

Gardasil[®] 9 (human papillomavirus 9-valent vaccine, recombinant) – Expanded indication

- On June 12, 2020, [Merck announced the FDA approval of Gardasil 9 \(human papillomavirus \[HPV\] 9-valent vaccine, recombinant\)](#), for the prevention of oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58 in males and females 9 through 45 years of age.
 - Previously, Gardasil 9 was approved in females 9 through 45 years of age for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
 - Previously, Gardasil 9 was approved in males 9 through 45 years of age for the prevention of anal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58.
 - The oropharyngeal and head and neck cancer indication is approved under accelerated approval based on effectiveness in preventing HPV-related anogenital disease. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- Gardasil 9 is also approved in females 9 through 45 years of age 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 and genital warts caused by HPV types 6 and 11.
- Gardasil 9 is approved in males 9 through 45 years of age for the prevention of anal precancerous or dysplastic lesions caused by HPV types 6, 11, 16, 18, 31, 33, 45, 52, and 58 and genital warts caused by HPV types 6 and 11.
- The effectiveness of Gardasil 9 against oropharyngeal and other head and neck cancers caused by HPV types 16, 18, 31, 33, 45, 52 and 58, is based on the effectiveness of Gardasil and Gardasil 9 to prevent anogenital disease caused by HPV types covered by the vaccine.
- The dose of Gardasil 9 for all indications is 0.5 mL intramuscularly as follows:

| 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 |

*If the second dose is administered earlier than 5 months after the first dose, administer a third dose at least 4 months after the second dose.