Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 303.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Adstiladrin (nadofaragene firadenov-vncg)

I. Policy:
Adstiladrin (nadofaragene firadenov-vncg)

II. Purpose/Objective:
To provide a policy of coverage regarding Adstiladrin (nadofaragene firadenov-vncg)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Nadofaragene firadenovec is a nonreplicating adenoviral vector-based gene therapy. It consists of rAd-IFNα, a nonreplicating recombinant adenovirus (serotype 5) vector-based gene therapy that transports a copy of interferon alfa-2b gene to urothelial cells, and Syn3, a polyamide surfactant that augments the viral transduction of the urothelium. Intravesicular administration produces cell transduction and transient local expression of the IFNα2b protein, which is believed to have antitumor effects.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

GRANDFATHER PROVISION – Members already established on therapy are eligible for approval as long as there is medical record documentation that the safety and effectiveness of use for the prescribed indication is supported by Food and Drug Administration (FDA) approval or adequate medical and scientific evidence in the medical literature.

Adstiladrin (nadofaragene firadenov-vncg) will be considered medically necessary for ALL lines of business when ALL of the following criteria are met:

- Medical record documentation of an age greater than or equal to 18 **AND**
- Medical record documentation that Adstiladrin is being prescribed by or in consultation with a hematologist, oncologist, or urologist **AND**
- Medical record documentation of high-risk Bacillus Calmette-Guerin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors **AND**
- Medical record documentation of a prescribed dose and administration that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

AUTHORIZATION DURATION: Initial approval will be for 6 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 6 months or less of the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

REFERENCES:

1. Adstiladrin [prescribing information]. Kastrup, Denmark: Ferring Pharmaceuticals; December 2022.
2. IPD Analytics. Adstiladrin for the Treatment of Bladder Cancer. New Drug Approval Review. January 2023. Accessed September 2023. www.ipdanalytics.com.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 11/21/23

Revised:

Reviewed:

MA UM Committee approval: Pending