NHS
Fylde and Wyre
Clinical Commissioning Group

Spironolactone

For use in refractory adult female acne

Commissioning Statement

Fylde and Wyre Clinical Commissioning Group has agreed to commission the prescribing of spironolactone for to treat refractory adult (post teenage) female acne vulgaris resistant to multiple oral antibiotics and isotretinoin and where there are clinical signs of hyperandrogenism only if the following apply:

- This preparation should only be prescribed by a Consultant Dermatologist

This medicine is classified as RED for this indication

- Spironolactone is not licensed for this indication
- The evidence to support its use is in a limited number of patients and is of low quality. Although it is recognised that this will be due to the medicine now being off patent.
- A double blind placebo controlled crossover randomised controlled trial (RCT) in 29 women reported an improvement in acne symptoms (defined as 50% reduction in number of lesions) in 58% of people taking 200 mg of spironolactone, when assessed double blind by the investigators using photographic means, compared to 21% improvement in the placebo group. The results from the two groups were pooled and reported a reduction in lesion counts from 37.8 ± 5.8 to 12.9 ± 3.3 in the spironolactone group and 23.5 ± 3.2 to 24.7 ± 3.9 in the placebo group.
- 86% of patients subjectively reported an improvement in acne symptoms whilst taking spironolactone in the same trial.
- Some people were permitted to take an oral contraceptive during the trial and so we cannot be confident the results seen were from the spironolactone alone.
- A placebo controlled trial in 17 male and 19 female patients found for doses ranging from 50 mg to 200 mg daily that the acne symptoms were better in 60 to 83% of people when assessed by photographic means, compared to 15% of those in the placebo group. 40 to 100% of patients (depending on the dose of spironolactone) reported their acne was better in the same trial, compared to 17% of those in the placebo group. No additional acne therapy was permitted during the trial. The trials were insufficiently powered to demonstrate whether the results found are statistically significant.
- In a retrospective analysis of 85 women, treated for 2 - 24 months with either spironolactone alone, spironolactone plus oral antibiotics, spironolactone plus oral contraceptives or spironolactone plus oral antibiotics and oral contraceptives, 66% of women had either a complete clearing or marked improvement of acne.
- All three trials report a high dropout rate; 38%, 28% and 14% respectively failed to complete the studies. Reasons reported were; adverse events and lack of improvement.
- The most commonly reported adverse events (AEs) were; menstrual irregularities, nausea, dizziness/headaches, diuresis and breast tenderness. These AEs did not always cause discontinuation of the study drug.
- A Cochrane review concluded that there is insufficient evidence of effectiveness of spironolactone in the management of acne vulgaris. It should be noted that the review only considered one trial paper [Muhlemann].
- Spironolactone is an inexpensive drug and would be used in a very small number of patients. It is estimated that the total annual cost could range from £247 to £1,080. However, due to the high dropout rates, it is unlikely that that the cost would be as high as £1,080 as many patients would fail to complete the treatment course

For 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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