Gardasil® 9 (HPV 9-valent vaccine, recombinant) – Expanded indication

- On October 5, 2018, the FDA announced the approval of Merck's Gardasil 9 (Human Papillomavirus [HPV] 9-valent vaccine, recombinant), for use in males and females aged 9 through 45 years, for the prevention of certain cancers and diseases caused by nine HPV types.
    - Girls and women: prevention of cervical, vulvar, vaginal, and anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts caused by HPV types 6 and 11; and the following precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58: cervical intraepithelial neoplasia (CIN) grade 2/3 and cervical adenocarcinoma *in situ*, CIN grade 1, vulvar intraepithelial neoplasia grade 2 and grade 3, vaginal intraepithelial neoplasia grade 2 and grade 3, and anal intraepithelial neoplasia grades 1, 2, and 3.
    - Boys and men: prevention of anal cancer caused by HPV types 16, 18, 31, 33, 45, 52, and 58; genital warts caused by HPV types 6 and 11; and anal intraepithelial neoplasia grades 1, 2, and 3 caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58.
- Previously, Gardasil 9 was only approved for use in males and females aged 9 through 26 years for these indications.
- Gardasil, a vaccine approved to prevent certain cancers and diseases caused by four HPV types, is no longer distributed in the US. In 2014, the FDA approved Gardasil 9, which covers the same four HPV types as Gardasil, as well as an additional five HPV types.
    - The effectiveness of Gardasil is relevant to Gardasil 9 since the vaccines are manufactured similarly and cover four of the same HPV types.
- The approval of Gardasil 9's expanded indication was based on a study evaluating the efficacy of Gardasil in 3,253 women 27 through 45 years of age, using a combined endpoint of persistent infection, genital warts, vulvar and vaginal precancerous lesions, cervical precancerous lesions, and cervical cancer related to HPV types covered by Gardasil. Patients received Gardasil or an amorphous aluminum hydroxyphosphate sulfate control.
    - Gardasil was 87.7% (95% CI: 75.4, 94.6) effective in the prevention of the combined endpoint after a median duration of follow-up of 3.5 years.
    - In the long-term extension of this study (n = 600), no cases of HPV 6-, 11-, 16-, or 18-related CIN (any grade) or genital warts were observed.
- The effectiveness of Gardasil 9 in men 27 through 45 years of age is inferred from the data in women 27 through 45 years of age, as well as efficacy data from Gardasil in younger men (16 through 26 years of age), and immunogenicity data.
- Gardasil 9 should be administered as a 0.5 mL intramuscular (IM) injection using the dosing schedule below. The IM injections should be administered in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

Age	Regimen	Schedule
9 through 14 years	2-dose	0, 6 to 12 months*
	3-dose	0, 2, 6 months
15 through 45 years	3-dose	0, 2, 6 months

Continued . . .

- *If the second dose is administered earlier than 5 months after the first dose, a third dose should be administered at least 4 months after the second dose