Guideline for the Pharmacological Management of Chronic Pain across the Milton Keynes Health Economy

Classification :	Guideline		
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Authors Division:	Core Clinical		
Groups this Document Applies to:	All Clinical Staff in Primary and Secondary care		
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To be read in conjunction with the following documents: Tapentadol Shared Care Guideline		
Required CQC evidence? n/a	**Key CQC Question:** Safe/Effective	

Disclaimer

Since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided in this document on the basis that the healthcare professionals responsible for patient care will retain full and sole responsibility for decisions relating to patient care. The document is intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.

The ultimate responsibility for the use of the guideline, dosage of drugs and correct following of instructions as well as the interpretation of the published material, **lies solely with you** as the medical practitioner.

Index

Guideline Statement

This guideline describes the stepwise approach which should be taken by clinicians when managing patients with chronic pain.

It provides details of initial management options suitable to initiation in primary care followed by information on when to refer to secondary care based chronic pain services and the management options which may be initiated by secondary care and continued in primary care with the agreement of the GP.

Executive Summary

This document provides guidance for prescribers in both primary and secondary care on the management of patients with chronic pain.

An algorithm for the pharmacological management of chronic pain provides guidance on the use of analgesic agents and adjuvant therapies for patient presenting with nociceptive and neuropathic pain respectively.

Guidance is provided on the identification of 'red flags' and 'yellow flags' to suggest when alternative approaches to treatment may need to be considered.

Further guidance is also provided on appropriate referral to the secondary care chronic pain services.

1. Roles and Responsibilities

Non-Specialist Primary and Secondary Care Prescribers should follow the guidance in this document when making prescribing decisions in the management of adult patients with chronic pain.

Specialist Secondary Care Prescribers should follow the guidance in this document alongside their clinical expertise when making prescribing decisions in the management of adult patients with chronic pain. When there is a clinical need to deviate from the pathway described in this guideline, the prescriber has a responsibility to explain the rationale for this deviation to both the patient and to the GP who they ask to take on the ongoing prescribing.

Pharmacists should follow the guidance in this document when clinically screening prescriptions for the management of adult patients with chronic pain.

2. Implementation and Dissemination of Document

This document will be accessible via the Clinical Guidelines Portal on the Trust Intranet site and via the Formulary website at **www.formularymk.nhs.uk**.

3. Processes and Procedures

3.1 Purpose

The purpose of this guideline is to facilitate the appropriate pharmacological management of adults suffering with chronic pain.

3.2 Background

Chronic pain is pain that continues when the healing process has occurred or in the absence of tissue injury. It is sometimes defined as pain that has lasted for more than three months.

Pain is one of the most common reasons that patients present to primary care. According to the British Pain Society, one in seven people are thought to suffer from chronic pain and twenty percent of those report suffering for more than 20 years. People with pain consult their doctor up to five times more frequently than others, resulting in nearly 5 million GP appointments each year.

Poorly managed chronic pain can affect quality of life for sufferers and their carers, leading to helplessness, isolation, depression and family breakdown.

3.3 Referral Criteria

The Royal College of General Practitioners (RCGP) and The Pain Society recommend that primary care physicians and hospital specialists should work together to manage patients with chronic pain in the most appropriate setting.

Appropriate and timely referral is an essential part of effective pain management; these guidelines are designed as an aid to this, and describe appropriate criteria for referral to the specialist services available at Milton Keynes University Hospital NHS Foundation Trust.

Referral of patients with severe resistant pain should be considered in any of the following circumstances:

- Where no significant improvement after initial treatment escalation *or* rapid escalation of opioid dosage
- Where a patient is responding to treatment but is suffering unacceptable side effects which require alternative treatment options to be considered
- Where patients present with difficult pain syndromes eg. neuropathic pain, resistant trigeminal neuralgia (TGN), complex regional pain syndrome (CRPS) and complex cancer pain
- Where further advice or diagnosis on a particular clinical symptom set is needed
- Where prominent yellow flags (see below) are identified
- Where the patient does not want drug therapy

The RCGP states that it is important to continue to see patients awaiting specialist referral and to modify treatment where appropriate.

Clinical assessment of patients presenting with chronic pain should include review of the presence of any 'red or yellow' flags which may indicate a need to consider alternative management options.

Red Flags are clinical indicators of possible serious underlying conditions which may require further medical intervention. Red flags were designed for use in acute low back pain, but the underlying concept can be applied more broadly in the search for serious underlying pathology in any pain presentation.

Differential Diagnosis	Potential Red Flags from Patient History	Potential Red Flags from Examination
Possible fracture	• Major trauma • Minor trauma in elderly or osteoporotic	
Possible tumour or infection	• Age < 20 or > 50 years old • History of cancer • History of fever, chills, weight loss • Recent bacterial infection • Intravenous drug use • Immunosuppression • Pain worsening at night or when supine	
Possible significant neurological deficit	• Severe or progressive sensory alteration or weakness • Bladder or bowel dysfunction	• Evidence of neurological deficit (in legs or perineum in low back pain)

The presence of Red Flags may indicate a need for further investigation and possible specialist referral as part of the overall strategy. If there are no Red Flags present it is safe to reassure the patient and move ahead with a multimodal management approach.

Yellow Flags are psychosocial indicators suggesting increased risk of progression to long-term distress, disability and pain. Yellow flags were designed for use in acute low back pain. In principle they can be applied more broadly to assess likelihood of development of persistent problems from any acute pain presentation.

Attitudes and Beliefs	• Pain is harmful or severely disabling • Expectation that passive treatment not active participation will help • Feeling that 'no-one believes the pain is real' – related to previous experience
Emotions and Behaviour	• Fear-avoidance behaviour (avoiding activity due to fear of pain) • Low mood and social withdrawal
Psychosocial Factors	• Poor family relationships or history of abusive relationships • Financial concerns particularly related to ill-health or ongoing pain • Work related factors e.g. conflict over sickness, ability to perform job tasks • Ongoing litigation related to persistent pain condition

The presence of multiple biopsychosocial factors may highlight the need for a multi-disciplinary approach to care**.**

3.4 Scope

This document should be used to guide the management of all adult patients (aged 18 years or over) with chronic pain who are under the care of both specialist and non-specialist prescribers in both primary and secondary care settings.

3.5 Recommendations

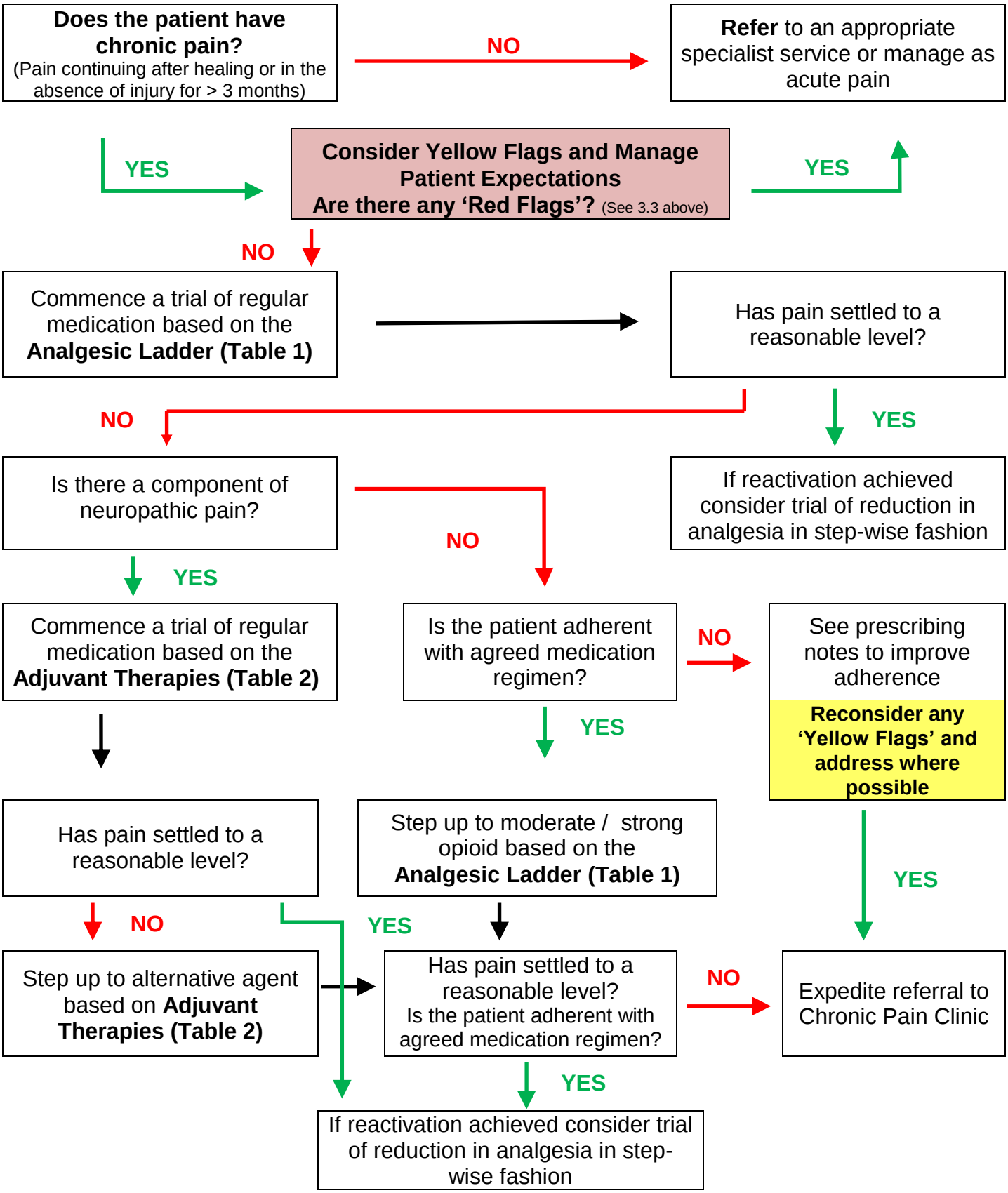
This guideline consists of a series of algorithms and tables which are designed to be used together to guide the management and referral of patients with chronic pain; they are based on established practice throughout the UK and reflect the guidance issued by the National Institute for Health and Care Excellence (NICE) and Healthcare Improvement Scotland (formerly SIGN).

It must be recognised that medicines are only one part of a multidisciplinary approach to managing chronic pain. Keeping fit, pacing activities and a generally healthy lifestyle are important.

Non Pharmacological methods of pain relief such as Transcutaneous Nerve Stimulation (TNS), acupuncture and physical methods in the reduction of muscle spasm are equally important.

Any co-existing mental health issues, any other potential diagnoses and alternative management strategies should all be considered before a decision to start any strong opioids is made.

3.5.1 Algorithm for Pharmacological Management of Chronic Pain



3.5.2 Table 1: Analgesic Ladder

Choices of analgesic for the management of chronic pain should broadly follow the WHO Analgesic Ladder (http://www.who.int/cancer/palliative/painladder/en/).

Details of the prescribing choices which are preferred within the MK Health Economy are described below.

Note (1): When assessing analgesic effectiveness and check of patient adherence to the agree regimen should be undertaken before moving to the next step.
Note (2): An assessment of any change in analgesic regimen should be made after 4 – 6 weeks.

STEP ONE	**Step 1a**	**Non-Opioid Analgesics** • Paracetamol PLEASE REFER TO CURRENT EDITION OF THE BNF OR SPC FOR DETAILED DOSING INFORMATION ON INDIVIDUAL DRUGS
	Step 1b	**Non Steroidal Anti-Inflammatory Drug (NSAID)** • Ibuprofen OR Naproxen; Stop Paracetamol
	Step 1c	**Non-Opioid Analgesic *plus* Non Steroidal Anti-inflammatory Drug (NSAID)** • Paracetamol ***plus*** Ibuprofen OR Naproxen
STEP TWO	**Step 2a** ***(then if ineffective)***	**Weak Opioid** ***(in addition to Step 1)*** • Codeine Phosphate *(titrate according to effect)*
	Step 2b ***(then if ineffective)***	**Moderate / Strong Opioid** ***(in addition to Step 1; to REPLACE Step 2a)*** • Tramadol (*titrate from low to high dose according to effect)*
STEP THREE	**Step 3a**	**1st Line : Strong Opioid – Low Dose** ***(in addition to step 1; to REPLACE step 2)*** • Morphine Sulphate Modified Release Capsules *(Recommended starting dose 10 – 40mg twice a day titrated according to effect)* OR ***(if morphine ineffective or not tolerated)*** • Buprenorphine Patch (Butrans®) *(Recommended starting dose 5 microgram per hour titrated according to effect)*
	Referral to the Chronic Pain Clinic should take place at this stage	
	Step 3b (For specialist Initiation Only)	**2nd Line: Strong Opioid – High Dose** ***(in addition to step 1; to REPLACE step 2, 3a)*** • Morphine Sulphate Modified Release Capsules *(Suggested dose upwards of 40mg twice a day titrated according to effect)* OR ***(if morphine ineffective or not tolerated)*** • Oxycodone Sustained Release *(Suggested dose 5 – 30mg twice a day titrated according to effect)* OR ***(if morphine or oxycodone ineffective or not tolerated)*** • Fentanyl Patch *or* Buprenorphine Patch (Transtec®) *(Suggested dose based on previous opioid exposure titrated according to effect)*
	Step 3c (For specialist Initiation Only)	**3rd Line: Strong Opioid** ***(in addition to step 1; to REPLACE step 2, 3a, 3b)*** • Tapentadol Modified Release *(Suggested starting dose 50 twice a day titrated according to effect)* ***(Tapentadol is approved for use in patient who have experienced treatment failure or intolerable side effects following trial of multiple other agents – when initiated the specialist is responsible for prescribing the 1st months' supply)***
Note: If opioid use does not improve function / doses escalate due to poor effect, it is likely to be non-opioid responsive pain; opioids should be tailed off. When pain control is stable, Opioids should be reviewed at least every six months by the prescriber and the lowest effective dose used		

3.5.3 Additional Prescribing Information – Opioid Therapy

Before Initiating Opioid Therapy

- Use opioids only as part of a wider management plan aimed at reducing disability and improving quality of life.
- Set realistic individualised goals of therapy for each patient; make it clear to patients that if trial is unsuccessful then opioid treatment will be discontinued.
- Be clear that treatment success will be demonstrated by functional improvement.
- Be cautious in patients with history of drug abuse, mental health or psychological problems

Cautions

- In renal impairment dose reduction should occur if eGFR < 30 ml/min. Seek specialist advice.
- Patients should not drive when starting opioids, adjusting the dose or if they feel unfit to drive.
- Patients should inform the DVLA and their car insurance company when prescribed opioids.

Prescribing

- Be clear who is responsible for prescribing; prescribe for a maximum of 30 days at any one time.
- Use regular dosing with oral modified release preparations; AVOID the use of immediate release formulations in all but exceptional circumstances.
- Start with a low dose and titrate according to response and side effects, increasing not more frequently than every two weeks; generally do not increase the dose by more than 50% in a single step
- Do not exceed maximum recommended doses without referring to specialist pain services
- A trial period of 6 weeks at the maximum tolerated dose is adequate providing the patient has been compliant with prescribed regimen.
- Review regularly, initially at least monthly, more often if there are concerns. When on a stable dose monitor at least biannually
- Discuss alternative strategies for exacerbations of pain such as education, explanation and reassurance, physical therapies, TNS machine, acupuncture or complementary therapies

Switching Opioids

- Efficacy and adverse effects are similar for all opioids although patients may tolerate one opioid better than another
- When switching, consider reducing dose by 25 – 50% to allow for incomplete cross tolerance and monitor regularly.
- Withdrawal symptoms eg, sweating, yawning and abdominal cramps occur if an opioid is stopped or the dose is reduced abruptly.

Adverse Effects

- Constipation is a common side effect; it can be minimised by encouraging lots of fluids, fruit and fibre. Laxatives should always be prescribed. The preferred choices for opioid induced constipation are stimulant laxatives and faecal softeners.
- Nausea is common during the first 2 weeks of opioid therapy, especially in opioid naïve patients. Where nausea is a problem, the dose should be weaned down and titrated slowly according to response.
- Possible endocrine / immunological effects may result from long term treatment morphine at doses of 120mg per day or more; consideration should be given to measuring plasma testosterone or oestradiol and referring to an appropriate specialist if symptoms persist.

Dependence and Addiction

- Physical Dependence (where the body adapts to the drug, requiring more of it to achieve a certain effect) is inevitable; Psychological Dependence (addiction and craving) is rare.
- Pharmacological effects of physical dependence and ease of discontinuation helped by limiting maximum dose
- Be alert for signs of abuse or addiction when reassessing patients.

3.5.4 Table 2: Adjuvant Therapies

STEP ONE (may combine with Step 2 to optimise treatment)

Tricyclic Antidepressants

- Amitriptyline or Imipramine if side effects not tolerated

A typical dosing regimen:

Step 1	Step 2	Step 3	Step 4	Step 5
10mg at night* for 2 weeks	20mg at night* for 6 weeks then evaluate response	30mg at night*	40mg at night*	50mg at night* (may be increased up to 75mg at night if needed)

**Ensure the patient tolerates each step before increasing the dose. After step 2 the dose can be increased gradually according to tolerance and the patient's needs*

STEP TWO (may combine with Step 1 to optimise treatment)

Anticonvulsants (1st Line)

- Gabapentin Capsules

A typical dosing regimen:

Step 1	Step 2	Step 3	Step 4	Step 5	Step 6
300mg once daily until tolerated*	300mg twice daily until tolerated*	300mg three times daily until tolerated*	300mg morning and 300mg mid-day + 600mg night until tolerated*	600mg morning and night and 300mg mid-day until tolerated*	600mg morning, 600mg mid-day and 600mg night until tolerated*

** Ensure the patient tolerates each step before increasing the dose; this may take up to one week per step*

Anticonvulsants (2nd Line - *if gabapentin gives good effect but side-effects cannot be tolerated*)

- Pregabalin

A typical dosing regimen:

Sensitive Patients	Step 1	Step 2	Step 3
25mg morning and night until tolerated*	75mg morning and night until tolerated*	150mg morning and night until tolerated*	300mg morning and night until tolerated*

** Ensure the patient tolerates each step before increasing the dose; this may take up to one week per step*

Other Adjuvant Agents

- Capsaicin Cream 0.075%
  (for the management of local neuropathic pain in patients who cannot tolerate oral medication)
  Apply sparingly 3–4 times daily (no more than every 4 hours); review after 8 weeks

STEP THREE (For Pain Specialist Use Only)

Referral to the Chronic Pain Clinic should take place at this stage

Other Adjuvant Agents
(for specialist initiation according to the clinical need of individual patients)

- Duloxetine
  60 mg once daily; max. 120 mg daily in divided doses
- Lidocaine Plasters 5% - 700mg/plaster
  Apply plaster(s) once daily for up to 12 hours, followed by a 12-hour plaster-free period; discontinue if no response after 4 weeks
- Capsaicin Patch 8% – 179mg/plaster (Qutenza®)
  Hospital Use Only Apply only under the supervision of a clinician experienced in its use

3.5.5 Additional Prescribing Information – Adjuvant Therapies

3.5.5.1 Tricyclic Anti-depressants (TCAs)

- **Amitriptyline** (unlicensed indication) is the TCA of choice for the management of neuropathic pain. **Imipramine** (unlicensed indication) may be used if amitriptyline is not well tolerated.
- Doses should be titrated according to patient response; an example of a typical dosage regimen is given in **Table 2**.
- Doses above 50mg are rarely required. It may take two to six weeks for the drug to be effective.
- Patients should be advised on initiation and after an increase in dose of the risk of drowsiness which may affect the performance of skills tasks eg. driving or operating machinery.
- If not tolerated TCAs should be withdrawn gradually over 1-2 weeks; if symptoms persist gabapentin should be considered

3.5.5.2 Anticonvulsants

- **Gabapentin** (licensed indication) is the anticonvulsant of choice for the management of neuropathic pain; capsules are the most cost-effective formulation.
- Gabapentin can be used in combination with a tricyclic anti-depressant,
- Gabapentin doses should be started slowly and titrated according to response; an example of a typical dosage regimen is given in **Table 2**.
- In renal impairment, the elderly or drug sensitive patients this titration may need to be done in 100mg increments.
- Slower titration and particular caution is advised on initiation and after an increase in dose in patients who drive or operate machinery.
- Gabapentin can make patients drowsy or dizzy and occasionally causes severe headaches. Headache does not tend to resolve. Serious adverse effects are rare.
- If no improvement is seen within 8 weeks of reaching the maximum tolerated therapeutic dose; an alternative treatment should be considered.
- Gabapentin should not be stopped abruptly and should be reduced gradually over a minimum of 1 week, depending on dose and duration of treatment.

- **Pregabalin** (licensed indication) is an alternative therapy in patients who have not achieved adequate pain relief from gabapentin, or have not tolerated, first and second line treatments. Twice daily dosing is more cost-effective than three times a day dosing.
- Pregabalin can be used in combination with a tricyclic anti-depressant, but it must not be co-prescribed with gabapentin.
- Pregabalin should be started slowly and titrated to response and tolerability; an example of a typical dosage regimen is given in **Table 2**.
- In renal impairment the dose must be reduced and may need to be reduced in older people, or drug sensitive patients.
- Slower titration and particular caution is advised on initiation and after an increase in dose in patients who drive or operate machinery.
- Pregabalin can make patients drowsy or dizzy and may cause confusion.
- Pregabalin should be stopped if the patient has not shown sufficient benefit within 8 weeks of reaching the maximum tolerated therapeutic dose and referred to the Pain Clinic.
- Pregabalin should not be stopped abruptly and should be reduced gradually over a minimum of 1 week, depending on dose and duration of treatment.

Gabapentin and Pregabalin have well defined roles in the management of neuropathic pain. However they are known to be drugs which can lead to dependence and may be misused or diverted. Prescribers must prescribe these drugs appropriately to reduce the risks of misuse or dependence.

4.0 Statement of Evidence / References

Statement of Evidence:

This guideline has been compiled using national guidance and considering the practice within the field in other areas of the country.

References:

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Chronic Pain
http://www.rcgp.org.uk/clinical-and-research/a-to-z-clinical-resources/chronic-pain.aspx
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Opioids for Persistent Pain
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[accessed 03/08/15]

Advice for Prescribers on the Risk of the Misuse of Pregabalin or Gabapentin
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[accessed 19/08/15]

5.0 Governance

5.1 Record of changes to document

Version number: 1		**Date:** August 2015		
Section Number	**Amendment**	**Deletion**	**Addition**	**Reason**
	New Policy			

5.2 Consultation History

Stakeholders Name/Board	Area of Expertise	Date Sent	Date Received	Comments	Endorsed Yes/No
Dr Yasser Mehrez (Consultant Anaesthetist)	Chronic Pain	04/08/15 21/08/15	10/08/15	Discussed – all comments incorporated	
Dr Sarah Aturia (Consultant Anaesthetist)	Chronic Pain	04/08/15 21/08/15	19/08/15	Discussed – all comments incorporated	
Dr Grassiana Massolini (Consultant Anaesthetist)	CSU Lead	21/08/15		No comments received	
Carole Jellicoe (ANP for Acute Pain)	Chronic Pain / NMP Lead	04/08/15 21/08/15		No comments received	
Ann Cascone (ANP for Chronic Pain)	Chronic Pain	04/08/15 21/08/15	19/08/15	Emailed comments acknowledged – to be discussed further	
Helen Chadwick (Clinical Director for Pharmacy)	Pharmacy	31/07/15 21/08/15	03/08/15	Discussed – all comments incorportated	
Dupe Fagbenro (Principal Pharmacist MKPAG)	Pharmacy	21/08/15		No comments received	
Zainab Alani (Principal Pharmacist – MI)	Pharmacy	21/08/15	23/09/15	Comments reviewed in light of MKPAG discussions – relevant points incorporated.	
Janet Corbett (Chief Pharmacist, MKCCG)	Pharmacy	03/08/15	03/08/15	Discussed – all comments incorporated	
Dr Nigel Fagen (GP)	General Practice	21/08/15		Discussed – comments via CCG incorporated	
Dr Martin Cave (MSK Clinical Lead)	Primary Care	21/08/15		Discussed – comments via CCG incorporated	
Members of MKPAG	MK Health Economy	21/08/15	23/09/15	Discussed – comments incorporated	
Members of MK CCG Prescribing Sub Group	Primary Care	21/08/15	10/09/15	Discussed – comments incorporated	
Members of MKPAG	MK Health Economy		25/05/2016	Discussed – further primary care comments incorporated	Yes

5.3 Audit and monitoring

This Guideline outlines the process for document development will be monitored on an ongoing basis. The centralisation of the process for development of documents will enable the Trust to audit more effectively. The centralisation in recording documents onto a Quality Management database will ensure the process is robust.

Audit/Monitoring Criteria	Tool	Audit Lead	Frequency of Audit	Responsible Committee/Board
N^{o} of prescriptions for Tapentadol Initiation	JAC Pharmacy System	Lead Pharmacist – Anaesthetics	Annual	Pharmacy CIG Anaesthetic CIG
N^{o} of prescriptions for Qutenza	JAC Pharmacy System	Lead Pharmacist – Anaesthetics	Annual	Pharmacy CIG Anaesthetic CIG
N^{o} of prescriptions for non formulary medicines for management of chronic pain	JAC Pharmacy System	Lead Pharmacist – Anaesthetics	Annual	Pharmacy CIG Anaesthetic CIG

5.4 Equality Impact Assessment

This document has been assessed using the Trust's Equality Impact Assessment Screening Tool. No detailed action plan is required. Any ad-hoc incident which highlights a potential problem will be addressed by the monitoring committee.

Impact	Age	Disability	Race	Gender	Religion or Belief	Sexual Orientation
Do different groups have different needs, experiences, issues and priorities in relation to the proposed Guideline?	No	No	No	No	No	No
Is there potential for or evidence that the proposed Guideline will not promote equality of opportunity for all and promote good relations between different groups?	No	No	No	No	No	No
Is there potential for or evidence that the proposed Guideline will affect different population groups differently (including possibly discriminating against certain groups)?	No	No	No	No	No	No
Is there public concern (including media, academic, voluntary or sector specific interest) in potential discrimination against a particular population group or groups?	No	No	No	No	No	No