PADCEV (enfortumab vedotin-ejfv) Access and Reimbursement Information

PADCEV®
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

of PADCEV reimbursement claims are approved on first submission*

75% of **commercially** insured patients on PADCEV experienced **$0** in **annual** OOP costs for PADCEV†

For the remaining 25% of commercially insured patients who have OOP costs, approximately 80% of patients paid between $53 and $3,990 annually on PADCEV.

53% of **Medicare**-insured patients on PADCEV are estimated to have **less than $500** in **annual** OOP medical spend costs for PADCEV‡

41% of Medicare-insured patients are estimated to have OOP costs between $500 and $4,999 for PADCEV, and 6% are estimated to have OOP costs of $5,000 or more for PADCEV.

OOP costs may vary throughout the course of the year. This information is not a guarantee of coverage or payment. Actual benefits may vary and are determined by each plan.

26 days

Average number of days for insurance reimbursement of PADCEV claims*

94% of all payer policies cover PADCEV to label§‖

Data provided by MMIT

PADCEV claims are reimbursed through many types of insurance*:

Based on 2024 data*

If your patients are experiencing challenges with OOP costs,
call PADCEV Support Solutions℠ at 1-888-402-0627 Monday-Friday, 8:30 AM to 8:00 PM ET

CMS, Centers for Medicare and Medicaid Services; CY24, calendar year 2024; FFS, Fee-for-Service; IV, intravenous; MMIT, Managed Markets Insight & Technology; OOP, out of pocket

*Source: focalPoint® reimbursement claims data from CY24. Individual coverage may vary. Coverage is subject to change. focalPoint provides access and reimbursement metrics based on real-time data and is subject to change without notice by a health plan or state. Please contact the plan or state for the most current information.

†Source: Milliman claims data from CY24. This analysis utilized the Milliman Consolidated Health Cost Guidelines Source Database (CHSD). This dataset included 588 patients that were identified with 2+ prescriptions filled for PADCEV in the commercial claims data during CY24. Of the 588 patients, 345 had OOP information contributed for each claim and are the basis of the results. $0 OOP costs were likely due to meeting maximum OOP on other services/drugs and/or higher-coverage benefit designs. PADCEV patients paid a median of $3,000 in OOP costs on all medical claims during the year.

‡Source: Milliman claims data. For this analysis, the study cohort includes anyone with 2+ claims for PADCEV during CY24 in the Medicare FSS Research Identifiable Files (RIF) claims data, including patients with partial-year Medicare enrollment. Patient Part A and B OOP experience under various Medicare coverage types (e.g., Medicare with Medigap, Medicare-Medicaid, Medicare Advantage) was modeled using published benefit designs.

§Source: MMIT data for percentage of lives covered, based on 317.6 million overall lives from June 2025.

‖Prior authorization (PA) requirements may apply.

BOXED WARNING: SERIOUS SKIN REACTIONS

- **PADCEV (enfortumab vedotin-ejfv) can cause severe and fatal cutaneous adverse reactions including Stevens-Johnson syndrome (SJS) and Toxic Epidermal Necrolysis (TEN), which occurred predominantly during the first cycle of treatment, but may occur later.**
- **Closely monitor patients for skin reactions.**
- **Immediately withhold PADCEV and consider referral for specialized care for suspected SJS or TEN or severe skin reactions.**
- **Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.**

Please see additional Important Safety Information on pages 3-6 and see full Prescribing Information, including BOXED WARNING FOR SERIOUS SKIN REACTIONS.

Helping Patients Receive the Medication They Need

PADCEV Support Solutions℠ offers access and reimbursement support to help patients access PADCEV. PADCEV Support Solutions provides information regarding patient healthcare coverage, financial assistance information that may be available to help patients with financial needs, and coding and billing information for PADCEV.

PADCEV® enfortumab vedotin-ejfv Injection for IV infusion 20 mg & 30 mg vials

SUPPORT℠ SOLUTIONS

Coverage Support

Benefits Investigation

PADCEV Support Solutions offers benefits investigation assistance to evaluate the patient's insurance coverage for PADCEV and provide a summary of benefits.

PA Assistance

If the patient's insurer requires a PA before PADCEV will be covered, PADCEV Support Solutions can obtain the appropriate PA form for completion by the prescriber's office.*

Appeals Assistance

If the patient's insurer denies a PA request, and the prescriber and patient determine that an appeal is appropriate, PADCEV Support Solutions can provide information about the appeals process, including the additional required documentation and, if requested, appeal status tracking.*

Patient Assistance

Copay Assistance Program

Patients who have private commercial health insurance and are not insured by any federal or state healthcare program may be eligible for the PADCEV Copay Assistance Program.†

Patient Assistance Program

The PADCEV Patient Assistance Program provides PADCEV at no cost to uninsured patients who meet the program eligibility requirements.‡

Financial Assistance Information

PADCEV Support Solutions can provide information about potential programs and patient assistance options that may be available to your patients.

Additional Patient and Caregiver Support

Patient Connect

Patient Connect provides patients who have been prescribed PADCEV and their caregivers with information about various independent local and national organizations that may provide emotional, logistical and informational support.§

Coding and Billing

Coding and Billing Information

PADCEV Support Solutions can provide information about coding and billing requirements under different types of payers and plans.

Appeals Information

PADCEV Support Solutions may be able to help you understand the information needed for an appeal submission.*

*The healthcare provider remains responsible for providing all clinical information.
†Subject to eligibility criteria. Terms and conditions may apply. Offer is not valid for cash-paying patients. Offer is not insurance and is void where prohibited by law. Certain rules and restrictions, including an annual copay assistance limit of $25,000, apply. For full terms and conditions, visit https://www.padcev.com/padcev-support-solutions.
‡Subject to eligibility restrictions. Program terms and conditions may apply.
§Support is provided through third-party organizations that operate independently and are not controlled or endorsed by Astellas or Pfizer. Availability of support and eligibility requirements are determined by these organizations.

Please see additional Important Safety Information on pages 3-4 and see full Prescribing Information, including BOXED WARNING FOR SERIOUS SKIN REACTIONS.

INDICATION

PADCEV, in combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, is indicated for the treatment of adult patients with locally advanced or metastatic urothelial cancer (mUC).

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Skin reactions Severe cutaneous adverse reactions, including fatal cases of SJS or TEN occurred in patients treated with PADCEV. SJS and TEN occurred predominantly during the first cycle of treatment but may occur later.

Skin reactions occurred in 70% (all grades) of the 564 patients treated with PADCEV in combination with intravenous pembrolizumab for the treatment of locally advanced or mUC in clinical trials. The majority of skin reactions that occurred included maculo-papular rash, macular rash, and papular rash. Grade 3-4 skin reactions occurred in 17% of patients (Grade 3: 16%, Grade 4: 1%), including maculo-papular rash, bullous dermatitis, dermatitis, exfoliative dermatitis, pemphigoid, rash, erythematous rash, macular rash, and papular rash. A fatal reaction of bullous dermatitis occurred in one patient (0.2%). The median time to onset of severe skin reactions was 1.7 months (range: 0.1 to 17.2 months). Skin reactions led to discontinuation of PADCEV in 6% of patients. Of the patients who experienced a skin reaction and had data regarding resolution (n=391), 59% had complete resolution and 41% had residual skin reactions at their last evaluation. Of the patients with residual skin reactions at last evaluation, 27% (43/159) had Grade ≥2 skin reactions.

Monitor patients closely throughout treatment for skin reactions. Consider topical corticosteroids and antihistamines, as clinically indicated. For persistent or recurrent Grade 2 skin reactions, consider withholding PADCEV until Grade ≤1. Withhold PADCEV and refer for specialized care for suspected SJS, TEN or for Grade 3 skin reactions. Permanently discontinue PADCEV in patients with confirmed SJS or TEN; or Grade 4 or recurrent Grade 3 skin reactions.

Hyperglycemia and diabetic ketoacidosis (DKA), including fatal events, occurred in patients with and without pre existing diabetes mellitus, treated with PADCEV. Patients with baseline hemoglobin A1C ≥8% were excluded from clinical trials. In clinical trials of PADCEV as a single agent, 17% of the 720 patients treated with PADCEV developed hyperglycemia of any grade; 7% of patients developed Grade 3-4 hyperglycemia (Grade 3: 6.5%, Grade 4: 0.6%). Fatal events of hyperglycemia and diabetic ketoacidosis occurred in one patient each (0.1%). The incidence of Grade 3-4 hyperglycemia increased consistently in patients with higher body mass index and in patients with higher baseline A1C. The median time to onset of hyperglycemia was 0.5 months (range: 0 to 20 months). Hyperglycemia led to discontinuation of PADCEV in 0.7% of patients. Five percent (5%) of patients required initiation of insulin therapy for treatment of hyperglycemia. Of the patients who initiated insulin therapy for treatment of hyperglycemia, 66% (23/35) discontinued insulin by the time of last evaluation. 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.

Pneumonitis/Interstitial lung disease (ILD) Severe, life-threatening or fatal pneumonitis/ILD occurred in patients treated with PADCEV.

When PADCEV was given in combination with intravenous pembrolizumab for the treatment of locally advanced or mUC, 10% of the 564 patients had pneumonitis/ILD of any grade and 4% had Grade 3-4. A fatal event of pneumonitis/ILD occurred in two patients (0.4%). The median time to onset of any grade pneumonitis/ILD was 4 months (range: 0.3 to 26 months).

Monitor patients for signs and symptoms indicative of pneumonitis/ILD such as hypoxia, cough, dyspnea or interstitial infiltrates on radiologic exams. Evaluate and exclude infectious, neoplastic and other causes for such signs and symptoms through appropriate investigations. Withhold PADCEV for patients who develop Grade 2 pneumonitis/ILD and consider dose reduction. Permanently discontinue PADCEV in all patients with Grade 3 or 4 pneumonitis/ILD.

Peripheral neuropathy (PN) When PADCEV was given in combination with intravenous pembrolizumab for the treatment of locally advanced or mUC, 67% of the 564 patients had PN of any grade, 36% had Grade 2 neuropathy, and 7% had Grade 3 neuropathy. The median time to onset of Grade ≥2 PN was 6 months (range: 0.3 to 25 months). Of the patients who experienced neuropathy and had data regarding resolution (n=373), 13% had complete resolution, and 87% of patients had residual neuropathy at last evaluation. Of the patients with residual neuropathy at last evaluation, 45% (146/326) had Grade ≥2 neuropathy.

Monitor patients for symptoms of new or worsening PN and consider dose interruption or dose reduction of PADCEV when PN occurs. Permanently discontinue PADCEV in patients who develop Grade >3 PN.

Please see additional Important Safety Information on page 4-6 and see full Prescribing Information, including BOXED WARNING FOR SERIOUS SKIN REACTIONS.

PADCEV®
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials

IMPORTANT SAFETY INFORMATION (cont'd)

Ocular disorders were reported in 40% of the 384 patients treated with PADCEV as a single agent in clinical trials in which ophthalmologic exams were scheduled. The majority of these events involved the cornea and included events associated with dry eye such as keratitis, blurred vision, increased lacrimation, conjunctivitis, limbal stem cell deficiency, and keratopathy. Dry eye symptoms occurred in 30% of patients, and blurred vision occurred in 10% of patients, during treatment with PADCEV. The median time to onset to symptomatic ocular disorder was 1.7 months (range: 0 to 30.6 months). 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.

Infusion site extravasation Skin and soft tissue reactions secondary to extravasation have been observed after administration of PADCEV. Of the 720 patients treated with PADCEV as a single agent in clinical trials, 1% of patients experienced skin and soft tissue reactions, including 0.3% who experienced Grade 3-4 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. Two patients (0.3%) 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. 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

Most common adverse reactions, including laboratory abnormalities (≥20%):

- **PADCEV in combination with intravenous pembrolizumab for the treatment of locally advanced or mUC:** increased aspartate aminotransferase (AST), increased creatinine, rash, increased glucose, peripheral neuropathy, increased lipase, decreased lymphocytes, increased alanine aminotransferase (ALT), decreased hemoglobin, fatigue, decreased sodium, decreased phosphate, decreased albumin, pruritus, diarrhea, alopecia, decreased weight, decreased appetite, increased urate, decreased neutrophils, decreased potassium, dry eye, nausea, constipation, increased potassium, dysgeusia, urinary tract infection, and decreased platelets.

EV-302 Study: 440 patients with previously untreated locally advanced or mUC (PADCEV in combination with intravenous pembrolizumab)

Serious adverse reactions occurred in 50% of patients treated with PADCEV in combination with intravenous pembrolizumab. The most common serious adverse reactions (≥2%) were rash (6%), acute kidney injury (5%), pneumonitis/ILD (4.5%), urinary tract infection (3.6%), diarrhea (3.2%), pneumonia (2.3%), pyrexia (2%), and hyperglycemia (2%). **Fatal adverse reactions** occurred in 3.9% of patients treated with PADCEV in combination with intravenous pembrolizumab including acute respiratory failure (0.7%), pneumonia (0.5%), and pneumonitis/ILD (0.2%).

Adverse reactions leading to discontinuation of PADCEV occurred in 35% of patients. The **most common adverse reactions (≥2%) leading to discontinuation** of PADCEV were PN (15%), rash (4.1%) and pneumonitis/ILD (2.3%). Adverse reactions leading to dose interruption of PADCEV occurred in 73% of patients. The **most common adverse reactions (≥2%) leading to dose interruption** of PADCEV were PN (22%), rash (16%), COVID-19 (10%), diarrhea (5%), pneumonitis/ILD (4.8%), fatigue (3.9%), hyperglycemia (3.6%), increased ALT (3%) and pruritus (2.5%). Adverse reactions leading to dose reduction of PADCEV occurred in 42% of patients. The **most common adverse reactions (≥2%) leading to dose reduction** of PADCEV were rash (16%), PN (13%) and fatigue (2.7%).

DRUG INTERACTIONS

Effects of other drugs on PADCEV *(Dual P-gp and Strong CYP3A4 Inhibitors)*

Concomitant use with dual P-gp and strong CYP3A4 inhibitors may increase unconjugated monomethyl auristatin E exposure, which may increase the incidence or severity of PADCEV toxicities. Closely monitor patients for signs of toxicity when PADCEV is given concomitantly with dual P-gp and strong CYP3A4 inhibitors.

SPECIFIC POPULATIONS

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

Hepatic impairment Avoid the use of PADCEV in patients with moderate or severe hepatic impairment.

Please see full Prescribing Information, including BOXED WARNING FOR SERIOUS SKIN REACTIONS.

Reference: Pfizer and Astellas. PADCEV. Data on File.

astellas

Pfizer Oncology

© 2026 Astellas Pharma Inc. or its affiliates and Pfizer Inc. MAT-US-PAD-2025-00474 03/26
All trademarks are the property of their respective owners.

PADCEV®
enfortumab vedotin-ejfv
Injection for IV infusion 20 mg & 30 mg vials