Adstiladrin
(nadofaragene firadenovec-vncg)

Policy Number: 068

<table>
<thead>
<tr>
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<th>Commercial and Qualified Health Plans</th>
<th>MassHealth</th>
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<tbody>
<tr>
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Adstiladrin is a non-replicating adenovirus vector-based gene-therapy 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.

Criteria

1. Criteria for Initial Approval
   Authorization may be granted to members 18 years of age or older when the following criteria are met:
   A. The member has non-muscle invasive bladder cancer with carcinoma in situ (with or without papillary tumors); AND
   B. The member has high risk disease that is unresponsive to BCG defined as one of the following:
      i. Stage T1 disease following a single induction course of BCG; or
      ii. Persistent or recurrent disease following at least five of six doses of an initial induction course of BCG plus either:
         o At least two of three doses of maintenance therapy; or
         o At least two of six doses of an additional induction course.
   C. The member has undergone transurethral resection of bladder tumor (TURBT) to remove all resectable disease (Ta and T1 components).

2. Dosing and Administration
   • The recommended dose of Adstiladrin is 75 mL at a concentration of 3 x 10^{11} viral particles (vp)/mL instilled once every 3 months into the bladder via a urinary catheter.
   • Premedication with an anticholinergic before instillation of Adstiladrin.
   • Adstiladrin should be administered by intravesical instillation only.
   • Adstiladrin should be left in the bladder for 1 hour following instillation.

3. Continuation of Therapy
   • Authorization of additional courses of therapy may be approved up to 12 months if the member meets all of the following:
     i. The member continues to meet the criteria for initial approval;
     ii. There is disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread;
     iii. There is an absence of unacceptable toxicity to the drug.
   • If members with CIS do not have a complete response to treatment after 3 months or if CIS recurs, then providers should consider cystectomy.
4. Contraindications/Exclusions
   - The member has extra-vesical (i.e., urethra, ureter, or renal pelvis), muscle invasive (T2-T4), or metastatic urothelial carcinoma
   - The member is currently receiving systemic therapy for bladder cancer
   - The member has received prior treatment with adenovirus-based therapies
   - The member has a hypersensitivity to interferon alfa
   - The member is immunosuppressed or immunodeficient

Medicare Variation
Mass General Brigham Health Plan uses guidance from the Centers for Medicare and Medicaid Services (CMS) for coverage determinations for its Medicare Advantage plan members. 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 there is no guidance from CMS for the requested service, Mass General Brigham Health Plan’s medical policies are used for coverage determinations.

Codes
The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

This list of codes applies to commercial and MassHealth plans only.

<table>
<thead>
<tr>
<th>Authorized CPT/HCPCS Codes</th>
<th>Code Description</th>
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<tr>
<td>J9029</td>
<td>Injection, nadofaragene firadenovec-vncg, per therapeutic dose</td>
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Effective
March 2024: Annual Review.
October 2023: Effective Date

References

Nadofaragene firadenovec-vncg [package insert]. Kupio, Finland: Ferring Pharmaceuticals; 2022