



TRANSPARENCY COMMITTEE

OPINION

19 FEBRUARY 2020

human papillomavirus 9-valent vaccine (recombinant, adsorbed)
GARDASIL 9 suspension for injection in a pre-filled syringe
GARDASIL 9 suspension for injection

Amendment of inclusion conditions following a new vaccine strategy
Reevaluation

► Key points

Favourable opinion for reimbursement in the prevention of infections and lesions due to certain oncogenic types of Human Papillomavirus (HPV), in girls and boys, in accordance with the conditions defined in the current vaccine schedule.

► What therapeutic improvement?

Therapeutic improvement 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.

► Role in the care pathway?

In accordance with current national recommendations, GARDASIL 9 (nonavalent recombinant vaccine against HPV infections) can be used in the context of its MA for the following populations:

- 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.

Role of the medicinal product in the care pathway

The preferential use of the GARDASIL 9 vaccine is recommended since it contains nine HPV valences, whereas the GARDASIL vaccine contains four and the CERVARIX vaccine contains two. However, in the absence of interchangeability data, it is recommended that the whole vaccination course be completed using the same vaccine (CERVARIX or GARDASIL or GARDASIL 9).

COMMITTEE'S CONCLUSIONS

Clinical Benefit

- ▶ GARDASIL 9 is a vaccine against HPV 6, 11, 16, 18, 31, 33, 45, 52 and 58 for the prevention of:
 - premalignant lesions and cancers affecting the cervix, vulva, vagina and anus caused by the oncogenic HPV types contained in the vaccine, which can be life-threatening;
 - 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 high.
- ▶ There are vaccine alternatives (GARDASIL quadrivalent vaccine, which will ultimately be replaced by GARDASIL 9, and CERVARIX bivalent vaccine).
- ▶ GARDASIL 9 can be used in accordance with its MA in the context of current vaccine recommendations.
 - ▶ Public health impact:
Considering:
 - the seriousness and incidence of premalignant lesions and cancers associated with HPV infection,
 - the medical need in the prevention of HPV infections with a high oncogenic risk,
 - the efficacy of GARDASIL 9, comparable to that of GARDASIL, in the prevention of high-grade lesions due to HPV 6, 11, 16, 18 and 97.4% (95% CI [85.0; 99.9]) in the prevention of high-grade lesions due to additional HPV 31, 33, 45, 52 and 58,
 - the potentially favourable impact on the organisation of care,GARDASIL 9 is liable to have an impact on public health, as long as optimal vaccination coverage is achieved in the populations for whom vaccination is recommended. This impact is liable to be increased by extending the vaccination strategy to include boys.

Considering these elements, the Committee deems that the clinical benefit of GARDASIL 9 is substantial in the MA indication and for the populations (girls and boys) recommended following the HAS opinion of December 2019.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and for the populations (girls and boys) recommended following the HAS opinion of December 2019.

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),

the Committee considers that GARDASIL 9 provides a 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.