Hepatitis B Immunization Protocol

NAME AND STRENGTH OF VACCINE TO BE USED

HepB Vaccine / Age group	Dose	Route
Recombivax HB		IM
Children and adolescents aged 7-19 yrs	5 mcg (0.5 mL)	
Adults aged ≥20 yrs	10 mcg (1 mL)	
Adults on hemodialysis and other immunocompromised adults aged ≥20 yrs	40 mcg (1 mL)	
Engerix-B		
Children and adolescents aged 7-19 yrs	10 mcg (0.5 mL)	
Adults aged ≥20 yrs	20 mcg (1 mL)	
Adults on hemodialysis and other immunocompromised adults aged ≥20 yrs	40 mcg (2 mL)	
Heplisav-B		
Adults aged ≥18 yrs	20 mcg (0.5 mL)	
PreHevbrio (ACIP-recommended in 2022)		
Adults aged ≥18 yrs	10 mcg (1 mL)	

INTENDED AUDIENCE AND PATIENT POPULATION

A) Unvaccinated persons age 7 through 18 should complete a series of Recombivax HB or Engerix-B

B) Hepatitis B vaccination is universally recommended for all adults aged 19-59 years

C) Adults aged 60 years or older with risk factors for hepatitis B:
   a. Persons at risk for infection by sexual exposure
      i. Men who have sex with men
      ii. Persons who are sexually active and not in a long-term, mutually monogamous relationship (e.g., persons with >1 sex partner during the previous 6 months)
      iii. Sex partners of HBsAg-positive persons
      iv. Persons seeking evaluation or treatment for a sexually transmitted infection (STI)
   b. Persons at risk for infection by percutaneous or mucosal exposure to blood
      i. Current or recent injection drug users
      ii. Household contacts of HBsAg-positive persons
      iii. Residents or staff of an institution for persons with developmental disabilities
      iv. Health care personnel and others at occupational risk of infection through exposure to blood or blood-contaminated body fluid

v. Persons on maintenance dialysis, including in-center or home hemodialysis and peritoneal dialysis, and persons who are predialysis
vi. Persons with diabetes at the discretion of the treating physician

c. Others
i. International travelers to countries with high or intermediate levels of endemic hepatitis B virus infection (HBsAg prevalence of ≥2%)
ii. Persons with chronic liver disease including, but not limited to, hepatitis C virus infection, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, and ALT or AST level greater than twice the upper limit of normal
iii. Persons with HIV infection
iv. Persons who are inmates of long-term correctional facilities

D) Anyone age 60 years or older without known risk factors for hepatitis B may still receive hepatitis B vaccines

PRECAUTIONS AND CONTRAINDICATIONS

1. A history of severe allergic reactions (e.g. anaphylaxis) after a previous dose of hepatitis B vaccine or to a hepatitis B vaccine component (including baker's yeast).

2. Moderate or severe acute illness with or without fever.

3. Pregnancy is not a contraindication to vaccination. Available vaccines containing noninfectious HBsAg and should cause no risk of infection to the fetus. Data on Heplisav-B and PreHevbrio are currently insufficient to inform vaccine-associated risks in pregnancy. Providers should vaccinate pregnant persons needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix.

SIDE EFFECTS AND ADVERSE REACTIONS

(A) Injection site reactions include: soreness, pain, tenderness, pruritis, erythema, ecchymosis, swelling, warmth, and nodule formation.

(B) Mild to moderate fever, fatigue, weakness, headache, malaise

(C) Anaphylaxis and symptoms of immediate hypersensitivity reactions including rash, pruritus, urticaria, edema, angioedema, dyspnea, chest discomfort, bronchial spasm, palpitation, or symptoms consistent with a hypotensive episode have been reported within the first few hours after vaccination. An apparent hypersensitivity syndrome (serum-sickness-like) of delayed onset has been reported days to weeks after vaccination, including: arthralgia/arthritis (usually transient), fever, and dermatologic reactions such as urticaria, erythema multiforme, ecchymoses and erythema nodosum.

ADMINISTRATION

(A) Standard Schedule using appropriate dose listed on page 1

Hep B Vaccine* / Age group	Schedule
Recombivax HB	
7-19 yrs	3 doses at 0, 1, and 6 mos
≥20 yrs	3 doses at 0, 1, and 6 mos
Adults on hemodialysis and other immunocompromised adults aged ≥20 yrs	3 doses at 0, 1, and 6 mos
Engerix-B	
7-19 yrs	3 doses at 0, 1, and 6 mos
≥20 yrs	3 doses at 0, 1, and 6 mos
Adults on hemodialysis and other immunocompromised adults aged ≥20 yrs	4 doses at 0, 1, 2, and 6 mos (dose administered as a single 2-mL injection or two 1-mL injections)
Heplisav-B	
≥18 yrs	2 doses at 0 and 1 mos
PreHevbrio (ACIP-recommended in 2022)	
≥18 yrs	3 doses at 0, 1, and 6 mos

*Minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 8 weeks / dose 1 to dose 3: 16 weeks
*Doses considered valid if administered ≤4 days before the minimum interval or age

Note: Post-vaccination serology testing and revaccination (if anti-HBs < 10 mlU/mL) is recommended for certain populations such as: infants born to HBsAg-positive mothers, health care providers, hemodialysis patients

(B) Alternative Schedules:

1. **Schedule for those who have fallen behind:** If the series is delayed between doses, DO NOT RESTART the series. Continue from where the schedule was interrupted. 3-dose series can be started at any age.

2. **Alternative dosing schedule for unvaccinated adolescents age 11 through 15 years**: Give 2 doses Recombivax HB 1.0 mL (**adult formulation** 10 µg/mL) spaced 4–6 months apart. (Engerix-B is not licensed for a 2-dose schedule.)

    a. When scheduled to receive the second dose, persons aged ≥16 years should be switched to the 3-dose series, with doses 2 and 3 consisting of the pediatric formulation administered on an appropriate schedule.

(B) Procedure

(1) Prescription is required for patients who are seven years of age or older but not more than 13 years of age. (per Ohio Revised Code 4729.41)

(2) Patient or legal guardian must first sign a consent form before the vaccination is administered.

(3) Provide patient/legal guardian with a copy of the most current federal Vaccine Information Statement (VIS) for hepatitis B vaccine.

(4) Inject the appropriate dose of Hepatitis B vaccine (see above for dosage according to age group) **intramuscularly** into the thickest point of a relaxed **deltoid** muscle. Most patients will receive 25 gauge, 1-inch needle. For patients weighing less than 130 lbs [60 kg], a 5/8-inch needle may be used for injection in the deltoid muscle only if the subcutaneous tissue is not bunched and the injection is made at a 90-degree angle. For obese patients, a 1½ -inch needle will be used.

(5) Give with caution to persons on anticoagulant therapy or with bleeding tendencies. After giving the injection, apply steady pressure to the injection area.

(6) Dispose of all supplies properly.

(7) Record the date of administration, name/manufacturer/strength/dose of the immunization, lot number and expiration date of the immunization, route of administration, location of the injection site, and positive identification of the person administering the vaccine.

(8) Monitor patients in the general vicinity of the administering pharmacist or pharmacy intern for at least **10 minutes** after giving the injection and treat accordingly.

(9) Advise patient to report any adverse reaction to their pharmacist or primary care physician.

(C) Monitoring Parameters

(1) Patients who faint should be placed supine. Check their pulse and blood pressure immediately.

(2) Watch for rapidly falling blood pressure, difficulty breathing, sustained unconsciousness. Observe for adequate airway and pulse; administer CPR if needed. Have another member of the pharmacy staff call 911. Follow procedures in next section for treatment of severe allergic/anaphylactic reactions.

(3) Treat externally for shock. Keep patient warm, head low and feet elevated.

(4) Contact protocol physician as soon as possible to report the condition of the patient.

PROTOCOL FOR MANAGEMENT OF SEVERE ALLERGIC/ANAPHYLACTIC REACTIONS

(A) Pre-Vaccination Procedures

(1) Be prepared to call 911.

(2) Take a thorough history for allergies and prior adverse events before any immunization.

(3) Allow adequate physical space for fainting or collapse without injury and to lay patient flat on a hard surface in the event CPR is needed.

(4) Maintain current competency in vaccine administration and in cardiopulmonary resuscitation; observe all vaccinees for at least 10 minutes after immunization; remind vaccinees to report any adverse events to you.

(B) Supplies to Stock

(1) Epinephrine USP, 1 mg/ml (1:1000). May be in vials of solution, *Ana-Guard* syringes, or in an *Epi-Pen* (0.15 mg & 0.3 mg). At least three adult and children's doses of epinephrine will be available wherever immunizations are given.

(2) Diphenhydramine liquid and injection

(3) Blood-pressure cuff, adult size, with stethoscope

(C) Recognition of Anaphylactic Reaction

(1) Sudden onset of itching, redness, with or without hives, within several minutes of administering a medication. The symptoms may be localized or generalized.

(2) Angioedema (swelling of the lips, face, throat)

(3) Bronchospasm

(D) Emergency treatment

(1) If itching and swelling are confined to the extremity where the immunization was given, observe patient closely for a suitable period of time, watching for generalized symptoms. If none occur, go to paragraph D(8).

(2) If symptoms are generalized, activate the emergency medical system (EMS). Call 911 **and** the protocol physician for instruction. This should be done by a second person, while the immunizer treats and observes the patient.

(3) Administer epinephrine IM (refer to dosing chart). Standard dose is 0.01mg/kg up to 0.5 mg maximum in adults. Site of administration can be the anterolateral thigh if using auto-injector, or deltoid muscle above the vaccine injection site.

(4) Administer diphenhydramine by IM injection (refer to dosing chart). DO NOT administer diphenhydramine or any other drug by mouth if the patient is not fully alert or if the patient has respiratory distress.

(5) Monitor the patient closely until EMS arrives. Perform CPR and maintain airway, if necessary. Keep patient in supine position unless they are having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. Monitor vital signs frequently.

(6) If EMS has not arrived and symptoms still persist, repeat dose of epinephrine every 10-20 minutes for up to 3 doses, depending on patient response.

(7) Record all vital signs, medications administered to the patient, including the time, dosage, response, and other relevant clinical information.

(8) Patient must be referred for medical evaluation, even if symptoms resolve completely. Symptoms may recur after epinephrine and diphenhydramine wear off, as much as 24 hours later. After the event is concluded, complete a VAERS form. Report forms may be obtained online at www.vaers.hhs.gov or by calling 1-800-822-7967.

Suggested Dosing of Epinephrine and Diphenhydramine				
Age Group Dose	**Weight * in kg**	**Weight * in lbs**	**Epinephrine Dose**** 1 mg/mL injectable (1:1000 dilution) intramuscular	**Diphenhydramine (Benadryl)** 12.5 mg/5 mL liquid 25 and 50 mg capsules or tablets 50 mg/mL injectable
1-6 mos	4-7 kg	9-15 lbs	0.05 mg (0.05 ml)	5 mg
7- 18 mos	7-11 kg	15-24 lbs	0.1 mg (0.1 ml)	10 mg
19-36 mos	11-14 kg	24-31 lbs	0.15 mg (0.15 ml)	15 mg
37-48 mos	14-17 kg	31-37 lbs	0.15 mg (0.15 ml)	20 mg
49-59 mos	17-19 kg	37-42 lbs	0.2 mg (0.2 ml)	
5-7 yrs	19-23 kg	42-51 lbs	0.2 mg (0.2 ml)	30 mg
8-10 yrs	23-35 kg	51-77 lbs	0.3 mg (0.3 ml)	
11-12 yrs	35-45 kg	77-99 lbs	0.4 mg (0.4 ml)	40 mg
13 yrs & older	45+ kg	99+ lbs	0.5 mg (0.5 ml)	50-100 mg

*Dosing by body weight is preferred
**Epinephrine can also be administered using an autoinjector available in 0.15 mg and 0.3 mg doses. Children weighing 15 to 30 kg should receive 0.15 mg if given by autoinjector.

ACCIDENTAL NEEDLE STICK

(A) Procedures

(1) Wash needle stick site with soap and water.

(2) Report the exposure to the physician on the protocol. Prompt reporting is essential because, in some cases, post-exposure treatment may be recommended and it should be started as soon as possible. **The National Clinicians' Post Exposure Prophylaxis Hotline (PEPline) has current recommendations (888.448.4911).**

(3) Discuss risks of acquiring HBV, HCV, HIV and the need for post-exposure treatment with the provider managing your exposure.

(4) Person giving the vaccination should already have received the Hepatitis B vaccine (extremely safe and effective).

(5) Follow-up testing should be available to all workers concerned about possible infection through occupational exposure.

(B) Treatment of Exposure

HCV - no treatment available

HBV - Post-exposure treatment of HBV is highly effective in preventing infection. Treat exposure as soon as possible after exposure, preferably within 24 hours and no later than 7 days after exposure. Hepatitis B vaccine and hepatitis B immune globulin (HBIG) are both approved for treatment use. If any symptoms suggesting HBV infection develop, patient should contact a physician.

HIV - Start as soon as possible, ideally within 72 hours of exposure. Benefit of treatment delayed beyond 72 hours is not defined. No medications are FDA-approved for prevention. Pharmacist will follow current HIV prevention guidelines recommended by CDC. Truvada® (emtricitabine and tenofovir disoproxil fumarate) plus Isentress® (raltegravir) OR Truvada® plus Tivicay® (dolutegravir) are recommended for 28 days with repeated testing to confirm HIV negative status.

Precautions During Follow-Up

HBV – no precaution recommended

HCV – low risk, so no precautions are recommended

HIV -- 6-12 weeks is when most of the signs and symptoms of infection show. Do not donate blood, semen, or organs during this time. Do not have sexual intercourse during this time, or else use a condom consistently and correctly. Women should not breast feed. HIV is transmitted through breast milk.

See page 8 for Physician Authorization

Administration of the Hepatitis B vaccine, under the direction of the physician who signed below, may be performed by the following individuals:

_____ _____ _____

_____ _____ _____

Administration of the Hepatitis B vaccine, under the direction of the physician who signed below, may be performed at the following location(s) including street address(es):

_____

_____

As the authorizing physician, I will review, on a biennial basis, the activities of the health care providers administering the vaccine under this protocol.

Date: _____
*MUST BE RENEWED WITH PHYSICIAN ON A BIENNIAL BASIS

Physician Signature: _____

Physician Name: _____

Address: _____

City: _____ State: _____ Zip:_____

Medical License #: _____

Pharmacist in Charge Name_____

Pharmacist in Charge Signature_____

Date_____ Pharmacist in Charge License #_____

Pharmacy Name_____

Pharmacy Address_____

City_____ State_____ Zip_____

PHYSICIAN/BOARD OF HEALTH NOTIFICATION
Notify the individual's primary care physician, or if the individual has no family physician, the County Board of Health of the district in which the individual lives, within 30 days after administering the immunization; document accordingly.