Human Papillomavirus Vaccine [Bivalent (Types 16 and 18) Recombinant]  
CERVARIX®  
Supplier: GlaxoSmithKline Inc.

INDICATIONS:
Women 26 years of age and younger at the time of series commencement and born before 1994 can be offered CERVARIX® if unimmunized against HPV. This is a one-time program which started in April 2012 and will continue until available vaccine has expired.

RECOMMENDED BY THE NATIONAL ADVISORY COMMITTEE ON IMMUNIZATION BUT NOT PROVIDED FREE IN BC:
- Females 9-45 years of age

DOSES AND SCHEDULE:
Those who are immunocompetent and initiating immunization prior to their 15th birthday should be immunized using a 2 dose series. Those initiating immunization at 15 years of age and older should be immunized using a 3 dose series.

Girls 9-14 years of age (inclusive): 2 doses given as 0.5 mL IM, separated by at least 6 months. All other indications: 3 doses given as 0.5 mL IM at 0, 1, and 6 months.

BOOSTER DOES:
No booster doses are recommended at this time.

SEROLOGICAL TESTING:
Serological testing is not recommended before or after immunization.

CONTRAINDICATIONS:
1. History of anaphylactic reaction to a previous dose of CERVARIX® or to any component of the vaccine.
2. Pregnancy. The vaccine should not be given to pregnant women because safety of receipt of HPV vaccine has not been adequately studied during pregnancy. Women who become pregnant before series completion should defer immunization until no longer pregnant. In pregnant women who are inadvertently vaccinated, there is no need to consider any intervention except reassurance, as the vaccine has not been associated with teratogenicity.

A Individuals who are known to have immune system defects associated with solid organ transplant, stem cell transplant or HIV infection should receive a 3 dose HPV schedule at 0, 1, and 6 months.
B GARDASIL® is the product recommended and provided for the routine program for girls and young women born in 1994 or later who are in Grade 6 and older.
C If the interval between doses in a 2 dose HPV schedule is shorter than 5 months (150 days), a 3rd dose should be given at least 24 weeks after the 1st dose and 12 weeks after the 2nd dose.
D GSK maintains a pregnancy register to monitor fetal outcomes associated with inadvertent immunization during pregnancy. Patients and health care providers are encouraged to report inadvertent CERVARIX® administration during pregnancy by calling 1-800-387-7374.
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PRODUCT COMPONENTS:
Potential allergens: none.
Other components: 3-O-desacyl-4'-monophosphoryl lipid A (MPL), aluminum hydroxide, sodium dihydrogen phosphate dihydrate.

PRECAUTIONS:
Not applicable.

SPECIAL CONSIDERATIONS:
- Eligible women may be immunized even if already sexually active, if they have had previous Pap abnormalities (including cervical cancer), or known HPV infection. The likelihood they have been exposed to both types of HPV contained in the vaccine is low and they stand to benefit from immunization. Sexually active vaccine recipients should continue to be routinely screened for cervical cancer. If applicable, advise vaccine recipients there are no data to suggest the vaccine will have any therapeutic effect on existing cervical lesions (i.e., vaccine does not prevent the consequences of current HPV infection).
- Females who are immunocompromised, either from disease or medication, can receive this vaccine; however, the immune response to vaccination and vaccine efficacy may be less than in immunocompetent females.
- Whenever possible, the same HPV vaccine (CERVARIX® or GARDASIL®) should be used to complete a vaccine series. If the brand of the previously received doses is not known, either vaccine may be used to complete the series. Both vaccines provide protection against HPV types 16/18 and therefore clients are likely to achieve protective antibody levels against these HPV types. However, unless a complete series of quadrivalent HPV vaccine was administered, complete protection for HPV types 6 and 11 (genital warts) cannot be assured.

ADVERSE EVENTS:
Local: pain, redness, swelling.
Systemic: fatigue, myalgia, arthralgia, headache.