

PAN MERSEY AREA PRESCRIBING COMMITTEE PRESCRIBING POLICY STATEMENT REF: PS169 FINAL Are

Pan Mersey
Area Prescribing Committee

FIRST APC BOARD DATE: 28 SEP 2016 LAST APC BOARD DATE: 25 JUL 2018

E - Cigarettes

BLACK

The Pan Mersey Area Prescribing Committee does not recommend the prescribing of E - Cigarettes, except as part of Local Authority commissioned Stop Smoking Service arrangements.

The first licensed e-cigarette, e-Voke[®], was granted a marketing authorisation in November 2015 with the indication to relieve and/or prevent withdrawal symptoms and reduce the cravings associated with tobacco dependence. The launch of e-Voke[®] was originally planned to be sometime in 2016, new launch plans are not clear. As this is a licensed medical product there is the potential for it to be supplied on NHS prescription. Other licensed e-cigarettes may follow.

Due to the lack of data showing the benefits of using the e-Voke[®] device, e-cigarettes are **not** recommended for prescribing by the Pan Mersey APC. There are no published trials using e-Voke[®]. The clinical study submitted to support the licensing application was a pharmacokinetic study and did not include any evidence of effectiveness. Further data is required to evaluate the use of e-Voke[®] and to compare its use to other nicotine replacement therapies (NRT) that are currently used within the NHS. Robust safety data is also needed.

NICE NG92: Stop Smoking Interventions and Services¹ recommends that people who smoke and who are using, or are interested in using, a nicotine-containing e-cigarette on general sale to quit smoking, should be able to receive advice on this from a health professional.

The Cochrane Review – Electronic cigarettes for smoking cessation² (updated September 2016), concluded that the quality of evidence for the use of e-cigarettes to help people stop smoking in the long-term, is overall 'low' by GRADE standards because it is based on only a small number of studies that compared e-cigarettes to placebo, with low event rates and wide confidence intervals around the estimated mean. The lack of difference between the effects of e-cigarettes compared with nicotine patches found in one trial is uncertain for similar reasons. The long-term safety of e-cigarettes is unknown. The update noted that further trials are ongoing.

Stop Smoking Services, including those provided by community pharmacy, are commissioned by local authorities under their public health remit, as part of their duty to improve the health of people in their area. The decision to use e-cigarettes as part of these services is theirs alone, but GPs should not be asked to prescribe e-cigarette for patients accessing these services unless the local authority commissions them to do so. Patients presenting at GP surgeries requesting e-cigarettes can be referred to local stop smoking services for advice and support.

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

E - CIGARETTES

EFFECTIVENESS

The "hybrid medicine" application process only requires the manufacturer to provide information on the quality of the medicine and supply data to demonstrate bioequivalence with the reference medicine, Nicorette® inhaler. No published trials using e-Voke® were provided, however a clinical study was submitted to support the marketing authorisation application.3 This was a pharmacokinetic study with a crossover design, comparing bioavailability of nicotine, in 24 adult males, when delivered by e-Voke® 10mg or 15mg cartridges, Nicorette® 15mg Inhalator, or smoking a Benson and Hedges Gold cigarette. The levels for e-Voke® were found to fall between those of the Nicorette inhaler and a cigarette. No further efficacy data was required or submitted for the licensing application This study did not include any evidence for effectiveness in smoking cessation.

COST

A price for e-Voke[®] is not yet available. **Estimates** propose a cost of £20 per kit and £10 for refills – this equates to approximately £600 per patient per year.⁴

As this could involve a large cohort of patients, if patients are prescribed e-Voke® on a long-term basis this could have a significant impact on the health economy.

SAFETY

The pharmacokinetic study concluded that the peak plasma levels of nicotine in the e-Voke® inhaler products are lower than those with normal cigarette use. This indicates that these products can be considered at least as safe in terms of nicotine consumption as cigarette smoking. There did not appear to be additional adverse event reporting following four administrations of e-Voke® over a period of 3 hours. No other safety events or outcomes were reported.

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No length of treatment course, maximum or otherwise, is recommended in the SPC. There is no data for safety in long-term use, including inhalation of additives, or on passive inhalation of

vapour.

For full details of side effects and contraindications, see the Summary of Product Characteristics SPC via MHRA

PATIENT FACTORS

While e-cigarettes have the potential to support harm reduction, any advantages to public health are not yet established. People who are unwilling to try established NRT should be advised that although the safety and efficacy of e-cigarettes cannot be assured they are likely to be a safer option than continuing to smoke.⁵

E-Voke[®], along with other e-cigarettes, will be available to purchase by patients should they favour the use of an e-cigarette, however those patients that want to quit and require nicotine replacement therapy should be offered more established NRT alongside support by the local stop smoking service, which have been proven to be the most effective way to quit smoking.

PRESCRIBING INFORMATION

E-cigarettes are not recommended for prescribing, except as part of local authority commissioned Stop Smoking Service arrangements.

REFERENCES

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