SUMMARY

corifollitropin alfa
ELONVA 100 and 150 µg,
solution for injection
New indication

Adopted by the Transparency Committee on 18 January 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion for reimbursement of ELONVA (corifollitropin alfa) in the *"treatment of adolescent males (14 years and older) with hypogonadotropic hypogonadism (HH), in combination with human Chorionic Gonadotropin (hCG)".*

Role in the care pathway?

Role of the medicinal product

The non-comparative nature of the study provided by the pharmaceutical company does not enable the different treatments to be ranked in order to determine the role of ELONVA (corifollitropin alfa) compared to the other therapeutic options recommended and used off-label in HH in adolescent males.

ELONVA (corifollitropin alfa), in combination with human Chorionic Gonadotropin (hCG), is a new treatment option for adolescent males (14 years and older) with hypogonadotropic hypogonadism (HH). This is a first-line treatment for HH in adolescent males (14 years and older).

Transparency Committee's conclusions

Clinical Benefit

- Male hypogonadism is defined as a testosterone deficiency that can result in clinical signs (regression of secondary sexual characteristics, changes in body composition, asthenia, reduced libido, erectile dysfunction, mood disorders, osteopenia that can progress to osteoporosis causing fractures, etc.) impairing quality of life.
- The medicinal product ELONVA (corifollitropin alfa) is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- There are therapeutic alternatives used off-label. The clinically relevant comparators of ELONVA (corifollitropin alfa) in the MA indication assessed are the medicinal products recommended and used off-label mentioned in section 2.3.1.
- ELONVA (corifollitropin alfa) is a first-line treatment for HH in adolescent males (14 years and older).

Public health benefit

Considering:

- the seriousness of the disease and its rarity;
- the partially met medical need;
- the partial response to the identified need, with:
  - the lack of any demonstrated additional impact in terms of morbidity or quality of life compared to the therapeutic alternatives used off-label, in the absence of comparative data,
  - an expected additional impact on the care and/or life pathway due to the simpler administration regimen (administration every two weeks versus 3 administrations per week with the off-label alternatives), which is of interest in adolescents to facilitate compliance with treatment.

ELONVA (corifollitropin alfa) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit (CB) of ELONVA (corifollitropin alfa) is substantial in the MA indication extension.

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

Recommended reimbursement rate: 65%

Clinical Added Value

Considering:

- the non-comparative nature of the only study available concerning a sample of 17 patients with acquired HH or congenital HH, it is not possible to quantify the clinical benefit of a combination of corifollitropin alfa and hCG in HH in adolescent males (14 years and older) compared to the therapeutic alternatives recommended and used off-label,
- the fact that it is not possible to determine the effect size of ELONVA (corifollitropin alfa) in either congenital HH or acquired HH. Yet these two diseases differ in terms of the extent of the hormone deficiency,
- the administration methods for ELONVA (corifollitropin alfa) with a dosage regimen of one injection every two weeks, which is of interest in terms of promoting compliance in adolescents,
- the safety profile of ELONVA (corifollitropin alfa), used in combination with hCG, which appears to be favourable,

the Committee deems that ELONVA provides minor clinical added value (CAV V) in the current care pathway, which includes the clinically relevant comparators (see 2.3.1).