

## STANDARD OPERATING PROCEDURE (SOP)

### Issuing of bupropion e-voucher by a Yorkshire Smokefree Advisor and supply of bupropion by pharmacy professional through PGD

#### SECTION 1

Version	Date	Author	Status	Comment
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### 1. Purpose

The purpose of this SOP is to enable the issue of an e-voucher and the supply of bupropion to appropriate clients attending the Yorkshire Smokefree Service (YSF).

The rationale for supplying products via a voucher is to provide greater access to bupropion. Bupropion, which is a prescription only medicine, will be supplied by community pharmacy professionals via a Patient Group Direction (PGD).

### 2. Scope

This SOP covers all stop smoking specialists and advisors working for the Yorkshire Smokefree Service.

Only clients receiving stop smoking support from the Yorkshire Smokefree Service may be issued with a bupropion voucher.

This SOP also acts as guidance to community pharmacy professionals that have signed the YSF bupropion PGD and are contracted to supply bupropion through the service level agreement with YSF.

**This is not a complete SOP for the pharmacy professional, it aims to make clear the responsibilities of the pharmacy professional, and the role of the advisor.**

### 3. Applicable Regulations and Policies



PGD - Bupropion -  
Barnsley Calderdale D

### 4. Who will Undertake the Procedure

All stop smoking specialists and advisors working for, or subcontracted to the Yorkshire Smokefree Service, who have completed the level 2 or intermediate stop smoking skills training will carry out the initial suitability assessment with the client.

Community pharmacy professionals that have signed the YSF bupropion PGD and are contracted to supply bupropion through the service level agreement with YSF.

### 5. Procedure (advisor and pharmacy professional)

Check the client's identification (name, date of birth, address) against the record on QuitManager.

Inform the client that information relating to the supply of bupropion under the PGD will be passed to their GP to ensure patient safety. This information will be sent by the pharmacy professional that supplies bupropion. Check that the client consents to this and consent is recorded on QuitManager (QM). If the client declines consent to contact their GP, a voucher cannot be issued.

### 6. Eligibility to receive a voucher for bupropion

Advisor and pharmacy professional must check the client's eligibility against the inclusion and exclusion criteria of the PGD below (Complete the checklist on QuitManager). **The advisor is performing an initial suitability assessment, but it is the pharmacy professional that will decide whether the client is suitable to receive bupropion via the PGD.** The client must be informed of this by the advisor. The advisor and the pharmacy professional must complete the relevant checklist on Quitmanager.

**Please note it is the pharmacy professional's responsibility to check the inclusion/exclusion criteria. The pharmacy professional carries the legal responsibility for the supply of bupropion under the PGD.**

<b>Bupropion voucher inclusion criteria (Answers must be YES to all)</b>
Age 18 years or above
Tobacco users sufficiently motivated to quit
Receiving support from a Yorkshire Smokefree service
Consent to share information with the client's GP
Individual agrees to having baseline blood pressure (BP) check followed by a further BP check at each supply. Also agrees to receive advice and treatment from the registered healthcare professional in line with this PGD.

## **Bupropion voucher exclusion criteria (answers must all be NO)**

### **Is bupropion contraindicated/not recommended for any of the following reasons:**

If the answer to any of the questions is **YES**, a voucher **CANNOT BE ISSUED**

- Client under 18 years
- Pregnant/ breastfeeding
- Hypersensitivity to bupropion or any excipients
- Epilepsy, or any history of fits or seizures
- Known CNS (brain) tumour
- Current or history of anorexia nervosa or bulimia
- Bipolar disorder
- Severe hepatic cirrhosis
- Unable to swallow/absorb oral tablets
- Withdrawing from alcohol, sedatives or benzodiazepines
- Previous experience of serious or worrying side effects from bupropion
- Receiving bupropion or any other stop smoking treatment from GP
- Client taking monoamine oxidase inhibitors (MAOIs)\*
- Client taking clozapine
- Blood pressure >140/90 (will be measured at pharmacy)

### **OTHER CLINICAL CONDITIONS which may increase the risk of seizures**

- Taking other drugs known to lower seizure threshold (e.g antipsychotics, antidepressants, anti-malarial, tramadol, theophylline, oral steroids, quinolones, sedating antihistamines)
- Alcohol abuse (heavy drinking)
- A history of head trauma
- Diabetes treated with hypoglycaemic tablets or insulin
- Use of stimulants or slimming products

### **OTHER CLINICAL CONDITIONS THAT ARE CAUTIONS**

- Age over 65 years
- Renal/hepatic (kidney/liver) impairment

**The pharmacy professional should ask the client about the OTHER clinical conditions above and decide whether bupropion may be supplied. If it is supplied, the dose should be ONE TABLET DAILY and labelled clearly.**

- Brugada syndrome (a rare inherited heart rhythm disorder)
- Serotonin syndrome – increased risk if taking SSRI or SNRI drugs e.g. citalopram

**The Pharmacy professional should make the clinical decision whether or not to supply.**

### **Medications that can be affected by stopping smoking:**

- Patient taking warfarin/theophylline /aminophylline      Yes/No
- Patient taking olanzapine/erlotinib/riociguat              Yes/No

**If YES to any of the medications affected by stopping smoking, the advisor must:**

- 1) securely email the prescriber of the medication informing them that their patient intends to quit, and the drug may require monitoring and a dose adjustment
- 2) Inform the client that they must also contact their GP and tell them that they are stopping smoking.

If the client agrees to contact this, the advisor may issue the voucher. If not, the voucher cannot be issued.

When the e-voucher is presented at the pharmacy,

**The pharmacist must:**

- 1) Check that the client understands that a medicine they are taking might be affected by stopping smoking and has contacted their GP to let them know and that they are willing to adjust their dose if necessary.
- 2) Make the clinical decision whether to supply bupropion
- 3) If a supply is made, ensure the client knows any symptoms that may indicate they need to contact their GP
- 4) If a supply is made, inform the GP within 48 hours

The patient information leaflet that will have been given to the client will give useful information on the above

**IF THE CLIENT HAS ONE OR MORE OF THE EXCLUSION CRITERIA ABOVE, INFORM THEM THAT YOU ARE UNABLE TO SUPPLY A VOUCHER FOR BUPROPION. EXPLAIN THEIR OTHER OPTIONS.**

**NOTE: Even if you give them a voucher, they may disclose something to the pharmacy professional they have not disclosed to you. The pharmacy professional may have access to more clinical information than you, so issuing a voucher does not guarantee they will receive bupropion.**

**The pharmacy professional will also measure the client's blood pressure before each supply to ensure they can safely take bupropion**

Some people need to take a lower dose as they may be more likely to get side effects (this includes people aged over 65, those who have liver or kidney disease or those at higher risk of having a fit for some other reason-see table below).

**ADVISERS ARE NOT COMPELLED TO ASK ABOUT THE 'OTHER CLINICAL CONDITIONS'. IT IS THE PHARMACIST'S RESPONSIBILITY TO ASK ABOUT OTHER CONDITIONS AND MEDICATIONS, AND MAKE THE DECISION WHETHER TO SUPPLY BUPROPION AND AT THE FULL RECOMMENDED DOSE (ONE DAILY FOR 6 DAYS THEN ONE TWICE DAILY THEREAFTER) OR AT THE REDUCED DOSE OF ONE TABLET DAILY FOR THE ENTIRE COURSE**  
The pharmacy professional will assess what dose should be taken if they decide to supply bupropion to clients where there is one or more cautions and put the dosage on the label.

## **7. Explain how to take bupropion**

Start taking bupropion while you are still smoking and set a target stop date ideally during the second week of taking it.

Days 1 to 6 -take one tablet once a day, on day 7 increase your dose to one tablet twice a day (unless advised to stay at one tablet daily), at least 8 hours apart, and not near to bedtime. If the client misses a dose, they should not take a double dose, just take their next dose at the usual time. If the client has not stopped smoking after 7 weeks treatment, the client should be advised to stop taking bupropion.

Bupropion can be taken with or without food. The tablets must be swallowed whole, not crushed, chewed or split.

## **8. Discuss possible side effects:**

The common side effects include difficulty sleeping, dry mouth, difficulty concentrating, headache, nausea, vomiting, feeling anxious or agitated, feeling shaky (tremor), stomach pain or other upsets (such as constipation), changes in the

taste of food, fever, dizziness, sweating, skin rash (sometimes due to an allergic reaction), itching.

Advise the client to read the product information leaflet prior to commencement of treatment.

The advisor generates a voucher code using the e-voucher on QM which can be sent directly to the client's phone via an SMS or given verbally to the client.

Inform the client of the participating pharmacies where the voucher can be redeemed **and that they must attend the same pharmacy for all supplies of bupropion. In exceptional circumstances e.g., where a pharmacy has a locum who is unable to supply under the PGD the client may access another pharmacy**

The client will need to speak to the pharmacist in person and arrange for the clinical assessment including blood pressure check.

Bupropion will be supplied to the client via the bupropion PGD. If the client is ineligible to be supplied bupropion via the PGD the pharmacist will advise them to contact their GP or their YSF stop smoking adviser.

## **9. Nominal treatment regime**

For clients who have been assessed by the pharmacy professional as suitable to take the full dose (one tablet daily for 6 days then one daily), a total of 2 vouchers (60 tablets per voucher) will be issued by the adviser approximately 4 weeks apart.

For clients assessed by the pharmacy professional as suitable to take a lower dose (one tablet daily for the whole course), only ONE voucher will be issued, and this will be a full course of treatment.

## **10. Side effects**

See SPC for full list of side effects with this medication. Clients experiencing severe side effects should contact their pharmacy professional/GP.

If the client has a fit or a severe allergic reaction, they should stop the tablets immediately and seek medical advice.

## **11. Adverse Reaction Procedure**

Compliance and adverse reactions will be monitored at the client follow-up appointments with the advisor and also by the pharmacy professional when the client returns for a further supply or consults them regarding a possible adverse reaction.

Mild adverse reactions may be alleviated by the client reducing the dose to one tablet daily. If this does not solve the issue the client can be advised to stop taking bupropion and consider Nicotine Replacement Therapy.

Severe adverse reactions should be recorded in the client record and reported to the Yorkshire Smokefree Service Manager (or deputy) immediately. The client should be

advised to stop taking bupropion immediately and to see their GP as soon as possible.

Adverse reactions will be reported by the advisor, pharmacy professional or the client in accordance with the UK Adverse Drug Reaction Reporting Guidelines (Yellow card system available at: <https://yellowcard.mhra.gov.uk/>)

## 12. Follow-up Advice

Clients will be contacted by the stop smoking advisor weekly for at least 4 weeks after the quit date and by the pharmacy professional at each supply of bupropion. Clients should be advised to call their local Yorkshire smokefree service if they need support or advice in addition to the weekly appointment.

Criteria for the stopping of bupropion treatment immediately:

- The client does not want to continue treatment.
- The stop smoking advisor or pharmacy professional believes that bupropion treatment is no longer appropriate.
- An absolute contra-indication is brought to light or develops.
- Side effect is so severe as to impair quit attempt

## 13. Definitions

Quit Manager (QM) is the Yorkshire Smokefree service dedicated electronic client record.

## Appendices



GP letter FINAL.docx



SC FINAL letter.docx