SUMMARY

spesolimab

SPEVIGO 450 mg

concentrate for solution for infusion

Modification of the listing conditions

Adopted by the Transparency Committee on 11 December 2024

Summary of opinion

Favourable opinion for reimbursement in the treatment of generalised pustular psoriasis (GPP) flares in adolescents from 12 years of age as monotherapy.

Transparency Committee's conclusions

Clinical Benefit

- Generalised pustular psoriasis (GPP) is a rare inflammatory disease characterised by sudden flares in the form of non-infectious pustules on the skin, often associated with systemic signs (fever, extreme fatigue), with an unpredictable course and complications that can be potentially serious and lead to death.
- SPEVIGO 450 mg (spesolimab) concentrate for solution for infusion has a suspensive effect on symptoms.
- The efficacy/adverse effects ratio is high.
- As in adults, this is a first-line treatment for generalised pustular psoriasis (GPP) flares in adolescents from 12 years of age as monotherapy.

Public health benefit

Considering:

- the seriousness of the disease and its low prevalence,
- the unmet medical need,
- the partial response to the identified need given:
  - evidence of an additional impact on morbidity,
  - the lack of evidence of an impact on mortality and quality of life,
  - the lack of evidence of an impact on the organisation of care, and the care and/or life pathway for patients or their families,

SPEVIGO 450 mg (spesolimab) concentrate for solution for infusion is unlikely to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by SPEVIGO 450 mg (spesolimab) concentrate for solution for infusion is substantial in the indication for the treatment of generalised pustular psoriasis (GPP) flares in adolescents from 12 years of age as monotherapy.

The Committee issues a favourable opinion for inclusion of SPEVIGO 450 mg (spesolimab) concentrate for solution for infusion in the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.

Clinical Added Value

Considering:

- an unmet medical need in the treatment of GPP flares in adolescents,
- the absence of specific data in adolescents from 12 years of age assessing spesolimab 450 mg (intravenous route) in the treatment of generalised pustular psoriasis (GPP) flares;

but the extrapolation to adolescents that can be made based on:

- efficacy data in adults having demonstrated the superiority of spesolimab 450 mg (intravenous route) compared to placebo in the treatment of generalised pustular psoriasis (GPP) flares for the complete disappearance of pustules 1 week after only one infusion (randomised, double-blind, multicentre phase 2 EFFISAYIL 1 study in 53 patients);
- efficacy data in adults and adolescents having demonstrated the superiority of spesolimab 150 mg every 4 weeks (Q4W, subcutaneous route) compared to placebo in the preventive treatment of generalised pustular psoriasis (GPP) flares for the time to onset of a first GPP flare and for the proportion of patients having had at least one GPP flare during the 48 weeks of the study (randomised, double-blind, multicentre phase 2 EFFISAYIL 2 study in 125 patients, including 23 in the spesolimab 300 mg Q4W group);
- data from the EFFISAYIL ON study (extension study of the EFFISAYIL 1 and 2 studies) demonstrating a low percentage of patients with a GPP flare during the 156-week follow-up period;
- pharmacokinetic data demonstrating the coherence of pharmacokinetic profiles between adults and adolescents;
- long-term safety data (EFFISAYIL ON) comparable to those obtained initially in the treatment of flares in adults, with no evidence of specific adverse events in adolescents treated with spesolimab, marked primarily by infections, with, however, uncertainties remaining with respect to the risk of the occurrence of serious or opportunistic infections, malignancies and peripheral neuropathy,

the Committee deems that SPEVIGO 450 mg (spesolimab) concentrate for solution for infusion provides a minor clinical added value (CAV IV) in the current management of generalised pustular psoriasis flares in adolescents from 12 years of age.