

UNCLAS //N06200//

SUBJ: IMPLEMENTATION OF ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL PROGRAM A. IMMUNIZATIONS AND CHEMOPROPHYLAXIS, COMDTINST M6230.4 (SERIES) 1. ON 16 MAR 11, THE FOOD AND DRUG ADMINISTRATION (FDA) LICENSED THE ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE, MANUFACTURED BY TEVA PHARMACEUTICALS USA/BARR LABORATORIES, FOR USE IN MILITARY POPULATIONS 17 TO 50-YEARS OF AGE. THIS MESSAGE PROVIDES GUIDANCE ON HOW TO ADMINISTER ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE AMONG COAST GUARD RECRUITS AT THE TRAINING CENTER CAPE MAY. ADENOVIRUS TYPES 4 AND 7 VACCINE PROTECTS THE INDIVIDUAL VACCINATED FROM ACUTE RESPIRATORY DISEASE CAUSED BY ADENOVIRUS TYPES 4 AND 7 (REFERENCE A).

2. COAST GUARD TRAINING CENTER CAPE MAY WILL BEGIN ADMINISTERING ADENOVIRUS VACCINE TO RECRUITS, 17 TO 50-YEARS OF AGE, AS SOON AS THE VACCINE IS AVAILABLE. THIS POLICY ONLY APPLIES TO COAST GUARD TRAINING CENTER CAPE MAY RECRUITS. IT DOES NOT APPLY TO COAST GUARD TRAINING CENTER CAPE MAY CADRE, OTHER COAST GUARD TRAINING CENTERS OR COAST GUARD ACADEMY CADETS.

3. CLINICAL INFORMATION.

A. ADENOVIRUS TYPES 4 AND 7, LIVE, ORAL VACCINE IS A SINGLE DOSE ADMINISTERED AS TWO-ENTERIC COATED TABLETS: ONE TABLET OF ADENOVIRUS TYPE 4 (WHITE TAB) AND ONE TABLET OF ADENOVIRUS TYPE 7 (LIGHT PEACH TAB).

B. ADENOVIRUS VACCINE TYPES 4 AND 7 CAN BE ADMINISTERED SIMULTANEOUSLY OR AT ANY INTERVAL BEFORE OR AFTER OTHER VACCINES, INCLUDING LIVE VACCINES. THE ADENOVIRUS VACCINE IS ADMINISTERED ONLY ONCE, AT THE RECRUIT TRAINING CENTER AND BOOSTERS ARE NOT REQUIRED.

C. TABLETS MUST BE SWALLOWED WHOLE, NOT CHEWED OR CRUSHED TO AVOID RELEASING THE LIVE ADENOVIRUS IN THE UPPER RESPIRATORY TRACT.

D. EACH VACCINE ADMINISTRATION WILL BE DIRECTLY OBSERVED TO VERIFY TABLETS ARE SWALLOWED.

4. VACCINE CONTRAINDICATIONS.

A. DO NOT ADMINISTER ADENOVIRUS VACCINE TO PREGNANT FEMALES.

B. DO NOT ADMINISTER TO INDIVIDUALS WHO DEVELOPED A SEVERE ALLERGIC REACTION AFTER PREVIOUS RECEIPT OF ANY COMPONENT OF THE VACCINE AND/OR THOSE WHO HAVE A SENSITIVITY TO FDC YELLOW 6-ALUMINUM LAKE DYE.

C. DO NOT ADMINISTER TO INDIVIDUALS WHO ARE INCAPABLE OF SWALLOWING THE TABLETS WHOLE WITHOUT CHEWING.

D. POSTPONE VACCINE ADMINISTRATION TO INDIVIDUALS WITH VOMITING AND/OR DIARRHEA.

5. VACCINE WARNINGS/PRECAUTIONS.

A. WOMEN SHOULD NOT BECOME PREGNANT FOR AT LEAST 6-WEEKS AFTER RECEIVING THE VACCINE.

B. ADENOVIRUS VACCINE CONTAINS LIVE ADENOVIRUS THAT IS SHED IN THE STOOL FOR UP TO 28-DAYS FOLLOWING VACCINATION. STRICT HANDWASHING AND PERSONAL HYGIENE IS REQUIRED TO MINIMIZE RISK OF TRANSMITTING THE VIRUS TO OTHERS.

C. VACCINEES SHOULD PAY CLOSE ATTENTION TO PERSONAL HYGIENE WHEN AROUND CHILDREN 7 YEARS OF AGE AND YOUNGER, IMMUNOCOMPROMISED INDIVIDUALS, AND PREGNANT WOMEN FOR 28-DAYS FOLLOWING VACCINATION.

D. REPORT ADVERSE EVENTS AFTER IMMUNIZATION TO THE VACCINE ADVERSE EVENT REPORTING SYSTEM, www.vaers.hhs.gov.

6. EDUCATION.

A. DETAILED CLINICAL AND BASIC INFORMATION ABOUT THE ADENOVIRUS VACCINE IS AVAILABLE AT WWW.VACCINES.MIL/ADENOVIRUS.

B. FEMALE PERSONNEL WHO RECEIVED THE VACCINE DURING PREGNANCY OR BECAME PREGNANT WITHIN 7 WEEKS OF VACCINATION SHOULD BE PROVIDED INFORMATION ABOUT THE ADENOVIRUS VACCINE PREGNANCY REGISTRY FOR SELF REFERRAL. PER THE PACKAGE INSERT, ALL CASES IN WHICH A WOMEN RECEIVES ADENOVIRUS TYPE 4 AND TYPE 7 VACCINE, LIVE, ORAL DURING PREGNANCY OR BECOMES PREGNANT (CONCEPTION OCCURS) WITHIN 6 WEEKS FOLLOWING VACCINATION SHOULD BE REPORTED TO THE ADENOVIRUS PREGNANCY REGISTRY BY CALLING 1-866-790-4549.

C. HANDOUTS. THE CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) ISSUED A VACCINE INFORMATION STATEMENT (VIS) FOR THE ADENOVIRUS VACCINE. THIS VIS IS THE COAST GUARD STANDARD FOR PATIENT-LEVEL INFORMATION ABOUT ADENOVIRUS VACCINE, AND IS AVAILABLE AT WWW.VACCINES.MIL/ADENOVIRUS.

D. PROVIDE ALL VACCINEES EDUCATIONAL MATERIALS AND THE OPPORTUNITY TO READ THE VIS (POSTERS OR VIS HANDOUT).

7. DOCUMENTATION. ALL IMMUNIZATIONS GIVEN TO MILITARY PERSONNEL WILL BE IMMEDIATELY RECORDED INTO THE MEDICAL READINESS REPORTING SYSTEM (MRRS). THE MRRS CODE FOR ADENOVIRUS TYPES 4 AND 7 VACCINE IS 143.

8. ADMINISTRATION/LOGISTICS.

A. THE US ARMY MEDICAL MATERIEL AGENCY (USAMMA) WILL COORDINATE THE DISTRIBUTION OF THE ADENOVIRUS VACCINE TO THE SUPPORTING MEDICAL SUPPLY ACTIVITIES OF ALL SERVICES. LOCAL MEDICAL LOGISTICS SUPPORTING ELEMENTS MUST HAVE SUFFICIENT REFRIGERATION CAPACITY TO PRESERVE VACCINE INTEGRITY, INCLUDING TEMPERATURE ALARMS AND BACK UP POWER CAPACITY. POCS AT USAMMA: (1) USAMMA DISTRIBUTION OPERATIONS CENTER COMM: 301-619-4318/1197/4198, (2) WEBSITE:

WWW.USAMMA.ARMY.MIL.

B. THE MANUFACTURER WILL SHIP THE ADENOVIRUS VACCINE DIRECTLY TO THOSE INSTALLATIONS THAT RECEIVE AND PROCESS RECRUITS. USAMMA DISTRIBUTION OPERATIONS CENTER WILL COORDINATE WITH ALL APPROPRIATE INSTALLATION MEDICAL SUPPLY ACTIVITIES WHEN THE DOD IS READY TO COMMENCE SHIPMENT OF VACCINE.

9. POCS FOR THIS POLICY AT HSWL SUPACT ARE CDR JOHN HARIADI AT 757-628-4331, JOHN.HARIADI(AT)USCG.MIL AND AT CG-1121, CDR ERICA SCHWARTZ AT 202-475-5172, ERICA.G.SCHWARTZ(AT)USCG.MIL.

10. CAPT MAURA DOLLYMORE, OFFICE OF HEALTH SERVICES SENDS.

11. INTERNET RELEASE AUTHORIZED.