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Title GARDASIL 9– A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2983518/fr/gardasil-gardasil-9

Aim

Assessment of GARDASIL 9 (Human Papillomavirus 9-valent Vaccine (recombinant, adsorbed)) with a view to funding by the French national health insurance system, and of its clinical contribution compared to other strategies in the indication of active immunisation of individuals from the age of 9 years against the following HPV diseases:

- Premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by vaccine HPV types.
- Genital warts (*Condyloma acuminata*) caused by specific HPV types.

Conclusions of Transparency Committee

Clinical Benefit

- GARDASIL 9 is a vaccine against HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58 for the prevention of:
  - potentially life-threatening premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by the oncogenic HPV types contained in the vaccine;
  - genital warts (*Condyloma acuminata*), which are recurrent benign tumours that are not life-threatening but can have an impact on quality-of-life.
- GARDASIL 9 is a preventive treatment (primary prevention).
- The efficacy/adverse effects ratio of GARDASIL 9 is significant.
- There are vaccine alternatives (GARDASIL quadrivalent vaccine which will eventually be replaced by GARDASIL 9, and CERVARIX bivalent vaccine).
- GARDASIL 9 can be used according to its MA within the framework of current vaccination recommendations.
- GARDASIL 9 is likely to have an impact on public health, as long as optimal vaccination coverage is achieved in the populations for which vaccination is recommended. This impact is liable to be increased by extending the vaccination strategy to include boys.

Considering all of the above, the Committee deems that the clinical benefit of GARDASIL 9 is substantial in the MA indication and for the populations recommended, which refers to:

- all girls and boys from 11 up to and including 14 years of age, with catch-up vaccination possible for all adolescents and young adults (men and women) from 15 up to and including 19 years of age;
- men who have sex with men (MSM) up to 26 years of age.

Clinical Added Value

Considering:

- the efficacy of GARDASIL 9 in the prevention of premalignant lesions and genital warts (*Condyloma acuminata*) affecting the cervix, vulva, vagina and anus caused by the HPV types contained in the vaccine, initially recommended in girls and men who have sex with men (MSM),
- the new recommendation extending vaccination with GARDASIL 9 to boys,
- and which recommends starting any new vaccination course against HPV infections with GARDASIL 9 (in girls and boys),

GARDASIL 9 provides moderate clinical added value (CAV III) - in the same way as GARDASIL on its initial assessment in girls - in the strategy for the prevention of premalignant anogenital lesions and cancers associated with certain types of HPV in the populations (girls and boys) and in accordance with the recommended conditions.

Recommendations

The Transparency Committee issued its approval for the funding of GARDASIL 9 by the French national health insurance system (retail and hospital) in the MA indication and for the recommended populations.

Methods

The assessment of GARDASIL 9 was founded on evidence-based medicine with a critical analysis of the clinical data and within the framework of current vaccination recommendations.

Written by

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