Northern Treatment Advisory Group

Northern (NHS) Treatment Advisory Group

Treatment Appraisal: Decision Summary

Date	9th September 2014
Appraisal & Details	**Ulipristal (EllaOne®) for post-coital contraception:** Updated data concerning the effect of body weight (BMI) on efficacy of both levonorgestegel and ulipristal products.
Recommendation	The NHS Northern Treatment Advisory Group has not opted to change the previous NETAG recommendation following an updated appraisal of ulipristal (EllaOne®) for post-coital contraception. **Ulipristal (EllaOne®) is recommended as the preferred drug treatment option for post-coital contraception for patients who present between 72 and 120 hours following unprotected intercourse. Levonorgestrel is still recommended for patients who present at up to 72 hours following unprotected intercourse.** When considering ulipristal, patients should be advised of the requirement for additional barrier contraception until their next menstrual period, its unknown teratogenic effects, and its common adverse effects such as menstrual delay and gastro-intestinal effects.
Clinical evidence summary	The group acknowledged that, with full publication of the clinical data, the efficacy and safety of ulipristal for post-coital contraception had been adequately demonstrated. Following the publication of the post-hoc analyses of the combined data set in patients with high BMI the group supported the EMA stance and considered this data to be methodologically weak. It was therefore felt that the previous recommendation should remain.
Safety	The safety of ulipristal for post-coital contraception had been adequately demonstrated in clinical trials. The EU wide review assessed whether bodyweight affects the effectiveness of ulipristal (and levonorgestrel) and stated that *the data are too limited and not robust enough to conclude with certainty that contraceptive effect is reduced with increased body weight*.
Patient Perspective	Previous changes in commissioning arrangements for emergency contraception have greatly improved access for patients. Convenience, flexibility and timeliness are likely to be valued by women and may contribute to greater overall effectiveness. Data suggests that only a very small number of women opt for intra-uterine devices despite being counselled about greater efficacy. Many women are likely to prefer the convenience and simplicity of oral methods.
Cost analysis summary	The group noted the substantial relative cost differential between ulipristal and levonorgestrel. However the total budget impact from a shift in prescribing policy towards ulipristal would be limited by the modest overall treatment volumes.
Financial impact PbR: In-tariff	The cost per dose of ulipristal is about £17 compared with about £6 for levonorgestrel 1.5 mg. As the group has opted not to change the previous NETAG recommendation no significant change in costs is expected.