

Position Statement; Prescribing of immediate release fentanyl preparations (also known as transmucosal fentanyl preparations) is not supported

Castle Point and Rochford and Southend Clinical Commissioning Groups do not support the routine prescribing of immediate release fentanyl preparations for any indication other than breakthrough pain in cancer patients who are already using strong opioids and are unable to take other short-acting opioid preparations.

Prescribing should be under the direction of a specialist in palliative care.

Morphine sulfate should be used as the first line agent for breakthrough pain. Oxycodone can be used in patients who cannot tolerate, or have a contraindication to, morphine.

Immediate release fentanyl formulations include sublingual tablets (Abstral®), buccal film (Breakyl®), buccal tablets, lozenges (Actiq®) and nasal spray (Instanyl®).

Rationale

- The National Institute for Health and Care Excellence's (NICE) clinical guidance CG140 (palliative care for adults: strong opioids for pain relief) states that oral immediate release morphine should be offered first line as rescue medication of breakthrough pain in patients on maintenance oral morphine treatment.¹ It states that immediate release fentanyl should not be offered as first line rescue medication.¹
- The Guidance Development Group for NICE CG140 was satisfied that there was limited evidence to suggest that immediate release fentanyl is more clinically effective than immediate release morphine or immediate release oxycodone. The cost impact of recommending immediate release fentanyl over immediate release morphine or oxycodone would be considerable and therefore could not be justified¹.
- The Scottish Medicines Consortium (SMC) has advised that immediate release fentanyl preparations should be restricted for the management of breakthrough pain in adults using opioid therapy for chronic cancer pain, when other short-acting opioids are unsuitable.^{2,3,4,5}
- Immediate release fentanyl preparations are licensed only for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain.⁶ There is very limited published evidence to support the use of these preparations in the management of other types of non-cancer/non-palliative pain e.g. refractory migraine or pain at dressing changes, which are all unlicensed uses.
- In 2007, the US Food and Drug Administration issued a safety warning for a brand of fentanyl after reports of serious overdoses and deaths in the USA.⁷ The factors that contributed to these adverse events included the use of the product in non-opioid tolerant patients, misunderstanding of dosing instructions and brand substitution without dose adjustments, e.g. swapping from one brand to another with like for like dosing.

Guidance and recommendations for clinicians

- Do not offer immediate release fentanyl as a first line rescue medication for breakthrough pain in patients who are already receiving maintenance opioid treatment.
- Use immediate release morphine sulphate as the first line agent for breakthrough pain in patients who are already receiving maintenance opioid treatment. Oxycodone can be used in patients who cannot tolerate, or have a contraindication to, morphine.
- Do not prescribe immediate release fentanyl in opioid-naïve patients.
- Only prescribe immediate release fentanyl under direction of a specialist in palliative care, for the management of breakthrough pain in cancer patients who are already receiving maintenance opioid treatment and who are unable to take other short-acting opioids. Prescribe in line with local formularies and guidelines.
- Review patients who are currently being prescribed immediate release fentanyl for any other indication to establish whether prescribing is safe and appropriate. This may require communication with specialist services if the prescription request has originated from them. There may be some exceptional circumstances where a pain or palliative care specialist recommends that immediate release fentanyl is prescribed outside of the licensed indications.
- Prescribe immediate release fentanyl preparations by **brand**. The brands are not interchangeable and there is a need for dose adjustment if the brand needs to be changed.

- If a patient is regularly using more than 4 doses of immediate release fentanyl a day, the pain/palliative care specialist should be alerted so that they can review their background opioid to an optimal dose.

Guidance for patients, carers and guardians

- Immediate release fentanyl is a fast acting strong painkiller known as a strong opioid. It is used for breakthrough pain in cancer patients who are already receiving strong opioid painkillers.
- Other fast acting strong opioids such as morphine and oxycodone are also effective for breakthrough pain and are less costly.
- If you are being prescribed fast acting fentanyl for non-cancer pain, or if you have not tried other opioid painkillers before, your doctor will assess your pain relief and may consider changing to a suitable alternative medication. This is to ensure that you receive the most effective treatment available that also provides good value for the NHS without affecting quality of your care.

A patient information leaflet is available: <https://www.prescqipp.info/items-which-should-not-routinely-be-prescribed-patient-leaflets>

References:

¹ National Institute of Health and Care Excellence (NICE) CG 140. Palliative Care for Adults strong opioids for pain relief. Accessed 04/10/17. Available at <https://www.nice.org.uk/guidance/CG140>

² Scottish Medicines Consortium, SMC Advice: Fentanyl (Instanyl). Accessed on 04/10/17. Available at

https://www.scottishmedicines.org.uk/SMC_Advice/Advice/750_11_fentanyl_instanyl_single_dose_nasal_spray/fentanyl_instanyl_single_dose_nasal_spray

³ Scottish Medicines Consortium. SMC Advice: Fentanyl (PecFent). Accessed on 04/10/17. Available at

https://www.scottishmedicines.org.uk/SMC_Advice/Advice/663_10_fentanyl_pectin_nasal_spray_PecFent/fentanyl_pectin_nasal_spray_PecFent

⁴ Scottish Medicines Consortium. SMC Advice: Fentanyl (Effentora). Accessed on 04/10/17. Available at

https://www.scottishmedicines.org.uk/SMC_Advice/Advice/510_08_fentanyl_buccal_tablets_Effentora_/fentanyl_buccal_tablets_Effentora

⁵ Scottish Medicines Consortium. SMC Advice: Fentanyl (Abstral). Accessed on 04/10/17. Available at

https://www.scottishmedicines.org.uk/SMC_Advice/Advice/534_09_sublingual_fentanyl_Abstral_/fentanyl_sublingual_Abstral

⁶ Electronic Medicines Compendium. Accessed 04/10/17. Available at <https://www.medicines.org.uk/emc/search>

⁷ US Food & Drug Administration. Information for Healthcare Professionals: Fentanyl Buccal Tablets (marketed as Fentora). Accessed 04/10/17. Available at

<https://www.fda.gov/drugs/drugsafety/postmarketdrugssafetyinformationforpatientsandproviders/ucm126082.htm>

Further Information available from:

NHS England. Items which should not routinely be prescribed in primary care: Guidance for CCGs.

<https://www.england.nhs.uk/publication/items-which-should-not-be-routinely-prescribed-in-primary-care-guidance-for-ccgs/>.

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Approved for use in Castle Point & Rochford and Southend CCGs	Drugs and Therapeutics Committee (DATE APPROVED)
Title	The prescribing of immediate release fentanyl preparations (also known as transmucosal fentanyl preparations)

Adapted for use from SWL CCGs (NHS Croydon CCG, NHS Kingston CCG, NHS Merton CCG, NHS Richmond CCG, NHS Sutton CCG and NHS Wandsworth CCG) position statement on prescribing of immediate release fentanyl preparations.