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Introduction

Accurate and appropriate coding and billing can help avoid delays in claims processing and facilitate timely reimbursement. Astellas and Seattle Genetics are providing this guide as an educational reference, providing general coding and billing information to facilitate medically appropriate patient access to PADCEV™ (enfortumab vedotin-ejfv).

This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Astellas and Seattle Genetics do not guarantee third-party coverage or payment or reimbursement for denied claims.

Because insurance coverage, coding, claims filing, and reimbursement vary by setting of care as well as by payer type, the information included in this guide is general. Healthcare providers should always verify coverage prior to initiating therapy and determine the appropriate codes on a case-by-case basis.

While Astellas and Seattle Genetics have made every effort to be current as of the publication of this guide, the information may not be as current when you view it. Similarly, all Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes are supplied for informational purposes only. This information does not represent any statement, promise, or guarantee by Astellas and Seattle Genetics about coverage, levels of reimbursement, payment, or charge. Additional information may exist, and actual coverage and reimbursement decisions are made by individual payers. Providers should contact the applicable third-party payers for specific information on coding and billing requirements.

Avoiding Denied Claims

Understanding the reasons why medical claims may be denied by insurers can help limit the number of denials. Potential causes of delayed or denied claims may include:

• Invalid or missing codes (CPT, J-code, International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10-CM])
• Incorrect product information
• Missing or incorrect National Drug Code (NDC), prior authorization number, National Provider Identifier
• Incorrect patient identifier information (eg, insurance identification number, date of birth)
• Failure to follow payer-specific requirements

Reminders for Submitting Claims

The following reminders may help when submitting claims for PADCEV:

- Determine if PADCEV is covered as a medical or pharmacy benefit prior to infusion and if there are any applicable prior authorization requirements
- Accurately complete and submit the prior authorization form, if required
- Ensure medical records include full and proper documentation of the patient’s history, prior therapy, and rationale for treatment to justify coding
- Specify the correct number of product units on the CMS-1500 Claim Form or on the UB-04/CMS-1450 Claim Form (see pages 12 and 14 for instructions on filling out claim forms)
- If required, include a Letter of Medical Necessity that provides the patient’s medical history and rationale for the therapy
- Verify that all identification numbers and names are entered correctly
- Use the correct ICD-10-CM, CPT, and HCPCS codes, including modifiers if applicable
- Verify the proper use of billing codes
- For the hospital outpatient setting, confirm that the correct revenue code is used with the appropriate supporting HCPCS code
- Submit the claim in a timely fashion
- Track clearinghouse claims to ensure successful transmission

IMPORTANT INFORMATION: The coding, coverage, and payment information contained herein is gathered from various resources, general in nature, and subject to change without notice. Third-party payment for medical products and services is affected by numerous factors. It is always the provider’s responsibility to determine the appropriate healthcare setting and to submit true and correct claims conforming to the requirements of the relevant payer for those products and services rendered. Pharmacies (or any other provider submitting a claim) should contact third-party payers for specific information on their coding, coverage, and payment policies. Information and materials provided by PADCEV Support Solutions™ are to assist providers, but the responsibility to determine coverage, reimbursement, and appropriate coding for a particular patient and/or procedure remains at all times with the provider and information provided by PADCEV Support Solutions, Astellas, or Seattle Genetics should in no way be considered a guarantee of coverage or reimbursement for any product or service.
Billing for New Drugs

The Healthcare Common Procedure Coding System (HCPCS) is used to identify products, supplies, and services that are billed to private and government payers by hospitals, physicians, and other healthcare professionals.

For new drugs that have not yet been assigned a permanent HCPCS code, the appropriate “miscellaneous/not otherwise classified/unclassified” code(s) should be used. These codes are used while a permanent code is under consideration by the HCPCS review process.1

PADCEV™ (enfortumab vedotin-ejfv) is a new drug waiting to be assigned a permanent HCPCS code as of December 2019. For relevant miscellaneous codes for PADCEV, see pages 8–9.

Additional Requirements

For miscellaneous codes, most payers will require additional information on the claim form, such as2,3:

- Drug name and generic name
- Total dosage administered
- Method of administration
- National Drug Code (NDC)

Typically, drugs are assigned a product-specific HCPCS J-code within 12 to 18 months after launch. In the past, the Centers for Medicare & Medicaid Services (CMS) assigned product-specific J-codes once per year in October or November, which took effect the following January. However, beginning in January 2020, CMS will implement quarterly HCPCS code application opportunities for drugs and biological products. Moving forward, new codes would take effect in January, April, July, or October, depending on the date the application was submitted. For example, if an application for a newly approved drug is submitted on or before January 6, 2020, CMS could assign a product specific J-code in April 2020 with the new J-code would take effect on July 1, 2020.

### Coding for New Drugs

<table>
<thead>
<tr>
<th>Setting</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Physician Office Setting</strong></td>
<td>A miscellaneous J-code is usually used when submitting reimbursement claims for new drugs that are waiting to receive a product-specific J-code. The miscellaneous HCPCS codes for PADCEV in the physician office setting are J3490, J3590, or J9999.</td>
</tr>
<tr>
<td><strong>Outpatient Hospital Setting</strong></td>
<td>CMS may issue a temporary C-code to be used for outpatient hospital reimbursement claims. The miscellaneous HCPCS code for PADCEV in the outpatient hospital setting is C9399.</td>
</tr>
</tbody>
</table>

This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Astellas and Seattle Genetics do not guarantee third-party coverage or payment or reimbursement for denied claims.
### Relevant Billing Codes for PADCEV™ (enfortumab vedotin-ejfv)

The billing codes listed below may be appropriate when billing for PADCEV and its administration for the treatment of the FDA-approved indication.

It is the healthcare provider’s responsibility to determine the appropriate codes and to submit accurate claims for products and services provided. Astellas and Seattle Genetics do not guarantee coverage and/or reimbursement for PADCEV. Coverage, coding, and reimbursement policies vary significantly by payer, patient, and setting of care. Actual coverage and reimbursement decisions are made by individual payers following the receipt of claims. Healthcare providers should verify coverage, coding, and reimbursement guidelines on a case-by-case basis.

### National Drug Code (NDC)

You may be required to include an NDC for PADCEV on a claim form. The 10-digit NDCs are listed below.

<table>
<thead>
<tr>
<th>NDC for PADCEV</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>51144-020-01</td>
<td>20 mg solution in a single-dose vial for intravenous infusion</td>
</tr>
<tr>
<td>51144-030-01</td>
<td>30 mg solution in a single-dose vial for intravenous infusion</td>
</tr>
</tbody>
</table>

### Healthcare Common Procedure Coding System (HCPCS)

Until a product-specific permanent HCPCS code is assigned, PADCEV should be billed using one of the miscellaneous codes listed below. To verify the most recent HCPCS codes for PADCEV, visit [PADCEVSupportSolutions.com](http://PADCEVSupportSolutions.com).

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
<th>Payers and Settings of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drugs</td>
<td>Most payers and care settings</td>
</tr>
<tr>
<td>J3590</td>
<td>Unclassified biologics</td>
<td>Most payers and care settings</td>
</tr>
<tr>
<td>J9999</td>
<td>Not otherwise classified antineoplastic drugs</td>
<td>Most payers and care settings</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologicals</td>
<td>Hospital outpatient claims billed to most private payers and Medicare (under the Medicare Hospital Outpatient Prospective Payment System [HOPPS])</td>
</tr>
</tbody>
</table>


The appropriate CPT® code for the administration of PADCEV will depend on the actual service performed.

<table>
<thead>
<tr>
<th>CPT® Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96413</td>
<td>Chemotherapy administration, intravenous infusion technique, up to 1 hour, single or initial substance/drug</td>
</tr>
<tr>
<td>96415</td>
<td>Chemotherapy administration, intravenous infusion technique, each additional hour (list separately in addition to code for primary procedure)</td>
</tr>
</tbody>
</table>

Healthcare providers should consult the current CPT® manual and always select the code that accurately describes the administration service performed for the patient. Healthcare providers should also contact the payer for additional coding information required.

This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Astellas and Seattle Genetics do not guarantee third-party coverage or payment or reimbursement for denied claims.

*HCPCS coding requirements vary by payer, setting of care, and date of service. Please verify patient-specific insurance benefits to confirm specific coding and billing guidelines for PADCEV.*

*Current Procedural Terminology® (CPT) codes and descriptions are ©2019 American Medical Association (AMA). All rights reserved. The AMA assumes no liability for data contained herein.*
### Relevant Billing Codes for PADCEV™ (enfortumab vedotin-ejfv)

**International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes**

ICD-10-CM codes are used to identify a patient’s diagnosis. At least 1 ICD-10-CM diagnosis code must be included in all hospital and physician office claims to describe the patient’s condition.

<table>
<thead>
<tr>
<th>Metastatic Urothelial Cancer° ICD-10-CM Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C65.1</td>
<td>Malignant neoplasm of right renal pelvis</td>
</tr>
<tr>
<td>C65.2</td>
<td>Malignant neoplasm of left renal pelvis</td>
</tr>
<tr>
<td>C65.9</td>
<td>Malignant neoplasm of unspecified renal pelvis</td>
</tr>
<tr>
<td>C66.1</td>
<td>Malignant neoplasm of right ureter</td>
</tr>
<tr>
<td>C66.2</td>
<td>Malignant neoplasm of left ureter</td>
</tr>
<tr>
<td>C66.9</td>
<td>Malignant neoplasm of unspecified ureter</td>
</tr>
<tr>
<td>C67.0</td>
<td>Malignant neoplasm of trigone of bladder</td>
</tr>
<tr>
<td>C67.1</td>
<td>Malignant neoplasm of dome of bladder</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Metastatic Urothelial Cancer° ICD-10-CM Codes</th>
<th>Code Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C67.2</td>
<td>Malignant neoplasm of lateral wall of bladder</td>
</tr>
<tr>
<td>C67.3</td>
<td>Malignant neoplasm of anterior wall of bladder</td>
</tr>
<tr>
<td>C67.4</td>
<td>Malignant neoplasm of posterior wall of bladder</td>
</tr>
<tr>
<td>C67.5</td>
<td>Malignant neoplasm of bladder neck</td>
</tr>
<tr>
<td>C67.6</td>
<td>Malignant neoplasm of ureteric orifice</td>
</tr>
<tr>
<td>C67.8</td>
<td>Malignant neoplasm of overlapping sites of bladder</td>
</tr>
<tr>
<td>C67.9</td>
<td>Malignant neoplasm of bladder, unspecified</td>
</tr>
<tr>
<td>C68.0</td>
<td>Malignant neoplasm of urethra</td>
</tr>
</tbody>
</table>

The ICD-10-CM diagnosis codes listed above are provided only as examples of potentially relevant codes. Providers should consult a current ICD-10-CM manual and select the most appropriate diagnosis code(s) to accurately describe a patient’s condition. All diagnosis codes should be supported with adequate documentation.

This guide is offered for informational purposes only and is not intended to provide reimbursement or legal advice. Each healthcare provider is responsible for determining the appropriate codes, coverage, and payment for individual patients. Astellas and Seattle Genetics do not guarantee third-party coverage or payment or reimbursement for denied claims.
Physician Office CMS-1500 Claim Form

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the healthcare provider. Astellas and Seattle Genetics do not guarantee reimbursement for any services or product.

Item 19
For miscellaneous codes, payers may require drug name, total dosage, method of administration, and 10-digit NDC to be provided in Item 19.²

Item 21
Enter appropriate site-specific ICD-10-CM diagnosis code(s) based on the patient’s documented medical record.¹⁰

Item 24A and 24B
Enter the date of service and the appropriate place of service code.¹⁰

Item 24D
Enter CPT/HCPCS code(s) for procedures, services, or supplies provided.²² If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.³

Item 24E
Enter the diagnosis code reference letter or number from Item 21 that relates to the product or procedure listed in Item 24D.²²

Item 24G
Report billing units here. List 1 unit of service in Item 24G. Do not quantity-bill miscellaneous/not otherwise classified drugs and biologicals, even if multiple units are provided.²²
Sample Claim Form

Outpatient Hospital CMS-1450 (UB-04) Claim Form

This sample form is provided for informational purposes only. The accurate completion of claims documentation is the responsibility of the healthcare provider. Astellas and Seattle Genetics do not guarantee reimbursement for any services or product.

A. Item 42
Enter a 4-digit revenue code that best describes the service provided, in accordance with the hospital billing policy.12

B. Item 43
Enter the corresponding description for the revenue code listed in Item 42.12

C. Item 44
Enter the appropriate HCPCS code for PADCEV™ (enfortumab vedotin-ejfv).3 If applicable, discarded product should be reported on a separate line with the HCPCS code and JW modifier.3

D. Item 45
Enter the date of service.12

E. Item 46
Report billing units here. List 1 unit of service in Item 46. Do not quantity-bill miscellaneous/not otherwise classified drugs and biologicals, even if multiple units are provided.12

F. Item 66
Enter the appropriate diagnosis code(s).12

G. Item 67A-67G
Enter the site-specific ICD-10-CM diagnosis codes for the malignancy being treated as documented in the patient’s medical records.12

H. Item 80
For claims using a miscellaneous C9399 code, payers may require additional information such as the quantity of the drug administered (expressed in units of measure applicable to the drug or biological), the date the drug was furnished to the beneficiary, and 10-digit NDC to be entered in Item 80. Requirements vary by payer.

Please see indication and important safety information for PADCEV on pages 18–19. Please click here to see full prescribing information at padcev.com/hcp.
PADCEV Support SolutionsSM

PADCEV Support Solutions offers access and reimbursement support to help patients access PADCEV™ (enfortumab vedotin-ejfv). PADCEV Support Solutions provides information regarding patient health coverage, financial assistance information that may be available to help patients with financial needs, and coding and billing information for PADCEV.

Coverage Support
- Benefits investigation
- Prior authorization assistance
- Appeals assistance

Coding and Billing
- Coding and billing information
- Appeals information

Patient Assistance
- Copay Assistance Programa
- Patient Assistance Programa
- Financial assistance information

Patient Support
- Patient Connect

References:

aProgram is subject to eligibility restrictions and Program terms and conditions.

PLEASE SEE INDICATION AND IMPORTANT SAFETY INFORMATION FOR PADCEV ON PAGES 18–19. PLEASE CLICK HERE TO SEE FULL PRESCRIBING INFORMATION AT PADCEV.COM/HCP.
**Indication**

PADCEV (enfortumab vedotin-ejfv) is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC) who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting.

This indication is approved under accelerated approval based on tumor response rate. Continued approval may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Important Safety Information**

**Warnings and Precautions**

**Hyperglycemia** occurred in patients treated with PADCEV, including death and diabetic ketoacidosis (DKA), in those with and without pre-existing diabetes mellitus. The incidence of Grade 3-4 hyperglycemia increased consistently in patients with higher body mass index and in patients with higher baseline A1C. In one clinical trial, 8% of patients developed Grade 3-4 hyperglycemia. Patients with baseline hemoglobin A1C ≥8% were excluded. Closely monitor blood glucose levels in patients with, or at risk for, diabetes mellitus or hyperglycemia. If blood glucose is elevated (>250 mg/dL), withhold PADCEV.

**Peripheral neuropathy (PN),** predominantly sensory, occurred in 49% of the 310 patients treated with PADCEV in clinical trials; 2% experienced Grade 3 reactions. In one clinical trial, peripheral neuropathy occurred in patients treated with PADCEV and with or without preexisting peripheral neuropathy. The median time to onset of Grade ≥2 was 3.8 months (range: 0.6 to 9.2). Neuropathy led to treatment discontinuation in 6% of patients. At the time of their last evaluation, 19% had complete resolution, and 26% had partial improvement. Monitor patients for symptoms of new or worsening peripheral neuropathy and consider dose interruption or dose reduction of PADCEV when peripheral neuropathy occurs. Permanently discontinue PADCEV in patients that develop Grade ≥3 peripheral neuropathy.

**Ocular disorders** occurred in 46% of the 310 patients treated with PADCEV. The majority of these events involved the cornea and included keratitis, blurred vision, limbal stem cell deficiency and other events associated with dry eyes. Dry eye symptoms occurred in 36% of patients, and blurred vision occurred in 14% of patients, during treatment with PADCEV. The median time to onset to symptomatic ocular disorder was 1.9 months (range: 0.3 to 6.2). Monitor patients for ocular disorders. Consider artificial tears for prophylaxis of dry eyes and ophthalmologic evaluation if ocular symptoms occur or do not resolve. Consider treatment with ophthalmic topical steroids, if indicated after an ophthalmic exam. Consider dose interruption or dose reduction of PADCEV for symptomatic ocular disorders.

**Skin reactions** occurred in 54% of the 310 patients treated with PADCEV in clinical trials. Twenty-six percent (26%) of patients had maculopapular rash and 30% had pruritus. Grade 3-4 skin reactions occurred in 10% of patients and included symmetrical drug-related intertriginous and flexural exanthema (SDRIFE), bullous dermatitis, exfoliative dermatitis, and palmar-plantar erythrodysesthesia. In one clinical trial, the median time to onset of severe skin reactions was 0.8 months (range: 0.2 to 5.3). Of the patients who experienced rash, 65% had complete resolution and 22% had partial improvement. Monitor patients for skin reactions. Consider appropriate treatment, such as topical corticosteroids and antihistamines for skin reactions, as clinically indicated. For severe (Grade 3) skin reactions, withhold PADCEV until improvement or resolution and administer appropriate medical treatment. Permanently discontinue PADCEV in patients that develop Grade 4 or recurrent Grade 3 skin reactions.

Infusion site extravasation Skin and soft tissue reactions secondary to extravasation have been observed after administration of PADCEV. Of the 310 patients, 1.3% of patients experienced skin and soft tissue reactions. Reactions may be delayed. Erythema, swelling, increased temperature, and pain worsened until 2-7 days after extravasation and resolved within 1-4 weeks of peak. One percent (1%) of patients developed extravasation reactions with secondary cellulitis, bullae, or exfoliation. Ensure adequate venous access prior to starting PADCEV and monitor for possible extravasation during administration. If extravasation occurs, stop the infusion and monitor for adverse reactions.

**Embryo-fetal toxicity** PADCEV can cause fetal harm when administered to a pregnant woman. Advise patients of the potential risk to the fetus. Advise female patients of reproductive potential to use effective contraception during PADCEV treatment and for 2 months after the last dose of PADCEV. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with PADCEV and for 4 months after the last dose.

**Adverse Reactions**

Serious adverse reactions occurred in 46% of patients treated with PADCEV. The most common serious adverse reactions (≥3%) were urinary tract infection (6%), cellulitis (5%), febrile neutropenia (4%), diarrhea (4%), sepsis (3%), acute kidney injury (3%), dyspnea (3%), and rash (3%). Fatal adverse reactions occurred in 3.2% of patients, including acute respiratory failure, aspiration pneumonia, cardiac disorder, and sepsis (each 0.8%). Adverse reactions leading to discontinuation occurred in 16% of patients; the most common adverse reaction leading to discontinuation was peripheral neuropathy (6%). Adverse reactions leading to dose interruption occurred in 64% of patients; the most common adverse reactions leading to dose interruption were peripheral neuropathy (18%), rash (9%) and fatigue (6%). Adverse reactions leading to dose reduction occurred in 34% of patients; the most common adverse reactions leading to dose reduction were peripheral neuropathy (12%), rash (6%) and fatigue (4%). The most common adverse reactions (≥20%) were fatigue (56%), peripheral neuropathy (56%), decreased appetite (52%), rash (52%), alopecia (50%), nausea (45%), dysgeusia (42%), diarrhea (42%), dry eye (40%), pruritus (26%) and dry skin (26%). The most common Grade ≥3 adverse reactions (≥5%) were rash (13%), diarrhea (6%) and fatigue (6%).

**Lab Abnormalities**

In one clinical trial, Grade 3-4 laboratory abnormalities reported in ≥5% were: lymphocytes decreased, hemoglobin decreased, phosphate decreased, lipase increased, sodium decreased, glucose increased, urate increased, neutrophils decreased.

**Drug Interactions**

**Effects of other drugs on PADCEV** Concomitant use with a strong CYP3A4 inhibitor may increase free MMAE exposure, which may increase the incidence or severity of PADCEV toxicities. Closely monitor patients for signs of toxicity when PADCEV is given concomitantly with strong CYP3A4 inhibitors.

**Specific Populations**

**Lactation** Advise lactating women not to breastfeed during treatment with PADCEV and for at least 3 weeks after the last dose.

**Hepatic impairment** Avoid the use of PADCEV in patients with moderate or severe hepatic impairment.
Contact PADCEV Support Solutions℠

There are 3 ways to contact PADCEV Support Solutions for assistance

CALL
1-888-402-0627
Monday–Friday, 8:30 AM–8:00 PM ET

GO ONLINE
PADCEVSupportSolutions.com

FAX
1-877-747-6843

PLEASE SEE INDICATION AND IMPORTANT SAFETY INFORMATION FOR PADCEV ON PAGES 18–19. PLEASE CLICK HERE TO SEE FULL PRESCRIBING INFORMATION AT PADCEV.COM/HCP.