enrolled in the Texas Vaccines for Children (TVFC) program of two separate, but related issues. The first issue is an upcoming change in the packaging of pneumococcal conjugate vaccine (PCV7). The second issue is to notify providers of a shift towards prefilled syringes for other vaccines and the effect this will have on vaccine storage.

Wyeth Pharmaceuticals, the manufacturer of PCV7, has notified the TVFC program that they will be replacing the current single dose vials with prefilled syringes as soon as the inventory of vials is depleted. The syringes will be available in packages of 10 one-dose (0.5 mL) units. Please note that there are no changes to the storage requirements, dosing, and administration of the prefilled syringes as compared to the vials. The CPT code, 90669, will not change.

Several manufacturers are already producing prefilled syringes for other vaccines or have plans to do so in the future. Providers enrolled in the TVFC have also expressed a preference for prefilled syringes over vials in a recent survey. As this trend becomes more prevalent and the option for vials is reduced, providers will need to consider the additional storage space needed in order to maintain equivalent vaccine inventories. High demand seasons, such as back-to-school and influenza season, could pose a challenge with regard to storage space.

Prefilled syringes require needles that are not provided by the manufacturer or the TVFC. Needles will need to be purchased separately by providers. The TVFC will provide notice of packaging changes so that providers can ensure that needles are available and that no missed opportunities occur.

MENINGOCOCCAL CONJUGATE VACCINE (MCV4)

Effective immediately, providers enrolled in the TVFC may begin ordering meningococcal conjugate vaccine (MCV4), Menactra®, using the attached Biological Order Form, C-68. Children who may receive MCV4 must be TVFC-eligible and meet one of the CDC and ACIP criteria for highest risk for meningococcal disease listed below:

- Adolescents aged 11-18 years traveling to countries in which *N. meningitidis* is hyperendemic or epidemic, particularly if contact with the local population will be prolonged.
- Adolescents aged 11-18 years with terminal complement deficiencies and those with anatomic or functional asplenia.
- Adolescents aged 11-18 years who are infected with HIV.
- Adolescents aged 11-12 years old at their preadolescent assessment visit.
- Adolescents at high school entry who were not vaccinated at the preadolescent visit.
- College freshmen who live in dormitories (18 years and younger only).

This vaccine will be implemented as a two-tiered vaccine. Underinsured children may receive this vaccine only if they present for services in a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). Regional and local health departments are encouraged to renew relationships with FQHCs and RHCs that were in place when PCV7 was two-tiered, to determine the nearest referral sites so that underinsured children will have an opportunity to receive this vaccine.

The TVFC strongly recommends administering MCV4 in conjunction with the adolescent dose of Tdap vaccine. The Medicaid billing CPT code for MCV4 is 90734.

Limited MCV4 Vaccine Supply
Sanofi Pasteur, the manufacturer of MCV4, is unable to produce the vaccine in sufficient quantity to vaccinate all of the above-recommended cohorts nationwide. The TVFC will receive a monthly allocation approved by the CDC and will reallocate the vaccine across the state to ensure that every provider receives some vaccine each month. Emergency orders will not be accepted for MCV4 and the TVFC may cut orders to ensure that all providers with need receive some portion of the state's allocation. The supply of this vaccine may not improve significantly for the next two years.

MCV4 Background
MCV4 is similar to meningococcal polysaccharide vaccine (MPSV4) or Menomune®. MPSV4 has never been offered by the TVFC, however, providers in private practice and local health departments may have purchased and used this vaccine independent of the TVFC. Both vaccines prevent the same four serogroups of *Neisseria meningitidis* (A, C, Y and W-135), however, MCV4 provides longer lasting immunity and reduces person-to-person transmission.

In May 2005, the ACIP and the American Academy of Pediatrics (AAP) issued expanded recommendations for the use of meningococcal vaccine. These recommendations can be found at their respective websites (http://www.cdc.gov/mmwr/PDF/rr/rr5407.pdf and http://www.aap.org/advocacy/releases/MengPolicyFinal.pdf).

MEASLES, MUMPS, RUBELLA, AND VARICELLA (MMRV)
Effective immediately, providers enrolled in the TVFC may begin ordering Merck & Co., Inc.'s, combined live attenuated measles, mumps, rubella, and varicella (MMRV) vaccine, ProQuad®. MMRV is approved for children age 12 months to 12 years. MMRV is not indicated for vaccination of children <1 year of age. MMRV should not be administered for the second dose of MMR except when a dose of varicella vaccine is also indicated, or if MMR vaccine is not available at the time the second dose of MMR is indicated.

It is the responsibility of TVFC providers to use their current inventory of varicella vaccine before changing to MMRV. Providers may also choose to continue using the individual MMR and varicella vaccines. The Medicaid billing CPT code for MMRV is 90710.

When reconstituted, MMRV is a clear pale yellow to light pink liquid. Providers should withdraw the entire amount of the reconstituted vaccine from the vial into the same syringe and inject the entire volume. **This vaccine cannot be stored in the refrigerator for up to 72 hours as the traditional varicella vaccine may be. To minimize loss of potency, the vaccine should be administered immediately after reconstitution. Discard reconstituted vaccine if it is not used within 30 minutes.**

For dosage interval information, contraindications, and warnings on MMRV, please refer to the product package insert or the following website:
http://www.merck.com/product/usa/pi_circulars/p/proquad/proquad_pi.pdf.

Storage for MMRV

- MMRV must be stored frozen at an average temperature of 5°F (-15°C) or colder.
- Any freezer (eg., chest, frost-free) that reliably maintains an average temperature of 5°F (-15°C)or colder and has a separate sealed freezer door is acceptable for storing MMRV.
- Protect from light at all times.
- Store diluent separately at room temperature (68°F-77°F or 20°C-25°C). Diluent may also be stored in the refrigerator, but not the freezer.

An updated TVFC Biological Order Form (C-68) and Monthly Biological Report (C-33) are attached. Both forms have been revised to include the MMRV and MCV4. In addition, the order of the vaccines has changed. All vaccines are now listed in alphabetical order on both forms with the exception of the vaccines that ship separately (MMR and MMRV). These vaccines continue to be listed at the bottom of the C-68 form.

If you have additional questions regarding these new procedures, please contact your Health Service Region.

Attachments

cc: Casey S. Blass
Director, Disease Prevention and Intervention Section

Filename:	DPI-006-208 VFC 2006 Changes Memo.doc
Directory:	C:\Documents and Settings\jjamail\Local Settings\Temporary Internet Files\OLK5D3
Template:	C:\Documents and Settings\jjamail\Application Data\Microsoft\Templates\Normal.dot
Title:	Texas Department of Health
Subject:	
Author:	Charles E Bell MD
Keywords:	
Comments:	
Creation Date:	3/31/2006 7:49 AM
Change Number:	2
Last Saved On:	3/31/2006 7:49 AM
Last Saved By:	Bureau of Immunization and Pharmacy Support
Total Editing Time:	2 Minutes
Last Printed On:	4/11/2006 11:23 AM
As of Last Complete Printing	
	Number of Pages: 4
	Number of Words: 1,464 (approx.)
	Number of Characters: 8,346 (approx.)