

<b>ISSUE DATE</b>  April 5, 2019	<b>EFFECTIVE DATE</b>  October 5, 2018	<b>NUMBER</b>  01-19-11, 08-19-13, 09-19-11, 31-19-11, 33-19-11
<b>SUBJECT</b>  Update to the Administration of the Human Papillomavirus (HPV) Vaccine	<b>BY</b>   Sally A. Kozak, Deputy Secretary Office of Medical Assistance Programs	

**IMPORTANT REMINDER:** All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe™ to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at:

[http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S\\_001994](http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994).

## **PURPOSE:**

The purpose of this bulletin is to inform providers enrolled in the Medical Assistance (MA) Program that the MA Program will pay for the administration of the human papillomavirus (HPV) vaccine for MA beneficiaries who are 9 through 45 years of age.

## **SCOPE:**

This bulletin applies to all physicians, Certified Registered Nurse Practitioners, certified nurse midwives, outpatient hospitals and independent medical surgical clinics enrolled in the MA Program who administer immunizations to MA beneficiaries in the Fee-For-Service and managed care delivery systems. Providers rendering services in the MA managed care delivery system should address any coding or payment related questions to the appropriate MA managed care organization (MCO).

## **BACKGROUND:**

The U.S. Food & Drug Administration (FDA) first approved Gardasil 9® (human papillomavirus 9-valent vaccine, recombinant) for the prevention of certain cancers and diseases caused by nine types of HPV on December 10, 2014, for individuals 9 through 26 years of age. Gardasil® (Human Papillomavirus Quadrivalent (4vHPV)), a vaccine previously approved by the FDA in 2006 to prevent cancer and diseases caused by four HPV types, is no longer distributed in the United States. Gardasil 9® protects against the same four HPV types as Gardasil® plus five additional HPV types. On October 5, 2018, the FDA approved a

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll free number for your provider type.

Visit the Office of Medical Assistance Programs Website at:  
<http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm>.

supplemental application for Gardasil 9<sup>®</sup> that expands the age for approved use of the vaccine to include females and males 27 through 45 years of age.

Gardasil 9<sup>®</sup> is indicated for the prevention of cervical, vulvar, vaginal and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52 and 58; for the prevention of genital warts caused by HPV types 6 or 11; and for the prevention of cervical, vulvar, vaginal, and anal precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58. The Centers for Disease Control and Prevention (CDC) has stated that HPV vaccination prior to becoming infected with the HPV types covered by the vaccine has the potential to prevent more than 90 percent of these cancers from ever developing.

Routine vaccination at 11 or 12 years of age has been recommended by the Advisory Committee on Immunization Practices (ACIP) since 2006 for girls and 2011 for boys. For children with a history of sexual abuse or assault, ACIP recommends routine HPV vaccination beginning at 9 years of age. Complete vaccination recommendations of ACIP for Gardasil 9<sup>®</sup> may be obtained from the CDC website at:

<https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm>.

## **DISCUSSION:**

HPV infection is nearly universal among sexually active women and men. Recent data indicate that a significant portion of HPV infections in mid-adult women and men (defined here as 27 through 45 years age) are newly acquired infections, not the reactivation of an earlier infection. As most individuals who are 27 through 45 years of age have not been exposed to all nine HPV types covered by Gardasil 9<sup>®</sup>, vaccination against HPV in the mid-adult population has the potential for meaningful benefits. In a News Release, the FDA pointed to a study involving women 24 through 45 years of age vaccinated with Gardasil<sup>®</sup> (4vHPV) with long term follow-up at six years, results indicated Gardasil<sup>®</sup> was 88 percent effective in the prevention of cancers and diseases related to the HPV types covered by the vaccine. Effectiveness against the additional five HPV types covered by Gardasil 9<sup>®</sup> was extrapolated based on the data from this study.

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622715.htm>.

Vaccination for HPV will still have the greatest impact when it is administered prior to onset of sexual activity and HPV exposure. Providers should recommend HPV vaccine just as they do other childhood and adolescent vaccines. The American Academy of Pediatrics recommends that physicians discuss the importance of the HPV vaccine to prevent HPV-related cancers when talking with families of adolescents. The HPV vaccine can be administered at the same time as other necessary adolescent vaccinations such as Tdap and meningitis vaccines.

Gardasil 9<sup>®</sup> is approved for administration in a 2- or 3-dose schedule. For girls and boys who initiate the vaccine series prior to reaching 15 years of age, a 2-dose schedule is recommended. The second dose in a 2-dose series should be administered 6 to 12 months after the first dose, with a minimum interval of 5 months. If the second dose is administered after a shorter interval, a third dose is recommended. The 3-dose schedule should be administered at intervals of 0, 1 or 2, and 6 months. If the vaccination schedule is interrupted,

it does not need to be restarted. The number of doses is based on age when first dose is administered. Gardasil 9<sup>®</sup> may be used to continue or complete a vaccination series started with earlier formulations of the vaccine (4vHPV or 2vHPV). For individuals with primary or secondary immune-compromising conditions that might reduce cell-mediated or humoral immunity, three doses are recommended by ACIP.

Gardasil 9<sup>®</sup> is contraindicated for individuals with a history of an immediate hypersensitivity to yeast. Vaccination with Gardasil 9<sup>®</sup> is not recommended during pregnancy; however, routine pregnancy testing prior to vaccination is also not recommended. When pregnancy is discovered after initiating the vaccine series, remaining doses should be delayed until after completion of the pregnancy. If a vaccine dose is administered during pregnancy, no intervention is needed, but exposure should be reported to the vaccine pregnancy registry at 800-986-8999.

Current procedural terminology (CPT) code 90651 (human papillomavirus vaccine types 6, 11, 16, 18, 31, 33, 45, 52, 58, nonavalent (9vHPV), 2 or 3 dose schedule, for intramuscular use) was added to the Outpatient Fee Schedule, under MA Bulletin 99-15-06, "2015 HCPCS Updates and Other Procedure Code Changes", effective September 1, 2015, and providers were advised to use this CPT code to bill the Department for the administration of the HPV 9 vaccine.

The Outpatient Fee Schedule is available at:

<http://www.dhs.pa.gov/publications/forproviders/schedules/mafeeschedules/index.htm>.

### **PROCEDURE:**

The MA Program will pay for the administration of the Gardasil 9<sup>®</sup> vaccine to MA beneficiaries, 9 through 45 years of age, for dates of service on or after October 5, 2018, using the CPT code 90651, consistent with the indicated use of this vaccine as approved by the FDA.

The MA Fee Schedule rate for the administration of each vaccine is \$10.00 per administration. Providers participating in a MA MCO should address questions related to the fee for administration of the vaccine to the MCO.

The Pennsylvania Department of Health (DOH) Vaccines for Children (VFC) Program includes Gardasil 9<sup>®</sup> on the list of vaccines available at no cost to VFC-enrolled providers for administration to children, including MA children, under 19 years of age. MA providers are encouraged to participate in the VFC program. Enrollment information is provided in the VFC Provider Handbook which can be found on the DOH website at:

<https://www.health.pa.gov/topics/Documents/Programs/Immunizations/VFC%20Handbook%20-%20Section%202.pdf>.

MA providers may bill the Department for Gardasil 9<sup>®</sup> vaccine for MA beneficiaries who are 19 years of age and older, consistent with the indicated use of the vaccine by the FDA and current ACIP recommendations, by indicating on the claim submission the appropriate National

Drug Code and the units dispensed for the vaccine. Providers may access the online version of the MA Drug Fee Schedule under the Department's website at:

<http://www.dhs.pa.gov/publications/forproviders/schedules/drugfeeschedule/index.htm>.

**RESOURCES:**

CDC HPV

<https://www.cdc.gov/hpv/hcp/index.html> Resources for Clinicians

Morbidity and Mortality Weekly Report

Meites E, Kempe A, Markowitz LE. *Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices*. MMWR Morb Mortal Wkly Rep 2016;65:1405–1408. DOI:

<http://dx.doi.org/10.15585/mmwr.mm6549a5>

FDA New Release

U.S. Food & Drug Administration. (2018). *FDA approves expanded use of Gardasil 9 to include individuals 27 through 45 years old*. U.S. Food & Drug Administration [Press release].

Retrieved from

<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622715.htm>

**OBSOLETE:**

MA Bulletin 01-07-06, 08-07-05, 09-07-03, 31-07-04, 33-07-02, titled, "Gardasil<sup>®</sup>, Human Papillomavirus (HPV) Vaccine", issued March 23, 2007; MA Bulletin 01-10-14, 08-10-15, 09-10-16, 31-10-17, 33-10-02, titled, "Updated Recommendations for Gardasil<sup>®</sup>, Quadrivalent Human Papillomavirus (HPV) Vaccine," issued May 3, 2010; and MA Bulletin 01-15-29, 08-15-29, 09-15-29, 31-15-29, 33-15-28, titled, "Addition to the Medical Assistance Program Fee Schedule for Administration of HPV 9 Vaccine" are obsolete with the issuance of this bulletin.