

Position Statement: *To be adhered to in line with the [Worcestershire Prescribing Policy](#)*

Treatment	Eflornithine (Vaniqa®) cream for facial hirsutism
Commissioning position	<p>The use of eflornithine 11.5% cream (Vaniqa®) for facial hirsutism is not supported for patients registered with a GP in Worcestershire or those patients resident in Worcestershire but not currently registered with a GP.</p> <p>Worcestershire Area Prescribing Committee (APC) does not consider eflornithine cream suitable for use within the Worcestershire health economy due to limitations in existing clinical trial data and a lack of evidence of value for money for use of NHS funds.</p> <ul style="list-style-type: none"> Eflornithine 11.5% cream is only licensed for the treatment of facial hirsutism in women over 18 years of age.¹ Eflornithine 11.5% cream offers very little benefit for the management of facial hirsutism in women. There is limited evidence for clinical efficacy and patient satisfaction with eflornithine. Furthermore, there are no trials comparing eflornithine with established hirsutism treatments such as co-cyprindiol.^{2,3,4,5} The treatment of facial hirsutism <u>from any cause</u> is a cosmetic procedure which is not routinely funded within Worcestershire, as noted within the Aesthetic Surgery commissioning policy. NICE Clinical Knowledge Summary provides guidance on the management of hirsutism in premenopausal and postmenopausal women.⁶ It is important that a patient is properly assessed and underlying causes addressed before pharmacological therapy is considered as hirsutism can result from serious underlying disorders (e.g. polycystic ovary syndrome, androgen secreting neoplasm) or certain medications (e.g. ciclosporin, glucocorticoids, phenobarbitone, phenytoin, combined oestrogen androgen hormone replacement therapy).¹ Self-funded cosmetic treatments for reduction in hair growth or hair removal (e.g. shaving, plucking, laser treatment, electrolysis) should be the primary options for the majority of women with hirsutism.
Summary of Evidence ^{2,3,4,5,7}	<p>The efficacy of eflornithine has been demonstrated in a number of trials, none of which have been fully published.</p> <p>The two main double blind randomised vehicle (placebo) controlled trials involved 596 women treated for a duration of 24 weeks (plus 8 weeks follow up without any treatment), assessed the efficacy of eflornithine 11.5% cream compared to vehicle. The primary efficacy measure was a four point Physicians Global Assessment of improvement or worsening of the condition compared to baseline.</p> <p>In each of these studies statistically significant improvement for eflornithine versus eflornithine vehicle was seen. These improvements resulted in a corresponding reduction in the darkening appearance of the facial skin associated with the</p>

presence of terminal hair. Improvement in the condition was seen within 8 weeks of starting eflornithine. The degree of improvement continued throughout the study but declined once treatment had stopped. The difference between the treatment groups was no longer significant 8 weeks after cessation of treatment.

Safety ^{1,7}

The majority of adverse events associated with eflornithine are skin related and mild in nature, with burning, tingling or stinging skin, erythema or rash more frequently reported in the eflornithine group. The most commonly reported adverse event in both groups was acne (very common) and pseudofolliculitis barbae (common $\geq 1/10$). There is a theoretical risk of skin atrophy with long-term use of eflornithine but published controlled trials to date have been too brief to assess this risk.⁷ Maximal applied doses used safely in clinical trials were up to 30 grams per month. Refer to [SPC](#) for further information.

Eflornithine product and price comparison

Costs £56.87 per 60g tube; the annual cost of Vaniqa[®] is approximately £370 per patient based on usage of 30g/month.^{8,9}

UK Licensed Products for Hirsutism	Cost per 28 days
Eflornithine 11.5% cream	£28.44 for 30g
Generic co-cyprindiol 2000/35 (cyproterone acetate 2mg, ethinylestradiol 35 micrograms) and Dianette [®] brand	£3.59 for 21 tablets plus 7 day pill free interval

Approved Date for Review

October 2019
October 2022

REFERENCES

1. Summary of Product Characteristics: Vaniqa[®] 11.5% cream. Last reviewed April 2017. Accessed online 19th September 2019 <https://www.medicines.org.uk/emc/medicine/21243>.
2. Scottish Medicines Consortium (SMC). [Eflornithine 11.5% cream \(Vaniqa[®]\) Resubmission; the treatment of facial hirsutism in women](#). September 2005.
3. Keele University: Midlands Therapeutics Review and Advisory Committee. Eflornithine (Vaniqa[®]) for the treatment of facial hirsutism in women. January 2006.
4. Somani N and Turvy J. Hirsutism: An Evidence-Based Treatment Update. *Am J Clin Dermatol*, 2014;15:247–266.
5. [NHS PrescQIPP. Bulletin 117](#). Drop List: Eflornithine review v4.2; July 2015.
6. [NICE CKS. Hirsutism – management](#). Revised December 2014; Accessed online 19 September 2019.
7. Drug and Therapeutics Bulletin. Does eflornithine help women with face hirsutism? *British Medical Journal* 2007, 45(8): 62-64.
8. National Health Service Business Services Authority. Electronic Drug Tariff, September 2019; Accessed online 19th September 2019.
9. BNF September 2019; Accessed online 19th September 2019.