SOP 31

Dispensing of Buprenorphine/ Naloxone (Suboxone®) for Opioid Dependency

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Prepared by	Yvonne Griffin MPSI Cormac Loughnane MPSI, Superintendent Pharmacist
Approved by (Supervising Pharmacist)	
Pharmacy to which this SOP relates	
Date of Implementation in this Pharmacy	
Roles to which this SOP relates	Pharmacists Pharmacy Assistants Pharmacy Interns/APPEL Students Pharmacy Technicians and Trainee Pharmacy Technicians Dispensary Staff

Allcare Pharmacy

Contents

1. Introduction

1.1 Context

Buprenorphine/Naloxone is used to treat dependence on opioid (narcotic) drugs such as heroin or morphine in patients who have agreed to be treated for their addiction. Buprenorphine/ Naloxone is used in adults and adolescents over 15 years of age, who are also receiving medical, social and psychological support.

The combination of Buprenorphine/ Naloxone is available in Ireland as Suboxone® sublingual tablets, which are not orally active.

1.2 Objective

The objectives of this SOP are:

- To ensure patient safety
- To satisfy all legal requirements when dispensing Buprenorphine/Naloxone
- To ensure that patients are registered on the Central Treatment List prior to dispensing
- To ensure supervised and take-away Buprenorphine/Naloxone doses are dispensed correctly

1.3 Scope

This SOP covers:

- Sourcing, storage and dispensing of Buprenorphine/Naloxone
- Supervision of Buprenorphine/Naloxone doses
- Record-keeping in respect of Buprenorphine/Naloxone

This SOP must be used in conjunction with all relevant SOPs including:

- SOP 12 Prescription Reception, Transfer and Handout
- SOP 13 Managing Pharmacy Errors and Near Misses
- SOP 14 Prescription Processing
- SOP 15 Controlled Drugs
- SOP 19 Sourcing, Storage and Disposal of Medicinal Products
- SOP 49 Data Protection

1.4 Responsibility

This policy applies to all dispensary staff.
It is the ultimate responsibility of the supervising pharmacist to ensure that staff are appropriately trained, and the SOP is implemented.
It is also the responsibility of the Supervising Pharmacist to ensure this SOP reflects day-to-day practice in their pharmacy.

1.3 Code of Conduct

Pharmacists must comply with the principles of the Pharmaceutical Society of Ireland (PSI) Code of Conduct and apply the principles to their everyday practice. Pharmacists must use their professional judgement and clinical expertise in order to make ethical decisions, while observing relevant legislation, practice standards and guidance.

2 Process

2.1 Pharmacology

- Buprenorphine is an opioid partial agonist which binds to the μ (mu) and κ (kappa) opioid receptors of the brain. It binds μ receptors with high affinity and will displace other opioids from the receptors, thereby precipitating withdrawal. As a partial agonist, the patient will experience reduced 'opioid' effect and feel more clear- headed than with methadone or morphine.
- Buprenorphine, when taken orally, undergoes first-pass metabolism in the small intestine and the liver. The use of this medicinal product by the oral route is therefore inappropriate. Peak plasma concentrations are achieved 90-150 minutes after sublingual administration
- Naloxone is an antagonist at μ-opioid receptors. When administered orally or sublingually in usual doses to patients experiencing opioid withdrawal, naloxone exhibits little or no pharmacological effect because of its almost complete first pass metabolism. However, when administered intravenously to opioid-dependent persons, the presence of naloxone in Suboxone produces marked opioid antagonist effects and opioid withdrawal, thereby deterring intravenous abuse.

2.2 Central Treatment List

• The Central Treatment List contains information on all persons for whom **Opioid Substitution Treatment (OST)** has been prescribed. The information contained in this list is based on information supplied by Doctors under Regulation 3 of the 2017 Misuse of Drugs Regulations. Information contained in the Central Treatment List is confidential.

- Pharmacists can check relevant information via the Central Treatment List (9am to 5pm, Monday to Friday, Phone: 01 6488640).
- Every OST patient must be registered on the Central Treatment List, prior to commencing treatment. Each patient is registered with one specific, appropriately trained GP and one specific pharmacy.

• An **Opioid Substitution Treatment Card** is issued in respect of all patients notified to the Central Treatment List. The card contains the name, photograph and treatment number of the patient, the name of their doctor and pharmacy. The card is sent directly to the pharmacy where it is held on behalf of the patient. Note that the card is specific to the treatment the patient is receiving – Methadone Treatment cards are white in colour while Buprenorphine Treatment cards are cream in colour.

• Prescriptions for OST may only be dispensed for patients for whom an Opioid Substitution Treatment card has been issued and remains valid.

• GPs must undergo specific training in order to provide Suboxone services to patients. There are two levels of training; level one GPs may only treat stabilised patients, whereas level two GPs may initiate treatment and can provide services to a greater number of opioid dependant patients. The level of training of the GP may be checked via the Central Treatment List.

2.3 Dispensing Buprenorphine/Naloxone (Suboxone®)

2.3.1 Sourcing and Storage of Buprenorphine/Naloxone

- Suboxone® (Buprenophine/Naloxone) is available as:
    - Buprenorphine 2mg / Naloxone 0.5mg (pack of 28)

    - Buprenorphine 8mg / Naloxone 2mg (pack of 28)
- They can be ordered from United Drug free of charge by pharmacies who have been approved to dispense for a named patient by the HSE and where United Drug have received permission to supply to the pharmacy from the HSE.
- Subutex® contains only Buprenorphine and comes in strengths 0.4mg, 2mg and 8mg.
- All products containing buprenorphine are Schedule 2 controlled drugs and should be stored in the pharmacy CD safe.

2.3.2 Initiation of therapy

- The recommended starting dose in adults and adolescents over 15 years of age is one to two Suboxone® 2 mg/0.5 mg tablets. An additional one to two Suboxone® 2 mg/0.5 mg may be administered on day one depending on the individual patient's requirement.
- During the initiation of treatment, daily supervision of dosing is recommended to ensure proper sublingual placement of the dose and to observe patient response to treatment as a guide to effective dose titration according to clinical effect.
- Following treatment induction on day one, the patient should be stabilised to a maintenance dose during the next few days by progressively adjusting the dose according to the clinical effect of the individual patient.
- Dose titration in steps of 2-8 mg is guided by reassessment of the clinical and psychological status of the patient, and should not exceed a maximum single daily dose of 24 mg.
- It is envisaged that the GP treating the patient may requisition Suboxone® from the pharmacy named as dispensing for that patient and will supervise the first dose/doses in their surgery.
- Prior to commencing supply to an OST patient, the pharmacist should discuss with the patient any issue that either deems significant, including:
    - The patient's privacy
    - The patient's and pharmacist's expectations from the service
    - Risks associate with giving OST or other medicines to another person
    - Risks to children ingesting prescribed medication
    - Risks associated with storing medicines incorrectly
    - General information about their OST therapy: directions for use, common side-effects, action to be taken if a dose is missed, interactions with alcohol and other drugs (e.g. benzodiazepines), cautions about driving or operating machinery and methods of safe disposal
    - The patient's wider medical and healthcare needs
    - The availability of the pharmacist to discuss relevant issues at each dispensing.
- In unusual situations, such as carrying OST abroad or patients transitioning between environments (e.g. hospital/addiction facilities/prison/home), the local HSE OST Liaison Pharmacist should be contacted for advice.
- It is important to communicate with the prescriber where any issues arise to ensure optimum care for the patient.

2.3.2 Maintenance therapy

- After a satisfactory stabilisation has been achieved the frequency of dosing may be decreased to dosing every other day at twice the individually titrated daily dose.
- For example, a patient stabilised to receive a daily dose of 8 mg may be given 16 mg on alternate days, with no dose on the intervening days.

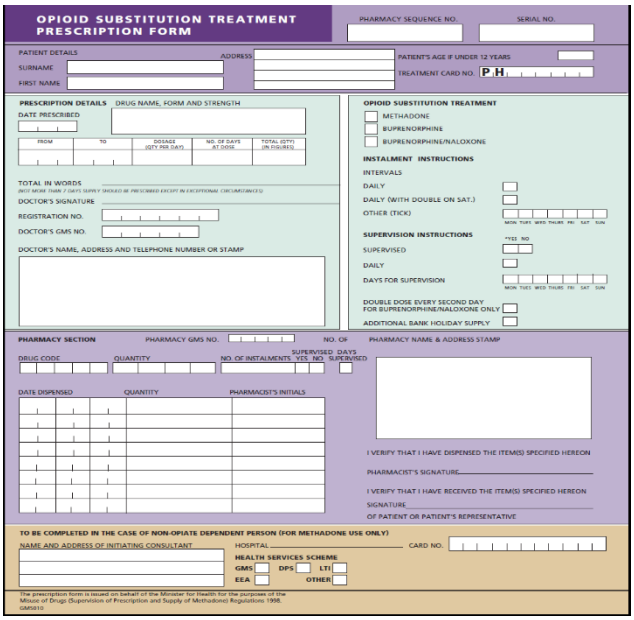
- In some patients, after a satisfactory stabilisation has been achieved, the frequency of dosing may be decreased to 3 times a week (for example on Monday, Wednesday and Friday). The dose on Monday and Wednesday should be twice the individually titrated daily dose, and the dose on Friday should be three times the individually titrated daily dose, with no dose on the intervening days.
- However, the dose given on any one day should not exceed 24 mg. Patients requiring a titrated daily dose> 8 mg/day may not find this regimen adequate.

2.3.3 Medical withdrawal

- After a satisfactory stabilisation has been achieved, if the patient agrees, the dosage may be reduced gradually to a lower maintenance dose; in some favourable cases, treatment may be discontinued. The availability of doses of 2 mg/0.5 mg and 8 mg/2 mg allows for a downward titration of dosage.
- For patients who may require a lower buprenorphine dose, buprenorphine 0.4mg (Subutex™) may be used.
- Patients should be monitored following medical withdrawal because of the potential for relapse.

2.3.4 Supervision of Suboxone doses

- The pharmacist should check that the patient does not have chewing gum or another similar product in his/her mouth to which the tablets might adhere. Ask them to remove.
- Ensure that the patient takes a glass of water
- Place complete dose on a plastic spoon or measure.
- Give the dose to the patient with the instruction to place it under the tongue and allow it to dissolve.
- Dissolution and absorption is variable and may take from 5- 10 minutes. During this period the pharmacist or an experienced technician must watch to ensure that the tablets are not removed from the mouth. The usual time required is 2-5 minutes
- Discard the plastic spoon or measure.
- The prescriber may request that the pharmacist look in the patient's mouth to ensure that the tablets have dissolved. (This may not be required.)
- The pharmacist should be discreet, friendly and chat to the patient.
- If the patient misses consecutive doses, the prescriber should be informed.
- If the patient misses consecutive 3 days dosing, it is necessary that they be reassessed by prescriber.


OPIOID SUBSTITUTION TREATMENT PRESCRIPTION FORM

PHARMACY SEQUENCE NO. SERIAL NO.

PATIENT DETAILS
SURNAME
FIRST NAME
ADDRESS
PATIENT'S AGE IF UNDER 12 YEARS
TREATMENT CARD NO. P H

PRESCRIPTION DETAILS DRUG NAME, FORM AND STRENGTH
DATE PRESCRIBED
FROM | TO | DOSAGE (QTY PER DAY) | NO. OF DAYS AT DOSE | TOTAL (QTY) (IN FIGURES)
TOTAL IN WORDS
DOCTOR'S SIGNATURE
REGISTRATION NO.
DOCTOR'S GMS NO.
DOCTOR'S NAME, ADDRESS AND TELEPHONE NUMBER OR STAMP

OPIOID SUBSTITUTION TREATMENT
METHADONE
BUPRENORPHINE
BUPRENORPHINE/NALOXONE

INSTALMENT INSTRUCTIONS
INTERVALS
DAILY
DAILY (WITH DOUBLE ON SAT.)
OTHER (TICK)
MON TUES WED THURS FRI SAT SUN

SUPERVISION INSTRUCTIONS
*YES NO
SUPERVISED
DAILY
DAYS FOR SUPERVISION
MON TUES WED THURS FRI SAT SUN
DOUBLE DOSE EVERY SECOND DAY FOR BUPRENORPHINE/NALOXONE ONLY
ADDITIONAL BANK HOLIDAY SUPPLY

PHARMACY SECTION
PHARMACY GMS NO.
NO. OF
PHARMACY NAME & ADDRESS STAMP
DRUG CODE
QUANTITY
NO. OF INSTALMENTS
SUPERVISED YES NO
DAYS SUPERVISED
DATE DISPENSED
QUANTITY
PHARMACIST'S INITIALS
I VERIFY THAT I HAVE DISPENSED THE ITEM(S) SPECIFIED HEREON
PHARMACIST'S SIGNATURE
I VERIFY THAT I HAVE RECEIVED THE ITEM(S) SPECIFIED HEREON
SIGNATURE
OF PATIENT OR PATIENT'S REPRESENTATIVE

TO BE COMPLETED IN THE CASE OF NON-OPIATE DEPENDENT PERSON (FOR METHADONE USE ONLY)
NAME AND ADDRESS OF INITIATING CONSULTANT
HOSPITAL
CARD NO.
HEALTH SERVICES SCHEME
GMS DPS LTI
EEA OTHER

The prescription form is issued on behalf of the Minister for Health for the purposes of the Misuse of Drugs (Supervision of Prescription and Supply of Methadone) Regulations 1998.
GMS010

2.3.5 OST Prescription Writing Requirements

- Prescriptions for OST must be written on an Opioid Substitution Treatment Form for all patients.
- As Buprenorphine is classed as a Schedule 2 Controlled Drug, prescriptions must comply with the following requirements.
- **The prescription must:**

- ✓ Be in ink or otherwise indelible and be signed by the practitioner with their usual signature and dated by them,
- ✓ Contain the full name and address of the patient being treated,
- ✓ The patient's Opioid Substitution treatment card number should be entered in the space provided on the OST prescription form;
- ✓ Clearly indicate the name of the practitioner issuing and specify their name and address.
- ✓ State that the person issuing it, is a registered medical practitioner, and the prescription details have been completed in full by the prescriber prior to dispensing.
- ✓ The pharmacy section of the form must also be completed in full and the form signed and stamped by the pharmacist.
- ✓ The patient must sign the form to verify receipt of their medication.
- ✓ Where a patient is prescribed both strengths of Suboxone®, a separate prescription form must be issued for each.
- ✓ Prescriptions are for a supply period of up to seven days (or eight where 'Additional Bank Holiday Supply' is indicated on the form).

2.3.6 Dispensing Buprenorphine/Naloxone

Prior to dispensing, the pharmacist must check the following:

- The prescription meets the legal requirements for a Controlled Drug Schedule 2;
- The pharmacy holds a valid treatment card for buprenorphine;
- The **dose** of Suboxone to be dispensed and the **frequency** of dispensing;
- Whether this supply must be supervised;
- The pharmacist must give a **Patient Information Leaflet** and **Warning Card** to each patient on the first occasion on which they dispense buprenorphine. They should be told to carry the warning card with them at all times. In the event the patient is admitted to hospital, it is essential that the treating staff are aware that the patient is using buprenorphine.
- As a Schedule 2 Controlled Drug, entries must be maintained in the pharmacy Controlled Drug Register (see SOP 15 Controlled Drugs).

2.4 Claims for OST services

- Prescriptions for OST must be written on the HSE OST Prescription Form shown above.
- The pharmacist should ensure all sections of this form are filled out before submitting the claims for payment.
- The following administrative codes should be used for Suboxone®claims:
  - 46102 Suboxone®2mg/0.5mg tablets (28)
  - 46117 Suboxone® 8mg/2mg tablets (28)
- All details of supervision and instalments must be clearly listed on the prescription.
- The top copy of this must be sent to the PCRS no later than 14 days after the last day of the calendar month in which the supply was completed.
- Claims should be forwarded by registered post to:

  HSE PCERS,
  P.O. Box 6422
  Finglas, Dublin 11

3. SOP Amendments

Version 3, May 2020, required review. Updated format, included new claiming arrangements.

4. References

- Clinical Guidelines for Opioid Substitution Treatment, HSE (accessed on hse.ie, 05/05/20)
- HSE PCERS Information and Administrative Arrangements for Pharmacists, 2020.
- HSE Circular Administrative Arrangements for Suboxone® (effective 1st May 2018)
- Misuse of Drugs Regulations 2017 (S.I. No. 173 of 2017)