OncoHealth

Non-Muscle Invasive Bladder Cancer

Original Effective Date: 7/15/2024
Revision Date(s): 7/5/2024; 11/22/2024; 1/1/2025; 12/15/2025; 02/16/2026; 4/1/2026; 6/9/2026
Review Date: 6/9/2026
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability.

Preference	Requires Prior Auth	Drug Name	HCPCS Code	Description
Preferred	Yes	**Nadofaragene firadenovec-vncg (Adstiladrin)**	**J9029**	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose
Preferred	Yes	**Pembrolizumab (Keytruda)**	**J9271**	Injection, pembrolizumab, 1 mg
Preferred	Yes	**Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda QLEX)**	**J9277**	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph
Non-preferred	Yes	**Nogapendekin alfa inbakicept-pmln (Anktiva)**	**J9028**	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram
Non-preferred	Yes	**Gemcitabine (Inlexzo)**	**J9183**	Gemcitabine intravesical system, 225 mg

- Members must have documentation of a contraindication, failure, or intolerance to any of the preferred agents prior to approval of a non-preferred product, when clinically appropriate.
- Preferred product requirements apply to new starts only.
- Step Therapy applies to all overlapping compendia supported indications/regimens.

Product Specific Criteria

Anktiva (nogapendekin alfa inbakicept-pmln)

- Member is 18 years of age or older; **AND**
- Member will be receiving nogapendekin alfa inbakicep-pmln (Anktiva) in combination with BCG; **AND**

- Member has non-muscle invasive bladder cancer with carcinoma in situ (CIS) that has the following characteristics:
    - High-grade; **AND**
    - Urothelial (transitional cell) histology[1]; **AND**
    - BCG unresponsive defined by one of the following:
        - Persistent or recurrent CIS within 12 months of receiving adequate BCG[2]; **OR**
        - Recurrent high-grade Ta/T1 disease within 6 months of receiving adequate BCG[3]; **OR**
        - T1 high-grade disease at the first evaluation following complete induction BCG course alone (5 of 6 doses of an initial induction course); **AND**
        - Prescribed by, or in consultation with, a urologist or oncologist

Inlexzo (gemcitabine)

- Member is 18 years of age or older; **AND**
- Member has BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ (CIS), with or without papillary tumors that has the following characteristics:
    - High-grade; **AND**
    - Urothelial (transitional cell) histology[1]; **AND**
    - BCG unresponsive defined by one of the following:
        - Persistent or recurrent CIS within 12 months of receiving adequate BCG[2]; **OR**
        - Recurrent high-grade Ta/T1 disease within 6 months of receiving adequate BCG[3]; **OR**
        - T1 high-grade disease at the first evaluation following complete induction BCG course alone (5 of 6 doses of an initial induction course); **AND**
        - Prescribed by, or in consultation with, a urologist or oncologist

Universal Approval Criteria:

Unless otherwise noted, the review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be considered if determined to be medically necessary per one or more of the following compendia:
    - Clinical Pharmacology (Strong For); **OR**
    - Wolters Kluwer Lexi-Drugs® (Level A); **OR**

[1] Mixed histology tumors are supported if transitional cell histology is predominant
[2] Adequate BCG trial is defined as at least 5 of 6 doses of an initial induction PLUS at least 2 doses as part of maintenance treatment or a second induction
[3] Adequate BCG trial is defined as at least 5 of 6 doses of an initial induction PLUS at least 2 doses as part of maintenance treatment or a second induction

- Other uses of drugs and biologics may be considered medically necessary if supported as safe and effective according to peer-reviewed articles from one of the following journals:
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology;
    - **Meeting abstracts and case reports are excluded from consideration;**
- Non-standard protocols may be approved based on unique clinical circumstances;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Billing

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Nogapendekin alfa inbakicept-pmln (Anktiva)	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram
Nadofaragene firadenovec-vncg (Adstiladrin)	J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose
Gemcitabine (Inlexzo)	J9183	Gemcitabine intravesical system, 225 mg
Pembrolizumab (Keytruda)	J9271	Injection, pembrolizumab, 1 mg
Pembrolizumab and berahyaluronidase alfa-pmph	J9277	Injection, pembrolizumab, 1 mg and berahyaluronidase alfa-pmph

References

1. Adstiladrin [package insert]. Ferring Pharmaceuticals. Kastrup, Denmark. Available at: https://ferringusa.com/wp-content/uploads/sites/12/2024/10/Adstiladrin_PI.pdf
2. Adstiladrin. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/

3. Anktiva [package insert]. ImmunityBio, Inc. Culver City, CA. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761336s000lbl.pdf
4. Anktiva. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
5. Inlexzo [package insert]. Janssen Biotech, Inc. Horsham, PA. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/219683s000lbl.pdf
6. Inlexzo. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
7. Keytruda [package insert]. Merck & Co, Inc. Whitehouse Station, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125514s178lbl.pdf
8. Keytruda. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
9. Keytruda QLEX [package insert]. Merck Sharp & Dohme, LLC. Rahway, NJ. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/761467s001lbl.pdf
10. Keytruda QLEX. NCCN Drugs & Biologics Compendium. Available at: https://www.nccn.org/professionals/drug_compendium/content/
11. Chamie K, Change SS, Kramolowsky E, Et al. IL-15 superagonist NAI in BCG-unresponsive non-muscle-invasive bladder cancer. NEJM Evid 2023; 2:EVIDoa2200167. Available at: https://evidence.nejm.org/doi/full/10.1056/EVIDoa2200167
12. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed November 13, 2025. To view the most recent and complete version of the guideline, go online to NCCN.org.
13. Clarke H. Nadofaragene firadenovec under regulatory review in Japan. *Urology Times*. September 11, 2025;53(10). https://www.urologytimes.com/view/nadofaragene-firadenovec-under-regulatory-review-in-japan
14. Ferring Pharmaceuticals. *Final Five-Year Analysis of Phase 3 Data with ADSTILADRIN® (nadofaragene firadenovec-vncg) Shows Durable Bladder Preservation and Consistent Long-Term Safety in BCG-Unresponsive NMIBC*. Ferring Pharmaceuticals USA, 6 May 2024, Accessed on February 10, 2026 from https://ferringusa.com/?press=final-five-year-analysis-of-phase-3-data-with-adstiladrin-nadofaragene-firadenovec-vncg-shows-durable-bladder-preservation-and-consistent-long-term-safety-in-bcg-unresponsive-nmibc.
15. Klaassen, Z. (2025, November 2–6). *WSAUA 2025: Real-world utilization of Adstiladrin in patients with BCG-unresponsive NMIBC*. UroToday. Accessed on February 10, 2026 from https://www.urotoday.com/conference-highlights/wsaua-2025/wsaua-2025-bladder-cancer/164433-wsaua-2025-real-world-utilization-of-adstiladrin-in-patients-with-bcg-unresponsive-nmibc.html
16. Moyer JA, Mi L, Nguyen MV, Durant AM, Zganjar AJ, Lyon TD, Shah PH, Boorjian SA, Tyson MD 2nd. Real-world outcomes of nadofaragene firadenovec for BCG-unresponsive non-muscle-invasive bladder cancer: A multicenter experience. *Urol Oncol*. 2025 Nov 17:S1078-1439(25)00442-9. doi: 10.1016/j.urolonc.2025.10.023. Epub ahead of print. PMID: 41253655.
17. Rosa K. Nadofaragene firadenovec NDA accepted for review in Japan for BCG-unresponsive NMIBC. OncLive. Published September 15, 2025. Accessed December 23, 2025.

https://www.onclive.com/view/nadofaragene-firadenovec-nda-accepted-for-review-in-japan-for-bcg-unresponsive-nmibc

Disclaimer

Drug Coverage Policies are developed as needed, reviewed and updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to utilizing this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice nor dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
7/05/2024	Policy creation
7/15/2024	Policy adoption by P&T
11/22/2024	For 1/1/2025 – update to permanent HCPCS Code per CMS HCPCS Code Updates
12/15/2025	Annual Review – OH P&T – inclusion of Inlexzo as NP agent; renaming of policy from Anktiva to NMIBC (step) policy; approved at OH December P&T
2/16/2026	Added additional RWE references; minimal updates to criteria; Added Keytruda Qlex J9999; added language Prescribed by, or in consultation with, a urologist or oncologist; Approved at OH P&T
4/1/2026	Update HCPCS for Inlexzo (from J9999 to J9183) and Keytruda Qlex (from J9999 to J9277)
6/9/2026	Policy adopted by P32H P&T