

Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

human papillomavirus 9-valent vaccine
(recombinant, adsorbed)

GARDASIL 9,

suspension for injection in a pre-filled syringe and suspension for injection

Modification of inclusion conditions following updating of the HAS recommendations in 2025

Adopted by the Transparency Committee on 11 June 2025

Summary of opinion

Favourable opinion for reimbursement in the MA indication 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 and the HAS vaccination recommendations of 30 April 2025.

Transparency 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.
- ➔ This is a preventive medicinal product.
- ➔ The efficacy/adverse effects ratio is high.
- ➔ There are vaccine alternatives (GARDASIL quadrivalent vaccine replaced by GARDASIL 9, and CERVARIX bivalent vaccine).
- ➔ This is a first-line treatment in view of the therapies available in the absence of available therapies.
- ➔ GARDASIL 9 can be used in accordance with its MA in the context of current vaccine recommendations.

→ Public health benefit

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,
- an expected impact on morbidity and mortality against the consequences of HPV infections in women and men,
- the potentially favourable impact on the organisation of care,

GARDASIL 9 (human papillomavirus 9-valent vaccine (recombinant, adsorbed)) is likely to have an additional impact on public health.

Updating of the vaccine strategy in accordance with the current HAS recommendations of 30 April 2025 does not modify the clinical benefit (opinion of 19 February 2020), which remains substantial in the strategy for the prevention of premalignant anogenital lesions and cancers associated with certain types of HPV in the populations (girls and boys), in accordance with the conditions defined in the current vaccine schedule and the HAS vaccination recommendations of 30 April 2025.

The Committee issues a favourable opinion for maintenance of inclusion of GARDASIL 9 (human papillomavirus 9-valent vaccine (recombinant, adsorbed)) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the active immunisation of women and men up to 26 years of age against HPV infections, in accordance with the conditions defined in the current vaccine schedule and the HAS vaccination recommendations of 30 April 2025.

→ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%

Clinical Added Value

Updating of the vaccine strategy in accordance with the current HAS recommendations of 30 April 2025 does not modify the clinical added value level (opinion of 19 February 2020), which remains moderate (level III) in the strategy for the prevention of premalignant anogenital lesions and cancers associated with certain types of HPV in the populations (girls and boys), in accordance with the conditions defined in the current vaccine schedule and the HAS vaccination recommendations of 30 April 2025.

GARDASIL 9, 11 June 2025

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