

Alert for Clinicians: FDA Approved use of HPV Vaccine to prevent anal cancer in men ages 9-26

The U.S. Food and Drug Administration (FDA) [announced](#) December 22, 2010 that it has approved the first vaccine for males and females ages 9 to 26 for the prevention of anal cancer and its associated precursor, anal intraepithelial neoplasia (AIN). The vaccine, called Gardasil, was already approved to prevent genital warts and cervical cancer in women in this age group.

Gardasil is a vaccine that protects against infection by four strains, or types, of human papillomavirus (HPV): Types 6 and 11, known to cause most cases of genital warts, and types 16 and 18, known to cause the majority of cervical and anal cancer cases. It was first approved in 2006 for use in girls and women ages 9 to 26 to prevent both genital warts and cervical cancer, and later approved in 2009 to prevent genital warts in boys and young men. Until now, however, the drug has not been approved to prevent anal cancer.

Anal cancer arises from the [anus](#), the [distal](#) orifice of the [gastrointestinal tract](#), from the surface (squamous) cells. The [American Cancer Society](#) estimates that about 5300 new cases are diagnosed and about 700 people die of anal cancer every year in the United States. Anal cancer is a distinct entity from [colon cancer](#), which is much more common. Though anal cancer is relatively rare in the general population, rates are far higher in men who have sex with men (MSM), and it is nearly 60 times more common in HIV-positive MSM. For this reason, providers who treat people with HIV have been eager to see the vaccine approved for this purpose.

Worldwide in 2002 there were an estimated 30,400 new cases of anal cancer, with approximately equal fractions in developing (15,900) and developed (14,500) countries. An estimated 90% (27,400) of cases were attributable to HPV. Approval of this new indication for HPV vaccine recognizes the hypothesis that the etiology of anal cancer mirrors the etiology of cervical cancer in women. As such it seems to lend greater support for routine anal cytology to detect early evidence of anal dysplasia. Studies suggest that it would make sense to do anal cytology yearly in HIV infected MSM and every two to three years in other sexually active MSM. This is an area where there is a critical need for more research to develop appropriate evidence to better inform clinical guidelines.

Some clinicians have asked whether all boys and young men 9-26, regardless of the number of sexual partners they have had, should be vaccinated. Most experts feel that vaccination should be empiric in this group as it is unlikely that all will have been exposed to all strains of HPV covered by the vaccine. Regarding older men, vaccination may still make sense, but given the current FDA approval, it may not be covered by insurance. The cost of the recommended three doses of the vaccine is currently approximately \$360 in addition to fees for administration charged by clinicians.

References

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