Medical Necessity Guidelines

Medical Benefit Drugs

ADSTILADRIN® (nadofaragene firadenovec-vncg)

Effective: January 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request.	Yes ☒ No ☐

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 617-673-0956

☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA) Approved Indications:

- ADSTILADRIN (nadofaragene firadenovec-vncg) is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.

The Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for its Medicare Advantage plan members. CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and documentation included in the Medicare manuals are the basis for coverage determinations. When CMS does not provide guidance, the Plan's internally developed medical necessity guidelines are used. CMS coverage guidelines are not established for this service. Point32Health covers Adstiladrin in accordance with MassHealth coverage criteria.

For the therapy Adstiladrin, evidence is sufficient for coverage. Adstiladrin received FDA approval in December 2022 based on the results of a phase 3 trial. Of those who participated in the trial, 51% achieved a complete response (CR) rate with a median duration of CR of 9.7 months, and 46% of those patients still had no detectable disease for at least 1 year. Adstiladrin provides an additional treatment option for a very specific patient population with bladder cancer.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See References section below for all evidence accessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan may cover Adstiladrin when all the following clinical criteria is met:

1. Member is 18 years or older; **and**
2. Member has a diagnosis of non-muscle-invasive bladder cancer (NMICB); **and** ;
3. The disease is high-risk with carcinoma in situ (CIS); **and**
4. The provider is an oncologist or urologist; **and**
5. Appropriate dosing; **and**
6. There is an inadequate response, adverse reaction, or contraindication to Bacillus Calmette Guerin (BCG)

Reauthorization Criteria

The Plan may authorize coverage for Adstiladrin for 1 year when all the following criteria are met:

1. Initial criteria is met; **and**

2. There is no evidence of unacceptable toxicity or disease recurrence

Limitations

- Initial authorization is limited to 1 year when initial authorization criteria are met.
- Reauthorization may be granted for 1 year if reauthorization criteria are met.
- The Plan will not cover Adstiladrin when:
    - Member is with hypersensitivity to interferon alfa or any component of the product
    - Member is immunocompromised or immunodeficient

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose

References:

1. United States Food and Drug Administration. Package Insert-ADSTILADRIN. Available at fda.gov. Last accessed June 26, 2023.
2. Black, P, et. al. Management of recurrent or persistent non-muscle invasive bladder cancer. UpToDate. Updated April 2023. Accessed June 23, 2023. https://www.uptodate.com/contents/management-of-recurrent-or-persistent-non-muscle-invasive-bladder-cancer
3. U.S. Food & Drug Administration. FDA approves first gene therapy for the treatment of high-risk, non-muscle-invasive bladder cancer. December 16, 2022. Accessed June 23, 2023. https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-high-risk-non-muscle-invasive-bladder-cancer
4. Kassouf W, Black, P. Treatment of primary non-muscle invasive urothelial bladder cancer UpToDate. Updated June 2022. Accessed June 23, 2023. https://www.uptodate.com/contents/management-of-recurrent-or-persistent-non-muscle-invasive-bladder-cancer
5. Boorjian SA, Alemozaffar M, Konety BR, et al. Intravesical nadofaragene firadenovec gene therapy for BCG-unresponsive non-muscle-invasive bladder cancer: a single-arm, open-label, repeat-dose clinical trial. *Lancet Oncol*. 2021;22(1):107-117. doi:10.1016/S1470-2045(20)30540-4
6. Azam F, Latif MF, Farooq A, et al. Performance Status Assessment by Using ECOG (Eastern Cooperative Oncology Group) Score for Cancer Patients by Oncology Healthcare Professionals. *Case Rep Oncol*. 2019;12(3):728-736. Published 2019 Sep 25. doi:10.1159/000503095
7. Carmack AJ, Soloway MS. The diagnosis and staging of bladder cancer: from RBCs to TURs. *Urology*. 2006;67(3 Suppl 1):3-10. doi:10.1016/j.urology.2006.01.026
8. American Cancer Society. Bladder Cancer Early Detection, Diagnosis, and Staging. Accessed June 26, 2023. Bladder Cancer Staging | Bladder Cancer Stages
9. Ozelo, M., Mahlangu, J., & Pasi, K. et al. (2022, March 17). *Valoctocogene Roxaparvovec gene therapy for hemophilia a | Nejm*. New England Journal of Medicine. https://www.nejm.org/doi/full/10.1056/NEJMoa2113708
10. MassHealth Drug List - health and human services. Table 57: Oncology Agents. March 2024. Accessed June 7, 2024. https://mhdl.pharmacy.services.conduent.com/MHDL/pubtheradetail.do?id=350&drugId=8644

Approval And Revision History

July 19, 2023: Reviewed by the Medical Policy Approval Committee (MPAC) effective October 1, 2023

Subsequent endorsement date(s) and changes made:

- November 16, 2023: Reviewed by MPAC, renewed without changes
- November 2023: Updated overview effective January 1, 2024
- December 1, 2023: Reviewed and approved by UM Committee effective January 1, 2024
- May 15, 2024: Reviewed by MPAC. Criteria update to align with MassHealth criteria effective July 1, 2024
- June 13, 2024: Reviewed and approved by UM Committee effective July 1, 2024
- November 21, 2024: Reviewed by MPAC, renewed without changes, effective January 1, 2025
- December 13, 2024: Reviewed and approved by the UM Committee, effective January 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member's benefit document, and in coordination with the Member's physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.