HAUTE AUTORITÉ DE SANTÉ

ENDOCRINOLOGY
FOCUS
June 2015

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

GONADOTROPHINE CHORIONIQUE ENDO (chorionic gonadotropin), ovulation induction

Insufficient clinical benefit in cryptorchidism in the absence of anatomical obstruction
Continued clinical benefit in the treatment or investigation of sterility

Main points

- GONADOTROPHINE CHORIONIQUE ENDO has Marketing Authorisation in the treatment of infertility in combination with FSH or hMG in women (stimulation of ovulation induction) and in men (inadequate deficient spermatogenesis in due to hypogonadotropic hypogonadism), in for the treatment of cryptorchidism in the absence of anatomical obstruction and in for the investigation of Leydig cell function investigations.
- Because of its lower success rate compared to surgical treatment, adverse effects (e.g. temporary virilisation) and its possible long-term consequences on spermatogenesis, treatment with chorionic gonadotropin has no longer a role in the therapeutic strategy for cryptorchidism. Surgical treatment (orchiopexy) is considered as the standard of care.
- In the other indications, the new efficacy and safety data are unlikely to affect the role of this medicinal product in the therapeutic and diagnostic strategy.

Clinical data

- The efficacy of hormonal treatment for cryptorchidism with hCG is between 5.9 and 34.5%, depending on the study. The efficacy of surgical treatment is between 33 and 100% depending on the study, testicular position (inguinal or abdominal) and surgical technique employed, which also depends on testicle localisation.
- The mean incidence of atrophy after surgery is between 1.83 and 28.1%, depending on the study and the surgical technique employed. The studies were considered to provide mostly a low level of evidence for both types of treatment.
- The side effects of hormonal treatment were signs of early sexual maturation, which may be only mild and transient, and long-term effects on fertility. This treatment is no longer recommended, or at least before the age of 4 years, whereas therapeutic management normally starts at 1 year and before 2 years of age so as to limit the risks of testicular atrophy and its effects on sterility.
- In the other indications, the new efficacy and safety data are unlikely to affect the earlier conclusions of the Committee.

Special prescribing conditions

- Medicinal product requiring special monitoring during treatment.
- Prescription restricted to specialists in gynaecology, gynaecology-obstetrics, endocrinology and metabolism, urology, or paediatrics.

Benefit of the medicinal product

- The actual benefit* of GONADOTROPHINE CHORIONIQUE ENDO is insufficient in the following indication “cryptorchidism in the absence of anatomical obstruction”. It remains substantial in the other indications.
- The Transparency Committee does not recommend to maintain inclusion on the list of medicines reimbursed by National Health Insurance in in the indication “cryptorchidism in the absence of anatomical obstruction”.

- The Transparency Committee recommends to maintain inclusion on the list of medicines reimbursed by National Health Insurance in the other indications.

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This document was created on the basis of the Transparency Committee Opinion of 17 June 2015 (CT-13067) and is available at **www.has-sante.fr**

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[i] * The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement in treatment provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".