

Prescribing Policy Statement: IMMEDIATE RELEASE (TRANSMUCOSAL) FENTANYL
Do not initiate in NEW PATIENTS. Do not increase doses for existing patients.

Immediate release fentanyl products are poor value for money compared to immediate release morphine. They are a **NICE Do Not Do Recommendation**. There are important safety considerations associated with use of immediate release fentanyl.

Approved indications:

- **Immediate release fentanyl products are licensed only for the management of breakthrough pain in adult patients using maintenance opioid therapy for chronic cancer pain**
- Maintenance opioid therapy is defined as taking at least 60 mg of oral morphine daily*, or an equi-analgesic dose of another opioid, for a week or longer
- There is a risk of accidental overdose in patients taking lower daily doses of opioid

Immediate release oral morphine is the first line rescue medication of breakthrough cancer pain in patients on maintenance oral morphine treatment. **Do not offer fast-acting fentanyl as first line rescue medication** (a NICE Do Not Do Recommendation).

Immediate release fentanyl is contraindicated in the management of acute or postoperative pain. Because life-threatening hypoventilation could occur at any dose in patients not taking chronic opiates, immediate release fentanyl **must not be used in opioid non-tolerant patients**, including those with only intermittent or “as needed” (PRN) prior exposure.

Use outside of the licence (e.g. for non-cancer pain, dressing changes or those on lower doses of opioid maintenance therapy) has patient safety implications and should not be initiated

All immediate release fentanyl products are restricted for use within Mid Essex CCG.

Recommendations for new patients:

- **Do not newly initiate** immediate release Fentanyl unless all of the licensing criteria above are met and demonstrated and patient has been initiated and stabilised by a specialist
- **Use of immediate release fentanyl for dressing changes is unsafe, off-label and not appropriate.** This use is predominantly for the speed of response but a similar effect will be obtained by administering short-acting morphine sulphate 15 – 20 minutes prior to the dressing change or by the use of Entonox®.
- If the reason for a new prescription of immediate release fentanyl is uncertain, discuss and consult with the initiating prescriber/specialist
- As with all opioids, risk of addiction and misuse should be borne in mind. The British Pain Society have stated that clinical experience suggests immediate release preparations are more associated with tolerance and problem drug use
- **If there are doubts about the safety of prescribing for an individual patient, the primary care physician may request that prescribing is retained by the specialist**

Recommendation for existing patients:

The availability of a number of different formulations of immediate release fentanyl with different dosage instructions and pharmacokinetic profiles creates potential for prescribing and dispensing errors. **Products should be prescribed by brand for any existing prescriptions to reduce this risk**

Do not further increase the dose or supply quantities for existing patients. If patients are requesting repeats more frequently than their usual supply interval then supply in weekly instalments. If this does not enable patient to self-manage their usage, prescriptions can be prepared on a FP10MDA (blue) prescription for instalments at more frequent intervals.

Brands, formulations and costs of immediate release fentanyl products available:

Brand	Formulation	Strengths	Cost per single dose unit	Total annual spend in MECCG
Actiq®	Lozenge	200mcg, 400mcg, 600mcg, 800mcg, 1.2mg, 1.6mg	£7.01 / lozenge	£289,328 (approx. 40 pts)
Abstral®	Sublingual tabs	100mcg, 200mcg, 400mcg, 600mcg, 800mcg	£5.00 / tablet	£18,838 (approx 3–4 pts)
Effentora®	Buccal tabs	100mcg, 200mcg, 400mcg, 600mcg, 800mcg	£4.99 / tablet	£44,673 (approx 8 pts)
PecFent®	Nasal spray	100mcg, 400mcg	£3.80 / spray	0
Recivit®	Sublingual tabs	133mcg, 267mcg, 400mcg, 533mcg, 800mcg	£4.42 / tablet	0
Instanyl®	Nasal spray	50mcg, 100mcg, 200mcg	£5.95 / spray	0

These products are NOT interchangeable, even different brands of the same formulation and strength / dose may have different bioavailability.

Other safety considerations:

“All health professionals involved in the prescribing, dispensing or administration of opioids have a responsibility to check that an intended opioid dose is safe and appropriate for that patient. They must also be familiar with the characteristics, e.g. dosing increments and side effects, of the opioid being used” **NPSA**

Rapid Response Report Opioids 2008

Fentanyl is extensively and rapidly metabolised in the liver by cytochrome P450 3A4. Concomitant use with drugs that inhibit or induce this enzyme should be avoided if possible. Commonly prescribed 3A4 inhibitors in primary care include, erythromycin, clarithromycin, fluconazole, diltiazem and verapamil (and grapefruit juice). These drugs may increase the concentration of fentanyl 2- 5 fold which could increase or prolong both the therapeutic and adverse effects and may cause serious respiratory depression.

Fentanyl can be dangerous if used incorrectly. **Accidental use, particularly by young children, can result in death.** Patients and their caregivers must be instructed to keep all tablets and lozenges out of the reach of children, and opened units properly discarded

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