Morecambe Bay

Primary Care Collaborative

Medicines Management & Prescribing Policy

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1. INTRODUCTION

1.1 Summary

Lancashire and South Cumbria Integrated Care Board (ICB) expects that prescribing of medicines, appliances and devices to patients at NHS expense should only be done so if commissioned within a clear evidence-based pathway of care.

Drugs and Therapeutics Medicines Management Group (DTMMG), responsible for the management of the Joint medicine's formulary, will appraise product suitability for prescribing in the Lancashire and South Cumbria ICB health economy based upon the product's clinical and cost effectiveness and update the formulary accordingly.

Clinicians have a responsibility to only prescribe or provide medicines, appliances and devices that are known to be clinically effective and provide a health benefit to patients.

1.2 Purpose

The purpose of this policy is to:

- promote legal, safe and cost-effective prescribing;
- set out the expected good practice for prescribing by all prescribers.

The Policy should be read in conjunction with the current version of the British National Formulary to access further details of prescribing procedure.

1.3 Scope

The purpose of this guidance is to outline the requirements for prescribing within primary care services provided by Morecambe Bay Primary Care Collaborative and undertaken by all prescribers employed by Morecambe Bay Primary Care Collaborative and delivering any NHS commissioned healthcare service where prescribing takes place and is provided by MBPCC.

All prescribers are required to follow this policy to ensure a consistent approach.

This policy will be reviewed as a minimum every 3 years. However, earlier revisions to the policy may be made considering published updates to local and national evidence of effectiveness and cost effectiveness, recommendations and guidelines from local, national and international clinical professional bodies or local prioritisation requirements.

2. BACKGROUND

Primary Care prescribers in England write over 900 million prescriptions per annum at a cost of almost 9 billion pounds to the NHS (2011 data). Suitably trained and registered nurses, pharmacists, physiotherapists, podiatrists, optometrists and radiographers are now eligible to prescribe within their competencies either as supplementary prescribers, prescribing in partnership with a doctor, or as independent prescribers (See MBPCC Non-Medical Prescribing Policy).

2.2 PRESCRIBING WITHIN THE 'COMPETENCY FRAMEWORK FOR ALL PRESCRIBERS'

A single competency framework for all prescribers was published in 2012 and has been updated on behalf of all prescribing professions within the UK (including the Royal College of Physicians and Royal College of General Practitioners).

The framework was implemented to support all prescribers to prescribe effectively. It is endorsed by NICE and by all the relevant professional bodies. The intention of the framework is to ensure that prescribers, regardless of their professional background, adhere to the same set of standards. The scope of the competency framework is:

1. It is a generic framework for any prescriber regardless of their professional background;
2. It must be contextualised to reflect different areas of practice and levels of expertise;
3. If reflects key competencies required by all prescribers;
4. It applies equally to independent and supplemental prescribers.

The competency framework sets out what 'good' prescribing looks like and all clinicians undertaking prescribing within their employment are expected to comply with this framework. There are ten competencies split in to two domains. Within each of the ten competency dimensions there are statements that describe the activity or outcome prescribers should be able to demonstrate.

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Prescribing%20competency%20framework/prescribing-competency-framework.pdf

2.3 RESPONSIBILITY FOR PRESCRIBING

Medicines may only be prescribed by registered doctors, dentists or non-medical prescribers. The person issuing the prescription is clinically responsible for the intervention. Medicines should be prescribed when they are necessary, and in all cases the benefit of the medicine should be considered in relation to the risk involved. Special care should be taken with patients who have disabilities, those for whom English is a second language, or have religious or cultural beliefs that may be a barrier to understanding or taking their medication. Measures should be undertaken to address any barriers for example supplying information in different formats or supplying mediation in appropriate forms.

3. SHARING INFORMATION WITH COLLEAGUES

General information on transfer of care

You should contribute to the safe transfer of patients between healthcare providers and between health and social care providers:

• You should share all relevant information with colleagues, including information about the patient's current and recent use of medicines, other conditions, allergies and previous adverse reactions to medicines.

• Provide relevant information with the patient or as soon as possible on admission to hospital whether an emergency or not.

• After an episode of care is complete, the patient's GP should be informed of any changes to patient's medicines (existing medicines changed or stopped and new medicines started), with reasons; length of intended treatment; monitoring requirements; any new allergies or adverse

reactions identifies, unless the patient objects or if privacy concerns override the duty, for example in sexual health clinics.
• Consider whether the information you have is sufficient and reliable enough to prescribe safely
Legal responsibility for prescribing lies with the doctor who signs the prescription. This is a particularly important consideration if a GP is intending to prescribe an unlicensed medicine or a licensed medicine either for an off-label indication or a dose outside that recommended in the Summary of Product Characteristics.

4. DRUG CHOICE

Medicines accepted for use across Lancashire and South Cumbria ICB health economy are classified by colour which depicts whether a medicine is funded or not and if funded where the prescribing responsibility lies across the whole health economy. The Lancashire Medicines Management Group (LMMG) consider individual new medicines or new indications for licensed medicines considering the safety and monitoring requirements of a medicine before assigning its colour classification and local adoption of the recommendations is managed via Morecambe Bay Area Prescribing Committee.

Antibiotic prescribing should follow NICE guidance
Antimicrobial prescribing table (nice.org.uk)

Only medicines included in Morecambe Bay Joint Formulary should be routinely prescribed within the health economy

Details of the Traffic Light System and the Morecambe Bay Joint Formulary are available at Morecambe Bay Joint Medicines Formulary (morecambebayformulary.nhs.uk)
The main aim of this formulary is to promote safe, evidence-based, cost-effective prescribing and to promote generic prescribing where appropriate.
Prescribing data collated by MLSCU will be shared with MBPCC to review the compliance with the formulary and to address any issues identified.

Medicines as Part of a Hospital Trust initiated Clinical Trial
Continued prescribing will not generally be taken over by primary care clinicians unless formal approval has been made through local decision making processes.

5. MEDICINES FOR DISCHARGE

Whichever system for discharge medicines is operated, hospitals should ensure that patients have sufficient medication to take home at discharge which allows the patient enough time to organise a new prescription from their GP.

The transfer of patient care is one of the high risk events in a patient's journey and this should be recognised if a medication is requested following discharge from hospital from a prescriber outside the patient's normal GP practice

UNLICENSED MEDICINES AND MEDICINES OFF-LABEL

Medicines prescribed should preferably be licensed and licensed for the indication for which they are prescribed. Doctors can prescribe unlicensed medicines, or licensed medicines for unlicensed uses (off-label).

However when a prescriber chooses to prescribe a product outside the terms of its license, the product liability passes to the prescriber and they are legally responsible for the medicine and any ensuing consequences. An unlicensed medicine may be prescribed on the basis of an assessment of the individual patient, for medical reasons and it is necessary to do so to meet the specific needs of the patient.

Advice to Prescribers from the MHRA

• Always consider prescribing an alternative licensed medicine within its licensed dose and indications instead of an unlicensed or off-label medicine.

• Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy

• Take responsibility for prescribing the medicine and overseeing the patient's care, including monitoring and follow-up.

• Record the medicine, reason for prescribing and that you discussed the relevant safety and efficacy issues with the patient and received their consent unless it is current practice to use the medicine out with its license.

6. BASIC RULES FOR GENERATING ALL PRESCRIPTIONS

With responsibility for spending large sums of public money, it is essential that the greatest care is taken when a prescription is issued.

Correct, legible, prescriptions with accurate instructions for patients that are for reasonable quantities of medicines mitigate for the dangers of:

• Errors in prescribing

• Waste

• Dangers of overdose

• Accidental poisoning

• Poor compliance

• Habituation and dependence

• Deterioration of medicines due to domestic storage problems

Illegible prescriptions can lead to serious inaccuracies in medicine dosage and instructions creating a risk to patient safety; as well as inappropriate quantities that promote waste. Where the patient is prescribed a drug dependant on a delivery device or piece of equipment e.g. an inhaler device or nebuliser, the patient should be instructed carefully on the use and maintenance of the device. It is important to check that the device continues to be used correctly as inadequate technique can be mistaken for a lack of response to the drug but also lead to generation of waste. The BNF and BNF for children's chapters 'Guidance on Prescribing' provides extensive advice on prescribing. The GMC Good practice in prescribing and managing medicines and devices also adds useful insight.

Prescriptions in any format must only be authorised by suitably qualified medical, dental and non-medical independent (within their areas of competency) and supplementary prescribers (within the scope of an approved clinical management plan).

Ensure prescriptions, whether computer generated or in exceptional circumstance handwritten are legible, indelible, dated, state the name and address of the patient, the address of the prescriber and the type of prescriber.

In addition:

1. Ensure prescriptions are authorised by the prescriber, but only after completion. DO NOT sign blank prescription forms
2. Always complete the age box as a matter of good practice.
3. This is a legal requirement for children under 12 years of age.
4. Ensure that the strength of each item is stated. Avoid unnecessary decimal points e.g. use 300mg NOT 0.3g. Use of the decimal point is acceptable to express a range e.g. 0.5 to1g.
5. Ensure that the quantity to be dispensed is clearly stated
6. Ensure that clear directions are given for each item prescribed. These should be in English without abbreviation. Avoid "as directed" Never abbreviate drug names.
7. Always prescribe generically except where there are bioavailability issues, compound preparations or specific formulations recommended by the British National Formulary (BNF) or in accordance with local formulary.
8. Ensure the term 'units' is used in all contexts and never abbreviated to 'u' or 'iu' Never abbreviate micrograms or nanograms.
9. Avoid adding additional handwritten items to computer generated prescriptions.
10. All alterations and additions must be initialled by the prescriber. However, it is preferable to cancel the incomplete or incorrect prescription and generate a fresh accurate version.
11. Always document prescriptions on the patient's electronic records. [3] Where this is not possible due to the environment of the prescribing, document the prescriptions on a repeat prescription card system. This will help to ensure that unnecessary duplicate repeat prescriptions are avoided and will assist in preventing drug misuse.
12. Ensure that repeat prescriptions are reviewed regularly. This is a key recommendation of the National Service Framework (NSF) for Older People. The NSF states that all people over 75 years should normally have their medicines reviewed at least annually and those taking four or more medicines should have a review 6 monthly. The Quality and Outcomes Framework (QOF) of the GMS contract only requires that a medication review is recorded in the notes in the preceding 15 months for all patients being prescribed repeat medicines.
13. Do not include too many items on one form. The number on computer generated forms need be limited only by the ability of the printer to produce clear and well-demarcated instructions with

sufficient space for each item and a spacer line before each fresh item. Practices may adjust their systems to set a limit on the number of items per prescription form e.g. 3 items

14. Where an urgent prescription has been telephoned to a pharmacy, the FP10 must be with the pharmacist within 72 hours. This is a legal requirement. Controlled Drugs cannot be supplied in this way, except phenobarbital or phenobarbital sodium prescribed for epilepsy.
15. Prescribe within the limits of your professional expertise and competence
16. Do not prescribe for yourself or for anyone with whom you have a close personal or emotional relationship, other than in an emergency.
17. An emergency is when treatment is immediately necessary and no other prescriber is available.
18. Each patient who requires a medicine each MUST have his or her own prescription. This is a legal and contractual requirement

DRUGS NOT AVAILABLE FOR PRESCRIBING ON THE NHS: It is a breach of the Terms of Service for both doctors and pharmacists to prescribe and dispense drugs, medicines and other substances listed in Part XV111A of the Drug Tariff. Such prescriptions are disallowed for payment. The regulatory requirements for general prescriptions are described in The Human Medicines Act 2012

GUIDELINES FOR QUANTITIES TO BE ISSUED

Best practice for prescribing includes quantities to be issued on prescriptions

Acute prescription:

Normally no more than one or two weeks supply for acute conditions, where applicable. For many infections, a short course of only 3-5 days is likely to be appropriate

Repeat prescriptions: would not normally be provided within the scope of this policy

Normally no more than 28 days' supply of medicines for non-acute conditions. 28 day quantities are regarded as best practice pertaining to safe repeat prescribing systems.

The decision to provide a longer quantity has to be balanced against patient need (including financial considerations), safety and the potential for waste.

Pre-payment certificates may help some patients financially and repeat dispensing may offer convenience for patients on regular stable medication. A specific Hormone Replacement Therapy Prepayment Certificate is also available.

Up to 3 months' supply should be met by issuing separate prescriptions for one month at a time.

For the oral contraceptive pill, prescriptions should normally be for 3 to 6 months' supply

Examples of conditions where no more than one month's supply should be prescribed:

- Controlled Drugs
- Psychotropic Drugs

Most Initial Prescriptions Prepayment certificates are the most economical way of paying for prescriptions when more than one regular prescription item is required each month. Prepayment certificates are available at http://www.nhsbsa.nhs.uk/healthcosts/2131.aspx .

7. REPEAT PRESCRIBING AND REPEAT DISPENSING

It is recognised that Repeat Prescribing is unlikely to be undertaken within the scope of this policy but information is included to provide an understanding of the essential links to GP practice prescribing processes and use of Electronic Prescription Service

Repeat Prescribing EPS (Electronic Prescription Service) enables prescribers - such as GPs and practice nurses - to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. This makes the prescribing and dispensing process more efficient and convenient for patients and staff.

The prescriber is responsible for any prescription they authorise for electronic transfer or sign, including repeat prescriptions for medicines initiated by colleagues, and so should make sure that any repeat prescription authorise or sign is safe and appropriate.

Secure procedures must be in place for prescribing with repeats and generating repeat prescriptions.

Ensure that:

- The right patient is issued with the correct prescription
- The correct dose is prescribed, particularly for patients whose dose varies during the course of their treatment
- The patient's condition is monitored, taking account of medicine usage and effects.
- Only staff who are competent to do so prepare repeat prescriptions for authorisation.
- Patients who need further examination or assessment are reviewed by an appropriate health professional.
- Monitoring whether the medicine is still safe and necessary for the patient.

A method of limiting the number of prescriptions the computer will issue without further authorisation should be used. Patients should be given ample warning of when a review will be necessary, to avoid inconvenience. Automatic generation of prescriptions should be avoided

Prescribing with Repeats or Repeat Dispensing

Repeat dispensing is the process by which patients can obtain supplies of their repeat medicines over a defined period of time, without the need to contact their GP practice on each occasion a new supply is required. People with chronic conditions that are likely to remain stable for the duration of the repeatable prescription are most likely to benefit from repeat dispensing services. The decision whether to use a repeat dispensing service is a matter for the prescriber's clinical judgement and mutual agreement between the prescriber, the patient and, ideally, the pharmacist.

Repeat dispensing will not be suitable for all patients, nor is it an overnight 'quick fix' for longstanding supply problems. It requires commitment and support from all those involved to realise all of the potential benefits.

Under the repeat dispensing system, the prescriber produces a master 'repeatable' prescription on a standard FP10 prescription form for the patient's repeat medicines.

The patient nominates the pharmacy to provide the service and presents the repeatable prescription at that pharmacy for dispensing in the usual way.

Medication Review

Medication Review is an important part of repeat prescribing. It is defined as a structured, critical examination of a patient's medicines with the objective of reaching an agreement with the patient about treatment, optimising the impact of medicines, minimising the number of medication-related problems and reducing waste.

At each review it should be confirmed that the patient is taking their medicines as directed and that the medicines are needed, effective and tolerated, especially after a hospital stay or home visit.

Consider poor compliance leading to inadequate therapy or adverse effects. Concordance agreement with the patient is important. If it is identified that a patient is not taking, and has made an informed choice not to take a medicine, it should be removed from the patient's medication list, fully documented and where necessary exception reported. This saves waste and reduces risks related to inappropriate medication administration if patient goes to hospital.

Emergency supplies and Retrospective Prescriptions

No prescription only medicines or appliances should be supplied to a patient without an authorised prescription. However the Human Medicines Regulations 2012 allow exemptions from the Prescription Only requirements for emergency supplies to be made by a person lawfully conducting a retail pharmacy business at the request of either the prescriber or the patient so long as certain qualifying criteria are met – see current version of the BNF.

When making a decision whether to provide an emergency supply or not, the Royal Pharmaceutical Society's guidelines state that the pharmacist should consider the medical consequences of not supplying a medicine in an emergency; and if the pharmacist is unable to make an emergency supply of a medicine the pharmacist should advise the patient how to obtain essential medical care. Retrospective prescriptions will only be issued by the prescriber in an emergency situation at the request of the patient/patient's carer or clinical specialist as described above. Dispensing appliance contractors and pharmacy contractors should not request retrospective prescriptions for items already supplied, that are outside the emergency supply qualifying criteria. Such requests may be refused by the prescriber

8. CONTROLLED DRUGS

Controlled drugs (CDs) are not currently stored or administered within the services provided by MBPCC but prescriptions for any CDs prescribed must comply with legislation and best practice.

Controlled Drug Prescription Requirements

It is unlawful for a practitioner to issue, or a pharmacist to dispense, any prescription for a Schedule 2 or 3 Controlled Drug (except temazepam) unless it meets ALL the required Regulations (see current version of the BNF).

The prescription must include details required as for general prescription writing, but the following are additional legal requirements.

• FORM of Preparation, for example, tablet or capsules

• NAME of preparation

• STRENGTH of Preparation (where necessary)

• DOSE – vague terms such as a prn, mdu, sos, etc., are NOT acceptable as doses. ONE as directed is acceptable.

• TOTAL QUANTITY in both WORDS and FIGURES.

N.B. The number of days' supply is NOT acceptable unless the dose happens to be one daily.

It is strongly recommended by the Department of Health that the quantity of Schedule 2, 3 and 4 Controlled Drugs prescribed should not exceed 30 days' supply. Pharmacists may legally dispense a quantity greater than 30 days. The prescriber will need to be able to justify a supply of more than 30 days on the basis of clinical need and this should be recorded on the patient's notes.

• SIGNED by the PRESCRIBER IN OWN HANDWRITING if written prescription or electronic signature if via EPS.

• The DATE can be stamped or computer generated.

• Prescribers must use FP10 MDA prescriptions to order the supply of Methadone etc. for daily instalments. FP10MDA prescriptions must not be used for single amounts. It must have BOTH the dose AND the instalment amount, the total quantity, the amount of instalments and the intervals to be observed.

From 1 April 2019, Gabapentin and Pregabalin are Schedule 3 controlled drugs under the Misuse of Drugs Regulations 2001, and Class C of the Misuse of Drugs Act 1971. This means that additional requirements are needed on the prescription. For example, the dose must be clearly defined.

PRIVATE PRESCRIPTIONS for schedule 2 and 3 CDs (including temazepam and midazolam) must be written on specially designated forms FP10PCD. The prescription must specify the prescriber's identification number and address.

• A PRESCRIPTION for a controlled drug in schedules 2, 3 or 4 (including temazepam and midazolam) is only valid for 28 days from the date stated thereon.

• No repeats are allowed.

• Pharmacists can amend the prescription if it specifies the total quantity only in words or in figures or if it contains minor typographical errors, as long as they are indelible and clearly attributable to the pharmacist.

All practitioners working with controlled drugs (CDs) must comply, and keep up to date with current legislation. The BNF has a helpful chapter on Controlled Drugs and drug dependence

Safety in prescribing controlled drugs

When prescribing, in anything other than acute emergencies, any recent opioid dose should be confirmed.

If a dose increase is intended, it should be safe for the patient.

Prescribers should ensure that they are familiar with the characteristics of the opioid and follow their local policy.

Any concerns, errors or discrepancies concerning controlled drugs should be reported to the Accountable Officer for Controlled Drugs. Currently the AO for North West is Davina Hassall.

All CD incidents and concerns should be reported via https://www.cdreporting.co.uk

Prescribers must take all reasonable steps to ensure that medicines liable to substance misuse are not being diverted by monitoring the time interval between prescription requests.

National Patient Safety Agency in Rapid Response Report 005 recommends: "When prescribing, dispensing or administering these medicines the healthcare practitioner or their clinical supervisor should:

• Confirm any recent opioid dose, formulation, frequency of administration and any other analgesic medicines prescribed for the patient.

• Ensure where a dose increase is intended, that the calculated dose is safe for the patient.

Check the usual starting dose, frequency of administration, standard dosing increments, symptoms of overdose, and common side effects of that medicine and formulation."

Data relating to the prescribing of Controlled Drugs will be shared by MLCSU for review and to provide assurance that this falls within current legislation and best practice.

9. PRESCRIBING FOR CHILDREN

Children are different from adults in relation to their response to medication. Special care is needed in the neonatal period. Prescribing decisions must take into account the child's age, weight and development stage. For detailed advice, consult the current version of the BNF for Children. Medicines licensed for use in children in the specific age range and for specific disease must always be used if available. However, many drugs are not licensed for use in children. Thus the informed use of unlicensed medicines or of medicines for off-label use is often unavoidable. All such use must be well documented in the patient's medical records. (See Section 8 Unlicensed Medicines and Medicines Off-label.)

Prescriptions for Children The consequences of errors in prescribing can be more serious in children that in adults. A common source of error is the misplacement of decimal points in dose calculations.

Decimal points should be avoided where possible e.g. 500mg not 0.5g; "micrograms", "nanograms" and "units" should not be shortened and strengths of liquids should be clearly stated.

All dose calculations must be double checked to ensure accuracy.

Prescribers must refer to the most current version of the BNF for children for general guidance.

Adverse Drug Reactions in Children

As children may be more susceptible to the toxic effects of some medicines, reporting of adverse reactions, no matter how minor, in children under 18 years, is strongly encouraged through the Yellow Card Scheme even if the black triangle for intensive monitoring has been removed. This includes unlicensed medicines and licensed medicines used off label.

See the most current version of the BNF for children chapter on adverse reactions to drugs. The Yellow Card reporting site can be found at http://yellowcard.mhra.gov.uk/ or yellow cards which are found at the back of the BNF can be sent to FREEPOST YELLOW CARD (no other details required) MHRA 24-hour Freephone advice and information on adverse drug reactions 0800 731 6789

Gillick competence and Fraser Guidelines

The age at which children are ready to take care of, and be responsible for their own medicines varies. Health professionals must assess, with parents and children the appropriate time to make this transition. The courts have determined that children can be legally competent if they have "sufficient understanding and intelligence to enable them to understand fully what is proposed". This concept is known as Gillick Competence . Any assessment of such competency must be fully documented in the patient's medical records. Fraser guidelines apply to contraceptive products only

10. PRESCRIBING IN THE ELDERLY

Elderly patients often receive multiple drugs for co-morbidities. This greatly increases the risk of drug interactions as well as adverse reactions, and may affect compliance. The balance of benefit and harm of some medicines may be altered in the elderly e.g. increased falls risk. Therefore, elderly patients' medicines must be reviewed regularly and medicines which are not of benefit should be stopped.

Non-pharmacological measures, where they may be appropriate, should be considered. In some cases prophylactic drugs are inappropriate if they are likely to complicate existing treatment or introduce unnecessary side effects however elderly patients should not be denied medicines which may help them e.g. anticoagulants, statins, osteoporosis drugs.

11. PRESCRIBING IN PALLIATIVE CARE

Palliative care is the active total care of patients whose disease is not responsive to curative treatment. Careful assessment of symptoms and needs of the patient should be undertaken by a multidisciplinary team. Guidance on prescribing is available in the most current version of the BNF, via hospice teams and in local guidelines. Although drugs can usually be administered by mouth to control the symptoms of advanced cancer, the parenteral route may sometimes be necessary.

Syringe Drivers

Incorrect use of syringe drivers is a common cause of drug errors. Staff using them must be adequately trained and different rate settings should be clearly identified and differentiated. In December 2010, the NPSA issued a Rapid Response Alert stating that ambulatory syringe drivers and pumps used in healthcare should have rate settings in millilitres (ml) to minimise the risk of error.

Prescribers must be aware of the suitability and compatibility of medicines intended for use within syringe drivers. Provided that there is evidence of compatibility, selected injections can be mixed in syringe drivers.

Not all types of medication can be used in subcutaneous infusion. In particular, chlorpromazine, prochlorperazine, and diazepam are contraindicated as they cause skin reactions at the injection site; to a lesser extent cyclizine and levomeprozine also sometimes cause local irritation

12. PRESCRIBING MEDICINES TO PEOPLE WHO LACK CAPACITY TO CONSENT

When patients lack the mental capacity to consent to treatment, medication may still be prescribed and administered to them, provided the principles of the Mental Capacity Act 2005 are followed.

For full details refer to the following source documents:

• The Mental Capacity Act 2005

• The Mental Capacity Act: Code of Practice 2007

In summary:

• The person's capacity to consent to the treatment must be formally assessed according to the process prescribed in Section 2 and 3 of the Mental Capacity Act 2005, and Mental Capacity (Amendment) Act 2019, for which more detailed guidance is provided in Chapter 4 of the Mental Capacity Act Code of Practice (Department of Constitutional Affairs 2007).

• When an adult lacks the mental capacity to give or withhold consent to treatment, no one else can give consent on their behalf other than an attorney under the Lasting Power of Attorney (LPA) or a deputy appointed by the Court of Protection, where the decision is within the scope of their authority.

• If the person lacks capacity to consent, and in the absence of an attorney or deputy with relevant authority, the treatment can still be given, provided it is in the patient's "best interests". The process of determining best interests must be carried out in accordance with Section 4 of the Mental Capacity Act 2005, and Mental Capacity (Amendment) Act 2019, for which more detailed guidance is provided in Chapter 5 of the Mental Capacity Act Code of Practice (DCA 2007).
• The process of assessing capacity and determining best interests must be documented in the clinical records.

• Staff should be aware that the Mental Capacity Act 2005 and Mental Capacity (Amendment) Act 2019 includes provision for adults, who have the capacity to do so, to make advance decisions to refuse specified treatment for a time in the future when they lack capacity to consent to it. Provided it can be established that an advance decision is valid and applicable, it has the same effect as a decision made by a person with capacity, and healthcare professionals must respect this decision. Further guidance on this is available in Chapter 9 of the Mental Capacity Act Code of Practice and in the best practice guidance "Advance Decisions to Refuse Treatment: A Guide for the Health and Social Care Professionals" (NHS End of Life Care Programme & the National Council for Palliative Care 2008).

The GMC consent guidance summarises 'Making decisions when a patient lacks capacity' as follows: In making decisions about the treatment and care of patients who lack capacity, you must:

a. make the care of your patient your first concern

b. treat patients as individuals and respect their dignity

c. support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care.

d. Treat patients with respect and not discriminate against them.

You must also consider:

a. whether the patient's lack of capacity is temporary or permanent

b. which options for treatment would provide overall clinical benefit for the patient

c. which option, including the option not to treat, would be least restrictive of the patient's future choices

d. any evidence of the patient's previously expressed preferences, such as an advance statement or decision

e. the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, (holders of lasting powers of attorney and court-appointed deputies) or has been appointed to represent them (Independent Mental Capacity Advocates)

f. the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient's best interests

g. What you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values.

13. PRESCRIBING NEW DRUGS and VACCINES - BLACK TRIANGLE DRUGS

New drugs are intensively monitored to ensure that any new safety hazards are identified promptly. The Commission on Human Medicines (CHM) and the MHRA encourages the reporting of all suspected reactions to newer drugs and vaccines (including those to be considered not serious), which are denoted by an inverted Black Triangle symbol (▼).

This symbol appears next to the name of a relevant product in the BNF, BNF for Children, MIMs, ABPI advertising material and the MHRA Drug Safety Updates. The list of these drugs is updated monthly on the MHRA website. Reporting of adverse reactions is done using the Yellow Card Scheme. Report forms can be found in the BNF, MIMs or online. These drugs should be used with caution and alternative drugs with a more established safety profile should be considered first line.

For new drugs (denoted by ▼) ALL adverse reactions should be reported. For established drugs and vaccines (including over-the-counter and herbal medicines), report all suspected adverse reactions that you consider to be SERIOUS. They should be reported even if the effect is well recognised.

14. PRESCRIBING OF HIGH RISK MEDICINES

Prescribing of Insulin

Errors in the administration of insulin are common. To address this, the National Patient Safety Agency (NPSA) has produced two patient safety alerts:

1. NPSA/2010/RRR013 all regular and single insulin (bolus) doses should be measured and administered using an insulin syringe or commercial insulin pen device. Intravenous syringes must never be used for insulin administration. The term 'units' should used in all contexts. Abbreviations, such as 'U' or 'IU' must never be used.

Prescribing Of Low Molecular Weight Heparin (LMWH)

The dose of LMWH depends on the patient's current weight, renal function and its clinical indication. Overdosing increase the risk of bleeding and under dosing increases the risk of a further thromboembolic event see NPSA (NPSA/2010/RRR014)

The prescribing of LMWH in primary care should comply within the Shared Care Guidelines

Available at low-molecular-weigh-heparins-summary-prescribing-guide-version-14.pdf (lancsmmg.nhs.uk)

Prescribing of Lithium

Some patients taking lithium have been harmed because they have not had their dosage adjusted based on recommended regular blood tests. If patients are not informed of the known side effects or symptoms of toxicity, they cannot manage their lithium therapy safely. Regular blood tests are important, linked to adjust of dose as necessary. Clinically significant alterations in lithium blood levels occur with commonly prescribed and over-the counter medicines. The blood level of lithium is dependent on kidney function and lithium has the potential to interfere with kidney (renal) and thyroid functions.

Prescribers and community pharmacists should that blood tests have been monitored regularly and that it is safe to issue a prescription.

Prescribing of Methotrexate

Oral methotrexate is a safe and effective medication if taken at the right dose and with appropriate monitoring. However, very occasionally problems with taking the medication can cause serious harm and even death. Two thirds of all incidents result from the wrong dose being prescribed and a fifth are linked to poor monitoring. Extreme caution should be shown if a request to prescribe Methotrexate is made out with the normal GP Practice systems and evidence of recent monitoring should be sought.

Prescribing of Warfarin

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harms and admissions to hospitals. Managing the risks associated with anticoagulants can reduce the chance of patients being harmed in the future. The NPSA issued a Safety Alert NPSA/2007/17 and gave advice to GPs but if requests for warfarin to be prescribed are received, and evidence of recent monitoring and dosing should be sought

15. PRIVATE PRESCRIBING

The 2009 department of health document 'Guidance on NHS patients who wish to pay for additional private care' and the NHS constitution define situations in which patients can access additional private care alongside their NHS care. In summary, any additional private care must be delivered separately from NHS care (with some exceptions – see 'Guidance on NHS patients who wish to pay for additional private care') but can be delivered alongside NHS care. Patients also have the choice of switching from private care to NHS care at any time during their treatment.

Private Prescriptions for NHS Patients

GPs should provide their NHS patients with any medication available to NHS patients deemed clinically appropriate on an NHS FP10 prescription. GPs may not issue private prescriptions alongside or as an alternative to FP10s. However, GPs may write private prescriptions for patients for drugs not available through the Drug Tariff. However, GPs may not charge their registered patients for providing such a prescription. The only occasions when a doctor may charge for a private prescription are:

1. For drugs which are being issued solely in anticipation of the onset of an ailment while outside the UK, but for which the patient does not require treatment when the medicine is prescribed.

2. For drugs issued for the prevention of malaria.

16. TRAVEL ABROAD

Under NHS legislation, the NHS ceases to have responsibility for people when they leave the UK. However, to ensure good patient care the following guidance is offered.

Everyone should also obtain adequate holiday insurance cover. GPs are not responsible for prescribing items required for conditions which may arise while travelling e.g. travel sickness and diarrhoea. Patients should be advised to purchase these items locally prior to travel. Advice is available from community pharmacists if required. For conditions unresponsive to self-medication the patient should normally seek medical attention abroad.

To ensure continuity of care for patients on a stable medication regime, it is reasonable to provide a routine repeat prescription (usually one and no more than three months), to enable the patient to find a doctor who can continue their care in the country to which they are travelling.

GPs could be in breach of the Terms of Service if they issue an NHS prescription to cover an extended absence from the country (after three months, a patient would have to re-register as their name should be removed from their list).

The NHS normally will not pay for any treatment or services for patients no longer resident in the UK. This includes people who are in receipt of UK state retirement pension. Where a patient requires a prescription for larger supplies of his/her medication because of a longer stay abroad, the patient can be given a private prescription to cover the additional period of absence; however the Doctor is clinically responsible for prescribing, and for longer periods this may be clinically inappropriate, as they are not able to monitor and care for patients.

17. VITAMINS, MINERALS, SUPPLEMENTS, HERBAL AND HOMEOPATHIC MEDICINES WITHOUT A PRODUCT LICENCE

Most food supplements (such as herbal medicines, various vitamins and minerals) do not have a product licence (UK marketing authorisation). Products that do not have a product licence have not undergone the strict criteria laid down by the regulatory authorities to confirm the safety, quality and efficacy of these products. They are often not manufactured to the same high pharmaceutical standards used for licensed medicines to ensure consistency in formulation and potency. Patients may purchase these medicines to take as a complementary form of therapy, but should in all cases discuss the use of them with their GP or pharmacist but they must not be prescribed on FP10.

18. PRESCRIBING FOR MINOR AILMENTS

Lancashire and South Cumbria ICB will not routinely fund the prescribing of medicines and treatments for minor or short-term conditions where:

- self-care is the most appropriate route
- medicines and treatments are available to buy over the counter

Prescribers should direct any requests for medication to treat minor ailments to a community pharmacy.
LSCICB Advice on self-care available at https://www.lancashireandsouthcumbria.icb.nhs.uk/our-work/your-local-services/self-care

19. DOCTORS PRESCRIBING FOR THEMSELVES OR THEIR FAMILIES

Doctors (or any other prescribers) should not prescribe for themselves or their family. Prescribers must not treat themselves or family members other than in an emergency, or other exceptional circumstances which should be fully documented.

GMC Good practice in prescribing and managing medicines and devices provides further useful advice

20. PRESCRIBING FOR VISITORS FROM OVERSEAS

The National Health Service (Charges to Overseas Visitors) Regulations 2015 (the Charging Regulations) came into force on 6th April 2015 and were subsequently amended from 1st February 2016 [39].

In summary: The following services are free at the point of use for all patients:

A charge cannot be made or recovered from any overseas visitor for:

1. Accident and emergency (A&E) services, this includes all A&E services provided at an NHS hospital, e.g. those provided at an accident & emergency department, walk-in centre or urgent healthcare centre. This does not include those emergency services provided after the overseas visitor has been accepted as an inpatient, or at a follow-up outpatient appointment, for which charges must be levied unless the overseas visitor is exempt from charge in their own right;

2. Services provided outside an NHS hospital, unless the staff providing the services are employed by, or working under the direction of, an NHS hospital;

3. Family planning services (does not include termination of pregnancy);

4. Diagnosis and treatment of specified infectious diseases;

5. Diagnosis and treatment of sexually transmitted infections;

6. Treatment required for a physical or mental condition caused by:

a. torture;

b. female genital mutilation;

c. domestic violence;

d. sexual violence,

Except where the overseas visitor has travelled to the UK for the purpose of seeking that treatment. The following categories of overseas visitor are exempt from charge:

1. Those who have paid the health surcharge or are covered by transitional arrangements;

2. Vulnerable patients and those detained;

3. UK Government employees and war pensioners;

4. Those covered by reciprocal healthcare agreements, other international obligations and employees on UK-registered ships. Full details of those that are eligible to receive treatment or liable to pay for it can be found via the following: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/496951/Overseas_visitor_hospital_charging_accs.pdf

BMA Guidance at https://www.bma.org.uk/advice-and-support/ethics/refugees-overseas-visitors-and-vulnerable-migrants/access-to-healthcare-for-overseas-visitors

21. SECURITY OF PRESCRIPTION FORMS AND CONTROLLED STATIONERY

Background With several million blank prescriptions in circulation the potential for theft is a real possibility. The councils of the British Medical Association and the Royal Pharmaceutical Society have issued a joint statement on the security and validity of prescriptions. In particular prescriptions should:

• Not be left unattended at reception desks;

• Not be left in a car where they may be visible;

• When not in use, be kept in a locked drawer within the surgery and at home

General Advice

Organisations should maintain clear and unambiguous records on prescription stationery and stock received and distributed preferably using a computer system to aid reconciliation and audit FP10s or the equivalent non-medical prescribers FP10 forms e.g. FP10 CN should only be held by registered qualified / accredited practitioners who have been issued with them, and who are responsible for their security.

Stock order forms, requisition books (stock or non-stock) or prescription cards must also be treated as controlled stationery and kept in a secure area when not in use i.e. in a locked cupboard / drawer within a locked room. Doctors stamps should be kept in a separate, equally secure location to prescription forms.

It is important to record delivered and stored prescription stock. Deliveries should be thoroughly checked against the order and delivery note and only be signed for if the packaging is sealed and unbroken Recording requirements for prescription forms and other medicine order forms should include:

• Date of delivery

• Name of person accepting delivery

• Number of forms received (and serial numbers if applicable)

• Storage site

• Date of issue

• Name & signature of person to whom it was issued

• Name & signature of person issuing

• Number issued

• Serial numbers of forms issued if applicable

• Details of the prescriber

Records of serial numbers received and issued should be retained for at least three years.

Storage of Prescription forms

• Minimal stocks should be kept to reduce theft potential and keep stocks up to date.

• Prescribers are responsible for any forms they have and they should be locked away when not in use.

• Prescribers should ensure that forms are never left unattended and unauthorised staff or patients should never be allowed into secure areas where forms are stored.

• Supplies of forms should never be left in e.g. care homes for GP or locum visits.

• The prescription pad must only be produced when needed and must never be left unattended. When out visiting, prescribers must keep prescription pads with them out of sight; they must never be left in the car.

Use of Prescription Forms

• Prescribers should keep records of the first and last serial numbers of prescription forms issued to them, plus the number of the first remaining form on the current pad at the end of each session or day.

• Completed prescriptions should be locked away until issued to the patient and security checks put in place to ensure the form is being issued to the patient or an authorised person on their behalf.

• Computerised prescription forms should also be kept secure in printers in a locked room and patients should not be left unattended where they are in use. When ordering new printers consideration should be given to ordering a tray to secure the forms or locating the printer in a secure part of the building.

• Blank prescription should never be pre-signed

• Duplicate prescriptions should be securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate records kept

• Spoiled in error prescriptions should be securely destroyed as above.

• Personalised forms which are no longer in use should be securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate records kept. The person who destroys the forms should make a record of the serial number of the forms destroyed. Best practice would be to retain these prescription forms for local auditing purposes for a short period prior to destruction. The destruction of the forms should be witnessed by another member of staff. Records of forms destroyed should be kept for at least 18 months.

• All personalised unused prescription forms relating to these prescribers should be recovered and securely destroyed (e.g. by shredding) before being put into confidential waste, with appropriate records kept. The person who destroys the forms should make a record of the serial number of the forms destroyed. The person responsible for the recovery and destruction of forms should be in a position of suitable seniority. The destruction of the forms should be witnessed by another member of staff. Records of forms destroyed should be kept for at least 18 months.

Action in case of Lost or Stolen Prescription Forms

If missing prescriptions forms cannot be accounted for, the matter should be reported to the designated person with overall responsibility for prescription forms at MLCSU, the accountable officer for CDs and the police as required.

Medication Incidents

A medication incident is defined as - “A medication related incident or event which actually resulted in or had the potential for a detrimental consequence to a patient. Such events may be related to professional practice, healthcare products, procedures and systems including: prescribing; order communication; product labelling; packaging and product names; compounding; dispensing; distribution; administration; education; monitoring; and use.”

The reporting of medication incidents is somewhat unique since we are not only looking to identify those events which cause harm to patients, but equally those 'near-miss' events in order to maximise learning and reduce harm.

Medication incidents do not include unforeseen adverse drug reactions that could not have been predicted or prevented. These should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA) via the 'Yellow Card' scheme.

Any medication incident will be reported to MBPCC in line with the Incident Management policy and using form IR1 available on the intranet.

The primary purpose of any incident report is for learning and as a means to improve patient safety. Enough information is needed to describe patient demographics, the medicine(s) name, medicine process, staff involved, a short description of what happened, the underlying causes and whether the incident caused actual harm and the level of resulting harm.

All medication error reports will be collated and reviewed by MBPCC Medical Director, Dr Chris Coldwell, who has responsibility to oversee medication error incident reporting and learning as per MBPCC Incident Investigation and Management Policy.

All medicines incidents will be reported to MBCCG Quality and Safety Team for attention of MBCCG Medicines Safety Officer via mbccg.qst@nhs.net.

Safety and MHRA alerts

All Safety and MHRA alerts will be received and actioned as per MBPCC Alerts Cascade Policy.

Equality Impact Assessment & Statement

All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on race equality. This obligation has been increased to include equality and human rights with regard to disability, age, gender, sexual orientation, gender reassignment and religion.

MBPCC endeavours to challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

All staff are expected to deliver services and provide care in a manner which respects the individuality of patients and their Carer's and as such treat them and members of the workforce respectfully, regardless of age, gender, race, ethnicity, religion/belief, disability and sexual orientation.

Within Lancashire and South Cumbria ICB Providers and Commissioners are expected to use the appropriate interpreting, translating or preferred method of communication for those who have language and/or other communication needs. Practitioners will ensure that the Prescribing policy, in its application, is fair and equitable for all groups covered under the Equality Act 2010 and that they are implementing the Accessible Information Standard.

Any change to a service will require a conscious effort from the author(s) of that change to actively consider the impact that this will have on any Protected group(s) and act due diligently. Where an impact on any of the Equality groups is realised after the implementation of the Project/Service, the

commissioners and or Providers, who are implementing the said Project and or service will seek to minimise such an impact and simultaneously carry out a full review.

Acknowledgements to:

NHS Blackburn with Darwen

NHS East Lancashire

NHS North Lancashire (now NHS Morecambe Bay)

NHS Derby City

NHS Derbyshire County

LMMG

22. DEFINITIONS/GLOSSARY OF TERMS

Abbreviation or Term	Definition
MBPCC	Morecambe Bay Primary Care Collaborative
MCA	Mental Capacity Act
CQC	Care Quality Commission
LSCICB	Lancashire and South Cumbria Integrated Care Board
LPA	Lasting Power of Attorney
EPA	Enduring Power of Attorney
ADRT	Advance decision to refuse treatment
IMCA	Independent mental capacity advocate
DoLS	Deprivation of liberty safeguards
RPR	Relevant persons representative
LA	Local Authority
COP	Court of Protection
CSU	Commissioning Support Unit
CAD	Court Appointed Deputy

23. CONSULTATION WITH STAFF, PRACTICES AND PATIENTS

Name	Job Title	Date Consulted
Graham Atkinson (Ash Trees Practice Manager)	Practice Manager	14th June 2021
Dr Arun Thimmiah (Partner, Abbey Road)	GP	11th June 2021
	GP	14th June 2021

Dr Chris Coldwell (Partner, Abbey Road) Faye Prescott	Head of Medicine Management (MBCCG)	15th July 2021

24. DISSEMINATION/TRAINING PLAN

Action by	Action Required	Implementation Date
Tom Whitaker	Upload policy to MBPCC website	Following approval of V0.1 end June 2021
Tom Whitaker	Host current copy on Federation G Drive (supporting induction process), updating Policy tracker	Following approval of V0.1 end June 2021
Andrew Giles	Ensure all employees are aware of the policy and are asked to read and understand	MBPCC Board Meeting June 2021
Liz Stedman	Upload to TeamNet	July 2021
Andrew Giles	Ensure all employees are aware of the revised policy and are asked to read and understand	MBPCC Board Meeting Sept 2021

25. AMENDMENT HISTORY

Version No.	Date of Issue	Section/Page changed	Description of change	Review Date
V0.1	11/06/2021	All	New policy -created	14/06/2021
V1.0	14/06/21	Throughout document	Minor alterations based on consultation. Final Policy v1.0 for approval	15/06/2023
V1.1	20/08/21	(Controlled drugs, reporting of incidents, Alerts process, missing dates added)	Revisions based on CCG SME input	15/09/2023
V2.0	July 2023	Throughout document	Update to include LSCICB, Update of website links,	15/09/2025

			Update of guidance and best practice	