FDA Approves HPV Vaccine for Prevention of Oral Cancer

The American Cancer Society now calls for vaccination of girls and boys starting at age 9.

July 9, 2020 By Liz Highleyman

The Food and Drug Administration (FDA) has expanded the indication for the Gardasil 9 human papillomavirus (HPV) vaccine to include prevention of mouth and throat cancer. In related news, the American Cancer Society recently recommended routine HPV vaccination for boys and girls starting at age 9.

One of the most common sexually transmitted infections, HPV triggers abnormal cell growth that can lead to genital and anal warts, precancerous cell changes and, if left undetected and untreated, cancers of the cervix, anus, vulva, vagina, penis, mouth and throat.

Regular Pap smears and HPV testing have dramatically reduced the risk of progression to invasive cervical cancer by catching abnormal cell changes at an early stage when they can be treated. Similar tests can also be done to detect anal precancer, though they are not widely used.

But there are currently no such tests for early detection of oropharyngeal cancer, or malignancies involving the sides and back of the throat, the soft palate, the tonsils and the back of the tongue. According to the Centers for Disease Control and Prevention (CDC), oropharyngeal cancer has surpassed cervical cancer as the most common type of HPV-related cancer in the United States.

Gardasil 9 protects against nine types of HPV that cause cancer and genital or anal warts (types 6, 11, 16, 18, 31, 33, 45, 52 and 58). The CDC estimates that nearly 35,000 people in the United States develop HPV-elated cancers each year, and more than 90% of them are caused by the virus types covered by the vaccine.

The CDC's Advisory Committee on Immunization Practices recommends Gardasil 9 vaccination for boys and girls at age 11 or 12, with catch-up vaccines for those not immunized as adolescents. Two doses of the vaccine are recommended for children and adolescents up to age 14, and three doses for older individuals, but recent research suggests that a single dose may offer adequate protection.

Last year, the CDC recommended HPV vaccination for women and men through age 26. However, the vaccine is FDA-approved for adults up to age 45, and vaccination for those ages 27 to 45 is a

shared decision to be made by patients and their providers.

The American Cancer Society thinks vaccination should start even earlier. The organization now recommends routine HPV vaccination between ages 9 and 12 “to achieve higher on-time vaccination rates, which will lead to increased numbers of cancers prevented.” Health care providers are encouraged to start offering the HPV vaccine series at age 9 or 10. But the organization does not recommended vaccination for adults over 26.

With the latest FDA approval, Gardasil 9 is now indicated for the prevention of cervical, vaginal, vulvar, anal, oropharyngeal and other head and neck cancers as well as precancerous cell changes. The accelerated approval for oropharyngeal and head and neck cancer is based on the vaccine’s effectiveness in preventing anal and genital disease.

Oropharyngeal cancer is about five times more common in men than in women, which may be related to the fact that the original Gardasil vaccine was approved only for girls and young women until 2009. A recent study suggests that increasing vaccination of both young women and men might be providing men with herd immunity against oral HPV infection.

A confirmatory trial aiming to show a direct benefit in preventing oral HPV infection is currently underway, according to Merck, which manufactures Gardasil 9.

Click here for updated full prescribing information for Gardasil 9.
Click here to learn more about oral cancer
Read “I Wish I’d Had the Vaccine” in the Winter 2019 issue of Cancer Health.

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