

SUMMARY

Clostridium Botulinum neurotoxin type A

**XEOMIN 50, 100 and 200
UNITS****powder for solution for injection****Indication extension****Original French opinion adopted by the Transparency Committee on 7
June 2023****The legally binding text is the original French opinion version****Transparency Committee's conclusions****Clinical Benefit**

- ➔ Spasticity is an incapacitating disability that can impair quality of life and have significant social and family repercussions.
- ➔ This is a symptomatic medicinal product.
- ➔ As with other medicinal products containing botulinum toxin type A, the efficacy/adverse effects ratio is modest in this indication.
- ➔ The product is a first-line medicinal treatment for focal or multifocal spasticity, which should be used as an adjunct to physiotherapy.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of response to the identified need:
 - the absence of a demonstrated additional impact on morbidity and mortality,
 - the absence of a demonstrated additional impact on quality of life,
 - the absence of an additional impact on the organisation of care,

XEOMIN (Clostridium Botulinum neurotoxin type A) proprietary medicinal products are unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of XEOMIN (Clostridium Botulinum neurotoxin type A) proprietary medicinal products is substantial for the symptomatic treatment in adults of spasticity of the upper limb.

The Committee issues a favourable opinion for inclusion of XEOMIN (Clostridium Botulinum neurotoxin type A) proprietary medicinal products in the hospital formulary list of reimbursed proprietary medicinal products approved for use for the symptomatic treatment in adults of spasticity of the upper limb and at the MA dosages.

Clinical Added Value

The Committee considers that, as with the other medicinal products containing botulinum toxin type A currently available, XEOMIN (Clostridium Botulinum neurotoxin type A) proprietary medicinal products provide no clinical added value (CAV V) in the care pathway for the symptomatic treatment in adults of spasticity of the upper limb.