

GUIDELINES FOR THE USE OF TOPICAL MORPHINE FOR PAINFUL SKIN ULCERS IN PALLIATIVE CARE

Policy Details	
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Responsible Director	Medical Director
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Related Policies & other documents	MMP001 – Control of Medicines Policy
Freedom of Information category	Guideline

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1. DOCUMENT CONTROL SUMMARY

Document Title	Guidelines for the Use of Topical Morphine for Painful Skin Ulcers in Palliative Care
Document Purpose (executive brief)	To provide guidance on the use of topical morphine for painful skin ulcers in Palliative Care
Status: - New / Update/ Review	New
Areas affected by the policy	Inpatient hospice areas
Policy originators/authors	Melanie Harvey – Staff Nurse Cransley Hospice
Consultation and Communication with Stakeholders including public and patient group involvement	Medicines management Committee - meeting 7.12.12 Palliative care clinical governance group – meeting 27.11.12
Archiving Arrangements and register of documents	The Risk Management Team is responsible for the archiving of this policy and will hold archived copies on a central register
Equality Analysis (including Mental Capacity Act 2007)	See MMP001 - Control of Medicines Policy
Training Needs Analysis	See section 7
Monitoring Compliance and Effectiveness	See section 8
Meets national criteria with regard to	
NHSLA	N/A
NICE	N/A
NSF	N/A
Mental Health Act	N/A
CQC	N/A
Other	N/A
Further comments to be considered at the time of ratification for this policy (i.e. national policy, commissioning requirements, legislation)	N/A
If this policy requires Trust Board ratification please provide specific details of requirements	N/A

2. INTRODUCTION

Painful wounds often present a therapeutic challenge in palliative care. Management usually requires treatment with systemic opioids, but their use is commonly complicated by unpredictable bioavailability of the drug within the wound microenvironment due to impaired circulation caused by malignant infiltration of blood vessels supplying the skin. Systemic opioids can also lead to unfavourable side effects.

The hypothesis that opioids exert a local analgesic effect is based on several observations:

- Nociceptive afferent nerve fibres contain peripheral opioid receptors which are silent except in the presence of local inflammation.
- Morphine and its metabolites are largely undetectable systemically when applied topically to skin ulcers, suggesting the analgesic effect is local
- Peripheral opioid injections for local analgesia, such as intra-articular morphine after knee surgery, have been found to be effective in several trials

An effective topical opioid analgesic that could be applied to inflamed or open skin lesions would be a useful option for some patients where other options for pain relief have been exhausted.

3. PURPOSE

This guidance has been developed to aid local healthcare professionals working in the specialist field of palliative care to;

- safely evaluate and use topical morphine for painful skin ulcers
- enable them to gain experience in its use
- gather useful audit data
- ensure that this is done in the safest and most standardised way

4. DEFINITIONS

CD – Controlled drug

TTO – To take out (discharge) form

NHFT - Northamptonshire Healthcare NHS Foundation Trust

5. DUTIES

5.1. The Medicine Management Committee

Will approve and review these guidelines

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5.2. Unit Managers

Are responsible for ensuring staff have read, understood and adhered to the guideline. It is also their responsibility to ensure all necessary equipment and medication related to the guideline is available and fit for purpose.

5.3. Doctors

Are responsible for assessing uncontrolled wound pain and prescribing any treatment required as appropriate.

5.4. Nursing staff

Are responsible for identifying patients who have uncontrolled wound pain and bringing them to the attention of the doctor.

6. PROCESS**6.1. Inclusion Criteria**

All patients MUST be reviewed by a member of the specialist palliative care team - see Appendix 1 for treatment algorithm;

- Terminal or palliative care patients only, with the aim of symptom management rather than wound healing, whose pain remains uncontrolled
- Painful superficial chronic wounds <10cm diameter
- Non-neuropathic, localised pain
- Opioid naive 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

6.2. Exclusion Criteria

- Hypersensitivity (e.g. rash) to morphine or other opioid derivatives
- Hypersensitivity to Intrasisite[®] gel
- Hypersensitivity to propylene glycol
- More than 2 wounds of <10cm diameter
- Any wound greater than 10cm diameter
- Age <18yrs old

6.3. Cautions

- Intolerance to the systemic side effects of morphine or other opioid derivatives
- Severe renal impairment or severe hepatic impairment – reduced doses may actually be used in preference to systemic treatments for this very reason. Monitor carefully for signs of opioid accumulation and toxicity over time

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- Heavily bleeding or exuding wounds (due to reduced ability of the Intrasisite[®] gel to stick to the wound surface)
- Concomitant use of MAO-inhibitors or within 14 days after discontinuation of MAO-inhibitors

6.4. Contraindications

- Do not use in or around the eyes because the product is not suitable for such application
- Severe impairment of the central nervous system (e.g. raised intracranial pressure, or head injury)
- Acute respiratory depression
- Topical management of infected wound (systemic treatment allowed)

6.5. Adverse Effects

Very few side effects have been reported in the literature regarding the use of transdermal morphine. However, the potential exists for systemic absorption, especially over large areas or with higher concentrations. Patients should be closely monitored for opioid side effects, especially if taking opioids orally/topically at the same time.

Some patients complain of pruritus with application of the morphine gel. Intrasisite[®] gel contains propylene glycol, which has been reported to be a potential irritant and sensitizing agent in a small number of patients.

6.6. Guidelines for the Use of Topical Morphine

*Please note this is an **unlicensed** indication.*

All prescribing and administration of medications must comply with MMP001 - Control of Medicines Policy. Appendix 2 details the treatment procedure.

6.6.1. Prescribing

For topical morphine the following needs to be prescribed;

“Morphine sulphate 10mg in Intrasisite[®] gel 8g”

For inpatient areas this will be prescribed on the drug chart. If to be continued on discharge a CD TTO form should be completed. In primary care CD requirements need to be met according to the Control of Medicines Policy.

6.6.2. Dose and frequency of application

Initially apply not more than 10mg of morphine in 8g Intrasisite[®] gel (this gives a 0.125% preparation) to cover each painful wound once daily for up to 24 hours, directly onto the wound bed. The amount

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of gel applied varies according to the size and the site of the wound but is typically 5 - 8grams (equivalent to 5-8ml) which should be assessed and monitored by the palliative care team.

The Intrasisite[®] gel should be washed off the wound with sodium chloride 0.9% before reapplying the next dose as detailed in Appendix 2.

6.6.3. Secondary dressing

Use foam adhesive dressing according to Northamptonshire Dressings Formulary over the wound and Intrasisite[®] gel/morphine mixture. If a foam dressing is not appropriate, then appropriate formulary film dressing may be used.

6.6.4. Monitoring

Initially patients should be monitored twice daily, using pain scores to measure any improvement from baseline. If there has been no response after 3 - 7 days, treatment should be discontinued.

Monitor for signs of opioid accumulation and toxicity, especially in patients with renal/hepatic impairment. Continue topical opioids unless contraindications arise or suitable long term arrangements can be made i.e. nerve block. During use consider frequency of application i.e. could be reduced to alternate days or increased to twice daily. Also consider reducing the systemic analgesia if topical treatment is effective and continue to review effectiveness regularly.

6.6.5. Preparation

Refer to Appendix 2 for instructions on how to prepare.

No commercially manufactured product for morphine 0.125% in Intrasisite[®] gel is available in the UK. In some areas pharmacy manufacturing units can compound the gel as 1 mg preservative-free morphine sulphate per gram of Intrasisite[®] gel on a 'named patient basis' but this is not available locally. Obtaining supplies through this route, especially from manufacturers other than NHS hospitals is very expensive.

6.6.6. Stability

The morphine component has been shown to be stable for up to 28 days when mixed with a neutral water-based hydrogel with no detectable breakdown products. However, when manufactured in any other place than a pharmacy compounding unit, **once mixed the gel should be used immediately and not stored**. This is due to concerns of microbiological contamination following mixing in a non-sterile environment, rather than the physical instability of the mixed gel.

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6.6.7. Disposal

The NHFT Control of Medicines Policy covers the disposal of controlled drugs in detail, and the advice below reflects this guidance. The information below was correct at the time of writing, but staff must ensure they are continually familiar with the most up to date version of the Control of Medicines Policy, which is hosted on the intranet.

Used dressings should be placed in a small sharps bin which is to be kept in an appropriate designated area. Please contact pharmacy for advice. The bin needs to be labelled '**contains mixed pharmaceutical waste and sharps.**' Prior to disposal, waste CD dressings that have been used on a patient should be folded in half. The clinician must wear gloves.

7. TRAINING

7.1. Mandatory Training

There is no mandatory training associated with this policy.

7.2. Specific Training not covered by Mandatory Training

Ad hoc training sessions based on an individual's training needs as defined within their annual appraisal or job description.

8. MONITORING COMPLIANCE WITH THIS DOCUMENT

The table below outlines the Trusts' monitoring arrangements for this document. The Trust reserves the right to commission additional work or change the monitoring arrangements to meet organisational needs.

Aspect of compliance or effectiveness being monitored	Method of monitoring	Individual responsible for the monitoring	Monitoring frequency	Group or committee who receive the findings or report	Group or committee or individual responsible for completing any actions
Duties	To be addressed by the monitoring activities below.				
Effectiveness of prescribing	Audit	Palliative Care Pharmacist	Annual	Palliative Care Clinical Governance Group Medicines Management Group	Medicines Management Group
Where a lack of compliance is found, the identified group, committee or individual will identify required actions, allocate responsible leads, target completion dates and ensure an assurance report is represented showing how any gaps have been addressed.					

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9. REFERENCES AND BIBLIOGRAPHY

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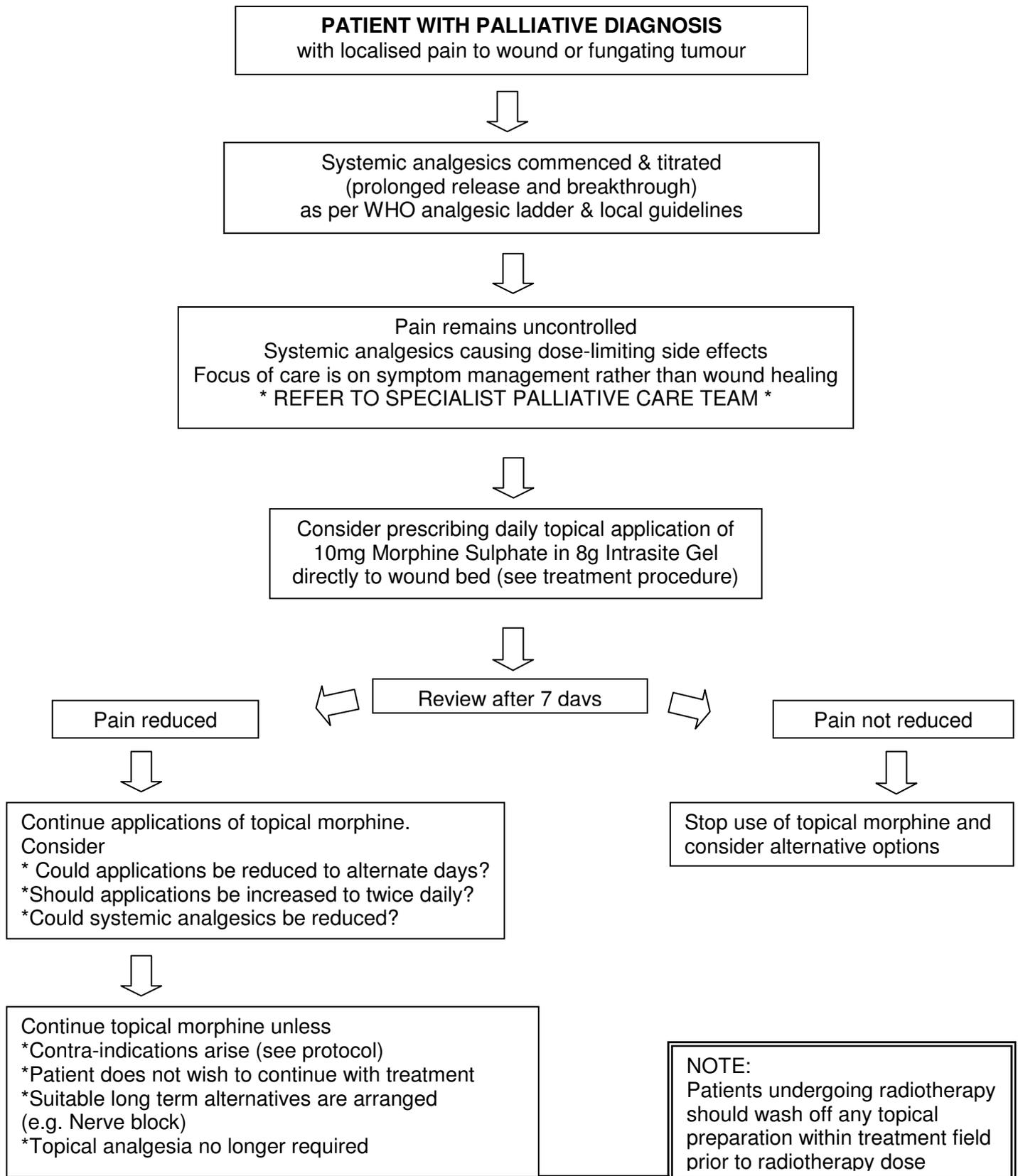
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10. RELATED TRUST POLICY

- MMP001 – Control of Medicines Policy

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APPENDIX 1 – TREATMENT ALGORITHM



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APPENDIX 2 – TREATMENT PROCEDURE

EQUIPMENT REQUIRED

- Sterile dressing pack – containing; plastic tray, apron, gloves, gauze swabs, sterile field. disposable bag
- 0.9% sodium chloride for irrigating/cleaning wound
- Appropriate foam dressing from wound care formulary
- Intrasite gel 8g
- Morphine Sulphate injection 10mg
- 2ml syringe & filter needle
- Plastic probe for mixing gel and morphine
- Sterile spatula
- Sharps bin

PROCEDURE

1. Check authorisation and appropriate documentation
2. Record pain score as reported by patient
3. Explain and discuss the procedure with the patient and obtain consent to proceed
4. Prepare clean dressing field area as per Trust guidelines.
5. Draw up morphine sulphate 10mg and mix with Intrasite Gel 8g in sterile plastic tray, following relevant CD procedures at all times.
6. Remove old dressing and irrigate/cleanse the wound with saline
7. Note size, appearance, odour and exudate from wound to document in notes
8. Apply Intrasite[®] gel and morphine solution directly to wound bed or onto dressing
9. Apply secondary dressing to wound
10. Dispose of any remaining mixture and any items which have been in contact with morphine in sharps bin. Refer to section 6.6.7 of the guidance.
11. Check that patient is comfortable and dressing is secure
12. Complete documentation
13. Record pain score 2 hours after dressing change

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