SUMMARY

Follitropin delta

REKOVELLE 12 micrograms/0.36 mL, 36 micrograms/1.08 mL, 72 micrograms/2.16 mL,

solution for injection in pre-filled pen

Reassessment at Transparency Committee's request

Original French opinion adopted by the Transparency Committee on 10 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Approval of reimbursement for "controlled ovarian stimulation to induce the development of multiple follicles in women undergoing Assistive Reproductive Technologies (ART) such as an in vitro fertilisation (IVF) or IVF with intracytoplasmic sperm injection (ICSI) cycle."

Transparency Committee's Conclusions

Clinical Benefit

- Infertility has a profoundly adverse impact on couples' quality of life.
- This is a curative medicinal product.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available.

➔ Public health benefit

In view of:

- the prevalence of assisted human reproduction,
- its impacts on the quality of life of couples affected,
- the small need, on account of substantial medical coverage of this need
- the lack of evidence of the effect of REKOVELLE on public health outcome measures (reduction of mortality or morbidity, improvement of quality of life, modification of delivery of care, etc.) or on delivery of care,

REKOVELLE (follitropin delta) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of REKOVELLE (follitropin delta), solution for injection, is substantial in the marketing authorisation indication.

The Committee approves continued inclusion of REKOVELLE (follitropin delta), solution for injection in the list of covered drugs for outpatients and in the list of covered drugs for inpatients in the indication and at the dosages of the marketing authorisation.

➔ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%

Clinical Added Value

In view of:

- **the new data submitted, in response to the Committee's request issued in its initial opinion of 5 April 2017, namely the post-trial follow-up findings in order to assess the cryopreserved cycles initiated in the year following the date of randomisation for patients included in ESTHER-1, and in the year following the start of controlled ovarian stimulation of the final cycle in ESTHER-2,**
- **the fact that the pregnancy follow-up data collected from the cryopreserved cycles from the ESTHER-1 and ESTHER-2 studies do not suggest a difference in terms of risk of pregnancy loss when patients undergo controlled ovarian stimulation with REKOVELLE (follitropin delta) compared with GONAL F (follitropin alfa),**
- **the fact that, hence, the data do not demonstrate a particular signal,**
- **the fact that these follow-up findings do not demonstrate any data liable to modify the Committee's previous assessment,**

the Committee deems that REKOVELLE (follitropin delta), solution for injection provides no clinical added value (CAV V) compared with GONAL-F (follitropin alfa).