SUMMARY

asfotase alfa

STRENSIQ 40 and 100 mg/mL,

solution for injection

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 5 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

- Hypophosphatasia is a serious metabolic genetic disease that is life-threatening, particularly when the lesions develop at an early stage (perinatal and infantile forms).
- The proprietary medicinal product STRENSIQ (asfotase alfa) is a replacement therapy.
- The available data are not of a nature to modify the Committee's previous conclusions in terms of the efficacy/adverse effects ratio, the efficacy/adverse effects ratio remains high.
- There are no therapeutic alternatives to STRENSIQ (asfotase alfa).
- STRENSIQ (asfotase alfa) remains a first-line treatment.

- **Public health benefit**

The new data available are not of a nature to modify the Committee's previous assessments. STRENSIQ (asfotase alfa) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of STRENSIQ 40 and 100 mg/mL (asfotase alfa) solution for injection remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of STRENSIQ (asfotase alfa) in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%**

Clinical Added Value

The Committee considers that the new data are not of a nature to modify the assessment of the clinical added value formulated in its previous opinion of 16 March 2016.