SUMMARY

Herpes zoster vaccine (recombinant, adjuvanted)

SHINGRIX,

powder and suspension for suspension for injection

Initial inclusion

Original French opinion adopted by the Transparency Committee on 27 March 2024

The legally binding text is the original French opinion version

Summary of opinion

Approval of reimbursement for prevention of herpes zoster and post-herpetic neuralgia in adults 65 years of age and older, and adults 18 years of age and older at increased risk of herpes zoster, according to the HAS guidelines in force dated 29 February 2024.

Transparency Committee's Conclusions

Clinical Benefit

- Herpes zoster is a disease with potentially serious complications (post-herpetic pain, ocular involvement, etc.).
- This is a preventive medicinal product.
- The efficacy/adverse effects ratio is high.
- There is an alternative vaccine for immunocompetent adults.
- SHINGRIX (adjuvanted recombinant herpes zoster vaccine) may be used according to its marketing authorisation within the scope of the vaccination guidelines in force.

Public health benefit

In view of:

- the high incidence of herpes zoster in the general population increasing rapidly with age, and its substantial repercussions on patients' quality of life and resulting economic consequences;
- the medical need for effective and well-tolerated vaccines in particular for immunocompromised individuals, as vaccination is the most effective preventive tool against herpes zoster and its complications;
- the response to the medical need, considering

- evidence of an additional impact on morbidity in terms of reduction in the number of herpes zoster cases in the light of the efficacy, immunogenicity and safety data available,
- an expected additional impact on the care and life pathway and on the delivery of care in particular in immunocompromised individuals for whom ZOSTAVAX vaccine was contraindicated.

SHINGRIX (adjuvanted recombinant herpes zoster vaccine) is likely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of SHINGRIX (adjuvanted recombinant herpes zoster vaccine) is substantial in prevention of herpes zoster and post-herpetic neuralgia in adults 65 years of age and older, and adults 18 years of age and older at increased risk of herpes zoster, according to the HAS guidelines in force dated 29 February 2024.

The Committee approves inclusion of SHINGRIX (adjuvanted recombinant herpes zoster vaccine) in the list of covered drugs for outpatients and in the list of covered drugs for inpatients for prevention of herpes zoster and post-herpetic neuralgia in adults 65 years of age and older, and adults 18 years of age and older at increased risk of herpes zoster, according to the HAS guidelines in force dated 29 February 2024 and at the dosages of the marketing authorisation.

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

Clinical Added Value

In view of:

- the persistent medical need for vaccines with evidence of efficacy in prevention of herpes zoster and post-herpetic neuralgia, in particular in individuals with risk factors:
- the evidence versus placebo of vaccine efficacy (VE) of SHINGRIX (adjuvanted recombinant herpes zoster vaccine) on reduction in the number of herpes zoster cases, estimated at:
  - 91.3%, $CI_{95\%}$ = [86.8; 94.5] in the grouped analysis of the randomised phase III studies, Zoster-006 and Zoster-022, in immunocompetent individuals 50 years of age and older,
  - 68.2%, $CI_{95\%}$ = [55.6; 77.5] dans Zoster-002 study in immunocompromised individuals 18 years of age and older, such as autologous HSC transplant recipients;
- the data considered for the HAS guidelines in force, in particular:
  - efficacy data from the systematic reviews available such as the meta-analysis by Mbinta et *al*. supporting the real-life VE findings in respect of SHINGRIX (adjuvanted recombinant herpes zoster vaccine) (79.3%, $CI_{95\%}$ = [57.6; 89.7]), and the network meta-analysis by Tricco et *al*. suggesting superiority of SHINGRIX (adjuvanted recombinant herpes zoster vaccine) in relation to ZOSTAVAX (live attenuated herpes zoster vaccine) in herpes zoster prevention (confirmed cases and suspected cases),
  - Immunogenicity data obtained from immunocompetent individuals 50 years of age and older, as well as immunocompromised individuals 18 years of age and older or individuals with chronic illnesses;

    - data from the ZOE-LFTU (ten-year) follow-up study suggesting an overall VE of Shingrix vaccine of 81.6%.
- a favourable safety profile;

and despite:

- the lack of robust comparative data in immunocompetent individuals in relation to the available vaccine ZOSTAVAX (live attenuated herpes zoster vaccine);
- long-term uncertainties, in particular with respect to the duration of protection provided and the need for booster doses, in particular in immunocompromised individuals. The need for booster doses following the primary vaccination schedule has not been established (see SPC),

the Committee deems that SHINGRIX (adjuvanted recombinant herpes zoster vaccine) provides moderate clinical added value (**CAV III**) in prevention of herpes zoster and post-herpetic neuralgia (PHN) in adults 65 years of age and older, and adults 18 years of age and older at increased risk of herpes zoster, according to the HAS guidelines in force dated 29 February 2024.