Group arrangements:
Salford Royal NHS Foundation Trust (SRFT)
Pennine Acute Hospitals NHS Trust (PAT)

Northern Care Alliance NHS Group

Fentanyl Lozenge (Actiq) or Fentanyl Sublingual (Abstral) for procedural pain in an Acute Pain Setting

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Division/ Department::	Neurosciences
Applies to:	Salford Royal Care Organisation
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Contents

1. What is this policy about?

1.1 This policy has been developed for the effective management of procedural pain associated with acute pain management.

For the purpose of this document 'procedural pain' is pain associated with painful procedures of short duration. This may include dressing changes, drain removal & patient transfer.
This is an **off license** application of immediate release fentanyl products licensed for the management of breakthrough cancer pain.

The use of Abstral/Actiq in this context should only be considered when pain is severe and cannot be controlled using conventional opioids or Entonox

Sublingual Fentanyl (Abstral) and Fentanyl lozenges (Actiq) are only licensed for the management of breakthrough pain in patients already receiving maintenance opioid therapy for chronic cancer pain. (Minimum equivalent doses- Morphine Sulphate 60mg/ day; Oxycodone 30mg/day; Fentanyl Patches 25mcg/hour).

Sublingual Fentanyl (Abstral) has been added to the **Trust Medicines Formulary** for the second-line management of procedural pain such as dressing changes, drain removal, wound packing, Ilizarov procedures if Entonox or conventional opioids are ineffective or contraindicated. This is an off license indication.

Actiq is currently a **non- formulary** preparation. Abstral is currently the Trust preferred formulation and should be the first line of management.

If you have any concerns about the content of this document please contact the author or advise the Document Control Administrator.

2. Where will this document be used?

2.1

- All Medical and Nursing staff who manage patients undergoing painful procedures or transfers and whose pain is not well managed using conventional analgesia.
- All clinical staff who intend to use sublingual Fentanyl (Abstral) or Oral Trans mucosal Fentanyl Citrate (OTFC Actiq) for the management of procedural pain.
- Staff working in In-Patient settings.

2.2

- Applies to adult patients only
- This policy **does not** apply to the usage of immediate release Fentanyl products in the management of breakthrough cancer pain.
- Abstral or Actiq should only be prescribed in consultation with the Pain Team.

3. Why is this document important?

3.1 This is an **off license** application of immediate release fentanyl products licensed for the management of breakthrough cancer pain.
Serious risk to life can occur from the use of these products including sedation, respiratory depression and death.

This policy provides guidance for the safe prescribing, administration and monitoring of these Fentanyl products within the context of acute procedural pain not managed by conventional therapies.

4. What is new in this version?

4.1 This is an update of issue number 8 and there are no important changes to the content.

5. Policy

Pharmacokinetic Issues
Studies have compared the absolute and relative bioavailability of Sublingual Fentanyl (Abstral) and Oral Transmucosal Fentanyl citrate (Actiq). They demonstrated a 30-50% greater Fentanyl absorption in Sublingual Fentanyl (Abstral) compared with OTFC (Actiq).
The implications of this are that bioavailability between these products differs significantly.

Sublingual Fentanyl (Abstral) and Actiq doses should not be interchanged for an individual patient. If a patient requires rotation from one form to another, the process of titration must recommence starting at the lowest level as demonstrated on the flow chart

Patients already on Opioids

If patient on established opioid analgesia then contact Pain Team for advice re titration regime.

5.1 Sublingual Fentanyl (Abstral)

5.1.1 Method of administration

Sublingual tablets of Fentanyl (Abstral) are available in 100 mcg, 200mcg, 300mcg, 400mcg, 600mcg & 800mcg

Abstral should be administered directly under the tongue at the deepest part. Sublingual tablets should not be swallowed, but allowed to completely dissolve in the sublingual cavity without chewing or sucking.

Patients should be advised not to eat or drink anything until the sublingual tablet is completely dissolved.
In patients who have a dry mouth, water may be used to moisten the sublingual mucosa before administration. Rapid absorption of Fentanyl occurs over about 30 minutes following administration.

5.1.2 Dose titration

The optimal dose of sublingual Fentanyl (Abstral) will be determined by upward titration on an individual patient basis. Several doses are available for use during the dose titration phase. The initial dose of sublingual fentanyl (Abstral) used should be 100 micrograms, titrating upwards as necessary through the range of available dosage strengths (see algorithm section 5.2).
Patients should be carefully monitored until an appropriate dose is reached; i.e. that provides adequate analgesia for the procedure with no adverse reactions.

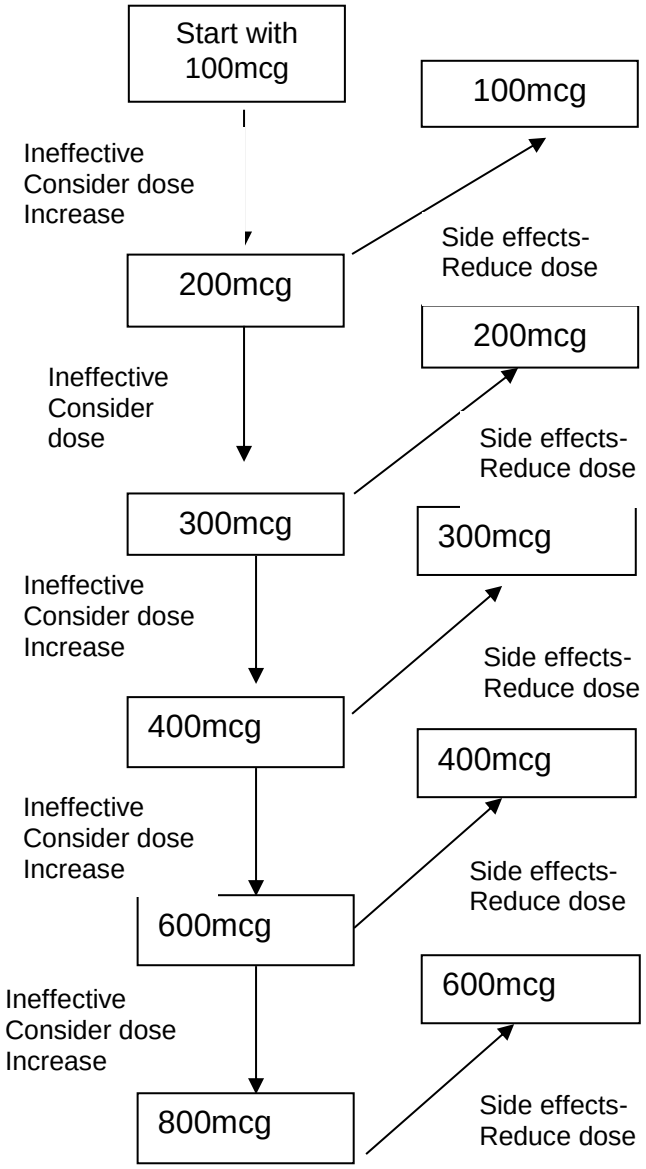
A second Sublingual tablet may be administered after 15 minutes if analgesia remains suboptimal **during** the procedure. This will normally be 100mcg in strength.
If effective, then for subsequent procedures, sublingual Fentanyl doses can be titrated based on the last effective dose (see algorithm section 5.2).

Doses of sublingual Fentanyl **should not** be offered at any other time than for the planned procedure.

If pain remains uncontrolled at a dose of 400mcg, contact the pain team for advice re further titration.

5.2 Sublingual Fentanyl (Abstral) for Opioid Naive Patients Algorithm

NOTE: SUBLINGUAL FENTANYL TABLETS HAVE GREATER BIOAVAILIBILITY THAN LOZENGES. THEY ARE NOT DOSE EQUIVALENT.



NB If intolerable side effects are experienced by the patient (e.g. sedation, nausea) without any reported benefit, then this is an indication to discontinue treatment

5.3 Fentanyl Lozenge (Actiq)

5.3.1 Method of administration

Fentanyl Lozenge (Oral Transmucosal Fentanyl Citrate- OTFC) (Actiq) is a solid formulation of Fentanyl citrate intended for oral Transmucosal administration. As the patient consumes the Fentanyl lozenge, the Fentanyl dissolves in the saliva and a proportion rapidly diffuses across the oral mucosa. The rest of the dissolved drug is swallowed and partly absorbed in the stomach and intestine. The Fentanyl that diffuses across the mucosa is rapidly absorbed, enabling a more rapid onset of action than oral opiates (from 4.2 minutes).

Fentanyl lozenge (Actiq) is available in 200mcg, 400mcg, 600mcg, 800mcg, 1200mcg, and 1600mcg doses

Actiq is intended for oral mucosal administration. Water may be used to moisten the oral mucosa in patients with a dry mouth. The lozenge should be placed in the mouth next to the cheek and the applicator used to move the lozenge around the mouth. This maximises the amount of mucosa exposed to the Fentanyl. The Actiq should **NOT** be chewed, but should be sucked to facilitate rapid absorption across the mucosa. The lozenge should be consumed over a 15 minute period or less if the painful procedure is complete and pain is subsiding.

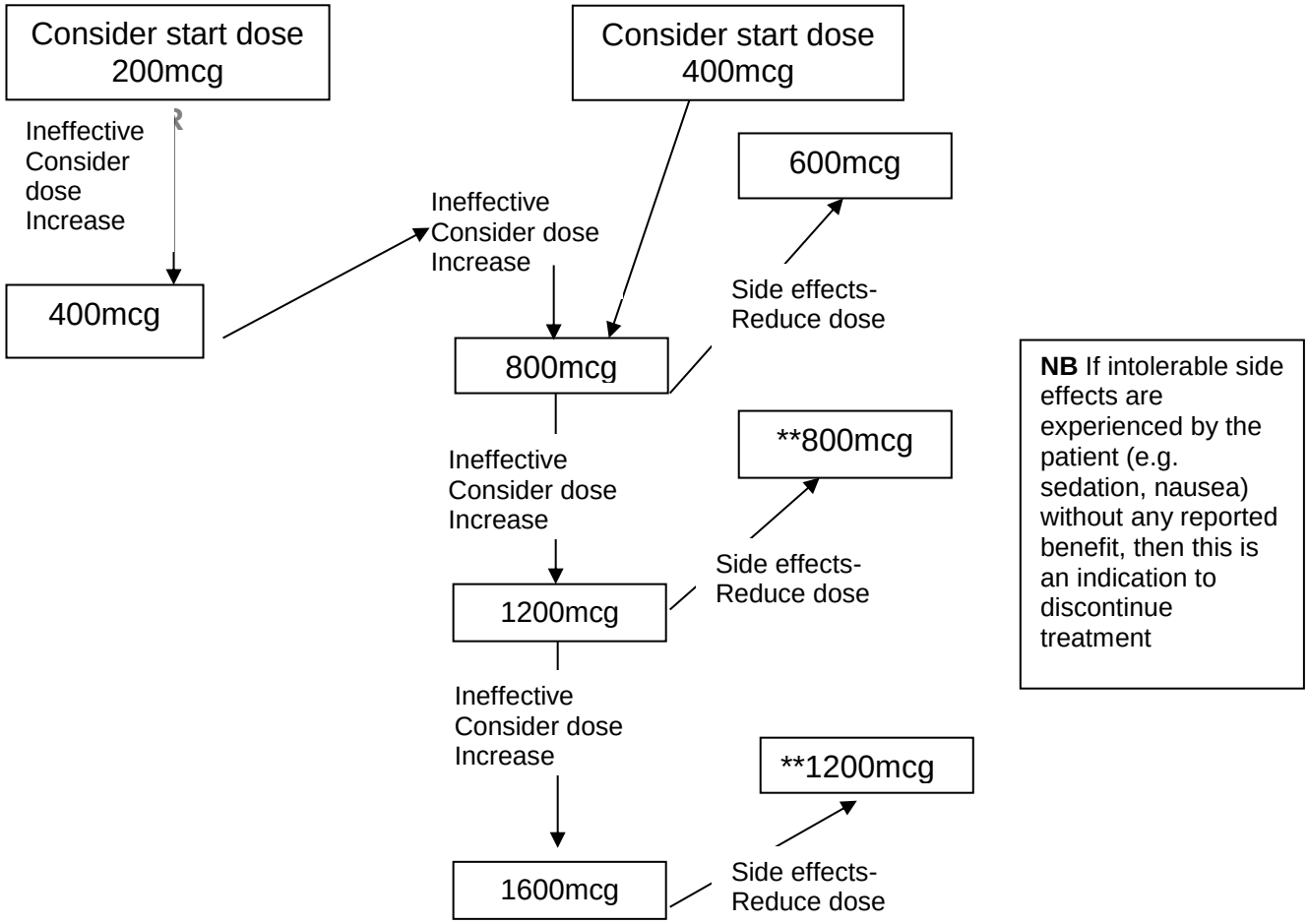
5.3.2 Dose titration

A second lozenge can be given after 15minutes if necessary during the procedure.
For subsequent procedures, continue to increase the dose by 400mcg each time if there is ineffective analgesia without side effects until a maximum 1600mcg. If still ineffective, contact Pain Team for advice.

If the patient becomes sedated during the use of Actiq, the remaining lozenge should be removed immediately, and a dose reduction considered with support from the pain team.

Measures should be employed to ensure that the patient is safe and monitoring should be increased until the effects have worn off.

5.4 Fentanyl lozenge (Actiq) For Opioid Naive Patients Algorithm



* No 1000mcg/1400mcg lozenge available,

If the Fentanyl lozenge (Actiq) is ineffective then increase dose by 400mcg as outlined above.

5.5 Monitoring and Management of Problems

Monitoring
Side effects of Opioid Analgesia

Sedation and respiratory depression are recognised side effects of opioid analgesia.

Respiratory rate and sedation scores should be recorded prior to administration of Abstral or Actiq and observed throughout administration. Record sedation and respiratory scores again following administration.

If the patient becomes sedated any remaining Fentanyl lozenge should be removed immediately and the dose reviewed prior to future administration.

Steps to ensure that the patient is safe should be employed and monitoring should be increased until resolved.

Opioid Toxicity- caused by the central effects of opioid analgesia

- Reduced respiratory rate < 8 breaths per minute.
- Sedation (A.V.P.U.) = V,P,U can be reversed by the administration of naloxone.
- (see naloxone policy).
- Naloxone is the reversal agent for opioid induced sedation and respiratory depression.
- Naloxone should be titrated as per APS guidelines.

Intravenous Titration of Naloxone:

1. Draw up 0.4mg (1ml) ampoule of Naloxone into a 5ml syringe
2. Make up to 4mls total volume with 0.9% Sodium Chloride
3. OR use minijets available in crash trolley on ward
4. Administer 1ml increments of the diluted Naloxone solution (0.1mg) at
5. 2 minute intervals until respiratory rate >12 and sedation score =A (AVPU)
6. Continue observations and prepare a solution of Naloxone for infusion if required.

Discharge from Hospital
If a patient is discharged into the community on Fentanyl lozenge or Sublingual Fentanyl the indication for use should be clearly stated on the discharge summary. This should also include advice on reducing the dose as the patient's condition improves, i.e. dressing change becomes less invasive and better tolerated i.e. reducing the dose by 30 to 50% and reassessing effectiveness.

6. Roles and responsibilities

6.1 Nursing Staff

Patients should be closely supervised during administration of Sublingual Fentanyl or Fentanyl lozenge by the nurse caring for the patient.

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Respiratory rate and sedation scores should be recorded prior to administration of Fentanyl and observed throughout administration. Record sedation and respiratory scores again following administration.

If the entire lozenge (Actiq) has not been consumed at the end of the procedure the remaining lozenge should be withdrawn and destroyed (dissolved in water and sluiced). Part lozenges should under no circumstances be left with the patient.

Nursing staff should report any adverse effects to the medical team.

6.2 Medical team

As the patient's condition improves, i.e. dressing change becomes less invasive, or better tolerated, then consideration needs to be given to reducing the strength of Fentanyl being used i.e. reducing by 30 to 50% and reassessing effectiveness. With sustained improvement, other analgesic techniques should be reconsidered to minimise the duration of use of Sublingual Fentanyl or Fentanyl Lozenges.

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6.3 Pain Team

Review of policy to incorporate important updates
Participate in compliance monitoring
Report back to assurance committees as needed
Review and action outcomes of adverse incidents

7. Monitoring document effectiveness

7.1 Seek advice from the Pain Team re the appropriateness of Sublingual Fentanyl or Fentanyl lozenges for an individual patient before prescribing.

Prescription for any other reason should be pain consultant basis only and supported by documentation in the medical notes, explaining why Sublingual Fentanyl or Fentanyl lozenges have been prescribed as opposed to an alternative opioid analgesia e.g. subcutaneous opioids

8. Abbreviations and definitions

Abstral is a sublingual formulation of Fentanyl.

Oral Transmucosal Fentanyl Citrate (OTFC)-Fentanyl Lozenge (Actiq) is a solid formulation of Fentanyl citrate intended for oral Transmucosal administration.

Procedural pain is pain associated with painful procedures of short duration. This may include dressing changes, drain removal & patient transfer.

9. References and Supporting Documents

9.1 References

Abstral Sublingual Tablets; Summary of Product characteristics. *Electronic Medicines compendium*, updated 03.04.2018 www.emc.medicines.org.uk

Actiq: Summary of Product characteristics. *Electronic Medicines compendium*, updated 08.06.2017 www.emc.medicines.org.uk

Christie JM, Simmonds M, Pratt R *et al*. (1998) Dose Titration, Multicentre study of oral Transmucosal Fentanyl citrate for the treatment of breakthrough pain in cancer patients using transdermal Fentanyl for persistent pain. *Journal of Clinical Oncology*; 16:3238-3245.

Coluzzi PH *et al* . (2001) Breakthrough cancer pain: a randomised trial comparing oral Transmucosal Fentanyl citrate and morphine sulphate immediate release. *Pain* 91:123-130

Farrar JT e*t al*. (1998) Oral Transmucosal Fentanyl citrate: randomised, double blinded, placebo-controlled trial for the treatment of breakthrough pain in cancer patients, *J Natl Cancer Inst* ; 90:611-616

Portenoy Rk *et al* (1999) Oral Transmucosal Fentanyl citrate for the treatment of breakthrough pain in cancer patients: A controlled dose titration study. *Pain* 79: 303-312.

Rauck RL *et al* (2009) Efficacy and long-term tolerability of sublingual fentanyl orally disintegrating tablet in the treatment of breakthrough cancer pain. Current Medical research and Opinion 25:12: 2877-2885

10. Document Control Information

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Applies to:					
	Salford CO ✓	Oldham CO	North Manchester CO	Bury & Rochdale CO	Northern Care Alliance Group (NCA)
Document developed in consultation with :	Pain Consultants Pain Specialist Nurses Pharmacy MM				
Keywords/ phrases:	Policies and Resources/ Search by Department/ Pain/ Sublingual Fentanyl/ Abstral				
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Document review arrangements:	This document will be reviewed by the author, or a nominated person, at least once every three years or earlier should a change in legislation, best practice or other change in circumstance dictate.				
Approval:	Medicines Management Committee: Richard Cooper, Chair				
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	Insert full approval date: 08/10/2018				
How approved:	Chair's actions - approved		Formal Committee decision- approved		

11. Equality Impact Assessment (EqIA) screening tool

Legislation requires that our documents consider the potential to affect groups differently, and eliminate or minimise this where possible. This process helps to reduce health inequalities by identifying where steps can be taken to ensure the same access, experience and outcomes are achieved across all groups of people. This may require you to do things differently for some groups to reduce any potential differences.

1a) Have you undertaken any consultation/ involvement with service users, staff or other groups in relation to this document? If yes, specify what.	*No*
1b) Have any amendments been made as a result? If yes, specify what.	*No*

2) Does this policy have the potential to affect any of the groups listed below differently?
Place an X in the appropriate box: *Yes, No or Unsure*
This may be linked to access, how the process/procedure is experienced, and/or intended outcomes. Prompts for consideration are provided, but are not an exhaustive list.

Protected Group	Yes	No	Unsure
Age *(e.g. are specific age groups excluded? Would the same process affect age groups in different ways?)*	x		
Sex *(e.g. is gender neutral language used in the way the policy or information leaflet is written?)*		x	
Race *(e.g. any specific needs identified for certain groups such as dress, diet, individual care needs? Are interpretation and translation services required and do staff know how to book these?)*		x	
Religion & Belief *(e.g. Jehovah Witness stance on blood transfusions; dietary needs that may conflict with medication offered.)*		X	
Sexual orientation *(e.g. is inclusive language used? Are there different access/prevalence rates?)*		X	
Pregnancy & Maternity *(e.g. are procedures suitable for pregnant and/or breastfeeding women?)*		X	
Marital status/civil partnership *(e.g. would there be any difference because the individual is/is not married/in a civil partnership?)*		X	
Gender Reassignment *(e.g. are there particular tests related to gender? Is confidentiality of the patient or staff member maintained?)*		X	
Human Rights *(e.g. does it uphold the principles of Fairness, Respect, Equality, Dignity and Autonomy?)*		x	
Carers *(e.g. is sufficient notice built in so can take time off work to attend appointment?)*		x	
Socio/economic *(e.g. would there be any requirement or*		X	

expectation that may not be able to be met by those on low or limited income, such as costs incurred?)			
Disability *(e.g. are information/questionnaires/consent forms available in different formats upon request? Are waiting areas suitable?) Includes hearing and/or visual impairments, physical disability, neurodevelopmental impairments e.g. autism, mental health conditions, and long term conditions e.g. cancer.*		**X**	

Are there any adjustments that need to be made to ensure that people with disabilities have the same access to and outcomes from the service or employment activities as those without disabilities? *(e.g. allow extra time for appointments, allow advocates to be present in the room, having access to visual aids, removing requirement to wait in unsuitable environments, etc.)*		**X**	

3) Where you have identified that there are potential differences, what steps have you taken to mitigate these?

- **Age: only for adults**
- **Caution with use in pregnancy. Pain Team should be contacted on 07623623107 for advice and support.**
- **Patients with poor command of English will need consent and education with the aid of Trust interpreters**

4) Where you have identified adjustments would need to be made for those with disabilities, what action has been taken?
(what action has been taken or will be taken, who is responsible for taking a future action, and when it will be completed by – may include adjustment to wording of policy or leaflet)

Will this policy require a full impact assessment? No
(*a full impact assessment will be required if you are unsure of the potential to affect a group differently, or if you believe there is a potential for it to affect a group differently and do not know how to mitigate against this - Please contact the Inclusion and Equality team for advice on* equality@pat.nhs.uk)

Author: Type/sign: Angela Leonard Date: 24.09.18

Sign off from Equality Champion: Emma Wright Date: 3/10/18