Drug Policy:

Adstiladrin™ (nadofaragene firadenovec-vncg)

POLICY NUMBER UM ONC_1472	**SUBJECT** Adstiladrin™ (nadofaragene firadenovec-vncg)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 3**
DATES COMMITTEE REVIEWED 02/08/23	**APPROVAL DATE** February 8, 2023	**EFFECTIVE DATE** February 24, 2023	**COMMITTEE APPROVAL DATES** 02/08/23	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**NCQA STANDARDS** UM 2		**ADDITIONAL AREAS OF IMPACT**	
CMS REQUIREMENTS	**STATE/FEDERAL REQUIREMENTS**		**APPLICABLE LINES OF BUSINESS** Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Adstiladrin (nadofaragene firadenovec-vncg) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the Preferred Drug Guidelines OR
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the Preferred Drug Guidelines OR

3. When Health Plans utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, and there is no Health Plan PDL applicable, the Preferred Drug Guidelines shall follow NCH recommended agents/regimens/preferred drugs AND
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision AND
5. When applicable, generic alternatives are preferred over brand-name drugs AND
6. When there is a documented drug shortage, disease progression, contraindication, or confirmed intolerance to a preferred drug/regimen, per NCH Policy and Pathway, the available alternative product may be used if deemed medically appropriate and the indication is listed in a standard reference compendium or accepted peer review literature. For a list of current drug shortages, please refer to FDA drug shortage website in the reference section.

B. Non-Muscle Invasive Bladder Cancer

1. The member has high-risk BCG unresponsive non-muscle invasive bladder cancer with carcinoma in situ (CIS), with or without papillary tumors, and Adstiladrin (nadofaragene firadenovec-vncg) will be used as monotherapy for intravesical instillation in members who are refractory to local (intravesical) therapy with Bacillus Calmette-Guérin (BCG) AND
2. BCG- Refractory carcinoma in situ (CIS) is defined as one of the following:
   a. Persistent or recurrent CIS (+/-recurrent Ta/T1 disease) within 12 months of receiving adequate BCG (at least 5 of 6 doses of an initial induction course plus either at least 2 of 3 doses of maintenance therapy or at least 2 of 6 doses of a second induction course)
   b. Recurrent high-grade Ta/T1 disease within 6 months of completion of adequate BCG (at least 5 of 6 doses of an initial induction course plus either at least 2 of 3 doses of maintenance therapy or at least 2 of 6 doses of a second induction course)
   c. T1 high-grade disease at the first evaluation following an induction BCG course alone (at least 5 of 6 doses of an initial induction course).

III. EXCLUSION CRITERIA

A. Disease progression while taking Adstiladrin (nadofaragene firadenovec-vncg) or prior treatment with adenovirus-based drugs.

B. Members with extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma.

C. Dosing exceeds single dose limit of Adstiladrin (nadofaragene firadenovec-vncg) 75 mL at a concentration of 3×10^{11} viral particles (vp)/mL.

D. Treatment exceeds the maximum months duration limit of 12 months or 4 doses (if the patient achieved a complete response).

E. Investigational use of Adstiladrin (nadofaragene firadenovec-vncg) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
   1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
   2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.

3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

IV. MEDICATION MANAGEMENT

A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

A. Review – Utilization Management Department

B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

A. None

VII. REFERENCES

A. Suderman J, St-Laurent MP, Black PC. Re: IL-15 Superagonist NAI in BCG-Unresponsive Non-muscle-invasive Bladder Cancer. Eur Urol. 2023 Feb 1:S0302-2838(23)00016-7.

B. Adstiladrin prescribing information. Ferring Pharmaceuticals Denmark 2023.

C. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

D. Clinical Pharmacology Elsevier Gold Standard 2023.

E. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

F. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

I. NCQA UM 2023 Standards and Elements.