Original French opinion adopted by the Transparency Committee

The legally binding text is the original French opinion version

SUMMARY

Human normal immunoglobulin (SCIg)HYQVIA 100 mg/mL

solution for infusion for subcutaneous use

Indication extension

Adopted by the Transparency Committee on 12 February 2025

Summary of opinion

Favourable opinion for reimbursement in "immunomodulatory therapy in adults, children, and adolescents (0 to 18 years) in chronic inflammatory demyelinating polyradiculo-neuropathy (CIDP) as maintenance therapy after stabilisation with IVIg"

Transparency Committee's Conclusions

Clinical Benefit

- CIDP is a serious, progressive and incapacitating disease that can cause motor disability, significantly impairing the quality of life of patients and their families.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a first-line treatment in the maintenance therapy of CIDP after stabilisation with IVIg.

Public health benefit

Considering:

- the seriousness of the disease and its low prevalence,
- the medical need currently met by the alternatives but also taking into account recurrent supply tensions,
- the partial response to the identified need given:
  - the lack of evidence of an additional impact on morbidity and mortality and on quality of life compared to the other normal human immunoglobulins available (IV or SC), in the absence of any comparison with these,
  - an additional impact on the organisation of care and on patients' care and life pathway. In fact, the pharmacokinetic properties of HYQVIA (human normal immunoglobulin) allow a monthly dose interval but two successive injections are required (a first injection of

recombinant human hyaluronidase followed by a second injection of human normal immunoglobulin), which consequently entails an increased administration time and volume.

HYQVIA (human normal immunoglobulin) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of HYQVIA (human normal immunoglobulin) 100 mg/mL solution for infusion for subcutaneous use is substantial in immunomodulatory therapy in adults, children, and adolescents (0 to 18 years) with chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) as maintenance therapy after stabilisation with IVIg.

The Committee issues a favourable opinion for inclusion of HYQVIA (human normal immunoglobulin) 100 mg/mL solution for infusion for subcutaneous use in the list of covered drugs for inpatients approved for use in immunomodulatory therapy in adults, children, and adolescents (0 to 18 years) with chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) as maintenance therapy after stabilisation with IVIg, and at the MA dosages.

Clinical Added Value

Considering:

- the currently met medical need, due to the availability of numerous therapeutic alternatives;
- the results of the ADVANCE-1 pivotal study having demonstrated a superiority of HYQVIA (human normal immunoglobulin) versus placebo on the proportion of patients who experienced a relapse at the end of the 6-month double-blind period (mean difference: -21.8%; 95% CI [-34.45; -7.94]; p<0.0045), but with methodological limitations, due, in particular, to a percentage of missing data for the analysis of the primary endpoint, more frequent in the HYQVIA group (human normal immunoglobulin) compared to the placebo group (9.7% versus 2.8%) and imputed as “absence of relapse”,
- the absence of clinical data in the paediatric population, for which the MA was extrapolated based on the clinical data observed in adults and in other diseases,
- the lack of comparative clinical efficacy data in relation to other human normal immunoglobulins administered intravenously or subcutaneously,
- the globally favourable safety profile marked by local adverse events (in particular, infusion site reactions) and general disorders (including headaches, pyrexia, diarrhoea),
- the presence of anti-rHuPH20 antibodies (titre ≥ 1/160) developing in a small number of patients included in the studies, and the transient detection of neutralising antibodies in two patients during the extension study (median follow-up of 33 months, with 56.5% of patients exposed for ≥ 2 years), meaning that it is not possible to eliminate the uncertainty relating to the long-term safety of the administration of recombinant human hyaluronidase, particularly with respect to fertility,

the Committee deems that HYQVIA (human normal **immunoglobulin) 100 mg/mL solution for subcutaneous infusion provides no clinical added value (CAV V) compared to the other human** normal **immunoglobulins administered intravenously or subcutaneously.**