

Enc 5 Appx 3

Clinical Expert Summary

Follitropin alfa (Bemfola^{®▼}) 75IU/0.125 ml, 150 IU/0.25 ml, 225 IU/0.375 ml, 300 IU/0.5 ml and 450 IU/0.75 ml solution for injection in a pre-filled pen

Follitropin alfa (Bemfola^{®▼}) in adult women for anovulation (including polycystic ovarian disease, PCOD) in women who have been unresponsive to treatment with clomiphene citrate; stimulation of multifollicular development in patients undergoing superovulation for assisted reproductive technologies (ART) such as in vitro fertilisation (IVF), gamete intra-fallopian transfer (GIFT) and zygote intra-fallopian transfer (ZIFT); or in association with a luteinising hormone (LH) preparation for the stimulation of follicular development in women with severe LH and FSH deficiency. In clinical trials these patients were defined by an endogenous serum LH level < 1.2 IU/l. In adult men for the stimulation of spermatogenesis in men who have congenital or acquired hypogonadotropic hypogonadism with concomitant human chorionic gonadotrophin (hCG) therapy.

1. Existing guidelines

There are no specific guidelines for such preparation; however, each advanced fertility service would have their own local guidance for dose calculations and for monitoring response in patients using Bemfola^{®▼}.

2. Disease prevalence/incidence

It was estimated that, in South Wales, the number of IVF cycles would be between 600 and 850 cycles per year (this would include fertility preservation for cancer patients). The number of intrauterine insemination (IUI) cycles in South Wales was estimated to be between 400 and 500 per year. For North and Mid Wales, the total IVF cycles would be between 400 and 450 cycles per year, and IUI cycles would be approximately 50 cycles per year.

3. Current treatment options

In Wales, the two common medicines used within the NHS are follitropin alfa (Gonal-f[®]) and the human menopausal gonadotrophin (hMG), menotrophin (FSH and LH). Both are readily available and are commonly used by specialised fertility clinics and in IVF. In IVF, the predominant treatment is hMG menotrophin.

4. Unmet needs

No areas of unmet need were highlighted.

5. Knowledge of product in given indication

Experts stated that Bemfola^{®▼} will be used if it can compete with the price of currently used treatments. It was noted that Bemfola^{®▼} can replace Gonal-f[®].