Mass General Brigham
Health Plan

Padcev (enfortumab vedotin-ejfv)
Effective 10/02/2023

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 and Specialty Medications** All Plans | Phone: 877-519-1908 | Fax: 855-540-3693		
	Non-Specialty Medications All Plans | Phone: 800-711-4555 | 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:

1. Diagnosis of locally advanced or metastatic urothelial cancer
2. Prescriber is an oncologist or provides consult notes from an oncologist are provided
3. **ONE** of the following:
    a. **ALL** of the following:
        i. Paid claims or physician attestation of inadequate response or adverse reaction to ONE platinum-based chemotherapy
        ii. Paid claims or physician attestation of inadequate response or adverse reaction to a PD-1 inhibitor or PD-L1 inhibitor therapy
        iii. Requested agent will be used as monotherapy
    b. **ALL** of the following:
        i. Contraindication to ALL cisplatin-containing chemotherapy
        ii. Member has received at least ONE prior line of therapy for requested indication
        iii. Requested agent will be used as monotherapy
    c. **BOTH** of the following:
        i. Contraindication to ALL cisplatin-containing chemotherapy
        ii. Requested agent will be used in combination with Keytruda

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.
2. Members who have already started treatment on Padcev® may be approved for any FDA-approved indication.
3. **Requests for Brand Name when generic is preferred:** In addition to any prior authorization requirements that may be listed above, if an A-rated generic equivalent is available, such prior authorization requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the generic equivalent drug (history of allergic reaction to the inactive ingredients used in the manufacturing process of a certain drug is acceptable).
4. **Requests for generic when Brand Name is preferred:** There are some drugs for which the Plan has determined it will be cost effective to prefer the use of the Brand Name formulation. In this case, the generic equivalent formulation is considered non-preferred and requires prior authorization. These requests require medical records documenting an allergic response, adverse reaction, or inadequate response to the Brand Name formulation. For the most up to date list of drugs where the Brand Name formulation is preferred, see the MassHealth Brand Name Preferred Over Generic Drug List (BOGL) at www.mass.gov/druglist.
5. Dosing

Drug	Dosing
Padcev® (enfortumab vedotin-ejfv) **Vial**: 20 mg 30 mg	Locally advanced or metastatic urothelial cancer: 1.25 mg/kg (up to a maximum dose of 125 mg) given as an intravenous infusion over 30 minutes on Days 1, 8 and 15 of a 28-day cycle until disease progression or unacceptable toxicity

References

1. Padcev® [package insert]. Bothwell (WA): Seattle Genetics; 2023 Apr.
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. Balversa® [package insert]. Horsham (PA): Janssen; 2019 April

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.