HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
SUMMARY
16 SEPTEMBER 2020
The legally binding text is the original French opinion version

type A botulinum toxin
DYSPORT 300 and 500 SPEYWOOD UNITS powder for solution for injection

Indication extension

Key points

Favourable opinion for reimbursement in the local symptomatic treatment of spasticity of the upper limbs in children two years of age or older.

What therapeutic improvement?

No clinical added value compared to BOTOX.

Role in the care pathway?

The conventional treatment of muscle hyperactivity of the upper limbs in children and adults includes rehabilitative therapy (passive stretching, posture and movement facilitation, fitting of orthotics), pharmacotherapy and surgical treatment (neurosurgery and/or orthopaedic surgery), in particular when fixed contractures have progressed and impede function.

Role of the medicinal product in the care pathway

The intramuscular injection of DYSPORT guided by electrical stimulation or ultrasound in combination with rehabilitative therapy methods is a therapeutic option in children and adolescents with focal spasticity of the upper limb when this impedes fine motricity, compromises rehabilitative treatments and hygiene care, causes pain or prevents the initiation of other therapies, such as the fitting of orthotics.

COMMITTEE'S CONCLUSIONS

Considering all of this information and further to debate and voting, the Committee considers:

Clinical benefit

◗ Spasticity can be a major cause of functional impairment, particularly when it affects the upper limb. It can be directly responsible for pain and have an impact on the child's growing skeleton. Impaired upper limb function can have an impact on self-care capacities, everyday activities and social participation.
◗ These proprietary medicinal products are part of a symptomatic treatment regimen.
◗ The efficacy/adverse effects ratio is modest; it is still to be established in the long term.
◗ There are few medicinal alternatives for the local treatment of spasticity.
◗ The intramuscular injection of DYSPORT guided by electrical stimulation or ultrasound in combination with rehabilitative methods is a therapeutic option in children and adolescents with focal spasticity of the upper limb when this impedes fine motricity, compromises rehabilitative treatments and hygiene care, causes pain or prevents the initiation of other therapies, such as the fitting of orthotics.

Public health impact

Considering:
- the functional impairment that spasticity can cause,
- the frequency of the symptom in the context of neurological disorders with deficiencies,
- the partially met medical need,
- the absence of data enabling demonstration of an impact on the care and/or life pathway of the patient,
- the lack of documented impact on the organisation of care (hospitalisation, AEs, etc.),
- the additional response to the identified medical need,

DYSPORT is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of DYSPORT 300 and 500 SPEYWOOD UNITS powder for solution for injection is substantial in the local symptomatic treatment of spasticity of the upper limbs in children two years of age or older.

The Committee issues a favourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication extension and at the MA dosages.

Clinical Added Value

Considering:
- **demonstration of a dose effect of DYSPORT on reduction of muscle tone 6 weeks after intramuscular injection in patients aged 2 to 17 years with cerebral palsy, mostly treated by physiotherapy or occupational therapy;**
- **the absence of demonstration of efficacy in terms of functional improvement and quality of life in these patients, which are relevant endpoints;**
- **the risk of adverse effects related to spread of toxin distant from the site of administration and uncertainties concerning the degree of morphological and functional recovery of skeletal muscle in the longer term;**
- **the absence of a comparison with the medicinal product BOTOX;**

the Committee considers that DYSPORT provides no clinical added value (CAV V) compared to BOTOX in the local symptomatic treatment of spasticity of the upper limbs in children two years of age or older.