Coding and Billing Guide

for VYJUVEK™ (beremagene geperpavec-svdt)

($5x10^9$ PFU/mL) biological suspension mixed with excipient gel for topical application

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information**.

VYJ-2300036

INDICATION AND USAGE

VYJUVEK™ (beremagene geperpavec-svdt) is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Accidental Exposure to VYJUVEK gel: VYJUVEK will not replicate in the subject's cells and does not integrate into the subject cells' native genetic material. For precautions, avoid direct contact with treated wounds (e.g., touching or scratching) and dressings of treated wounds for approximately 24 hours following treatment. Wear protective gloves when assisting subjects with changing wound dressings and handling the disposal. In the event of accidental exposure (e.g., through a splash to the eyes or mucous membranes), flush with clean water for at least 15 minutes.

Clean all surfaces that may have come in contact with VYJUVEK biological suspension or gel and treat all spills with a virucidal agent.

Dispose all materials (e.g., vial, syringe, needle, cleaning materials) that may have come in contact with VYJUVEK biological suspension or gel into a biohazard bag or container.

ADVERSE REACTIONS

The most common adverse reactions (>5%) were itching, chills, redness, rash, cough, and runny nose.

Purpose of This Guide

This Coding and Billing Guide for Vyjuvek is intended to support medically appropriate patient access by providing general information on coding, coverage, billing, and reimbursement to healthcare providers (HCPs) and their staff who prescribe and administer Vyjuvek.

Disclaimer

The content provided in this guide is for informational purposes only. It is not intended as legal advice or to replace an HCP's professional judgment. It is the sole responsibility of the treating HCP to confirm coverage, coding, and claim-submission guidance with the patient's health insurance plan to ensure Vyjuvek claims are accurate, complete, and supported by documentation in the patient's medical record.

Krystal Biotech, Inc., does not guarantee coverage or reimbursement for Vyjuvek or that payers will consider all codes appropriate for an encounter scenario. Please note that information related to coding, coverage policies, and payment methodologies is subject to change and should be verified for each patient prior to treatment. The information in this guide is current as of May 2023.

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information.**

Vyjuvek™
beremagene geperpavec-svdt
$5x10^9$ PFU/mL single-use vial

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Product Information

Indication and Usage[1]

VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

VYJUVEK is a biological suspension, mixed into excipient gel, for topical application. VYJUVEK biological suspension is supplied as a 1.0 mL extractable volume in a single-dose vial at a nominal concentration of 5×10^9 plaque-forming units (PFUs)/mL. The excipient gel is supplied as a 1.5 mL-fill volume in a separate single-use vial. VYJUVEK biological suspension (1 mL) is mixed into the excipient gel vial prior to administration as VYJUVEK gel.

Recommended Dosing[1]

The recommended dose of VYJUVEK gel is based on age. VYJUVEK gel is applied topically to wound(s) once a week. For patients aged 3 years and older, the weekly dose is up to 3.2×10^9 PFU (1.6 mL). The maximum weekly volume is the volume after mixing VYJUVEK biological suspension with the excipient gel.

For patients aged 6 months to 3 years, the weekly dose is up to 1.6×10^9 PFU (0.8 mL).

It may not be possible to apply VYJUVEK gel to all the wounds at each treatment visit. Apply VYJUVEK gel to wounds until they are closed before selecting new wound(s) to treat. Prioritize weekly treatment to previously treated wounds if they re-open. If a dose is missed, apply VYJUVEK gel as soon as possible and resume weekly dosing thereafter.

Apply VYJUVEK gel to the selected wound(s) in droplets spaced evenly within the wound, approximately 1cm-by-1cm apart. See Full Prescribing Information for a reference on dose per the approximate size of the wound.

How Supplied[1]

VYJUVEK is supplied in a single-use, 1 mL vial with a green cap. Each vial contains a volume of 5×10^9 PFU per mL and will appear as an opalescent yellow to colorless suspension following thaw from its frozen state. This should be mixed with supplied excipient gel prior to administration. The excipient gel consists of hydroxypropyl methylcellulose supplied in a single-use, 1.5 mL vial with a blue cap. It resembles a clear, viscous solution following thaw from its frozen state.

Not pictured to actual size.

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information.**

Vyjuvek™
beremagene geperpavec-svdt
5×10^9 PFU/mL single-use vial

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Storage and Handling[1]

Store the VYJUVEK carton at -15°C to -25°C (5°F to -13°F). If a freezer is not available, the carton can be refrigerated (2º to 8ºC [35.6º to 46.4ºF]) for up to 1 month. Prior to use, VYJUVEK requires mixing into excipient gel. Administration syringes containing the VYJUVEK gel may remain at room temperature (20º to 25°C [68° to 77°F]) for up to 8 hours. If immediate use is not possible, administration syringes can be stored for up to 48 hours in the refrigerator (2º to 8ºC [35.6º to 46.4ºF]).

National Drug Codes (NDCs)

NDC for:	10-Digit NDC (from Prescribing Information)	11-Digit NDC (HIPAA-complaint format)	Description
Carton (outer NDC)	82194-510-02	82194-0510-02	Box, 1 each beremagene geperpavec 5×10^9 PFU/mL, topical suspension and 1 each topical gel
Vyjuvek (inner NDC)	82194-501-01	82194-0501-01	Vyjuvek biological suspension 1.0 mL extractable volume in a single-use, single-dose vial containing 5×10^9 PFU/mL
Excipient gel (inner NDC)	82194-001-01	82194-0001-01	Excipient gel 1.5 mL fill volume in a separate single-use, single-dose vial

Key: HIPAA – Health Insurance Portability and Accountability Act.

Specialty Distributor

ASD Healthcare
Phone: 1-800-746-6273
Fax: 1-800-547-9413
Web: www.asdhealthcare.com

Specialty Pharmacies

Orsini Pharmaceutical Services
Phone: 1-800-809-7105
Fax: 1-877-718-8058
Web: www.orsinispecialtypharmacy.com

CVS Specialty
Phone: 1-866-643-4045
Fax: 1-855-330-1718
Web: www.cvsspecialty.com

Option Care Health
Phone: 1-864-583-8190
Fax: 1-410-558-6439
Web: www.optioncarehealth.com

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Introducing Krystal CONNECT™

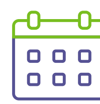
Krystal Biotech, Inc., created Krystal CONNECT to support patient access to Vyjuvek. Services include:

- One-on-one support from a dedicated case manager
- Help for HCPs and patients with access-related concerns:
  - Contracted specialty pharmacies and specialty distributors/wholesalers
  - Research on individual patients' health insurance coverage
  - Krystal CONNECT Copay Program and other financial support options
- Resources for living with dystrophic epidermolysis bullosa (DEB)

Contact Krystal CONNECT to get started:

PHONE:
1-844-5-KRYSTAL

FAX:
1-833-782-7852

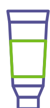


HOURS:
8:30 AM to 7:00 PM ET

Steps for Accessing Vyjuvek:

Together, with your patient, complete the Vyjuvek Enrollment Form, available at Vyjuvek.com. Enrollment forms can be printed and faxed to Krystal CONNECT at 1-833-782-7852.

Your patient's Krystal CONNECT Patient Access Liaison will contact you and review the next steps.



Krystal CONNECT will send your patient's Vyjuvek prescription to a specialty pharmacy and/or provide you with information about specialty distributors.

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Product Acquisition

HCPs have different options to acquire Vyjuvek. Payers may dictate how HCPs acquire the product. Each route of acquisition varies in terms of payer coverage, coding, and claims adjudication.

Questions	Buy-and-Bill Acquisition	Specialty Pharmacy Acquisition
How is the drug ordered?	• From a preferred wholesaler/ specialty distributor	• From a specialty pharmacy
Who buys the drug?	• The facility that administers the drug	• The specialty pharmacy
Who verifies the patient's health coverage?	• The prescriber and/or the facility that administers the drug	• The specialty pharmacy
Who submits the PA?	• The prescriber	• The prescriber
How is the drug billed?	• On a medical claim – CMS-1500 or CMS-1450 claim form (or the electronic equivalent). The claim type varies based on site of care	• Specialty pharmacies can bill either medical plans or prescription drug plans*
Who bills insurance for the cost of the drug?	• The facility that administers the drug	• The specialty pharmacy
Who collects the patient's share of cost for the drug?	• The facility that administers the drug	• The specialty pharmacy
Who is financially liable for paying the claim for the drug?	• The patient's medical plan	• The patient's medical plan and/or prescription drug plan*
How is the administration procedure billed?	• On a medical claim that includes coding information for the drug	• On a medical claim that is separate from the drug claim
Who bills insurance for the cost of the administration procedure?	• The facility that administers the drug	• The facility that administers the drug
Who collects the patient's share of cost for the administration procedure?	• The facility that administers the drug	• The facility that administers the drug
Who is financially liable for paying the claim for the administration procedure?	• The patient's medical plan	• The patient's medical plan

Key: CMS – Centers for Medicare & Medicaid Services; PA – prior authorization.
*Depends on patient's health insurance benefit design.

Krystal CONNECT offers a copay savings program for eligible, commercially insured patients.
Contact Krystal CONNECT at 1-844-5-KRYSTAL, 8:30 AM to 7:00 PM ET for more information.*

*Additional terms and conditions apply. See www.krystalconnect.com/pdf/us_terms.pdf for full terms and conditions.

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information**.

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Coverage

Plan Benefits

- Coverage for Vyjuvek and its application procedure varies by payer and health insurance plan type
- Private commercial insurers and Medicaid plans usually cover Vyjuvek under the medical benefit
  - Exceptions apply, with some payers covering it under a pharmacy benefit
- Some payers allow physicians and hospitals to buy and bill Vyjuvek while others require that Vyjuvek be ordered through a network specialty pharmacy provider
  - Specialty pharmacies may bill the payer through the medical or pharmacy benefit, depending on the patient's health plan benefit design

The table below provides additional information for each payer type and site of care:

Payer Type	Drug Coverage Options	Procedure Coverage Options
Physician office and hospital outpatient department sites of care		
Private commercial	Medical or pharmacy benefit	Medical benefit
Medicaid*	Medical or pharmacy benefit	Medical benefit
FFS Medicare[2]	Part B benefit (requires buy and bill)	Part B benefit
Medicare Advantage	Medical or pharmacy benefit	Medical benefit

Key: FFS – fee for service.
*May include FFS Medicaid plans or managed Medicaid plans.

PA Requirements

While there is no PA requirement for Medicare Part B-covered claims, it is very common for other payers – including Medicare Part D and Medicare Advantage – to require a PA both for new-to-market drugs and for services billed using miscellaneous (unspecified) procedure codes. Payers have varying requirements for PAs including coverage criteria, processes for requesting a PA, and information needed to fulfill a PA request. Contact each health plan directly to determine specific guidelines. **Double-check the accuracy of all information you submit to a payer: Missing or incorrect information is a leading reason for delays and denials.** The following information may be helpful to support a request for a PA:

- Letter of medical necessity
- Payer-specific PA form
- Patient chart notes
- Laboratory and/or pathology test results
- Procedure report
- Clinical history and disease progression
- Previous treatments
- List of current medications
- List of drug allergies
- Prescribed course of treatment (eg, dose, frequency, duration)
- US Food and Drug Administration approval letter
- Invoice and/or compendia listing containing drug wholesale acquisition cost (WAC)

Follow up directly with the health plan regarding any payer requests for additional information. For assistance, providers can contact Krystal CONNECT at 1-844-5-KRYSTAL, Monday-Friday, 8:30 AM to 7:00 PM ET.

PA Checklist

The checklist below is a useful resource for ensuring the most common clinical criteria are met when submitting a PA for Vyjuvek for your patient.

- ☐ Diagnosis of DEB
  – International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) code: Q81.2
  (Epidermolysis bullosa dystrophica)
- ☐ Documentation of relevant clinical confirmations (eg, genetic testing, biopsy, family history)
- ☐ Must be ≥6 months of age
- ☐ Documentation that initiation of the prescription is by or in consultation with a dermatologist or clinical expert in DEB
- ☐ Treatment will be administered by an HCP
- ☐ Documentation of DEB wounds:
  - ☐ Number of wounds
  - ☐ Wound size (eg, small, medium, large)
  - ☐ Duration (eg, recurrent, chronic)
  - ☐ Pictures (if applicable)

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Importance of Benefits Verification

Verifying a patient's health insurance plan coverage prior to ordering Vyjuvek will identify:

- Any site-of-care restrictions
- Ordering options
- Coding guidelines (including requested documentation when using miscellaneous billing codes)
- Coverage requirements
- Claims-submission criteria

Contact Krystal CONNECT for assistance verifying a patient's health insurance benefits. You can also ask Krystal CONNECT to forward your patient enrollment directly to a participating specialty pharmacy, if you wish.

Upon request, Krystal CONNECT will provide a detailed Summary of Benefits and share it with the requester via fax. The Summary of Benefits provides details on:

- The patient's health plan eligibility
- Coverage for Vyjuvek and its administration
- Acquisition options
- PA requirements
- The patient's out-of-pocket financial responsibility
- The patient's eligibility for assistance (eg, commercial copay support)

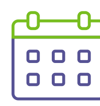
Contact Krystal CONNECT to get started:

PHONE:

1-844-5-KRYSTAL

FAX:

1-833-782-7852



HOURS:

8:30 AM to 7:00 PM ET

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5x10⁹ PFU/mL single-use vial

Coding by Site of Care

This section lists billing codes that may be appropriate to report services provided to patients undergoing treatment with Vyjuvek. The information provided here is divided by site of care: physician office and hospital outpatient department.

Physician Office

This section lists some of the billing codes that may be appropriate to report services provided to patients undergoing treatment with Vyjuvek in the **physician office setting**.

Patient Diagnosis

The medical necessity for treatment with Vyjuvek is reported with ICD-10-CM codes. Current codes do not differentiate between recessive DEB (RDEB) and dominant DEB (DDEB). The following ICD-10-CM diagnosis code may be appropriate for patients prescribed Vyjuvek:

Code Set	Code[3]	Description
ICD-10-CM	Q81.2	Epidermolysis bullosa dystrophica

Product Billing

Vyjuvek will not have a product-specific Healthcare Common Procedure Coding System (HCPCS) code at launch. Until a permanent code is assigned, HCPs may use a miscellaneous (unclassified) code on medical claims:

Code Set	Code[4]	Description*
HCPCS	J3490	Unclassified drugs
	J3590	Unclassified biologics

*Individual payer policies should be reviewed for reporting requirements, as it varies.

HCPCS codes must be accompanied by a billing unit value. Miscellaneous codes such as those in the above table are generally reported with “1 unit” in the units field of the medical claim form.

The Centers for Medicare & Medicaid Services (CMS) requires the following modifier to be reported along with the selected miscellaneous HCPCS code for a product packaged in a single-use vial:

Code Set	Code[5,*]	Description	Use
HCPCS modifier	-JZ	Zero drug amount discarded/not administered to any patient	Append to miscellaneous HCPCS code reported with 1 unit on medical claim

*Even if some amount of drug is discarded, the JW modifier *(Drug amount discarded/not administered to any patient)* is not permitted when the actual dose administered is less than the HCPCS billing unit. The HCP can report administering the full billing unit (1) along with the JZ modifier. The actual amounts administered and discarded should be documented in Item 19 of the CMS-1500 claim form or FL 80 of the CMS-1450 claim form (or their electronic equivalents). These amounts should also be documented in the patient's medical record.

Payers also require the 11-digit NDC in combination with a HCPCS code for Vyjuvek to be reported on medical claims. The NDC alone will be utilized in cases where Vyjuvek is furnished by a specialty pharmacy under the patient’s prescription drug plan.[1,6,7]

Code Set	Code[1,*]	Description
NDC	82194051002	Box, 1 each beremagene geperpavec 5×10^9 PFU/mL, topical suspension and 1 each topical gel

*NDC for carton is used on medical claims for the purposes of reporting use of Vyjuvek.

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Application Procedure

HCPs may use a Current Procedural Terminology (CPT®*) code to describe application of Vyjuvek by a medical professional. There is not a specific CPT code that describes the topical application for Vyjuvek. In the absence of a specific code, a miscellaneous (unspecified) code may be used. Verify guidance with individual payers as their requirements for miscellaneous CPT codes vary. Payers will likely require additional information, such as a procedure report, to accompany medical claims so the payer can identify the procedure and review its medical necessity. CPT codes that may be applicable to the topical application of Vyjuvek include:

Code Set*	Code[8]	Description
CPT	96999	Unlisted special dermatological service or procedure
	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

*CPT Copyright 2022 American Medical Association. All rights reserved. CPT is a registered trademark of the American Medical Association.

Tips for Complete Procedure Documentation

Use of a miscellaneous procedure code typically means providers will have to submit a procedure report with the claim to help the payer understand the service. Specific requirements for procedure/operative notes may vary. However, the following items generally make up a complete report:

- Name of HCP performing the procedure (and any assistants)
- Pre- and post-procedure diagnosis
- Name of procedure performed
- Findings and/or specimens removed
- Start and stop time of procedure
- Full detailed description/documentation of the procedure
- Complications

Place of Service (POS) Coding

POS codes identify the location where a service was performed. This is a required field (Item 24B) on the CMS-1500 claim form. The following POS codes may be applicable:

POS Code[9]	POS Name	Description
11	Office	Location, other than a hospital, skilled nursing facility (SNF), military treatment facility, community health center, state or local public health clinic, or intermediate care facility (ICF), where the health professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis
19*	Off campus-outpatient hospital	A portion of an off-campus hospital provider-based department which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization
22*	On campus-outpatient hospital	A portion of a hospital's main campus which provides diagnostic, therapeutic (both surgical and nonsurgical), and rehabilitation services to sick or injured persons who do not require hospitalization or institutionalization

*May be appropriate for an HCP to report on a CMS-1500 claim form for professional services.

Hospital Outpatient Department

This section lists some of the billing codes that may be appropriate to report services provided to patients undergoing treatment with Vyjuvek in **hospital outpatient departments, ambulatory infusion centers, or other facility-based settings**.

Patient Diagnosis

The medical necessity for treatment with Vyjuvek is reported with ICD-10-CM codes. Current codes do not differentiate between recessive DEB (RDEB) and dominant DEB (DDEB). The following ICD-10-CM diagnosis code may be appropriate for patients prescribed Vyjuvek:

Code Set	Code[3]	Description
ICD-10-CM	Q81.2	Epidermolysis bullosa dystrophica

Product Billing

Vyjuvek will not have a product-specific Healthcare Common Procedure Coding System (HCPCS) code at launch. Until a permanent code is assigned, HCPs may use a miscellaneous (unclassified) code on medical claims:

Code Set*	Code[4]	Description
HCPCS	J3490	Unclassified drugs
	J3590	Unclassified biologics
	C9399	Unclassified drugs or biologicals

*Individual payer policies should be reviewed for reporting requirements, as it varies

HCPCS codes must be accompanied by a billing unit value. Miscellaneous codes such as those in the above table are generally reported with "1 unit" in the units field of the medical claim form.

The Centers for Medicare & Medicaid Services (CMS) requires the following modifier to be reported along with the selected miscellaneous HCPCS code for a product packaged in a single-use vial:

Code Set	Code[5,*]	Description	Uses
HCPCS modifier	-JZ	Zero drug amount discarded/not administered to any patient	Append to miscellaneous HCPCS code reported with 1 unit on medical claim

*Even if some amount of drug is discarded, the JW modifier *(Drug amount discarded/not administered to any patient)* is not permitted when the actual dose administered is less than the HCPCS billing unit. The HCP can report administering the full billing unit (1) along with the JZ modifier. The actual amounts administered and discarded should be documented in Item 19 of the CMS-1500 claim form or FL 80 of the CMS-1450 claim form (or their electronic equivalents). These amounts should also be documented in the patient's medical record.

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The CMS requires modifiers on hospital outpatient claims to indicate whether drugs furnished to Medicare beneficiaries were acquired under the 340B Drug Discount Program.

For drugs acquired via the 340B program, modifier -JG will be appropriate to use on claims for Vyjuvek at launch, while modifier -TB will be needed once Vyjuvek is awarded temporary pass-through status[4]:

Code Set	Code[4]	Description	Uses
HCPCS modifier	-JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes	For drugs without temporary pass through status
	-TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities	For drugs awarded temporary pass through status

Payers also require the 11-digit NDC in combination with a HCPCS code for Vyjuvek to be reported on medical claims. The NDC alone will be used in cases where Vyjuvek is furnished by a specialty pharmacy under the patient's prescription drug plan.[10]

Code Set	Code[1,*]	Description
NDC	82194051002	Box, 1 each beremagene geperpavec 5×10^9 PFU/mL, topical suspension and 1 each topical gel

*NDC for carton is used on medical claims for the purposes of reporting use of Vyjuvek.

Revenue codes categorize hospital or institutional services by revenue or cost center and should be included for each hospital service code billed on the CMS-1450 claim. The following revenue codes may be appropriate to report use of Vyjuvek:

Code Set	Code[11]	Description
Revenue code	0636	Drugs requiring detailed coding
	0892	Special processed drugs – FDA-approved gene therapy

Key: FDA – United States Food and Drug Administration.
Other revenue codes may apply.

Application Procedure

HCPs may use a Current Procedural Terminology (CPT®*) code to describe Vyjuvek administration by a medical professional. There is not a specific CPT code that describes the topical application for Vyjuvek. In the absence of a specific code, a miscellaneous (unspecified) code may be used. Verify guidance with individual payers as their requirements for miscellaneous CPT codes vary. Payers will likely require additional information, such as a procedure report, to accompany medical claims. This helps payers to identify the procedure and review its medical necessity. CPT codes applicable to the topical application of Vyjuvek include:

Code Set	Code[8]	Description
CPT	96999	Unlisted special dermatological service or procedure
	17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

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Tips for Complete Procedure Documentation
Use of a miscellaneous procedure code typically means providers will have to submit a procedure report with the claim to help the payer understand the service. Specific requirements for procedure/operative notes may vary. However, the following items generally make up a complete report:

- Name of HCP performing the procedure (and any assistants)
- Pre- and post-procedure diagnosis
- Name of procedure performed
- Findings and/or specimens removed
- Start and stop time of procedure
- Full detailed description/documentation of the procedure
- Complications

The following revenue codes may be appropriate to report the topical application of Vyjuvek:

Code Set	Code[11]	Description
Revenue code	0940	Other therapeutic services, general
	0510	Clinic visit
	0870	Cell/gene therapy, general

Other revenue codes may apply.

Additional Identifying Information on Claims for Miscellaneous-Coded Drugs

Most payers require HCPs to submit drug-identifying information on the claim form when Vyjuvek is billed with a miscellaneous HCPCS code. Payer guidance varies on where this information should go on claim forms; however, this information is often reported in the Comment field (Item 19) of the CMS-1500 claim form or Remarks section (Form Locator 80) of the CMS-1450 (UB-04) claim form (or their electronic equivalents). Payers may request the following types of drug-identifying information on claim forms for Vyjuvek[1,6,7,10,12]:

Types of Information	Specifics for Vyjuvek
• NDC qualifier “N4” – Put in front of NDC • 11-digit NDC – Report on medical claims without hyphens or other punctuation marks • One blank space • Unit of measure qualifier – ML • Quantity – X.X	N482194051002 MLX.X
Drug name (brand/generic)	Vyjuvek (beremagene geperpavec-svdt)
Dose/dosage (amount administered/discarded, which together should equal 2.5 mL, the total NDC quantity in 1 carton)	Dose 3.2×10^9 PFU (1.6 mL), administered 1.6 mL and discarded 0.9 mL
Route of administration	Topical

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Sample Claim Forms

CMS-1500 Claim Form (Physician Office Claims)

Products and services provided in the physician office setting are billed using the CMS-1500 claim form or its digital equivalent – the electronic claim file (837P). A sample CMS-1500 claim form is provided below.

Item 21 Diagnosis: Enter the appropriate diagnosis code, eg:

- ICD-10-CM: Q81.2 for *epidermolysis bullosa dystrophica*. Final code depends on medical record documentation

Note: Check payer requirements for reporting diagnosis

Item 19 Additional Information: Enter the appropriate drug-identifying information (eg, drug name, route of administration, dose, amounts administered and discarded, and NDC)

Note: Check payer requirements for additional drug-identifying information

Item 24A Date(s) of Service: In the shaded area, above the date fields, enter:

- The "N4" qualifier (before the NDC)
- The NDC (without hyphens or other punctuation)
- Follow with 1 blank space, then appropriate 2-character NDC unit of measure qualifier and quantity

Note: Check payer requirements for reporting NDC and NDC modifiers

19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)
Vyjuvek topical dose 3.2x10^9 PFU (1.6 mL) administered 1.6 mL and discarded 0.9 mL NDC 82194051002

20. OUTSIDE LAB? YES NO $ CHARGES

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E) ICD Ind.
A. Q81.2 B. C. D.
E. F. G. H.
I. J. K. L.

22. RESUBMISSION CODE ORIGINAL REF. NO.

23. PRIOR AUTHORIZATION NUMBER

24. A. DATE(S) OF SERVICE From MM DD YY	To MM DD YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N482194051002 MLX.X Vyjuvek											
MM DD YY	MM DD YY	11		J3490	JZ	A	xx xx	1		NPI	
MM DD YY	MM DD YY	11		96999		A	xx xx	1		NPI	
										NPI	

Item 24B Place of Service: Enter the appropriate place of service code, eg:

- 11 for physician office

Note: Other codes may apply

Item 24D Procedures, Services, or Supplies: Enter the appropriate CPT/HCPCS codes and modifiers, eg:

- Drug: J3490 for Vyjuvek and modifier -JZ
- Administration: 96999 for Vyjuvek application

Note: Other codes may apply

Item 24E Diagnosis Pointer: Enter the letter (A-L) that corresponds to the diagnosis in Item 21A

Item 24G Units: Enter the appropriate number of units of service, eg:

- For J3490, 1 billing unit should be reported when using a miscellaneous code
- For 96999, 1 unit reports the topical application of Vyjuvek

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information**.

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Sample Claim Forms (cont.)

CMS-1450 (UB-04) Claim Form (Facility-Based Claims)

Products and services provided in the hospital outpatient department and other facility-based settings are billed using the CMS-1450 (UB-04) institutional claim form or its digital equivalent – electronic claim file (837I). A sample CMS-1450 claim form is provided.

FL 42 Revenue Code: Enter the appropriate revenue code, eg:
- 0636 for Vyjuvek
- 0940 for the topical application

Note: Other revenue codes may apply

FL 46 Units of Service: Enter the appropriate number of units of service, eg:
- For J3490, 1 billing unit should be reported when using a miscellaneous code
- For 96999, 1 unit reports the topical application of Vyjuvek

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
0636	N482194051002 MLX.X	J3490 JZ	MMDDYY	1	XXX XX		
0940	Dermatological procedure	96999	MMDDYY	1	XXX XX		

FL 43 Revenue Description: Enter descriptions for the drug and topical application, eg:
- Drug: Drug name, NDC, and NDC modifiers
  - List the "N4" qualifier
  - Follow with the NDC (do not include hyphens or other punctuation)
  - Enter 1 space, then the appropriate 2-character NDC unit of measure qualifier and quantity
- Administration: Dermatological procedure

Note: Check payer requirements and format for NDC reporting

FL 44 HCPCS: Enter the appropriate CPT/HCPCS codes and modifiers, eg:
- Drug: J3490 for Vyjuvek and modifier -JZ
- Administration: 96999 for Vyjuvek application

Note: Other codes may apply; check payer requirements

CREATION DATE | TOTALS

52 REL. INFO | 53 ASG. BEN. | 54 PRIOR PAYMENTS | 55 EST. AMOUNT DUE | 56 NPI | 57 OTHER

58 INSURED'S NAME | 59 P. REL | 60

63 TREATMENT AUTHORIZATION CODES

FL 67 and 67A-67Q Principal Diagnosis Code and Other Diagnosis Codes: Enter the appropriate diagnosis code, eg:
- ICD-10-CM: Q81.2 for *epidermolysis bullosa dystrophica*; final code depends on medical record documentation

Note: Other diagnosis codes may apply

66 DX: Q81.2 | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | 68

69 ADMIT DX | 70 PATIENT REASON DX a b c | 71 PPS CODE | 72 ECI | 73

74 PRINCIPAL PROCEDURE CODE DATE | a. OTHER PROCEDURE CODE DATE | b. OTHER PROCEDURE CODE DATE | 75 | 76 ATTENDING NPI QUAL

c. OTHER PROCEDURE CODE DATE | d. OTHER PROCEDURE CODE DATE

80 REMARKS
Vyjuvek topical dose 3.2×10^9 PFU (1.6 mL)
administered 1.6 mL and discarded 0.9 mL NDC
82194051002

81CC a b c d

FL 80 Remarks: Enter the appropriate drug-identifying information (eg, drug name, route of administration, dose, amounts administered and discarded, and NDC)

Note: Check payer requirements for reporting

Please see Indication and Important Safety Information for VYJUVEK on page 1 as well as **Full Prescribing Information**.

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Vyjuvek™
beremagene geperpavec-svdt
5×10^9 PFU/mL single-use vial

Reimbursement

Many payers, including commercial insurers and some managed Medicaid and Medicare plans, reimburse HCPs based on individual contracts. Contracts are set up between the payer and the medical professional or entity providing the drug and/or the medical services to the patient. **It is particularly important for HCPs to review their payer contracts for language that specifies how the payer will calculate reimbursement** for both:

- New-to-market products
- Procedures billed using a miscellaneous code

FFS Medicare reimburses drugs based on the site of care. Reimbursement amounts for miscellaneous procedure codes are "carrier priced," meaning that the payment is typically determined by individual Medicare contractors, based on their review of the supplemental documentation submitted with the claim.

FFS Medicaid plans and some managed Medicaid plans publish their payment rates via a fee schedule. They often follow a pre-determined methodology for calculating drug reimbursement.

This table summarizes potential reimbursement methodologies for Vyjuvek and its administration procedure:

Payer Type	Drug Reimbursement	Miscellaneous Procedure Reimbursement
Physician Office		
FFS Medicare[13]	• At launch: WAC + 3% • Once ASP is established: ASP + 6%	• Carrier determines payment based on review of claim and documentation
Private commercial Medicaid* Medicare Advantage	• Fee schedule • Invoice-based pricing • Percent of billed charges • Usual, customary, & reasonable charges • Bundled payment rates • Capitation • Contracted rate • Other methodology**	• Fee schedule • Invoice-based pricing • Percent of billed charges • Usual, customary, & reasonable charges • Bundled payment rates • Capitation • Contracted rate
Hospital Outpatient Department		
FFS Medicare[14]	• At launch: WAC + 3% • Once ASP is established: ASP + 6%	• Carrier determines payment based on review of claim and documentation
Private commercial Medicaid* Medicare Advantage	• Fee schedule • Invoice-based pricing • Percent of billed charges • Usual, customary, & reasonable charges • Bundled payment rates • Capitation • Contracted rate • Other methodology**	• Fee schedule • Invoice-based pricing • Percent of billed charges • Usual, customary, & reasonable charges • Bundled payment rates • Capitation • Contracted rate

Key: AAC – actual acquisition cost; ASP – average sales price; AWP – average wholesale price; FFS – fee for service; WAC – wholesale acquisition cost.
*May include FFS Medicaid plans or managed Medicaid plans.
**Drug-based reimbursement may be based on one of the following: WAC + a percentage, AWP - a percentage, AAC + a percentage, or ASP + a percentage.

References: **1**. Vyjuvek. Prescribing information. Krystal Biotech Inc.; 2023. **2.** CMS. Medicare benefit policy manual. Chapter 15. Covered medical and other health services. §50.3. Updated May 20, 2022. Accessed February 6, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf **3.** CMS. 2023 ICD-10-CM. Updated July 27, 2022. Accessed February 6, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm **4.** CMS. HCPCS quarterly update. July 2023 alpha-numeric HCPCS file. Updated May 3, 2023. Accessed May 15, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update **5.** CMS. Medicare program discarded drugs and biologicals: JW modifier and JZ modifier policy frequently asked questions. Accessed February 6, 2023. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf **6.** NUCC. 1500 health insurance claim form reference instruction manual for form version 02/12. Updated July 2022. Accessed February 6, 2023. https://www.nucc.org/images/stories/PDF/1500_claim_form_instruction_manual_2022_07-v10a.pdf **7.** CMS. Medicare claims processing manual. Chapter 26. Completing and processing the Form CMS-1500 data set. §10.4. Updated May 22, 2022. Accessed February 6, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c26pdf.pdf **8.** 2023 Current Procedural Terminology. AMA; 2022. **9.** CMS.gov. Place of service code set: place of service codes for professional claims. Updated September 2021. Accessed February 6, 2023. https://www.cms.gov/Medicare/Coding/place-of-service-codes/Place_of_Service_Code_Set **10.** CMS. Medicare claims processing manual. Chapter 25. Completing and processing the Form CMS-1450 data set. §75.5. Updated August 6, 2021. Accessed February 6, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c25.pdf **11.** Noridian Healthcare Solutions. Revenue codes. Updated June 28, 2022. Accessed March 14, 2023. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes **12.** CMS. Medicare claims processing manual. Chapter 17. Drugs and biologicals. §90.3. Updated August 25, 2022. Accessed February 6, 2023. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c17.pdf **13.** CMS. Medicare and Medicaid programs; CY 2023 payment policies under the Physician Fee Schedule and other changes to Part B payment and coverage policies; Medicare Shared Savings Program requirements; implementing requirements for manufacturers of certain single-dose container or single-use package drugs to provide refunds with respect to discarded amounts; and COVID-19 interim final rules. *Fed Regist*. 2022;87(222). https://www.federalregister.gov/d/2022-23873 **14.** CMS. Medicare program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; organ acquisition; rural emergency hospitals: payment policies, conditions of participation, provider enrollment, physician self-referral; new service category for hospital outpatient department prior authorization process; overall hospital quality star rating; COVID–1. *Fed Regist*. 2022;87(225). https://www.federalregister.gov/d/2022-23918

Please see Indication and Important Safety Information for VYJUVEK
on page 1 as well as **Full Prescribing Information**.

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