

## **Ivermectin cream 10mg/g (Soolantra®)**

### **For the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients**

#### **Commissioning Statement**

Fylde and Wyre Clinical Commissioning Group has agreed to fund the prescribing of Ivermectin cream 10mg/g for the topical treatment of inflammatory lesions of rosacea (papulopustular) in adult patients under the following criteria:

- For Moderate to Severe symptoms only AND
- If other agents have been tried and they did not work or were not tolerated
- Treatment to be discontinued after 3 months if no improvements

**This medicine is classified as GREEN for this indication**

#### **Summary of supporting evidence:**

- In two identical phase 3 trials (studies 1 and 2) with a total patient cohort of 1371:
  - a significantly greater proportion of patients in the ivermectin group (38% and 40%) achieved Investigator's Global Assessment (IGA) success compared with the vehicle (placebo) group (12% and 19%) (both  $p < 0.001$ , rounded to nearest percent).
  - The mean difference between treatment groups was -8.13 lesions (95% CI: -10.12 to -6.13,  $p < 0.001$ ) in study 1, and -8.22 lesions (95% CI: -10.18 to -6.25,  $p < 0.001$ ) in study 2
  - The secondary endpoint of improvements in quality of life, measured using RosaQoL, were statistically significantly greater for ivermectin compared with vehicle -0.62 vs -0.35, ( $p < 0.001$ ) in study 1 and -0.60 vs. -0.35 ( $p = 0.001$ ) in study 2
  - Percentage change in inflammatory lesion count from baseline to week 12 was assessed as a secondary outcome, and both studies showed a significantly greater reduction with ivermectin compared with vehicle. Mean (standard deviation) percentage change at week 12 was -65% (39.91) in the ivermectin group and -42% (38.83) in the vehicle group ( $p < 0.001$ ) in study 1, and -66% (33.18) in the ivermectin group and -43% (38.42) in the vehicle group ( $p < 0.001$ ) in study 2
- In a 40 week extension study combining the populations of studies 1 and 2
  - At week 12, 38.4% of people treated with ivermectin in study 1 and 40.1% in study 2 had an IGA score of 0 or 1 ('clear' or 'almost clear').
  - This increased to 71.1% and 76.0% respectively by week 52
- Compared with metronidazole 0.75% cream, ivermectin 1% cream, in an 962 patient study conducted for 16 weeks and then extended for a further 36 weeks:
  - Produced an 83% reduction in the inflammatory lesion count compared with 74% for metronidazole ( $p < 0.001$ ).

- A statistically significant difference was observed between groups from week 3 onwards.
- In absolute terms, from a baseline of about 32 lesions in both groups, this was a reduction of 28 lesions for ivermectin and 24 lesions for metronidazole
- Network meta-analyses show that ivermectin cream has a statistically greater likelihood of successful treatment of rosacea than azelaic acid 15% gel and metronidazole 0.75% cream at weeks 12 and 15 and has a higher percentage change in inflammatory lesion count than either comparator at 12 weeks.
- For success rate at week 12 compared to vehicle, ivermectin 1% cream OD has an NNT of 3, compared to 9 for azelaic acid gel 15% BD and 6 for metronidazole 0.75% cream BD

### Safety

- In the studies comparing ivermectin with placebo adverse events reported on average by 39% of the ivermectin group and 38% of the vehicle group
- The 40-week, long-term extension studies found the overall incidence of adverse events was similar for ivermectin 10 mg/g and azelaic acid 15% gel, reported in approximately 60% of participants.
- In the ivermectin/metronidazole study the incidence of adverse events was similar for ivermectin cream (32.4%) and metronidazole (33.1%)

### Economic Considerations

- One 30g tube of 10mg/g ivermectin cream costs £18.29, excluding VAT. A 4 month treatment course will cost £73.16
- A 4 month course of metronidazole gel treatment will cost £38.40
- A 4 month course of azelaic acid 15% gel will cost £29.92
- Based on the SMC assumptions, the net medicines budget impact for Lancashire is estimated at £6,516 in year 1 and £15,297 in year 5.

For details around the colour classification system please refer to the website of the Lancashire Medicines Management Group at: <http://www.lancsmmg.nhs.uk/>