



North Carolina Department of Health and Human Services
Division of Public Health – Women’s & Children’s Health Section
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Michael F. Easley, Governor

Dempsey Benton, Secretary

September 3, 2008

Memorandum

To: UCVDP Participants

From: Beth Rowe-West, R.N., B.S.N., Head,
Immunization Branch

Re: New Pediatric Vaccines (Kinrix, and Pentacel) Available via UCVDP

Effective immediately, the Universal Childhood Vaccine Distribution Program (UCVDP) will provide Kinrix, and Pentacel alternatives to currently available DTaP, polio, and Hib vaccines universally for children according to ACIP recommendations. The purpose of this memo is to announce the ordering, storage and accountability protocols and eligibility criteria associated with the administration of these vaccines if you should choose to use either of these new vaccines. Kinrix, manufactured by GlaxoSmithKline, is a combination vaccine licensed for only the 4-6 year booster dose of DTaP and polio vaccines. Pentacel, manufactured by sanofi pasteur, is a combination vaccine licensed for a four-dose series of DTaP, polio, and Hib at 2, 4, 6, and 15-18 months of age.

Please review the following documents for more information on the use of these vaccines:

- **Kinrix Package Insert:** http://us.gsk.com/products/assets/us_kinrix.pdf
- **Pentacel Package Insert:** http://www.vaccineshoppe.com/image.cfm?doc_id=10193&image_type=product_pdf
- **CDC Guidance on the use of Pediarix and Pentacel:** <http://www.cdc.gov/vaccines/pubs/downloads/pentacel-guidance.pdf>

Below are some questions and answers regarding the new vaccines their usage and how they will be implemented in North Carolina.

When can I order state-supplied Kinrix and Pentacel?

You can begin ordering immediately. Please allow one to two weeks for delivery of Kinrix. Because Pentacel is a Hib-containing vaccine, supplies are allocated to the State of North Carolina by the Centers for Disease Control and Prevention (CDC). We must process these orders separately and must reduce orders if demand exceeds supply. Please allow at least three weeks for the delivery of Pentacel.

For those providers not using the North Carolina Immunization Registry (NCIR) an order form is attached.

Am I required to use these vaccines?

No. UCVDP will continue to supply DTaP, polio, Hib (in limited quantities), and Pediarix (DTaP-IPV-HBV combination) vaccines. You may use either the vaccines already available and/or Kinrix or Pentacel. However, Pentacel does not relieve the current shortage of Hib vaccine. Therefore, it is possible that you will need to use both Hib products to assure adequate coverage for the children seen in your practice.

Who can receive these vaccines?

Kinrix is available for all children aged 4 through 6 years for the 4-6 year booster dose of DTaP and polio vaccines only.

Pentacel is available to all children as part of their primary series of DTaP, polio, and Hib vaccines. If you choose to use Pentacel, UCVDP recommends that you integrate Pentacel into your practice for children born on or after July 1, 2008, and that children already started on Pediarix or single-antigen vaccines finish the series with those same products. Pentacel is not licensed for and should not be administered to anyone over the age of 4 years.

If I choose to use Kinrix or Pentacel, what should I do with my current inventory of DTaP, polio, Hib, and/or Pediarix vaccines?

It is imperative that you continue to use your current supplies of single-antigen or alternative combination vaccines and not allow these vaccines to expire. If these vaccines expire due to your decision to use state-supplied Pentacel, you will be subject to the Financial Restitution Policy. **Do not destroy, allow to expire or return to the Immunization Branch any viable DTaP, polio, Hib, or Pediarix vaccines.**

If I choose to use Pentacel, can I begin administering the 12-15 month Hib booster?

No. National supplies of PedvaxHIB remain very low, and supplies of ActHIB have declined. The introduction of Pentacel should allow providers to continue administering the primary series of Hib vaccine. However, the Centers for Disease Control and Prevention (CDC) continue to recommend deferral of the 12-15 month booster. Due to those recommendations, Pentacel may **not be used for the 12 -15 month DTaP/Hib booster dose** in otherwise healthy children until further notice. You should administer single antigen DTaP and IPOL for this dose until adequate supplies are available.

How much should I order?

If you choose to use Kinrix or Pentacel please follow these steps before you call the Customer Service Unit to place your order:

Step 1: Consult with your managing/lead physicians to determine how you will use Kinrix or Pentacel in your practice;

Step 2: Count the number of doses of all vaccines in your inventory, especially, DTaP, polio, Hib, hepatitis B, and Pediarix.

The Immunization Branch Help Desk will help you determine how many doses of Kinrix or Pentacel you should order initially. Our goal is to assist you with a smooth transition if you choose to use these new vaccines and to ensure that no vaccine is wasted. **This may mean that you will be unable to order Pentacel or Kinrix until your current supply of vaccines has been reduced.**

Enclosed is an updated vaccine order form. Please destroy all other versions of this form and only use the attached updated version.

- If you choose to use Pentacel, please remember that you will need enough DTaP and polio vaccines (Tripedia, IPOL, or Kinrix) to complete the series for these vaccines since Pentacel may not be used for the 4th dose of IPV and DTaP at this time and is not licensed for the fifth dose of DTaP. Also, if you are reducing your use of Pediarix, you will need to increase your order for hepatitis B vaccine to cover that series. Each vaccine shipment containing Pentacel will include guidance from the CDC to assist providers in incorporating this vaccine into their practice.
- Like other Hib-containing products, doses of Pentacel are limited and allocated to states by the CDC. **Orders of Pentacel may be reduced (possibly cancelled) without notice** until the shortage of Hib vaccine has been resolved. CDC estimates that Merck will be able to bring their Hib vaccine back to market in the fourth quarter of this year.

Are there new Vaccine Information Statements (VIS) for these vaccines?

There is no VIS for Kinrix or Pentacel. Please continue to provide the current VIS for DTaP, polio, and Hib vaccines or the multiple vaccine VIS (designed for the routine birth-6 month shots) as appropriate before administering each dose of Kinrix or Pentacel.

How do I record and report administration of a dose of these vaccines?

For those providers on North Carolina Immunization Registry (NCIR), Kinrix and Pentacel are currently not available for provider inventories. If you wish to implement Kinrix and Pentacel at this time, you must record Kinrix as a historical dose of unbranded DTaP and polio vaccine and Pentacel as a historical dose of DAPTACEL, IPOL, and ActHIB. You should keep a list of children entered in this way so that when the registry has been populated with Kinrix and Pentacel, you can go back to the client and use the correct brand name. Every effort is being made to update NCIR quickly to accommodate the introduction of Kinrix and Pentacel. An announcement will be posted when they are available, and you will be able to contact the Immunization Help Desk to have on-hand, state-supplied doses of Pentacel[®] placed in your inventory.

For those providers not on NCIR, record a dose of Kinrix or Pentacel on your Vaccine Administered Logs (VALs) as a dose of DTaP, IPV, and/or Hib accordingly and write "Pentacel" or "Kinrix" in the notes section.

How do I bill Medicaid for the administration fees for these vaccines?

Although providers cannot bill for the cost of state-supplied vaccines, Medicaid requires that the vaccine CPT[®] codes be reported in the claim for the administration of vaccines. For Pentacel, the CPT[®] code is 90698; for Kinrix, the CPT[®] code is 90696. **Medicaid has asked that providers hold any claims which include these vaccines, pending changes to their billing system.** Please watch for the Medicaid *General Bulletin* announcement that their system is ready to process these claims.

Can Pentacel be used among Native American/Alaskan Native (NA/AN) populations?

Due to reduced immunogenicity of the PRP-T (ActHIB) component among NA/AN populations. The CDC and the American Academy of Pediatrics recommends that for NA/AN infants the first dose of a Hib conjugate vaccine should be PRP-OMP (PedvaxHIB). PRP-OMP remains the preferred Hib vaccine for practices seeing primarily Native American and Alaskan Native populations.



If I am using Pediarix, can I use Kinrix at the four-month visit to avoid giving an extra dose of hepatitis B vaccine?

No. Kinrix is ONLY licensed for the 4-6 year booster of DTaP and polio vaccines. Never use any UCVPD vaccines in any way other than licensed or approved by the ACIP.

Who should I call with questions?

If you have clinical questions not answered in this memo or the FDA's Product Approval Information, please call your Regional Immunization Nurse Consultant.

If you have questions about your current supply of vaccines, ordering state-supplied Pentacel, or the vaccine order form, please call the Immunization Branch Help Desk at 1-877-873-6247.

CC: SMT Joy Reed NC Immunization Branch Ann Nance NCIB Field Services Vaccine Manufacturers Steve Shore Dr. Leah Devlin Maclyn Powell

North Carolina Department of Health and Human Services
Division of Public Health

VACCINE REQUISITION/INVENTORY FORM

Call 1-877-873-6247 to place your order by phone or fax completed form to 1-800-544-3058.

FACILITY NAME _____ CONTACT _____ Fridge Temp this am? _____ Freezer? _____
 SHIPPING ADDRESS _____ FED ID # _____ Will you be closed in the next 30 days? If yes, when? _____
 CITY _____ ZIP CODE _____ DATE _____ Dates: _____
 PHONE NUMBER _____ EXT _____ FAX NUMBER _____ Business Hours: _____ Lunch: _____

Vaccines	Doses Used	Doses X3	Doses on Hand	Vaccine Type	Doses Req	Packaging (check preferred)	Flu Vaccines	Doses Req	Packaging
Pediatric DT				DT		Two dose pk	LAIV FLU VACCINE AVAILABLE ON OR AFTER AUGUST 18, 2008		
DTaP				Tripedia®		One dose vials~10 pk	FluMist®		PF One dose vials~10 pk
Combination Vaccines				Pentacel®		One dose vials~5 pk <input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk	TIV FLU VACCINES AVAILABLE ON OR AFTER SEPTEMBER 15, 2008		
				Kinrix™		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk			
				Pediarix™		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk			
Polio				IPOL®		Ten dose vial			
				Vaqta®		Currently not available			
Hepatitis A Ped				Havrix®		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk	Fluvirin®		Ten dose vial
				Engerix B®		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk	Fluzone® .25 PF syringes		PF One dose syringes~10 pk
Hepatitis B Ped				Recombivax®		One dose vials~10 pk	Fluzone® .50 PF syringes		PF One dose syringes~10 pk
				PedVax®		Currently not available			
				ActHib®		One dose vials~5 pk			
Hib				Gardisil™		One dose vials~10 pk			
HPV				Menactra®		One dose vials~5 pk			
Meningococcal MMR				MMR II®		One dose vials~10 pk			
Pneumococcal Conjugate 7				Prevnar®		One dose syr~10 pk			
Pneumo 23				PPV 23®		Five dose vial			
Rotavirus				RotaTeq®		One dose tubes~10 pk			
				Decavac®		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk			Ten dose vial
Td				Adacel™		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~10 pk			
Tdap				Boostrix®		<input type="checkbox"/> One dose vials~10 pk <input type="checkbox"/> One dose syr~5 pk			
Varicella				Varivax®		One dose vials~10 pk			

***Before giving any state supplied vaccines, see your most recently updated UCVDP Coverage Criteria for proper administration. The criteria can be found on our website at www.immunizenc.com/providers.

***By Federal law, a current Vaccine Information Statement must be given prior to administration of the vaccine, and it must be given out each time the vaccine is given.

Purpose: To request vaccine orders from the Universal Childhood Vaccine Distribution Program
Preparation: Complete original and retain one copy for your records
Distribution: Vaccine orders may be telephoned, faxed, or mailed to:
Telephone: 1-877-873-6247 Fax: 1-800-544-3058
Immunization Branch
1917 Mail Service Center
Raleigh, North Carolina 27699-1917

If an order is faxed or telephoned, do not mail the order. Additional forms may be ordered from the above office.

How to use this form:

1. Review your doses administered data by taking the following steps:
 - a. 1. Total all doses administered from the previous month for each vaccine type.
 2. Compare to last year's doses administered data for the future three months. (i.e. if you are placing an order in May, review April from this year and May, June, July from the previous year.)
 3. Enter the highest of the 4 monthly doses administered in **Total Monthly Vaccine Usage** column.
- b. Multiply **Monthly Usage** column by three to determine the **Three-Month Usage** column.
2. Inventory current stock.
 - a. Rotate stock to ensure vaccines with the shortest expiration dates are used first.
 - b. Enter inventory amounts in the **Doses on Hand** column.
3. Complete your vaccine order:
 - a. Subtract **Doses on Hand** column from the **Three-Month Usage** column.
 - b. Enter the difference in the **Doses Requested** column. Round up to the package size.
 - c. Call or fax your order to the Customer Service staff.

SPECIAL NOTES FOR HANDLING AND STORAGE OF VACCINES

- ◆ DTaP, DT Ped, EIPV, Hep B, Hepatitis A – Hepatitis B Adult, Hib, HPV, IG, Td Adult, Influenza, Pneumococcal Conjugate 7-valent (PCV7), Tdap, Hepatitis A Peds, Rotavirus, FluMist and Pneumococcal Polysaccharide 23-valent (PPV23) should be refrigerated between 36° F to 46° F (2° C to 8° C) with an optimum temperature of 40° F (5° C).
 - ◆ **Never expose refrigerated vaccine to temperatures below 36°F (2° C).**
 - ◆ Varicella and MMRV must be stored at 5°F (-15°C) or colder at all times in a freezer with a separate sealed freezer door. Store Varicella and MMRV at an optimum temperature of 0°F (-20°F) at all times.
 - ◆ Store MMR with Varicella and MMRV. Storing your MMR vaccine in the freezer with your frozen vaccines significantly increases the viability status of the MMR vaccine should you have a power outage or refrigerator malfunction.
 - ◆ Rotate your stock weekly to ensure vaccines with the shortest expiration dates are used first.
 - ◆ **Never** return viable vaccine to UCVDP.
 - ◆ Fill empty space in the refrigerator with jugs of water and line your freezer with gel packs to maintain temperature in the event of a power outage or refrigerator malfunction.
 - ◆ Store refrigerated vaccines on the middle shelf with a thermometer.
 - ◆ Never store vaccine in the door of the refrigerator or freezer.
 - ◆ Maintain a temperature log for the refrigerator and freezer and monitor twice a day – morning and evening.
 - ◆ Notify by either fax or phone if you have transferred vaccine to another provider/health department.
- ***** Your doses administered data is due to the Immunization Branch by the 10th of every month.