

The Advisory Committee on Immunization Practices (ACIP) made official its provisional [recommendations](#) regarding permissive use of Gardasil in males to prevent external genital warts. The provisional guidance was issued in October 2009, shortly after FDA licensed Gardasil for use with males ages 9-26. "Permissive" use means, essentially, the vaccine can be given at the health care provider's discretion. The Committee recommends routine use of the vaccine with girls and young women ages 9-26, and this stronger recommendation is primarily based on issues of cost-effectiveness and the fact HPV-related diseases disproportionately affect females.

ACIP also made official its provisional [recommendations](#) for use of GSK's bivalent Cervarix HPV vaccine in females ages 10-26. As with the Merck vaccine, Cervarix is recommended for the prevention of cervical, vulvar, and vaginal pre-cancers and cancers.

Organized by the Centers for Disease Control and Prevention (CDC), ACIP is the main body that makes vaccine program recommendation in the U.S., and many professional medical organizations follow the committee's lead and are strongly influenced by its counsel.

Merck to Seek Indication for MSM

A report in [Medscape Oncology](#) (Mulcahy, March 2010) says Merck plans to submit an application to the FDA seeking approval for use of its HPV vaccine, Gardasil, with men who have sex with men (MSM). While the company didn't state the specific indication they'll seek for use with MSM, many observers believe it will involve the prevention of anal precancers and/or cancers. Findings presented at the European Research Organization on Genital Infection and Neoplasia (EUROGIN) meeting in February showed that in clinical trials with 598 gay men, Gardasil was 77.5 % effective in preventing cell changes known as anal intraepithelial neoplasia (AIN) related to the HPV types covered by the vaccine. Anal cancer is fairly uncommon, and the American Cancer Society estimates about 5,300 new cases occur in the U.S. each year. The CDC says the risk of the disease in gay and bisexual men is 17 times greater than heterosexual men. HPV 16, which is covered by the vaccine, is the HPV genotype most strongly associated with anal cancer. [Click](#) to read more about Merck data on AIN.