

STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Raul Pino, M.D., M.P.H.
Commissioner



Dannel P. Malloy
Governor
Nancy Wyman
Lt. Governor

Immunization Program

TO: Health Care Providers
FROM: Mick Bolduc 
Vaccine Coordinator-Connecticut Vaccine Program (CVP)
DATE: June 1, 2016
SUBJECT: Change in ActHib[®] NDC

The primary purpose of this communication is to inform you of a change to the National Drug Code (NDC) for Sanofi Pasteur's ActHib[®] vaccine.

ActHib[®] NDC Change

Sanofi Pasteur has informed CDC that its ActHIB[®] vaccine will now be manufactured in a new facility and will include a latex-free rubber stopper for the diluent vial.

This change will result in a change to the NDC number on the diluent vial as well as on the unit of sale (carton), which is the NDC number used in VTrckS to submit orders, supporting documents, and returns.

Current NDC: 49281-0545-05

New NDC: 49281-0545-03

Providers should start seeing the new ActHib[®] NDC on orders distributed through the CVP in late June. Attached is a letter that Sanofi will be sending to providers about the change.

As always, if you have any questions, please feel free to contact me at (860) 509-7940.



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May 2016

Dear Health Care Provider:

I am writing to inform you of a required change to our ActHIB[®] (Haemophilus b Conjugate Vaccine [Tetanus Toxoid Conjugate]) National Drug Code (NDC) and updated Prescribing Information (PI), which is a result of a new state-of-the-art facility used to manufacture ActHIB vaccine. In addition, product manufactured in this new facility, specifically the diluent rubber stopper, will no longer contain latex. This change is effective on product that will begin shipping in late May 2016. The NDC number is a unique, three-segment number which serves as a universal product identifier for human drugs. A dose of ActHIB vaccine has 3 separate NDC numbers associated with it: the carton NDC number, and, because it is a reconstituted vaccine, separate NDC numbers for both the vaccine vial and diluent vial. The change is occurring for the carton and the diluent vial, while the vaccine vial is not changing.

Why this change is occurring: The new NDC numbers are a result of a change in the diluent vial, which now does not contain latex. Such changes in manufacturing require Food and Drug Administration (FDA) approval, which results in updated PI and new NDCs.

Coding and Billing: Because CPT^{®a} codes continue to be the primary method for billing immunizations and most payers do not require the use of an NDC, there should be limited impact to coding and billing for your practice. If the payer does not require NDC numbers, there will be no change to billing processes for that payer. If NDC numbers are required by your plans for billing, please ensure you have updated your billing systems to limit any confusion for you and your staff. The CPT code for ActHIB vaccine continues to be 90648.

Payer Claim Systems: We have communicated this change to payers so that those who require NDC numbers will update their systems. We have also asked payers to continue to recognize both the previous and new NDC numbers, as providers will continue to administer product received prior to this change. When an NDC number is required for billing, you should use the NDC number of the actual product you are administering.

Payer Fee Schedules: Sanofi Pasteur is working with pricing publications such as First Data Bank[®] and MediSpan[®] to include the new NDC number. We have asked them to keep all NDC numbers current until product with the previous NDC is expired. There is no change in the price of ActHIB vaccine at this time.

Ordering ActHIB vaccine: Ordering on VaccineShopper.com[®] will remain the same.

Medical Records: The only potential difference you may experience is a change in the digits of the NDC number written in a patient record, if documenting the NDC number is part of your immunization process.

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Below are the previous and new NDC numbers for ActHIB vaccine:

<i>ActHIB Vaccine</i>	<i>Previous NDCs^a</i>			<i>New NDCs - May 2016</i>		
	<i>Carton</i>	<i>Vaccine</i>	<i>Diluent</i>	<i>Carton</i>	<i>Vaccine</i>	<i>Diluent</i>
5 single-dose vials	49281-0545-05	49281-0547-58	49281-0546-05	49281-0545-03	49281-0547-58	49281-0546-58



Should you have questions or require additional information, please contact your Vaccine Specialist, our Customer Account Representatives, or our Reimbursement Support Services at **1-800-VACCINE** (1-800-822-2463). Please visit www.vaccineshoppe.com/NDC for additional NDC and billing resources.

Sanofi Pasteur apologizes for any inconvenience this change may cause, and we appreciate your understanding. We look forward to continuing to serve you and your patients.

Thank You,



Matthew Wilcox
Vice President of Marketing, US

^a CPT (Current Procedural Terminology) is a registered trademark of the American Medical Association.