Mass General Brigham
Health Plan

Padcev (enfortumab vedotin-ejfv)
Effective 08/10/2026

Plan	☒ MassHealth UPPL ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☐ Quantity Limit ☐ Step Therapy
Benefit	☐ Pharmacy Benefit ☒ Medical Benefit		
Specialty Limitations	N/A		
Contact Information	**Medical Benefit** **Pharmacy Benefit**	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview
Padcev (enfortumab vedotin-ejfv) is a nectin-4 directed antibody and microtubule inhibitor conjugate indicated for the treatment of locally advanced or metastatic urothelial cancer in adult patients.

Coverage Guidelines
Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

OR

Authorization will be granted when all the following criteria has been met:

Locally Advanced or Metastatic Urothelial Cancer

1. Diagnosis of locally advanced or metastatic urothelial cancer
2. Prescriber is an oncologist or provides consult notes from an oncologist are provided
3. Appropriate dosing
4. **ONE** of the following:
    a. **BOTH** of the following:
        i. Inadequate response or adverse reaction to ONE platinum-based chemotherapy
        ii. Inadequate response or adverse reaction to a PD-1 inhibitor or PD-L1 inhibitor therapy
    b. **BOTH** of the following:
        i. Contraindication to ALL cisplatin-containing chemotherapy
        ii. Member has received at least ONE prior line of therapy for requested indication
    c. Requested agent will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab alfa-pmph)

Neoadjuvant Treatment/Adjuvant Treatment for MIBC

1. Diagnosis of muscle invasive bladder cancer (MIBC)
2. Prescriber is an oncologist or consult notes from an oncologist are provided
3. Member is ≥ 18 years of age
4. Appropriate dosing

5. Requested agent will be used in combination with Keytruda (pembrolizumab) or Keytruda Qlex (pembrolizumab-berahyaluronidase alfa-pmph) as neoadjuvant treatment followed by adjuvant treatment after cystectomy
6. Contraindication to cisplatin therapy

Continuation of therapy

Reauthorization by physician will infer a positive response to therapy.

Limitations

1. Initial approvals and reauthorizations will be granted for 12 months.

References

1. Padcev [package insert]. Bothwell (WA): Seattle Genetics; 2025 Feb.
2. FDA. FDA approves new type of therapy to treat advanced urothelial cancer [webpage on the internet]. Silver Spring (MD): FDA; 2019 [cited 2020 Feb 3]. Available from:https://www.fda.gov/news-events/press-announcements/fda-approves-new-type-therapy-treat-advanced-urothelial-cancer.
3. The ASCO Post. FDA Grants Breakthrough Therapy Designation to Enfortumab Vedotin for Locally Advanced or Metastatic Urothelial Cancer [webpage on the internet]. Huntington (NY): The ASCO Post; 2019 [cited 2020 Feb 3]. Available from: https://ascopost.com/News/58667.
4. Mayo Clinic. Bladder Cancer [webpage on the internet]. Rochester (MN): Mayo Clinic; 2019 [cited 2020 Feb 3]. Available from: https://www.mayoclinic.org/diseases-conditions/bladder-cancer/symptoms-causes/syc-20356104.
5. Lotan. Clinical presentation, diagnosis, and staging of bladder cancer. In: Basow DS (Ed). UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited year 2021 Nov 3]. Available from: http://www.utdol.com/utd/index.do.
6. Bellmunt. Treatment of metastatic urothelial cancer of the bladder and urinary tract. UpToDate [database on the internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Nov 3]. Available from: http://www.utdol.com/utd/index.do.
7. Cancer.Net. Bladder Cancer: Statistics [webpage on the internet]. Alexandria (VA): Cancer.net; 2019 [cited 202 Feb 3]. Available from: https://www.cancer.net/cancer-types/bladder-cancer/statistics.
8. NCCN. Bladder Cancer version 5.2021 [webpage on the internet]. Plymouth Meeting (PA): NCCN; 2021 [cited 2021 Nov 5]. Available from: https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf.
9. FDA approves pembrolizumab with enfortumab vedotin-ejfv for muscle invasive bladder cancer [press release on the internet]. Food and Drug Administration. 2025 Nov 21 [cited 2025 Apr 10]. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-enfortumab-vedotin-ejfv-muscle-invasive-bladder-cancer
10. Bellmunt J, Gupta S. Neoadjuvant therapy for localized muscle-invasive urothelial carcinoma of the bladder. UpToDate [database on the internet]. Waltham (MA): UpToDate; 2026 Feb [cited 2026 Apr 10]. Available from: http://www.utdol.com/utd/index.do.

Review History

01/11/23 - Reviewed and created for Jan P&T; matched MH UPPL. Created criteria to be in compliance with MassHealth unified formulary requirements. Effective 4/1/23.
05/10/23 – Reviewed and updated for P&T. Updated approval criteria based on expanded indication for patients with locally advanced or metastatic urothelial cancer (mUC) who are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy. Effective 6/5/23.
09/13/23 – Reviewed and updated for P&T. Expanded indication added to guideline: Padcev in combination with Keytruda (pembrolizumab) for the treatment of adult patients with locally advanced (la) or metastatic urothelial

cancer (mUC) who are not eligible for cisplatin-containing chemotherapy. MH decision was also made to change Padcev to Medical Billing designation. Brand preferred and mandatory generic language was added under Limitations. Effective 10/2/23.
09/11/24 – Reviewed and updated for P&T. Criteria update for expanded indication of Padcev in combination with Keytruda for adults with locally advanced or metastatic urothelial cancer. Effective 10/1/24
06/11/25 – Reviewed and updated for P&T. NCCN recommendations support the removal of the requirement of Padcev to be used in monotherapy given combination pembrolizumab and Padcev can be used as subsequent therapy for patients following chemo- or immunotherapy. Effective 7/1/25
7/15/26 – Reviewed and updated for P&T. Added MIBC indication. Added Keytruda Qlex as another trial option. Updated contact info in header. Effective 8/10/26