

ACCESS & REIMBURSEMENT GUIDE



THE FIRST AND ONLY 2-DOSE HEPATITIS B VACCINE
FOR ADULTS ≥ 18 YEARS^{1,2}

2 doses –in– **1** month

INDICATION







HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (eg, anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Please see additional Important Safety Information on page 3 and accompanying full Prescribing Information.


CONTENTS

	Indication and Important Safety Information	3
	Quick-reference coding guide	4
	Submitting claim forms	5
	Tips for submitting claims.	6
	Appeals information.	7
	HEPLISAV-B Access Navigator™	8

Order HEPLISAV-B today

Please call 1-84-HEPLISAV (1-844-375-4728) for information on ordering, including a list of authorized distributors.

For reimbursement information:



Call **HEPLISAV-B Access Navigator™***
at 1-84-HEPLISAV (1-844-375-4728)
for coverage and reimbursement support
8 AM to 8 PM, ET, Monday through Friday
HeplisavB.com

*While many health insurance plans provide coverage for HEPLISAV-B, the type and level of coverage can vary. Any information provided by HEPLISAV-B Access Navigator is intended as a guideline only, and is not a guarantee of coverage. All claims are subject to individual plan coverage, guidelines, and submission of the actual claim. Coverage and reimbursement amounts are specific to the individual plan that a member or their employee has purchased, as well as the negotiated contract for each provider. Each plan decides its own reimbursement rate, which varies based on plan and patient group. Dynavax suggests that you contact the individual plan to determine reimbursement.

Please see Important Safety Information on page 3 and accompanying full Prescribing Information.

INDICATION

HEPLISAV-B is indicated for prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older.

IMPORTANT SAFETY INFORMATION

Do not administer HEPLISAV-B to individuals with a history of severe allergic reaction (eg, anaphylaxis) after a previous dose of any hepatitis B vaccine or to any component of HEPLISAV-B, including yeast.

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of HEPLISAV-B.

Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to HEPLISAV-B.

Hepatitis B has a long incubation period. HEPLISAV-B may not prevent hepatitis B infection in individuals who have an unrecognized hepatitis B infection at the time of vaccine administration.

The most common patient-reported adverse reactions reported within 7 days of vaccination were injection site pain (23%-39%), fatigue (11%-17%), and headache (8%-17%).



QUICK-REFERENCE CODING GUIDE

The table below provides a brief overview of relevant billing and coding information for HEPLISAV-B, presented in greater detail with the sample CMS-1500 form

Type	Code	Description
CPT®* Drug Code	90739	Hepatitis B vaccine, adult dosage 2-dose schedule, for intramuscular use
CPT Administration Code	90471	Immunization administration (includes percutaneous, intradermal, subcutaneous, or intramuscular injections); 1 vaccine (single or combination vaccine/toxoid)
HCPCS (Administration code for Medicare Part B)	G0010	Administration of hepatitis B vaccine
10-Digit NDC Number	43528-002-01	Single vial, 1 dose, 0.5 mL Package of 5 single-dose vials
	43528-002-05	
	43528-003-01	Prefilled Syringe, 1 dose (0.5 mL) Package of 5 single-dose prefilled syringes
	43528-003-05	
11-Digit NDC Number	43528-0002-01	Single vial, 1 dose, 0.5 mL Package of 5 single-dose vials
	43528-0002-05	
	43528-0003-01	Prefilled Syringe, 1 dose (0.5 mL) Package of 5 single-dose prefilled syringes
	43528-0003-05	
ICD-10-CM	Z23	Encounter for immunization
MVX Code	DVX	Dynavax
CVX Code	189	Hepatitis B vaccine (recombinant), adjuvant

Please note for TRICARE:

- The correct NDC number for reimbursement is on the package, not the vial/prefilled syringe
- Be sure to enter the 11-digit NDC number (the one with the extra “0”) on the claim form

CMS=Centers for Medicare and Medicaid Services; CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification, 7th ed.; NDC=National Drug Code.

*CPT is a registered trademark of the American Medical Association (AMA).

SUBMITTING CLAIM FORMS

Use this guidance when submitting claims for HEPLISAV-B in the office/noninstitutional setting (CMS-1500 form). First, complete the top half of the claim form with the patient’s information. Then, fill in the product and diagnosis codes in the sections indicated in the sample form below

HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

1. MEDICARE MEDICAID TRICARE CHAMPVA GROUP HEALTH PLAN FECA BLK (LUNG) OTHER

2. PATIENT'S NAME (Last Name, First Name, Middle Initial)

3. PATIENT'S BIRTH DATE

4. INSURED'S NAME (Last Name, First Name, Middle Initial)

5. PATIENT'S ADDRESS (No., Street)

6. PATIENT RELATIONSHIP TO INSURED

7. INSURED'S ADDRESS (No., Street)

8. RESERVED FOR NUCC USE

9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)

10. IS PATIENT'S CONDITION RELATED TO:

11. INSURED'S POLICY GROUP OR FECA NUMBER

12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE

14. DATE OF CURRENT ILLNESS, INJURY, OR PREGNANCY (LMP)

15. OTHER DATE

16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION

17. NAME OF REFERRING PROVIDER OR OTHER SOURCE

18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

20. OUTSIDE LAB?

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Indicate A-L to service line below (24E))

22. SUBMISSION CODE

23. PRIOR AUTHORIZATION NUMBER

24. DATES OF SERVICE

25. FEDERAL TAX I.D. NUMBER

26. PATIENT'S ACCOUNT NO.

27. ACCEPT ASSIGNMENT?

28. TOTAL CHARGE

29. AMOUNT PAID

30. Rev'd for NUCC Use

31. SIGNATURE OF PHYSICIAN OR SUPPLIER

32. SERVICE FACILITY LOCATION INFORMATION

33. BILLING PROVIDER INFO & PH #

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TIPS FOR SUBMITTING CLAIMS

- ✓ Verify that CPT code 90739 has been added to your payer contracts
- ✓ Ensure that your NPI number is verified against CPT code 90739
- ✓ Keep complete, legible, and easily accessible records
- ✓ Confirm the accuracy of both clinician- and patient-supplied information
- ✓ Rationale for services should be documented or easily inferred
- ✓ When reporting NDCs per individual payer requirements, NDCs must be documented in an 11-digit format. For HEPLISAV-B, this involves adding a “0” immediately after the first hyphen in each NDC. Please note that on the CMS-1500 claim form, no spaces or hyphens should be used when adding an NDC
- ✓ Communicate with appropriate payer contacts to determine plan-specific requirements
- ✓ Monitor the first few claims submitted to each plan to learn about the plan’s claim and reimbursement processes, and apply the knowledge to future claims

Private payer reimbursement varies and is based on the rate contracted with the provider

- ✓ Review your contracts to understand how each of the payers you work with reimburses
- ✓ Consider setting up your electronic medical records system to prepopulate appropriate claims information by payer

Additional tips for Medicare patients

- ✓ Medicare pays for hepatitis B vaccinations for individuals considered to be at high or intermediate risk. Consult Medicare’s coverage criteria for high or intermediate risk to determine your patient’s eligibility for HEPLISAV-B
- ✓ If your Medicare patient does not fall within the Medicare coverage criteria, an Advanced Beneficiary Notice prior to administering treatment may be required

ADDITIONAL RESOURCES

- Sample CMS-1500 forms can be accessed and downloaded from the CMS website: <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1500.pdf>
- Please see the CMS website for information on adult immunization resources for providers, coverage, billing, and more: CMS.gov or <https://www.cms.gov/Medicare/Prevention/Immunizations/Providerresources.html>

Please see Important Safety Information on page 3 and accompanying full Prescribing Information.

APPEALING DENIED CLAIMS

The Affordable Care Act grants the right to ask insurers to reconsider a denied claim or to appeal their decision. Make sure to take these important steps before beginning a formal appeals process:

- Understand the reason for denial
- Investigate the appeals guidelines
- Verify eligibility and reimbursement amounts with the health plan
- Get the phone contact information

APPEALS CHECKLIST

You may need to include certain forms and documents in an appeals package if an insurer denies treatment to your patient


- Each insurer and each patient might need different information

Please review each denial and the insurer’s guidelines to determine what to include in your patient’s appeals package

- ✓ Letter of Medical Necessity
 - Download sample letter at [HeplisavB.com](https://www.heplisavb.com)
- ✓ Copy of the patient’s health plan or prescription card (front and back)
- ✓ Letter of Appeal
 - Download sample letter at [HeplisavB.com](https://www.heplisavb.com)
- ✓ Denial information, including the patient’s denial letter or Explanation of Benefits (EOB) letter
- ✓ Supporting documentation

If the patient’s insurer has not responded within 30 to 60 days of receipt of the appeals package, contact the insurer to find out its status

- ✓ Keep a copy of everything you send with the patient’s appeal
- ✓ Keep a log of every phone call you make to the patient’s insurer
- ✓ Write down the date and the name of the person you spoke with



Call **HEPLISAV-B Access Navigator™**
at 1-84-HEPLISAV (1-844-375-4728)
for coverage and reimbursement support
8 AM to 8 PM, ET, Monday through Friday
[HeplisavB.com](https://www.heplisavb.com)



HEPLISAV-BTM

Hepatitis B Vaccine (Recombinant), Adjuvanted

ACCESS NAVIGATOR

HERE TO HELP WITH YOUR COVERAGE AND REIMBURSEMENT QUESTIONS, INCLUDING:



Billing and coding guidelines



Information on payer coverage and reimbursement



Sample claim form information



Guidance on payer authorization and appeal process



Tips for submitting claims

Call HEPLISAV-B Access NavigatorTM
at 1-84-HEPLISAV (1-844-375-4728)
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HeplisavB.com

References: 1. HEPLISAV-B [package insert]. Berkeley, CA: Dynavax Technologies Corporation; 2017. 2. Centers for Disease Control and Prevention. Recommended immunization schedule for adults aged 19 years or older, United States, 2017. <https://www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf>. Accessed October 5, 2017.

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July 2018

US-18-00-00017

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