



NC DEPARTMENT OF
**HEALTH AND
HUMAN SERVICES**

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Division of Public Health

May 2, 2019

MEMORANDUM

TO: North Carolina Immunization Program (NCIP) Participants

FROM: Wendy Holmes, R.N., Head *WH*

SUBJECT: Availability of Heplisav-B and Addition of a Supplemental Coverage Criterion

The purpose of this memo is to announce to NCIP providers the availability of the two-dose series, Hepatitis B vaccine product, Heplisav-B, and to alert participants of a new supplemental coverage criterion.

Beginning May 6, 2019, providers can begin ordering Heplisav-B either via the North Carolina Immunization Registry (NCIR) or by submitting the updated Vaccine Requisition Form located on our website for non-NCIR, VFC providers. Heplisav-B (Dynavax) is approved only for persons **18 years of age and older**. The vaccine is provided in a single dose 0.5 mL vial and given as a 2-dose series with doses separated by at least 1 month. For more information on this product, visit <http://bit.ly/MMWR04202018>. Completion of two doses of Heplisav-B does meet the North Carolina Immunization Law for college entry: <http://bit.ly/Heplisav10232018>. When ordering, consider the minimum age for this product (18 years). Providers are required to only order products in quantities that correspond with their current patient population profile. Those who do not see patients 18 years of age and older should not order this product.

Heplisav-B has been added to the NCIP Coverage Criteria. A new supplemental document has also been added to address the expansion of certain vaccine in special circumstances, such as a disease outbreak, in order to mitigate disease development and spread. Vaccines included within the supplement are time-limited and are only to be administered to the populations as described within the document. The updated coverage criteria can be found here: <http://bit.ly/CoverageCriteria>.

cc: SMT
Elizabeth Hudgins
Central Office Staff

Regional Immunization Consultants
Gregg Griggs

Local Health Directors
Vaccine Manufacturers

NC DEPARTMENT OF HEALTH AND HUMAN SERVICES • Division of Public Health, Immunization Branch

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NORTH CAROLINA IMMUNIZATION PROGRAM (NCIP)
COVERAGE CRITERIA FOR ALL CHILDREN PRESENT IN NORTH CAROLINA
Effective: May 6, 2019

The purpose of this document is to distinguish which cohorts of persons, present in North Carolina, are eligible for vaccine from the North Carolina Immunization Program (NCIP). NCIP vaccine is available for eligible children through the age of 18 in compliance with recommendations made by the Advisory Committee on Immunization Practices (ACIP) and the Vaccines for Children (VFC) program. Exceptions for adult vaccine usages are noted below. Additional exceptions for outbreak control purposes (if applicable) can be found in the NCIP Coverage Criteria Supplement. ACIP recommends certain vaccines for certain cohorts who are not covered by NCIP vaccine. Health care providers must use privately purchased vaccine for those cohorts who wish to have vaccine and are not covered by this coverage criteria. Questions about current recommendations for each vaccine can be found at: <https://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Local Health Departments (LHD); Federally Qualified Health Centers (FQHC) and Rural Health Clinics (RHC) are noted throughout when there is vaccine usage specific to their facilities.

VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
DT Pediatric	≥2 months through 6 years	UNIVERSAL	DT Pediatric can be ordered for any child, >2 months through 6 years, that has a known medical contraindication to any pertussis containing vaccine.
DTaP	≥2 months through 6 years	VFC ONLY	
DTaP, Hep B, and polio combination (Pediatrix®)	≥ 2 months through 6 years	VFC ONLY	
DTaP, polio, and Hib combination (Pentacel®)	≥ 2 months through 4 years	VFC ONLY	
DTaP/IPV combination (Kinrix®; Quadracel®)	≥ 4 years through 6 years	VFC ONLY	Only to be used for children > 4 years through 6 years of age. Kinrix as the 5th dose in the DTaP series, & as the 4th in the IPV series Quadracel as the 5th dose in the DTaP series, & as the 4th or 5th dose in the IPV series.
Hepatitis A Pediatric use	12 months through 18 years	VFC ONLY	Hepatitis A vaccine may be given to children 12 months through 18 years of age who are VFC-eligible only. Hepatitis A vaccine may be given to VFC -eligible infants 6 months through 11 months of age who are traveling to an area of the world except the United States, Canada, Japan, New Zealand, and Australia.
Hepatitis B Pediatric use	Birth through 18 years	VFC ONLY	The birth dose of Hepatitis B vaccine is available universally. Other doses of hepatitis B* vaccine may be given to children through 18 years of age who are VFC-eligible only. LHD Only: ❖ Children through 18 years of age, regardless of insurance status who are household, sexual or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing and vaccination. <i>*Heplisav-B® (two-dose series can be used for eligible individuals 18 years of age and older).</i>
Hepatitis B Pediatric Product (Engerix-B®) (Recombivax®) (Heplisav-B®)	Certain adults 19 years of age	UNINSURED 19 YEARS OF AGE	Any uninsured adult 19 years of age may receive state-supplied Hep B if the first dose of Hep B is administered before the 19th birthday. The series must be complete before the 20th birthday if using state- supplied vaccine. LHD Only: ❖ Uninsured immigrants with refugee status who are from endemic countries who are 19 years of age may receive Hepatitis B vaccine at the LHD. All immigrants with refugee status must be referred to the LHD for testing and vaccination. ❖ Adults 19 years of age, regardless of insurance status, who are household, sexual or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing/vaccination.

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Hepatitis B Adult use	Certain adults ≥ 20 years may receive state- supplied Hep B	ADULT USE	LHD Only: <ul style="list-style-type: none"> ❖ Individuals who are ≥20 years of age, regardless of insurance status, who are household, sexual or needle sharing contacts of an acute or chronic Hepatitis B infected person may receive Hepatitis B* vaccine at the LHD. All household, sexual, or needle sharing contacts of an acute or chronic Hepatitis B infected person must be referred to the LHD for testing and vaccination. ❖ Uninsured immigrants with refugee status who are from endemic countries who are ≥ 20 years of age may receive Hepatitis B vaccine at the LHD. All immigrants with refugee status must be referred to the LHD for testing and vaccination. <p><i>*Heplisav-B® (two-dose series can be used)</i></p>
HepA/HepB Combination (Twinrix®)	≥ 18 years	UNINSURED ADULT USE	LHD/FQHC/RHC Only: <ul style="list-style-type: none"> ❖ Any uninsured adult who meets one or more of the ACIP recommended coverage groups can receive a three-dose series of the combination Hep A/Hep B vaccine at the LHD, FQHC, or RHC. <p>State-supplied Hep A/Hep B vaccine cannot be used for the accelerated schedule, four dose series or for persons with a documented history of a completed hepatitis A or B series.</p>
Hib	≥ 2 months through 4 years	VFC ONLY	Certain high-risk children >59 months through 18 years of age, who are not appropriately vaccinated, may receive one dose.
9vHPV (Gardasil® 9)	Females and males 9 through 18 years	VFC ONLY	State-supplied Gardasil® (9-valent) vaccines for HPV are available for males and females 9 through 18 years of age. The series must be completed prior to the 19th birthday.
Influenza Pediatric use	≥ 6 months through 18 years	VFC ONLY	
Influenza Adult use IIV4 (Fluzone® 0.5 mL pre- filled syringes only)	Certain adults, (19 and older) without insurance	UNINSURED FEMALE ADULT USE	LHD/FQHC/RHC Only: <ul style="list-style-type: none"> ❖ Non-Medicaid, uninsured women who are pregnant during flu season, and receiving services at the LHD, FQHC, or RHC. ❖ Females enrolled in the Be Smart family planning program receiving services at the LHD, FQHC, or RHC.
Meningococcal Conjugate (Menactra®) (Menveo®)	≥ 2 months through 10 years	VFC ONLY	Available for children with high-risk conditions. Menactra® is licensed starting at 9 months of age. Menveo® starts at 2 months of age.
Meningococcal Conjugate (Menactra®) (Menveo®)	11 through 18 years	VFC ONLY	
Meningococcal Conjugate Adult use	Adults 19 years through 22 years	UNINSURED ADULT USE	A single dose of meningococcal vaccine is available for uninsured unvaccinated first year college students <u>living in dormitories</u> .
Meningococcal Serogroup B Bexsero® Trumenba®	10 through 18 years	VFC ONLY	MenB vaccines are recommended & available for children ≥10 through 18 years of age at increased risk of disease . MenB may be administered to adolescents aged 16–18 years of age who are not at increased risk for meningococcal disease based on the provider’s clinical discretion. Follow ACIP guidance.

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VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
MMR Pediatric use	≥ 12 months through 18 years	VFC ONLY	MMR vaccine may be given to children 12 months through 18 years of age who are VFC-eligible only. MMR vaccine may be given to VFC-eligible infants 6 months through 11 months of age who will be traveling internationally.
MMR Adult use	Certain adults (19 and older) without insurance	UNINSURED ADULT USE	<p>One dose of MMR vaccine is available for:</p> <p><u>LHD only:</u></p> <ul style="list-style-type: none"> ❖ Uninsured immigrants with refugee status of any age without documentation of a prior MMR may receive MMR at the LHD. <p><u>LHD/FQHC/RHC only:</u></p> <ul style="list-style-type: none"> ❖ All uninsured susceptible persons without documentation of a prior MMR may receive MMR at the LHD, FQHC, or RHC. <p>Two doses of MMR vaccine are available for:</p> <p>Any uninsured person entering a four-year college or university in North Carolina for the first time, in addition to, any uninsured adults attending any other post-high school educational institutions (i.e. community colleges and technical schools because:</p> <ul style="list-style-type: none"> ❖ Two doses of measles containing vaccine is required by law for all persons born in 1957 or later entering a North Carolina college/university*** for the first time on or after July 1, 1994. ❖ Two doses of mumps are also recommended and available for all uninsured adult students attending post-high school educational institutions (i.e. community colleges and technical schools). <p><u>LHD only:</u></p> <ul style="list-style-type: none"> ❖ All uninsured women ages 19-44 years.
MMRV	≥ 12 months through 12 years	VFC ONLY	
IPV-Polio	≥ 2 months through 17 years	VFC ONLY	
Pneumococcal Conjugate 13-valent (PCV13)	≥ 2 through 59 months	VFC ONLY	
Pneumococcal Conjugate 13-valent (PCV13)	≥ 60 months through 18 years	VFC ONLY	Children >60 months through 18 years with certain high-risk conditions.
Pneumococcal Polysaccharide 23-valent (PPSV23)	≥ 2 years through 18 years	VFC ONLY	Children > 2 years through 18 years with certain high-risk conditions.
Rotavirus	≥ 6 weeks through 7 months	VFC ONLY	
Td Pediatric use	≥ 7 years through 18 years	VFC ONLY	

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VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
Td Adult use	Certain adults (19 and older) without insurance	UNINSURED ADULT USE	Can be given to any uninsured person 19 years of age or older entering a North Carolina college/university*** (where Td is required by NC Immunization Law) for the first time and has not had a booster in 10 years or has not completed the 3 dose primary series. <u>LHD/FQHC/RHC Only:</u> ❖ Any uninsured person 19 years of age or older can receive Td at the LHD, FQHC, or RHC. Can be given to any uninsured person 19 years of age or older being seen in a hospital emergency department for wound management.
Tdap Pediatric use	≥ 7 years through 18 years	VFC ONLY	
Tdap Adult use	Certain adults, (19 and older) without insurance	UNINSURED ADULT USE	One dose of state-supplied vaccine may be administered to any uninsured adult for whom Tdap is indicated. <u>LHD only:</u> ❖ State-supplied Tdap may be administered to uninsured pregnant women 19 years and older (at any time during pregnancy regardless of prior vaccine history of Tdap, but preferably between 27-36 weeks' gestation). In addition, uninsured postpartum women 19 years and older may receive one dose of state supplied Tdap if there is no documentation of a previous Tdap vaccination. Both pregnant and postpartum women must be being served by the LHD in any capacity.
Varicella (Chickenpox)	≥ 12 months through 18 years	VFC ONLY	
Varicella (Chickenpox)	Certain adults, (19 and older) without insurance	UNINSURED FEMALE ADULT USE	<u>LHD Only:</u> ❖ One dose of varicella vaccine is available for uninsured women ages 19 through 44 years at the LHD.

VFC- Vaccines for Children: Children birth through 18 years of age that meet at least one of the following criteria are eligible for VFC vaccine:

- Medicaid enrolled - a child who is eligible or enrolled in the Medicaid program.
- Uninsured - a child who has no medical insurance coverage
- American Indian or Alaskan Native
- Underinsured (Can only be served by deputized providers such as LHD/FQHC/RHC). Underinsured includes:
 - Children who have commercial (private) health insurance but the coverage does not include vaccines,
 - Children whose insurance covers only selected vaccines (VFC-eligible for non-covered vaccines only),
 - Children whose insurance caps vaccine coverage at a certain amount - once that coverage amount is reached, these children are categorized as underinsured

Children who are covered by North Carolina Health Choice (NCHC) are considered insured, with one exception: NCHC children who are American Indian or Alaskan Native are eligible for VFC vaccines. **Note:** Children whose health insurance covers vaccinations are not eligible for VFC vaccines, even when a claim for the cost of the vaccine and its administration would be denied for payment by the insurance carrier because the plan's deductible had not been met or because the insurance did not cover the total cost of the vaccine

Health Care Sharing Ministries (HCSM)

HCSMs are nonprofit alternatives to purchasing health insurance from private, for-profit insurers. VFC eligibility depends primarily on recognition of the plan as insurance by the state. A child with this type of plan should be considered:

- Uninsured if the plan is not recognized as insurance by the North Carolina Department of Insurance (NCDOI)
- Insured if plan is recognized by the NCDOI and covers all ACIP-recommended vaccines
- Underinsured if plan is recognized by the NCDOI and does not cover all ACIP-recommended vaccines

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Providers are responsible for verifying the insurance plan with NCDOI prior to administration of VFC vaccine.

****ACIP Recommendation Highlights** The ACIP recommendations for each vaccine are located on the CDC website at <http://www.cdc.gov/vaccines/hcp/acip-recs/index.html>. Full and final recommendations are published as MMWR Recommendations and Reports. Updates are often sent out as Provisional Recommendations with the most pertinent information included before the final recommendations are released. There is also separate documentation for **Contraindication/Precautions** for all vaccines on the CDC web site at: <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html>.

*****Students attending colleges within the North Carolina Community College System are exempt from North Carolina Immunization Law for college/university entry. However, some programs at community colleges, such as medical programs, may have requirements specific to their program, but this does not allow them to receive state supplied vaccine unless it is specifically stated in the coverage criteria.**

*****LHD/FOHC/RHC only:** Persons covered by the Be Smart Family Planning Program are considered uninsured and may receive certain state-supplied vaccines as noted in this coverage criteria for uninsured adults if receiving services at a Local Health Department, Federally Qualified Health Center, or Rural Health Clinic. Unaccompanied minors (through 18 years of age) without proof of insurance presenting to a local health department Title X clinic can also be vaccinated with VFC vaccines.

Local health departments (LHD) who are considering using VFC vaccine for offsite clinics, must contact the Immunization Branch for specific guidance prior to scheduling the clinic. Proper storage and handling is critical at all times.

Unless specifically stated above, no NCIP vaccine may be administered to an insured individual unless the patient is an underinsured child at an FQHC, RHC, LHD, or deputized provider.

VFC vaccine cannot be used for allergy skin testing prior to vaccination.

**NORTH CAROLINA IMMUNIZATION PROGRAM (NCIP)
COVERAGE CRITERIA SUPPLEMENT FOR OUTBREAK
RESPONSE/PREVENTION**

Effective: May 6, 2019 until further notice, unless otherwise stated below

VACCINE	AGES COVERED	ELIGIBILITY	CRITERIA FOR NCIP VACCINE USAGE
Hepatitis A Adult use	Certain adults ≥ 19 years	UNIVERSAL	<p><u>LHD Only:</u></p> <ul style="list-style-type: none"> ❖ A single dose of Hepatitis A vaccine is available for adults 19 years of age and older, regardless of insurance status, who meet one or more of the following high risk-categories: <ul style="list-style-type: none"> – Persons who use injection and/or non-injection drugs; – Persons who are homeless; – Men who have sex with men; – Persons with chronic liver disease, including chronic hepatitis B or C; – Persons who are currently incarcerated in a county-owned facility/jail.
Hepatitis A Pediatric use	Certain adolescents, through 18 years	UNIVERSAL	<p><u>LHD Only:</u></p> <ul style="list-style-type: none"> ❖ A single dose of Hepatitis A vaccine is available for adolescents 18 years of age and younger, regardless of insurance status, who meet one or more of the following high-risk categories: <ul style="list-style-type: none"> – Persons who use injection and/or non-injection drugs; – Persons who are homeless; – Men who have sex with men; – Persons with chronic liver disease, including chronic hepatitis B or C; – Persons who are currently incarcerated in a county-owned facility/jail.
Td/Tdap	Certain individuals ≥ 7 years	UNIVERSAL	<p><u>LHD Only:</u></p> <ul style="list-style-type: none"> ❖ A single dose of Td or Tdap vaccine is available for the following individuals, regardless of insurance status, as indicated by ACIP through May 31, 2019: <ul style="list-style-type: none"> – Emergency response workers and individuals at increased risk for tetanus due to puncture wounds and/or exposure to flooding as part of Hurricane Florence response efforts. – NC Department of Transportation emergency response workers.

Key Points:

- For routine vaccination, see the full Coverage Criteria for eligibility requirements.
- Only one dose is available as part of these statewide initiatives.
- Vaccine availability is time limited. The NCIP will update all VFC-enrolled providers when expansion campaigns end.