PREMERA BLUE CROSS

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PHARMACY / MEDICAL POLICY – 5.01.632

Adstiladrin® (nadofaragene firadenovec-vncg)

Effective Date:	June 1, 2023	RELATED MEDICAL POLICIES:
Last Revised:	July 1, 2023	None
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | DOCUMENTATION REQUIREMENTS | CODING
RELATED INFORMATION | EVIDENCE REVIEW | REFERENCES |HISTORY

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Introduction

Bladder cancer occurs in the urinary system, with abnormal tissue developing in the lining of the bladder. Urothelial bladder cancer is the most common type of bladder cancer. Most new urothelial bladder cancers are considered non-muscle invasive. Treatment of bladder cancer depends on the tumor stage, tumor size, and other factors. Depending on how severe the cancer is, treatment options may include chemotherapy, radiation, surgery, or immunotherapy. This policy discusses when the use of Adstiladrin® may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Adstiladrin® (nadofaragene firadenovec-vncg) Intravesical	**Adstiladrin® (nadofaragene firadenovec-vncg) may be considered medically necessary for treatment of non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) in individuals aged 18 years and older when the following criteria are met:**

Drug	Medical Necessity

	• Individual is ineligible for or has elected not to undergo a cystectomy
	AND
	• Individual has Bacillus Calmette-Guérin (BCG)-unresponsive disease defined as ONE of the following:
	  ○ Persistent or recurrent disease following BCG therapy
	  OR
	  ○ T1 disease following a single induction course of BCG
	AND
	• Individual has an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less

Drug	Investigational
Adstiladrin® (nadofaragene firadenovec-vncg)	**All other uses of Adstiladrin® (nadofaragene firadenovec-vncg) not outlined in this policy are considered investigational.**

Approval	Criteria
Length of Approval	
Initial authorization	**Adstiladrin® (nadofaragene firadenovec-vncg) may be approved for up to 6 months.**
Re-authorization criteria	**Future re-authorization of Adstiladrin® (nadofaragene firadenovec-vncg) may be approved up to 12 months if the drug-specific coverage criteria are met, and chart notes demonstrate that the individual continues to show a positive clinical response to therapy.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, and medication history

Coding

Code	Description
HCPCS	
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose (Adstiladrin®) (new code effective 7/1/2023)
J9999	Injection, nadofaragene firadenovec-vncg, per therapeutic dose

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

Related Information

Benefit Application

Adstiladrin® (nadofaragene firadenovec-vncg) is managed through the medical benefit.

Evidence Review

Summary of Evidence

Adstiladrin® (nadofaragene firadenovec-vncg)

Adstiladrin® (nadofaragene firadenovec-vncg) is a nonreplicating recombinant adenovirus that acts as a gene therapy. The adenovirus delivers the human interferon alfa-2b (IFNα2b) gene to the individual's bladder urothelial cells. Intravesical instillation of Adstiladrin® results in cell transduction and transient local expression of the IFNα2b protein that is anticipated to have anti-tumor effects. The safety and effectiveness of Adstiladrin® was evaluated in the Phase 3 CS-003 trial (NCT02773849), an open-label, multicenter, single-arm study that enrolled a total of 157 adult individuals with Bacillus Calmette-Guérin (BCG)-unresponsive, high-risk non-muscle invasive bladder cancer (NMIBC) following transurethral resection. Among these, 103 individuals had carcinoma in situ (CIS) with or without papillary tumors, of which 98 were considered

evaluable for response. Adstiladrin® was administered directly into the individual's bladder by instillation once every 3 months. The trial met its primary endpoint, with more than half (51%) of the 98 evaluable individuals (95% confidence interval [CI], 41 to 61) with CIS with or without concomitant high-grade Ta or T1 disease (CIS ± Ta/T1) achieving a complete response (CR), all by 3 months. Of the individuals who achieved an initial CR, 46% (n = 23 of 50) continued to remain free of high-grade recurrence at 12 months. Safety analyses were done in all individuals who received at least one dose of treatment. Serious adverse reactions (SARs) occurred in 11% of individuals who received Adstiladrin®. SARs occurring in >1% of individuals included coronary artery disease and hematuria (blood in urine). Permanent discontinuation of Adstiladrin® due to an adverse reaction (AR) occurred in 3 individuals (1.9%). ARs that resulted in permanent discontinuation included bladder spasm instillation site discharge and benign neoplasm of the bladder. Dosage interruptions of Adstiladrin® due to an AR occurred in 54 (34%) individuals. ARs in >10% of individuals that required dosage interruption included instillation site discharge, bladder spasm, and micturition (urination) urgency. The most common (>10%) ARs, including laboratory abnormalities (>15%), were increased glucose, instillation site discharge, increased triglycerides, fatigue, bladder spasm, micturition urgency, increased creatinine, hematuria, phosphate decreased, chills, dysuria, and pyrexia (fever).

References

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6. Burger M, et al. Epidemiology and risk factors of urothelial bladder cancer. Eur Urol. 2013;63(2):234–41. doi:10.1016/j.eururo.2012.07.033
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History

Date	Comments
06/01/23	New policy, approved May 9, 2023. Added Adstiladrin (nadofaragene firadenovec-vncg) coverage criteria. HCPCS code J9999 added for Adstiladrin.
07/01/23	Coding update. Added new HCPCS code J9029.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.

Discrimination is Against the Law

Premera Blue Cross (Premera) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. Premera provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). Premera provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator ─ Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-4535, Fax: 425-918-5592, TTY: 711, Email AppealsDepartmentInquiries@Premera.com. You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Washington residents: You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx.

Alaska residents: Contact the Alaska Division of Insurance via email at insurance@alaska.gov, or by phone at 907-269-7900 or 1-800-INSURAK (in-state, outside Anchorage).

Language Assistance

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-722-1471 (TTY: 711).

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-722-1471 (TTY: 711).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-722-1471 (TTY：711）。

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-722-1471 (TTY: 711).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-722-1471 (TTY: 711) 번으로 전화해 주십시오.

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-722-1471 (телетайп: 711).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 800-722-1471 (TTY: 711).

MO LOU SILAFIA: Afai e te tautala Gagana fa'a Sāmoa, o loo iai auaunaga fesoasoan, e fai fua e leai se totogi, mo oe, Telefoni mai: 800-722-1471 (TTY: 711).

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注意事項：日本語を話される場合、無料の言語支援をご利用いただけます。800-722-1471 （TTY:711）まで、お電話にてご連絡ください。

PAKDAAR: Nu saritaem ti Ilocano, ti serbisyo para ti baddang ti lengguahe nga awanan bayadna, ket sidadaan para kenyam. Awagan ti 800-722-1471 (TTY: 711).

УВАГА! Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки. Телефонуйте за номером 800-722-1471 (телетайп: 711).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 800-722-1471 (TTY: 711)។

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ਧਿਆਨ ਦਿਓ: ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-722-1471 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 800-722-1471 (TTY: 711).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-722-1471 (TTY: 711).

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توجه: اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-722-1471 (TTY: 711) تماس بگیرید.