

APPENDIX 1

PROCEDURE NAME & NUMBER	Supply and Administration of Intranasal Fentanyl Spray
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Introduction

Morphine is the first line opioid of choice for patients in Wales. However, there is a small group of patients for whom morphine is not suitable. For such patients, alternatives including intranasal (IN) fentanyl may be considered.

The aim of the protocol is to facilitate the self administration of IN fentanyl preparations for such patients who are admitted to non specialist palliative inpatient settings within Aneurin Bevan Health Board. The protocol provides for the safe and legal storage, administration and monitoring of these products, improving patient access to prompt analgesia.

Purpose

To facilitate the safe use of IN fentanyl spray for inpatients, enabling patients with chronic cancer pain who are already maintained on opioid therapy (the equivalent of ≥ 60 mg of oral morphine per day) to receive breakthrough pain relief in a timely fashion, whilst maintaining a safe and legal system of practice.

Scope

This procedure applies to all medical, pharmacy and nursing staff involved in the supply, administration and monitoring of patients assessed as suitable for self administration of IN fentanyl spray in the inpatient setting.

Section One

Clinicians are reminded that, in line with national guidance, instant release nasal fentanyls are not the first line opiate of choice for breakthrough pain. See:

<http://www.wales.nhs.uk/sites3/Documents/814/ABHB%20PrescribingGuidanceFENTANYL%26BreakthroughPain%5BDec11%5D.pdf>

<http://www.medicinescomplete.com/mc/bnf/current/PHP18865-pain-management-with-opioids.htm>

<http://www.nice.org.uk/nicemedia/live/13745/59285/59285.pdf>

Prescribing / Initiation of Supply

Ideally the patient should be in a side ward or cubicle. A separate small metal safe with a digital lock will be attached to the frame of the bed for storage of the IN fentanyl only.

1. The patient must be assessed by a palliative care consultant as requiring IN fentanyl spray using the consultant checklist (Appendix 2) and as suitable for self medication using the self administration assessment form (Appendix 3).

2. The medication should be prescribed on the self administration chart (Appendix 4) and a note made on the front of the All Wales inpatient medication chart that a supplementary chart is in use. The medication must also be prescribed on the inpatient chart under 'PRN' medication with a note for assessment of patient competence every 24 hrs. This will be recorded by a registered nurse on the back of the self administration chart.

3. To obtain a supply, an individual prescription must be written for the patient on an outpatient form. Ward and pharmacy staff must be contacted when the form is completed to arrange supply of the labelled product. The prescription must fulfil the legal requirements for an outpatient controlled drug prescription, be handwritten and contain the following details:

- name and home address of the patient
- ward
- name and form of the product
- strength of preparation to be supplied
- number of sprays to be administered in each breakthrough pain episode
- minimum time period between use for separate pain episodes
- maximum dose permitted in 24 hours
- total quantity of spray to be dispensed in words and figures (e.g. 3 x 8 (eight) dose pack)

The prescription must be signed, not initialled, by the prescriber. Currently, only palliative care consultants can prescribe these products.

4. Ward staff must obtain a bedside safe from the equipment library.

5. The medication will be delivered to the ward and delivery is to be accepted by a registered nurse, as for all controlled drugs.

6. The registered nurse will take the medication to the patient's bedside and together with the patient will sign for receipt and for storage in the bedside safe on the reverse of the self administration chart.

7. The registered nurse must record the supply in the ward controlled drug register under 'Patient's Own' supply and annotate using/monitoring at bedside.

8. The palliative care consultant will be informed of arrival of medication on the ward and educate the patient, prior to administration. Detailed information leaflets are available from the manufacturers:

- PecFent® fentanyl pectin nasal spray (Archimedes Pharma UK)
http://www.pecfent.com/uk/pdfs/PecFent_UK_Patient_HowToUse.pdf
- Instanyl® (Takeda UK Ltd) information is available from the pharmacy or the palliative care team.

Section Two

Administration

NB. The patient may only self administer after successful completion of assessment and education by the palliative care consultant.

1. When a dose is required, the patient will call for the registered nurse, and will proceed to administer a dose. They do not need to wait for the nurse to arrive.
2. The patient will retrieve the IN fentanyl from the individual locker and self administer.
3. The patient will record administration on the self administration chart, recording the number showing on the counter (PecFent®) or the number of individual doses left (Instanyl®).
4. The registered nurse will countersign the self administration chart confirming either the number showing on the counter or the number of individual doses left.
5. The patient's ability to self medicate must be assessed daily by nursing staff and signed by the registered nurse on the reverse of the self administration chart.
6. The palliative care consultant or their nominated deputy will review the patient regularly, according to clinical need, to assess the effectiveness of the current dose and to titrate the dose accordingly. When a dose change is made, the new dose should be prescribed on the 'PRN' section of the patient's medication chart and on the self administration chart. A new outpatient prescription may also be needed and the doctor should liaise with the pharmacist to ensure that the correct supply is available for the new dose.

Section Three

Reconciliation / Audit

1. The supply from pharmacy is entered in the ward controlled drug book, under the patient's own section.
2. The registered nurse will verify the quantity left in the container after each administration on the self administration chart.
3. On discharge/discontinuation, an entry will be made in the ward controlled drugs register and any remaining medicine will be returned to the pharmacy by pharmacy staff.
4. The assessment form and the self administration chart will be filed in the patient's notes.
5. Any discrepancies should be investigated as per Aneurin Bevan Health Board Management of Controlled Drugs Policy.

Process Chart

Action	Person Responsible
Patient requiring IN fentanyl and assessed as competent to self administer	Palliative care consultant
Prescribed on inpatient medication chart, self administration chart, outpatient prescription	Palliative care consultant
Supply of medication	Pharmacy/registered nurse
Safe available	Registered nurse
Acceptance of delivery/supply	Registered nurse and patient
Ward Controlled Drug Register completed	Registered nurse
Education of patient	Palliative care consultant
Record of administration	Patient and registered nurse
24 hourly assessment of competence	Registered nurse
Dose titration	Palliative care consultant
Discharge	Palliative care consultant, registered nurse and patient
Discontinuation of treatment: completion of form, removal of medication to controlled drugs cupboard	Registered nurse
Removal of medication from ward	Pharmacy

Section Four

Discontinuation / Discharge

1. Self medication must cease immediately if at any time the registered nurse, consultant or patient assess the patient to be unable to self medicate.
2. The medication should be removed from the bedside safe, stored in the ward controlled drugs cupboard and an entry annotated in the ward controlled drugs register. The patient must complete the disclaimer section of the self administration chart.
3. The bedside safe should be returned to the equipment store.
4. On discharge the medication will be dispensed by the pharmacy in the usual way, ensuring the self administration chart is updated, along with the ward controlled drug register.

Appendix 2

CONSULTANT CHECKLIST

Please tick box to confirm:-

1. Pt on oral morphine 60 mg/24 hrs or equivalent. ☐
2. Pt has capacity. ☐
3. Pt physically able to operate device and digital safe. ☐
4. Pt education completed: ☐
5. What drug is. ☐
6. When to use it. ☐
7. How to prime the device. ☐
8. How to administer. ☐
9. Side effects. ☐
10. Storage and safety. ☐
11. Recording. ☐
12. Pt leaflets given to pts. ☐

Notes:

Signature: -----

Date: -----



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University Health Board

Patient
Addressograph

Appendix 3 (1 of 2)

IN fentanyl spray self administration patient assessment / consent form

Ward:

Consultant:

Safe number:

On completion this form should be attached to the IN fentanyl administration sheet and filed in the patient's medical notes when the patient has been discharged.

		Yes	No
1.	Does the patient administer his own medicines at home? (If "No" – Self administer is inappropriate)		
2.	Is the patient confused? <i>These patients should never be given custody of their medicines.</i>		
3.	Has the patient, to your knowledge, any other reason for caution? (Very careful consideration must be given to the benefits vs. risks for such individuals. If the decision is to include such patient, the reason for the decision must be documented in the patient's records and nursing care plan).		
4.	Are there any other patients in the bay likely to cause problems with drug/key custody? <i>Ideally patient should be in side room/cubicle</i>		
5.	Can the patient open the pack and operate the device?		
6.	Can the patient read/understand the label?		
7.	Can patient understand/complete the self administration record chart?		
8.	Can the patient access the cabinet?		
9.	Does the patient understand the - purpose of the treatment? - dose to take and when? - possible side effects? - special instructions?		
10.	Has the patient read and understood the card explaining "self administration – information for patients"? (Appendix 5)		
In my opinion this patient			
1) Should not be included in the self administration scheme.			
2) Should be included and will need minimal supervision.			
Palliative Care Consultant Assessment for Self Administration			
Date Assessed			
Signed			
Print name			

Appendix 3 (2 of 2)

Patient Consent on Admission

On this ward, appropriate patients can administer IN fentanyl.
For safety reasons this medicine must be locked in a separate safe during your stay. If your medication is changed, we may need to dispose of your old pack.
If you are willing for us to use your medication in this way and destroy any not suitable, please sign below.

Patient Consent for Self Administration

I have read and understood the information on "Self Administration of Medicines" and I am willing to take part in the scheme. I understand that I may withdraw consent at any time by informing my registered nurse or consultant.

Signed:

Print:



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Patient
Addressograph

Appendix 4 (1 of 2)

IN fentanyl spray self administration chart

Date:				
Medication:				
Dose:				
Frequency:				
Doctor's Signature:				

Self Administration form completed by: Date:

Date	Time	Number of sprays administered	Number of sprays left	Patient signature	Device reconciliation nurse signature

NB: Any wasted or partial dose must also be recorded on this chart.

Appendix 4 (2 of 2)

IN fentanyl spray self administration chart

Delivery

..... Packs accepted by (Patient Signature)

Storage witnessed by (Registered Nurses)

DAILY SELF MEDICATION ASSESSMENT

	Date	Date	Date	Date	Date
1. Significant change in condition?					
2. Mental capacity: a) can communicate b) takes in, retains and repeats correctly information about IN fentanyl use					
3. Able to operate digital safe and medication device?					
4. Medication stored in safe and code secure?					
5. Able to record use on chart?					
6. Side effects of medication?					
7. Signature/time/date on prescription chart?					
8. Signature/time/date					

Discontinuation

I agree to the removal of packs of IN fentanyl from my bedside safe for storage in the ward controlled drug cupboard and/or destruction by pharmacy.

..... (Patient Signature)

Removed by (Registered Nurse Signature)

Appendix 5

Patient information leaflet for self administration of IN fentanyl spray

You have been assessed by your medical nursing and pharmacy team to be offered the opportunity to be responsible for taking your own break-through pain medication, in the form of a nasal spray, while in hospital.

The reasons that you have been advised to use this method are:

1. You are taking a good dose of strong pain killer regularly, but still have episodes of pain.
2. You have episodes of pain which come on quickly, but may not last for a long time.
3. You are able to understand how to use, store and record your use of this type of pain relief.

What is this medication?

The medication is a strong pain killer called fentanyl. It is in the form of a nasal spray. This allows the pain killer to get into your system quickly and start relieving your pain. If this method suits you, you will be able to give yourself strong pain relief quickly and safely in hospital and continue when not in hospital.

Important things you need to know:

1. It is a strong pain killer. It must be stored safely as instructed at all times.
2. Never share your medicine with anyone else.
3. Always keep it out of the reach of children. Inform a member of staff immediately if anyone else uses or asks to use your medication.
4. Never use it for any other type of pain than the one it has been prescribed for.
5. Never use more than you have been instructed to use.
6. It is your responsibility to keep it stored securely in the safe attached to your bed.
7. It is your responsibility to fill in your self administration chart every time you use the spray.
8. You should tell a nurse immediately if you have any side effects after using the spray, you are worried or think you may have made a mistake, or if you do not understand anything about this medicine or process.
9. A nurse will check the spray and self administration chart with you regularly.
10. A pharmacist will also check that everything is working as it should for this medication.
11. You can choose to stop using the IN fentanyl spray at any time, for any reason. If you decide that you do not want to use this medication method any longer, please tell a nurse and the medicine, safe and self administration chart will be removed and an alternative method of pain relief prescribed by your doctor.

How to use your IN fentanyl spray

The doctor, nurse or pharmacist will show you how to use your spray. You will also be given an instruction leaflet to keep.