Testosterone gel (Testim®▼)

Treatment for female sexual dysfunction post oophorectomy or primary ovarian failure

Commissioning Statement

NHS Fylde and Wyre Clinical Commissioning Group has agreed not to fund testosterone gel (Testim®) for the treatment of female sexual dysfunction post oophorectomy or primary ovarian failure.

This medicine is classified as BLACK for this indication

The evidence to support the use of testosterone gel is limited to a single trial in 53 women and is only in patients with intact ovaries with female sexual dysfunction. There are currently no published trials on the use of testosterone gel in women with FSD post oophorectomy. There are several trials assessing the effectiveness of testosterone patches, these are now discontinued, however, when they were available they were not recommended for use due to questions around clinical significance of improvement (despite being statistical significance) compared to placebo.

Summary of supporting evidence:

- The majority of the evidence available supporting the use of transdermal testosterone relates to testosterone patches.
- The sizes of the populations in which testosterone gel was assessed for effectiveness were small and the results were based on subjective outcomes.
- It is questionable whether the median increase in score of 1 point (out of 7) is clinically significant despite being statistically significant compared to placebo.
- The evidence for the testosterone patches shows a modest improvement in HSDD.
- It is not clear what testosterone level needs to be attained to improve the symptoms of HSDD and it has been found that the serum levels do not always correspond to the symptoms are exhibited. It is believed that psychosocial support will provide the best outcomes for patients with female sexual dysfunction and HSDD.
- The proposed preparation is an off-label use of a licensed drug, which is formulated for men who require higher doses. Therefore, there are concerns over the ability to administer doses for the female population as they require significantly lower doses.
- Due to the inability to measure accurately the small doses required there is a potential for the patient to administer higher doses than that required and could leave patients at risk of supraphysiologic testosterone levels, which can lead to irreversible adverse events e.g. clitoral enlargement and voice changes.
- There are a number of concerns over the safety of transdermal testosterone. Some of the data published is contradictory but caution is still advised by regulatory bodies. Evidence suggests that the possible safety issues are dose related. This supports concerns relating to the inability to accurately measure doses using the proposed preparation.
- The cost of testosterone gel is relatively inexpensive as a tube is expected to last 10 days. Approximate annual costs would be £39.

For further details around the evidence, cost effectiveness and for an explanation of the colour classification system please refer to the website of the Lancashire Medicines Management Group at: http://www.lancsmmg.nhs.uk/

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