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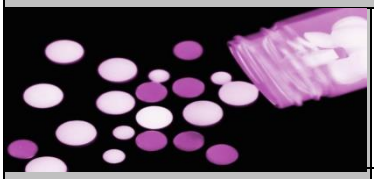
TRUSTWIDE PROCEDURE



MEDICINES STANDARD OPERATING PROCEDURE

DOCUMENT TITLE:	Administration of Topical Morphine Gel for painful skin lesions in palliative care
DOCUMENT NUMBER:	SOP118 v1
DOCUMENT REPLACES Which Version	This is the first version (replaces guideline)
LEAD EXECUTIVE DIRECTOR DGM	Divisional Manager for Diagnostics and Clinical Support Services
AUTHOR(S): Note should <u>not</u> include names	• Specialist Palliative Care Nurse • Specialist Palliative Care Team • Non-medical Prescribing Lead and Medicines Optimisation Specialist • Medicines Information Pharmacist

TARGET AUDIENCE:	• Registered Nurses • Registered Nursing Associates • Advanced Clinical Practitioners • Medical Staff
DOCUMENT PURPOSE:	To ensure that Topical Morphine Gel is administered safely and effectively to achieve optimal analgesia for palliative patients with painful cutaneous skin lesions.

To be read in conjunction with (identify which internal documents)	• Controlled Drugs Policy (C105) • ELHT/ELCCG Joint Wound Care Formulary (July 2019) • Hand Hygiene Policy (IC01) • Incident Management Policy (CO03) • Infection Control Policy (IC00) • Medicines Management Policy (CO064) and its associated procedures • Procedure for General Administration of Medication (MSOP059/CMSOP04) • Safe denaturing of Controlled Drugs (CDs) in the domiciliary setting following the death of a patient (CMSOP01) • Standard (Universal) Infection Control Precautions (IC18) • Waste Management (CO71)
REFERENCES	• Bradford, Airedale, Wharfdale and Craven Palliative Care Managed Clinical Network (July 2018) Topical Morphine in Palliative Care (information sheet) • British National Formulary • Care Quality Commission (CQC) requirements under Regulation 12: safe care and treatment specifies the expectations required that relate to medicines within sections 12(2)(f) and 12(2)(g) • Clinical Management Extra (March 2015) Palliative Wound Care Management Strategies for Palliative Patients and their Circles of Care • Northamptonshire Healthcare NHS Foundation Trust (November 2018) MMG029 Guidelines for the use of Topical Morphine for painful skin ulcers in Specialist Palliative Care • Palliative Care Formulary • Palliativedrugs.com • Palliative Meds Info (April 2017) Question: What is the evidence for the use of Morphine Solution for Injection mixed in gel and applied topically?

	• Smith and Nephew. Intrasite Gel. https://www.smith-nephew.com/professional/products/advanced-wound-management/intrasite-gel/. • The Consultant Pharmacist (April 2018) Use of Topical Morphine to Relieve Painful Pressure Ulcers, Vol 33, no.4 • The Royal Marsden Manual of Clinical and Cancer Nursing Procedures, 10th Edition

CONSULTATION		
	Committee/Group	**Date**
Consultation	Specialist Palliative Care Team Directorate	4th February 2021
Approval Committee	Medicines Safety & Optimisation Committee	9th February 2021
Ratification date at Policy Council:	Chairs Action March 2021	
EXPIRY DATE:	February 2024	
AMENDMENTS:	Replacing a treatment guideline	

Standard Operating Procedure (SOP)

For the administration of Topical Morphine Gel

Name of Discipline and Clinic/ Department/ Organisation

For use across the Trust by:

- Registered Nurses
- Nursing Associates
- Advanced Clinical Practitioners
- Medical Staff
- Trainees who have received training in wound care management as part of their pre-registration course with direct supervision from a registered healthcare professional who is competent in the skill.
- It excludes bank/agency/locum staff unless they can comply with all the requirements detailed in the SOP

Purpose of the Standard Operating Procedure

To ensure that Topical Morphine Gel is administered safely and effectively to achieve optimal analgesia for palliative patients with uncontrolled wound pain.

Criteria for Inclusion

- All patients MUST be reviewed by a member of the Specialist Palliative Care Team.
- There is a valid Drug Prescription Administration Record (DPAR) or Medicines Administration Record (MAR) in place.
- Patients 18 years and over.
- Patients who have a palliative diagnosis.
- Painful cutaneous skin lesions e.g. fungating wounds, ulcers <10cm in diameter
- Non-neuropathic, localised pain.
- Opioid naïve patients – only where the introduction of systemic opioids would be inappropriate, or is refused by the patient.
- Opioid tolerant patients – only where side effects prevent adequate dose escalation of the systemic opioid dose.

Criteria for Exclusion

- Patients younger than 18 years old.
- Patients with a known hypersensitivity to any ingredients of the product or excipients.
- Absence of valid consent from the patient.
- Any wound >10cm
- More than 2 wounds <10cm
- Wound is in or around the eyes
- The patient is receiving concurrent topical management for an infected wound
- Acute respiratory depression.
- Severe impairment of the Central Nervous System (e.g. raised intracranial pressure or head injury).

Cautions

- Intolerance to the systemic side effects of Morphine Sulfate.
- Severe renal/hepatic impairment – reduced doses may actually be used in preference to systemic treatments for this very reason but monitor carefully for signs of opioid accumulation and toxicity.
- Heavily bleeding or exuding wounds (due to the inability of the Topical Morphine Gel to adhere to the wound surface).
- Concomitant use of MAO-inhibitors or within 14 days after discontinuation.

Characteristics of Staff Authorised to Administer under this SOP

Staff within agreed areas who:

- Have successfully completed training in wound care and are deemed competent to complete the procedure.
- Have successfully completed and are up to date with Medicines' Management e-Learning module. (required every two years).
- Have successfully completed and are up to date with BLS training.
- Should have successfully completed Trust approved anaphylaxis training in the recognition and immediate treatment of anaphylaxis. (Available via learning hub. Anaphylaxis training is also included in other courses; Intermediate life support (adults and paediatrics), Advanced life support (adults and paediatrics) and IV therapies training)
- Are aware of and compliant with ELHT organisational policies linked to this procedure
- Have access to and successfully completed continued departmental training or updates

Description of the Medication	
Name of the medicine:	Morphine Sulfate 10mg/mL Injection & Propylene Glycol Gel 8g (i.e. Intrasite Gel®).
Legal Status of medicine	POM CD2 (Morphine Sulfate 10mg/mL Injection) Mixed with Medical Device Propylene Glycol Gel 8g (i.e. Intrasite Gel®). To create unlicensed medicine
Standard dose:	1.25mg/mL (0.125%) made by mixing 1mL of morphine sulfate 10mg/mL injection with 8g of Intrasite gel®
Route of administration	Topical
Frequency of Administration	As per prescribers instruction. Standard frequency is once or twice daily but can be used up to three times daily depending on response and wound condition.
Maximum total dose/ maximum number of doses that can be given in 24 hours:	Three

Details of Administration

The healthcare staff performing the procedure should:.

- Follow the Trust Standard Operating Procedure for General Administration of Medicines (SOP059/CMSOP04) in terms of ID check, informed consent, allergy status
- Record intensity and characteristics of pain experienced by the patient.
- Prepare clean dressing field area.
- Draw up 10mg/1mL Morphine Sulfate into sterile 10mL syringe and mix with 8g Intrasite Gel in sterile plastic container with sterile plastic probe.
- Remove old dressing and irrigate/cleanse the wound with 0.9% Sodium Chloride.
- Document the size, appearance, colour, odour and exudate from wound
- Apply Morphine Gel directly onto wound bed or onto non-adherent primary dressing (as per Trust wound care formulary. The amount of gel applied varies according to the size and the site of the lesion, but is typically is 5–10mL.
- Apply silicone foam secondary dressing as per Trust wound care formulary.
- Dispose of any remaining mixture and any items which have been in contact with the Morphine

into appropriate sharps container as per policy.

- Check that the patient is comfortable and the dressing is secure.
- Record intensity and characteristics of pain experienced by the patient 2 hours after dressing change. Initially, patients should be monitored twice daily, using pain scores to measure any improvement or deterioration from baseline. If there has been no response after 3-7 days, treatment should be discontinued.
- If prepared under sterile conditions, Morphine Sulfate is stable for at least 28 days when mixed with Intrasite gel at a concentration of 0.125% (1.25mg/mL).
- Patients undergoing radiotherapy should wash off any topical preparation within treatment field prior to radiotherapy dose.

Documentation

- The healthcare staff must record the administration in the Drug Prescription Administration Record/Medicines Administration Record of the patient's Drug Prescription or Medication Administration record.
- They should record:
  - Name of the product
  - The dose
  - The route
  - The batch number
  - The expiry date
  - The date and time of administration
  - Signature and printed name of the healthcare staff that administered the product.
- Incident reports must be completed in the following instances:
  - Severe adverse reactions
  - Medicine errors
  - Sharps injuries

This list is neither definitive nor exhaustive.

Side Effects/Adverse Reactions
Adverse reactions should be reported immediately to a registered healthcare professional and an Incident Report (Datix) completed. For serious reactions complete a Yellow Card Alert. **Side effects** include: ➢ Itching at application site – discontinue use immediately. ➢ Hallucinations & Confusion. ➢ Constipation. ➢ Drowsiness. Refer to current British National Formulary (BNF) or summary of product characteristics for all side effects and adverse reactions.
Dissemination and Implementation
• This standard operating procedure sets out what is expected of Registered Nurses, Registered Nursing Associates, Advanced Clinical Practitioners and Medical Staff working in Primary and Secondary Care, when administrating Topical Morphine Gel when dressing painful cutaneous skin lesions. • The SOP will be reviewed and revised by the review date or earlier in light of any near misses or significant events as appropriate and reflects the best practice and current evidence available at the time of ratification. • Managers are responsible for ensuring that they and the staff within their area of responsibility are aware of this SOP and enable adherence to it. • This SOP should be used / followed in the context of the current relevant medicines legislation, ELHT medicines policies & procedures and professional standards. Deviations to the SOP that do not conform to best practice must be risk assessed. It may be necessary to report as an incident deviation to any aspect of the procedure where patient safety is put at risk. • This SOP will be made available to appropriate staff via the Trust Intranet. • The Clinical Team Leader should ensure that the contents of this SOP are included within their induction and development programmes for appropriate staff with involvement in medicines administration. • The Clinical Team Leader will ensure practice has been reviewed at the PDR/appraisal. • Appropriate staff should read, agree to and be authorised as competent before completing the procedure by another already competent practitioner.

Monitoring Compliance

The Trust will audit practice in accordance with this SOP via:

Aspect of compliance being monitored	Tool/Method of monitoring	Individual or group responsible	Frequency of monitoring
Incidents reported related to any aspect of the SOP	Datix	Service or clinical Lead/Manager	With each incident
		Medicines Safety Optimisation Committee (MSOC)	Monthly
Adherence to best practice in general administration of medicines or specific administration requirements of this SOP	Nursing Assessment Performance Framework (NAPF)	Service or clinical Lead/Manager	Each NAPF inspection
		MSOC	Monthly
All staff who administer the medicine via this SOP meet the staff characteristics and have read, agreed and signed the SOP.	Audit of Appendix 1	Service or clinical Lead/Manager	Annually
All staff that have signed to use the SOP have been authorised to use the SOP by their manager	Audit of Appendix 1	Service or clinical Lead/Manager	Annually

- Where standards are not achieved, action plans will be developed, and changes implemented accordingly by those with responsibility.

APPENDIX 1

MSSOP11 - Administration of Topical Morphine Gel					
The SOP is to be read, agreed and signed by all healthcare staff to which it applies then also be authorised by their Service/Clinical Lead or Manager before it is used in clinical practice. A copy of the SOP must be available to staff at the point of use. Staff verified as competent and authorised to use this SOP:					
Name of Staff & Discipline	**Signature of Staff**	**Date signed**	**Name of manager**	**Signature of Manager authorising use of SOP**	**Date Signed**

Those signed up to and authorised to use the SOP must be reviewed and updated at least annually by Service or Clinical Lead/Manager.