



SmartPA

## Clinical Edit Criteria Proposal

Drug/Drug Class: Human Papillomavirus Vaccines

Date: June 30, 2011

Prepared for:

Prepared by: MO HealthNet

New Criteria

Revision of Existing Criteria

### Executive Summary

**Purpose:** Ensure appropriate utilization and control of Human Papillomavirus vaccines.

**Why was this Issue Selected:**

The human papillomavirus (HPV) vaccines may prevent infection with certain species of human papillomavirus associated with the development of cervical cancer, genital warts, and some less common cancers. Two HPV vaccines are currently on the market: Gardasil and Cervarix. Worldwide, HPV is the most common sexually transmitted infection in adults. More than 80% of American women will have contracted at least one strain of HPV by age fifty. Although most women infected with genital HPV will not have complications from the virus, worldwide there are an estimated 470,000 new cases of cervical cancer that result in 233,000 deaths per year. Since the vaccines only cover some high-risk types of HPV, experts still recommend regular Pap smear screening even after vaccination.

Program-specific information:	Drug	Claims	Expenses
	• Gardasil®	937	\$137,590
	• Cervarix®	1	\$150
			11/09-10/10

**Setting & Population:** Patients 9 to 26 years of age

**Type of Criteria:**

Increased risk of ADE                       Non-Preferred Agent

Appropriate Indications

Data Sources:  Only administrative databases

Databases + Prescriber-supplied

## Setting & Population

- Drug for review: Human Papillomavirus Recombinant
- Age range: Patients 9 to 26 years of age
- Gender: Males and Females

## Approval Criteria

- Gardasil
  - Gender– Males and Females
  - Patients 9 to 26 years of age
  - Dosing limitation – series of 3 injections given over 6 month period
    - First dose: elected date
    - Second dose: 2 months after first dose
    - Third dose: 6 months after first dose
- Cervarix
  - Gender – Females only
  - Patients 10 to 25 years of age
  - Dosing limitation – series of 3 injections given over 6 month period
    - First dose: elected date
    - Second dose: 1 month after first dose
    - Third dose: 6 months after first dose
- Administration outside of recommended age guidelines – subject to clinical consultant review

## Denial Criteria

- Pregnancy
- Lack of approval criteria

## References

1. Facts and Comparisons Online; 2010.
2. USPDI, Micromedex, 2010.
3. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
4. Merck & Co., "Gardasil Product Submission", Whitehouse Station, NJ, 08889; June 2006.
5. GlaxoSmithKline Biologicals, "Cervarix Product Submission", Research Triangle Park, NC, 27709; November 2009.