SUMMARY

SARS-CoV-2 Spike protein adjuvanted with Matrix-M

NUVAXOVID

dispersion for injection

First listing

Original French opinion adopted by the Transparency Committee on 28 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older, in accordance with the current HAS recommendations.

Transparency Committee's conclusions

Clinical Benefit

- SARS-CoV-2 is an acute viral disease that is potentially life-threatening, primarily in its severe form, following complications. It can also exist in the form of symptoms persisting for several months or more (long COVID-19). COVID-19 is a major public health problem of global concern due to its contagiousness, its seriousness and its impact on healthcare system organisation and, in particular, intensive care units.
- This is a preventive medicinal product.
- The efficacy (immunogenicity)/adverse effects ratio is significant.
- The available alternatives are the mRNA (modified nucleoside) vaccines against COVID-19, COMIRNATY and SPIKEVAX (in individuals over 30 years of age).
- NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) may be used in accordance with its marketing authorisation within the scope of the vaccination guidelines in force.

➔ **Public health benefit**

Considering:

- the very high frequency of SARS-CoV-2 infections, which can be a source of serious complications or even be life-threatening;
- the public health objective of lowering morbidity and mortality from this infection;
- the fact that vaccination is the most effective prevention tool against SARS-CoV-2 infections and their complications;
- the response to the identified medical need due to:
  - an expected additional impact of NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) on symptomatic forms of SARS-CoV-2 infection and on the associated morbidity and mortality in view of the available efficacy, immunogenicity and safety data,
  - an expected additional impact of vaccination on the organisation of care;

NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) is likely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) is substantial for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older, in accordance with the current HAS recommendations.

The Committee issues a favourable opinion for inclusion of NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older, in accordance with the current HAS recommendations and at the MA dosages.

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

Clinical Added Value

Considering:

- the persistent need to have access to vaccines in the prevention of SARS-CoV-2 infections based on the evolution of the epidemiological situation and the regular emergence of new variants, particularly in individuals who do not wish to or cannot receive an mRNA vaccine;
- the data taken into account by the current HAS recommendations, i.e.:
  - evidence versus placebo of the vaccine efficacy of original monovalent NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) in terms of the reduction in the number of symptomatic COVID-19 cases, including in individuals over 65 years of age, with a vaccine efficacy estimated to be 89.7%, 95% CI [80.2; 94.6] in 15,139 subjects aged 18 to 84 years for the 2019nCoV-302 trial conducted in the United Kingdom (inclusions from 28/09/20 to 28/11/20) and 90.4%, 95% CI [82.9; 94.6] in 29,582 adult subjects in the 2019nCoV-301 trial conducted in the USA and Mexico;
  - the immunogenicity data obtained with the different variants in primary and booster vaccination taken into account to draw up the current vaccine recommendations;

- new data added to the file which, to date, has not been used to update the vaccination recommendations;
- an acceptable safety profile, with reported cases of myocarditis, the course of which is not different from the course of myocarditis in general;

and despite:

- the absence of new clinical efficacy data in addition to the available immunogenicity data;
- the long-term uncertainties, in particular with respect to the duration of protection provided,

the Committee deems that, like SPIKEVAX (COVID-19 mRNA (modified nucleoside) vaccine), the clinical benefit of NUVAXOVID (SARS-CoV-2 Spike protein adjuvanted with Matrix-M) is substantial (CAV II) for active immunisation to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older, in accordance with the current HAS recommendations.