

Patient Group Direction for the supply of varenicline by community pharmacists ADDITIONAL NHS HIGHLAND TRAINING

7 March 2016

Read through the following and complete the attached Appendix 1 to ensure you are issued with a Completion Certificate before you can prescribe varenicline in NHS Highland.

Background

NHS Circular PCA (P) (2014) 12, *Public Health Services (PHS) – Smoking Cessation Service Revised Service Specification* was issued in June 2014 and advised of changes to the national Community Pharmacy Smoking Cessation Service including a revised Service Specification and an outline Patient Group Direction (PGD) for the provision of varenicline as a treatment option.

NHS Board Responsibilities:

- Defining the criteria for a localised NHS Highland varenicline PGD
- The local signing off and clinical governance of the varenicline PGD
- Providing additional training on the NHS Highland varenicline PGD in conjunction with the nationally recognised smoking cessation NES training
- The issuing of Completion Certificates to accredited pharmacists who have successfully completed varenicline training

Learning Objectives:

After completing this training on the NHS Highland varenicline PGD you should know:

- The additional factor listed in the Varenicline Clinical Risk Assessment Form in Appendix 2 of the PGD and why it is there
- The clinical criteria for exclusion in the PGD
- Which exclusion criteria require referral and prescribing by the Specialist Smoking Cessation Service or GP if appropriate and which can still be supplied by the community pharmacist provided the GP has advised that the patient is suitable
- How to access the NES Smoking Cessation Training if you have not already attended one of their evening workshops or watched the webinar or subsequent webcast as this training has to be completed too

NHS Highland Varenicline PGD:

Background

The BNF has “history of cardiovascular disease” listed as one of the cautions and the Summary of Product Characteristics for Champix[®] advises that “patients should be instructed to notify their doctor of new or worsening cardiovascular (CV) symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction or stroke”.

In June 2011 the US Food and Drug Administration (FDA) posted a warning that varenicline may increase the risk of heart complications (such as a heart attack) in people who have existing CV disease such as angina or peripheral vascular disease. This warning was based on a research study that followed 700 smokers with CV disease who were treated with varenicline or placebo.

The results of the study confirmed that varenicline was effective in helping people to quit smoking. Adverse CV events such as heart attack were uncommon overall but occurred slightly more frequently in those taking varenicline compared to placebo.

However the increased risk of CV events was not statistically significant (i.e. the small increased number of CV events could have happened by chance).

Therefore the FDA has said that it will continue to monitor the situation and has asked the manufacturer to provide more information on the data they hold. In the meantime they advise people who take varenicline to report to their doctor any new or worsening symptoms of cardiovascular disease e.g. shortness of breath or trouble breathing; new or worsening chest pain; new or worse pain in the legs when walking.

PGD

In light of the above cautions and possible concerns about heart problems the PGD Subgroup of NHS Highland decided in 2014 that “Does patient have a history of cardiovascular disease?” should be an additional factor listed in the Varenicline Clinical Risk Assessment Form in Appendix 2 of the PGD and in addition it is listed as one of the criteria for seeking further clarification from the doctor. So this does not mean that varenicline cannot be prescribed by pharmacists under the PGD, rather they need to check with the patient’s GP as to whether the GP thinks that it is suitable first, since pharmacists do not have direct access to a patient’s medical history.

This is also true of renal impairment as a patient may know that they have a history of this but are unlikely to know whether their glomerular filtration rate is less than 30mL/minute/1.73m², so again further clarification should be sought from the GP.

In addition a patient with a history of psychiatric illness isn’t necessarily excluded from being prescribed varenicline under the PGD provided their GP has confirmed that it is suitable.

It is not licensed for patients under 18 years of age and pregnant or breastfeeding women.

If a patient is excluded from treatment under this PGD then they should still be referred to their GP or the Specialist Smoking Cessation Service where they may still be prescribed varenicline but not by community pharmacists under the PGD.

NES Smoking Cessation Training:

If you have not already undertaken NES Smoking Cessation Training or attended one of the NES evening workshops run last year in May and June 2014 or watched the webinar or subsequent webcast then you must do so as you cannot be signed off as an accredited pharmacist until you have done so.

The eLearning *Scottish Community Pharmacy Smoking Cessation Programme* is available via the NES Portal (accessed via Dashboard>Search for eLearning>eLearning Catalogue>Smoking Cessation Training)

<https://portal.scot.nhs.uk/>

Once you have undertaken this training you must complete the two linked multiple choice questions (MCQs) to have this mandatory education validated.

MCQ 1 – for all staff who have attended local events, worked through the eLearning or watched the webinar/webcast

MCQ 2 (Varenicline) – is for pharmacists only

Click the relevant orange button to “order” your MCQs and then the blue button to “undertake MCQs” to access the questionnaires. At the end of each your answers are marked, a score given and the result is logged into the system.

This then flags to NES successful completion of the training which is reflected in the eLearning section of your vCPD report (accessed via Dashboard>Reports & Certificates>vCPD Record). This report can be exported and printed as evidence of your successful completion of the training.

References:

- British National Formulary (BNF) 70, September 2015 – March 2016 accessed 7 March 2016
- Summary of Product Characteristics for Champix® accessed 7 March 2016
<http://www.emc.medicines.org.uk>
- NHS Highland *Patient Group Direction for the supply of varenicline to adults over 18 years of age by community pharmacists under the public health service – smoking cessation service in NHS Highland* 13/05/16 2016
- Patient.co.uk *Varenicline (Champix®)* article accessed 20 March 2015
<http://www.patient.co.uk/health/varenicline-champixr>

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COMMUNITY PHARMACY SERVICES
Application for a Completion Certificate
to supply varenicline (Champix[®]) under
the NHS Highland PGD



I _____ pharmacist, GPhC registration no _____

Confirm that I have:

- Successfully completed the approved NES Pharmacy and NHS Highland training and apply to be accredited as an approved practitioner within this scheme
- Received and understood training to undertake the supply of medicines under a PGD and am familiar with the content of the NHS Highland PGD PowerPoint presentation
- Undertaken appropriate training to carry out clinical assessment of patients leading to a diagnosis that requires treatment according to the indications listed in the PGD
- Ensured that the organisation providing professional indemnity insurance has confirmed that this activity is included in their policy
- Understood that by agreeing to act as an approved practitioner under the PGD and NHS Scotland service level agreement I am adjusting my scope of professional practice
- Enclosed a signed copy of the NHS Highland individual authorisation form for the PGD
- Enclosed a copy of the NES Verifiable CPD Report confirming that I have successfully completed:
 - Smoking Cessation MCQ1 - For All Staff
 - Smoking Cessation MCQ2 - Varenicline

Pharmacist's Signature: _____ Date: _____

Post this form to:

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