SUMMARY

recombinant crisantaspase

ENRYLAZE 10 mg/0.5 mL

solution for injection/infusion

First listing

Adopted by the Transparency Committee on 29 May 2024

Summary of opinion

Favourable opinion for reimbursement "as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukaemia (ALL) and lymphoblastic lymphoma (LBL) in adult and paediatric patients (1 month and older) who developed hypersensitivity or silent inactivation to *E. coli*-derived asparaginase".

Transparency Committee's conclusions

Clinical Benefit

- ALLs are malignant clonal proliferations of immature haematopoietic cells (lymphoblasts), which invade the bone marrow then the peripheral blood and, finally, numerous organs. LBL is considered to be a lymphomatous variant of ALL in which extramedullary involvement is predominant. ALLs/LBLs are rare blood diseases with a very young median age at diagnosis. These are rare, life-threatening diseases.
- This is a curative medicinal product for ALL and LBL.
- The efficacy/adverse effects ratio of this proprietary medicinal product, in combination with other chemotherapies, is high.
- It is a salvage therapy for acute lymphoblastic leukaemia, primarily in paediatrics, in the event of the development of hypersensitivity (clinical allergy or silent inactivation) to native or pegylated L-asparaginase.

Public health benefit

Considering:

- the seriousness of ALL and LBL, as well as their high prevalence in the paediatric population (ALL is the most common paediatric cancer);
- the medical need partially met by CRISANTASPASE PORTON BIOPHARMA (formerly ERWINASE) (L-asparaginase from *Erwinia*);
- the lack of response to the identified need given:
  - the lack of evidence of an impact on morbidity and mortality and on quality of life;

- the lack of evidence of an impact on the care pathway;

ENRYLAZE (recombinant crisantaspase) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of ENRYLAZE (recombinant crisantaspase) 10 mg/0.5 mL solution for injection/infusion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion of ENRYLAZE (recombinant crisantaspase) 10 mg/0.5 mL solution for injection/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:

- the poor methodological quality of the purely descriptive and non-comparative study, preventing any formal conclusion from being reached with respect to the results;
- the results observed in this study, which suggest a partial maintenance of NSAA 48 hours post-dose ≥ 0.1 IU/mL (on a pharmacodynamic endpoint);
- the safety profile deemed to be acceptable and similar to that known for native crisantaspase;
- justification of the absence of a comparative study by the situation of persistent supply tensions for native crisantaspase between 2016 and 2023;
- the partially met medical need;

the Committee deems that ENRYLAZE (recombinant crisantaspase) 10 mg/0.5 mL solution for injection/infusion provides no clinical added value (CAV V) compared to the clinically relevant comparator (CRISANTASPASE PORTON BIOPHARMA (formerly ERWINASE) (L-asparaginase from *Erwinia*)).