
Medical Policy



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Category: Medicine

Title: Adenovirus Vaccine for Oral Use

**Procedure Code(s):
90476**

Description/Background

Adenoviruses are a frequent cause of acute upper respiratory tract (URT) infections, i.e. "colds." In addition, they also cause a number of other types of infection. They were first isolated in 1953 by investigators trying to establish cell-lines from adenoidal tissue of children removed during tonsillectomy and from military recruits with febrile illness. Historically, adenovirus types 4 and 7 have been the major causes of acute respiratory disease in the military.

Adenoviruses most commonly cause respiratory illness. However, depending on the infecting serotype, they may also cause various other illnesses, such as gastroenteritis, conjunctivitis, cystitis and dermatitis. Symptoms of respiratory illness caused by adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with compromised immune systems are especially susceptible to severe complications of adenovirus infection. Acute respiratory disease (ARD), first recognized among military recruits during World War II, can be caused by adenovirus infections during conditions of crowding and stress.

Most infections are mild and require no therapy or only symptomatic treatment. Because there is no virus-specific therapy, serious adenovirus illness can be managed only by treating symptoms and complications of the infection.

Vaccines were developed for adenovirus serotypes 4 and 7, but are available only for preventing Acute Respiratory Disease (ARD) among military recruits. Strict attention to good infection-control practices is effective for stopping nosocomial outbreaks of adenovirus-associated disease, such as epidemic keratoconjunctivitis.

Medical Policy Title: Adenovirus for Oral Use

This vaccine contains a selected viable strain of Type 4 adenovirus prepared from tissue cultures of human diploid fibroblast cells (Strain WI 38). The vaccine is formulated as a tablet, each of which contains not less than 32,000 tissue-culture infective doses.

The use of adenovirus vaccines has been shown to achieve dramatic reduction in the occurrence of disease and associated hospital admissions in *military* environments.

Through 1995, Wyeth Laboratories, Inc. provided the Department of Defense vaccines for both Adenovirus types 4 and 7. When stockpiles ran out in 1999, military training centers attained pre-vaccination infection levels: 20 to 30 percent of all recruits fell ill with the viruses. Several studies show that up to 40 percent of the recruits who become ill take up to two weeks to recover. Recuperations lasting that long require that recruits restart their training, increasing the cost of the program per recruit. The health dangers, coupled with lost training time, have prompted the Department of Defense to again consider manufacturing vaccines for types 4 and 7 adenoviruses. The Army is thinking about taking the lead in remanufacturing because of the military's experience with the original vaccines. Adenovirus vaccines are currently undergoing FDA approval process

CPT/HCPCS Level II Codes and Description

90476	Adenovirus vaccine, type 4, live, for oral use
90477	Adenovirus vaccine, type 7, live, for oral use

Diagnoses/Medical Conditions

None

Medical Policy Statement

The administration of adenovirus vaccines, types 4 and 7, is not an established therapy for the general public, although it has a history of effectiveness when administered to military personnel. While this service may be safe, it is currently not being manufactured and not available for administration to any patient.

Rationale

Acute respiratory disease (ARD), first recognized among military recruits during World War II, can be caused by adenovirus infections during conditions of crowding and stress. Vaccines to treat ARD are being developed, but are not currently FDA approved for general use. In addition, the vaccine has not been produced since 1995 and the U.S. stockpile of adenovirus vaccine ran out in 1999.

Medical Policy Position Summary (Non-clinical summary statement for customer use)

The administration of adenovirus vaccines, types 4 and 7, is not an established therapy for the general public, although it has a history of effectiveness when administered to military personnel. While this service may be safe, it is currently not being manufactured and not available for administration to any patient.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

None

Related Policies

Medicare Information

Vaccinations or inoculations are generally excluded from coverage unless they are directly related to the treatment of an injury or direct exposure to a disease or condition, such as anti-rabies, treatment, tetanus antitoxin or booster vaccine, botulin antitoxin, antivenin sera, or immune globulin.

(The above Medicare information is current as of the review date for this policy. Since Medicare coverage issues may be updated or revised by CMS (formerly HCFA) on a frequent basis, the most current information may not be contained in this document.)

References

- <http://www-micro.msb.le.ac.uk/335/Adenoviruses.html> "Adenoviruses," Microbiology and Immunology; BS335, Adenoviruses, last Updated: Tuesday 15th January 2002.
 - <http://www.hc-sc.gc.ca/hpb/lcdc/biosafety/msds/msds3e.html> Health Canada, Laboratory Centre for Disease Control, "Adenovirus types 1, 2, 3, 4, 5 and 7", Date prepared, November 1999.
 - <http://www.cdc.gov/ncidod/eid/vol5no6/mcneill.htm> K. Mills McNeill et al, "Large, Persistent Epidemic of Adenovirus Type 4-Associated Acute Respiratory Disease in U.S. Army Trainees", Centers for Disease Control (CDC) Dispatch, Emerging Infectious Diseases, Vol. 5, No. 6, November–December 1999.
 - <http://www.cdc.gov/ncidod/dvrd/revb/respiratory/eadfeat.htm> CDC, National Center for Infectious Diseases, Respiratory and Enteric Viruses Branch, "Adenoviruses," last reviewed August 20, 2001.
 - http://www.dcmilitary.com/army/standard/6_21/local_news/11350-1.html "Adenovirus vaccines remanufacturing begins," by Karen Fleming-Michael Standard Staff Writer, October 18, 2001.
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Joint BCBSM/BCN Medical Policy History

Date	Rationale
7/03/02	Joint policy established
11/18/03	Policy retired

Next Review: This policy is established and is no longer subject to periodic review.

Pre-Consolidation Medical Policy History

Original Policy Date		Comments
BCN	N/A	Revised: N/A
BCBSM	10/30/00	Revised: 12/7/00