NHS
Coventry and Warwickshire
Integrated Care Board

Commissioning for Integrated Medicines Management (CIMM) Policy

Reference Number:	This will be applied to all new ICB-wide PPSs by the Governance and Corporate Affairs Team and will be retained throughout its life span.
Version:	Version 1.0
Name of responsible Committee and date approved or recommended to Integrated Care Board Board:	Audit Committee
Date approved by the Integrated Care Board (if applicable):	1 July 2022
Next Review Date:	1 April 2024
Expiry Date:	1 October 2024
Name of author and title:	Altaz Dhanani, ICB
Name of reviewer and title:	Angela Brady, Chief Medical Officer, ICB
Department:	Corporate Office

VERSION HISTORY

Date	Version	Changes made to previous version	Consulting and Endorsing Stakeholders, Committees / Meetings / Forums etc.

1. Coventry & Warwickshire Area Prescribing Committee (APC)

1.1 The role of the APC is to provide strategic leadership and advice, and to monitor resulting outcomes, on the safe, effective, and efficient management of medicines across organisational interfaces, taking into account the impact on the entire health community of Coventry and Warwickshire and its stakeholders.

1.2 The Trust will ensure appropriate representation on the APC, in line with the Terms of Reference.

1.3 The Trust will ensure the dissemination of APC decisions to all clinicians and other relevant staff across the Trust where appropriate.

1.4 The Trust will support the APC through review processes as and when these occur to ensure that the function of the committee remains relevant to current needs.

1.5 The Trust's clinicians will use current APC guidance (supported by Trust Drugs and Therapeutics Committee (DTC) decisions) to inform routine prescribing decisions. New medicinal product(s), new indication(s) or new formulation(s) of existing formulary medicines will require initial consideration by the trust DTC prior to consideration at APC for formulary inclusion.

1.6 The APC has responsibility for development and review of the Coventry & Warwickshire Area Prescribing Committee Net Formulary which considers;

- Preferred, second line and non-formulary (qualified) choices.
- Designates specialist drugs as "Specialist Only" (SO), "Shared Care" (SC), "Specialist Initiated" (SI) or "Specialist Advised" (SA).
- Liquid preparations.
- Generic vs Branded medicines.
- National QIPP indicators.

1.7 Further information Available at

:- https://www.covwarkformulary.nhs.uk/default.asp?siteType=Full

2. Prescribing Principles for Trust Clinicians

2.1 Trusts should ensure that any new drugs are approved for routine use through the Trust Drugs and Therapeutics Committee. Where there is an impact on the commissioner or primary care these should also be reviewed and recommended for use by the Area Prescribing Committee for interface drugs or the ICBs/ NHS England for Tariff-excluded drugs.

2.2 Providers wishing to use new drugs or devices, including for new indications as well as use outside their licensed indications during the financial year, will be expected to follow the below steps:

1. In tariff: Trust decision and internal decision-making process to approve and self-fund, via D&T committee
2. Tariff excluded drugs: Discuss with commissioner to scope feasibility as per section 4.
3. NICE TA's or similar national mandates as per section 5

4. In year APC decisions which may create a cost pressure to the Trust. Since the APC makes the clinical decision, the financial decision would require a discussion and agreement between providers and commissioners.

2.3 Trust clinicians will not ask GPs to prescribe drugs that are designated "specialist only" on the APC Net Formulary.

2.4 Trust clinicians will not request that GPs prescribe drugs for use outside their licensed indications ("off-label") unless there is established practice or a substantial body of evidence to support it. Similarly, GPs will not initiate drugs for use outside their licensed indications ("off-label"), unless there is established practice or a substantial body of evidence to support it. The drug status can be found on the APC net formulary.

2.6 Approved generic names will be used except where there is good evidence to show that preparations for a named drug are not interchangeable and for those agents where it is clinically necessary to indicate the brand prescribed for therapeutic or safety reasons as per formulary recommendations, e.g., tacrolimus should always be prescribed by brand to prevent medication errors. For further information see: https://www.sps.nhs.uk/articles/which-medicines-should-be-considered-for-brand-name-prescribing-in-primary-care/.

2.7 Clinicians will aim to recommend a net formulary choice of drug

2.8 Trust clinicians will not routinely ask GPs to prescribe drugs that are not recommended by the APC. (For new drugs see section 2.1). Where drugs are APC-recommended, GPs should continue treatment initiated in secondary care as per APC guidance (unless designated "specialist only") and will not routinely initiate drugs which are not recommended by the APC.

2.9 When a GP has refused to continue treatment deemed appropriate for GPs to prescribe as per the APC, the specialist will continue to have prescribing responsibility if no alternative treatment can be found. The ICB will incur the reasonable costs of providing the drug using

appropriate invoicing procedures. The Trust will be expected to report the number of GP refusals and submit this information to the APC; this will allow the ICB Medicines Optimisation team to investigate any issues with the GPs who have refused to prescribe.

2.10 Trust clinicians will prescribe licensed products whenever clinically appropriate - the prescribing of “special” formulations should only be considered when suitable alternative licensed options are not available.

2.11 The Trust will support a joint primary/secondary care approach to a Coventry and Warwickshire Formulary through attendance at relevant committee meetings as well as upholding internal processes.

2.12 Trust clinicians will use the current Coventry and Warwickshire APC Net Formulary to inform routine prescribing decisions in the therapy areas covered by the formulary. It is acknowledged that there will be instances when prescribing outside of the Coventry and Warwickshire APC Formulary will be both necessary and appropriate within secondary care.

2.13 Novel or uncertain treatments that clinicians consider necessary for the treatment of patients should be managed through provider’s internal governance processes e.g., Drugs and Therapeutics Committees and research governance systems and should be funded from within existing provider income streams rather than through Individual Funding Requests (IFRs).

It should be noted that such service development reviews may take a considerable period of time; in the interim, patients for whom such treatments are judged clinically appropriate by their consultant should be managed and funded by the provider.

2.14 The provider should recognise the importance of a system wide approach to antimicrobial stewardship in line with NICE NG15: Antimicrobial Stewardship and ensure that all prescribers receive induction and training in prudent antimicrobial use and are familiar with the antimicrobial resistance and stewardship competencies.

2.15 The Trust will always act in accordance with any specific commissioning policies that are in place. Such policies should be informed by Specialist engagement. If the Trust believes that any policy contravenes professional guidance this should be discussed with the relevant commissioner.

2.16 The Trust will support the national and local drive to reduce prescribing of Over the Counter (OTC) Medication.

These prescriptions include items for a condition:

- That is considered to be self-limiting and so does not need treatment as it will heal or be cured of its own accord;
- Which lends itself to self-care i.e., the person suffering does not normally need to seek medical advice and can manage the condition by purchasing OTC items directly.

These prescriptions also include other common items:

- That can be purchased over the counter, sometimes at a lower cost than that which would be incurred by the NHS;

- For which there is little evidence of clinical effectiveness also known as low value medicines (LVM).

See the ICB website for policies regarding OTC and low value medicine prescribing.

3. Effective Shared Care Agreements (ESCAs)

3.1 Drugs are defined as “specialist” by the APC. Drugs are categorised as “specialist only”, “shared care”, “specialist advised”. “specialist initiated” or “specialist initiated with SIDCs (specialist-initiated drug checklist).

3.2 Effective shared care agreements (ESCAs) are used to ensure seamless care when transferring patients from specialist to general practitioner care and to ensure that there is a clear definition of responsibility for the patient.

3.3 The use of ESCAs allows GPs to prescribe appropriate specialist drugs with specialist support and have confidence that the practice is safe and effective. Coventry and Warwickshire ICB will actively support the use of ESCAs in primary care.

3.4 ESCAs should be produced / adapted by clinical specialists (primary and secondary care) and agreed at the APC, where there is representation from both providers and ICBs.

3.5 Trust clinicians will request that GPs participate in shared care using the agreed APC process and documentation. A general practitioner has the right to refuse to enter into shared care, **but to refuse on the grounds of drug cost alone is unacceptable.** When a GP has refused to enter into shared care, the specialist will continue to have prescribing responsibility. Coventry and Warwickshire ICB will incur the cost of providing the drug using appropriate invoicing procedures. The Trust (in conjunction with the ICB) will be expected to audit the number of GP refusals and report this information to the APC; this will allow the Coventry and Warwickshire ICBs’ medicines optimisation team to investigate any issues with the GPs who have refused to prescribe.

4. Managed Entry of New & High-Cost Drugs

4.1 All existing and new drugs and technologies should be provided within the scope of the National Tariff unless explicitly excluded through the National Tariff 2021-22 exclusions list e.g. excluded high cost drugs or as part of excluded services.

4.2 Coventry and Warwickshire ICB will only fund High-Cost Drugs excluded from the National Tariff which are listed as “funded” on the Coventry and Warwickshire Acute Drug Status List (ADSL). Drugs (including indications) not listed on the ADSL are considered within tariff unless funding has been agreed by commissioner.

Drugs and devices specifically excluded from the National Tariff will not automatically be funded by Commissioners.

4.3 The ADSL reflects Payment by Results high-cost drug and service exclusions, NICE technology appraisals and local arrangements. It will be updated monthly in line with agreed processes.

4.4 Drugs listed as “not funded” on the ADSL will only be paid for if approval via Individual Funding Request can be demonstrated. See the ICB website for policies regarding individual funding requests and experimental and unproven treatments.

4.5 Trust clinicians must not prescribe new high-cost drugs or existing high-cost drugs for indications not listed as funded on the Acute Drug Status List unless the use has been approved by the commissioner(s).

4.6 High-cost drugs specifically excluded from the National Tariff will not automatically be funded by commissioners, unless recommended by a NICE technology appraisal guidance (TAG). For drugs recommended by a NICE TAG these will only be commissioned in line with the specific NICE criteria. The routine use of new high-cost drugs or existing high-cost drugs for indications not listed on the ADSL will be considered by the commissioners following consideration via the due process.

4.7 New tariff excluded drugs which are not specified within contracts or approved by NICE technology assessment will be automatically considered as low priority for funding unless they are cost-saving or cost-neutral. See the ICB website for policies regarding in year service developments. If however, the provider feels that there is a compelling patient safety, effectiveness or critical need then such drugs would need to be discussed on a case-by-case basis with the commissioner and considered via due process.

4.8 Coventry and Warwickshire ICB must be assured that high-cost drugs are being initiated and monitored appropriately to ensure payment. The type of assurance required will be specified on the ADSL and regular audit will be undertaken by the ICB. Assurance may include use of the Blueteq system via prior approval proforma requests.

4.9 Coventry and Warwickshire ICB requires providers to utilise the high-cost drug with lowest acquisition cost that is appropriate for the patient’s condition and in keeping with locally agreed pathways related to tariff excluded drugs.

4.10 Providers are expected to proactively engage and support the ICB with Horizon Scanning, including the identification of more affordable treatments e.g., biosimilars.

4.11 Coventry and Warwickshire ICB may request providers to undertake post payment verification audits to assess whether high-cost drugs are being used in accordance with agreed criteria/service. The ICB will agree with providers, local arrangements for payments, if a proportion of the sample audited do not meet the Commissioner’s criteria for funding the treatment.

4.12 The Trust should ensure that clinicians are aware of the processes for formulary application to the Trust’s Drug and Therapeutics Committee. Clinicians should also be made aware how to refer a drug for discussion at the Area Prescribing Committee.

4.13 The Trust should ensure that clinicians are aware of the processes for applying for Individual Funding Requests and service developments for drugs not routinely commissioned.

5. NICE

5.1 The Trust is expected to conform where appropriate to NICE guidance. Commissioners are committed to meeting their statutory obligations of funding drugs approved in NICE TAGs within

6. Cost saving Schemes

6.1 Proposals for cost saving schemes should be collaboratively discussed and agreed between commissioner and provider medicines optimisation, finance and contracting teams as opportunities arise. Resourcing requirements to deliver cost savings may be considered before implementation.

7. Prices for Drugs and associated administration costs

7.1 NICE-approved drugs which rely on a patient access scheme (PAS) to ensure cost-effectiveness will only be funded if the ICB has evidence that the PAS has been correctly applied.

7.2 The ICB will only pay the actual cost incurred by the provider. Any associated costs need to be agreed with the ICB in advance.

three months of publication or sooner where specified by the NICE TAG. Trusts are responsible for implementation of the guidance.

5.2 When positive NICE TAGs are published a new clinical pathway must be agreed (which includes NICE starting and stopping criteria) so that commissioners can understand the implications of the new guidance. Anticipated activity levels and financial impact should be calculated. Providers should aim to complete this work during the three-month period after a positive NICE TAG. The impact of drugs with positive NICE appraisal will not be realised until this time, unless specifically agreed.

5.3 Coventry and Warwickshire ICB must be assured that eligibility criteria for NICE-approved drugs is correctly applied, adhered to and monitored for payment to be made. Assurance may be achieved by completion of prior approval proforma requests or regular audit. The type of assurance will be specified on the Acute Drug Status List.

7.3 The ADSL will be updated every month to reflect NICE TAGs and local agreements.

7.4 NICE Clinical Guidelines are guidelines by definition and, as such, commissioners will not routinely fund recommendations from such guidelines. Information pertaining to supporting evidence and change in pathway is required for consideration by the commissioners' due process. This requirement also applies to guidance/recommendations issued by other national committees or professional bodies e.g., Regional Medicines Optimisation Committee.

8. Medicines Brought into Hospital & Self-Administration

8.1 The Trust will have systems and procedures in place to maximise the appropriate use of "patients' own drugs" (PODs). These procedures should ensure that inappropriate destruction of such medicines is minimised. Coventry and Warwickshire ICB will encourage GP practices to support the use of PODs in hospital. This agreement is in place to reduce duplicate dispensing of medicines between patients' homes and hospitals, which minimises wastage and supports patients in their understanding of any changes to their medicines that needs to be continued after discharge.

8.2 The Trust will have a policy of supporting self-administration of medication (SAM) wherever possible and safe to do so.

8.3 The Trust will work with primary care to improve communication and develop processes to aspire towards having a medicines reconciliation service which is available on admission as per NICE NG5 and QS120.

8.4 Providers should have systems to identify prescribing or dispensing errors from the community and report these in line with relevant incident reporting systems.

9. Medicines Prescribed and / or Supplied by the Trust

9.1 Medicines Handling & Assessment:

- The provider should be fully compliant with/be working towards the requirements and standards outlined in accordance with NICE;
    - NG5 Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes and the NICE Quality Statement, 'Medicines optimisation' [QS120].
    - NICE CG76: Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence.
    - NICE MPG2: Patient Group Directions.

9.2 The Trust will ensure that patients being discharged from their care have sufficient information to use their medicines safely and effectively. The Trust must commit to improving the post-discharge support for patients by facilitating early medicine reconciliation (in line with NICE QS 120) thereby reducing re-admissions / emergency department attendances and reduce errors on medication prescribed and supplied in the community following changes instigated in hospital.

9.3 The Trust will work towards GPs being informed of discharge information in relation to any new medicines started, doses adjusted, and medicines stopped – reasons should be given for any change. The discharge information should also state whether drugs should be continued long term or state duration of treatment and provide the contact information of the prescriber (including printed name), consultant team and ward (in line with NICE NG5).

9.4 Inpatients & Day case

The provider will ensure the Service User is discharged with at least 7 days of medication. For Coventry and Warwickshire ICB, the local agreement is 28 days of medication supply, except when the Service User already has an adequate quantity and/or will receive an adequate supply via an existing repeat prescription from the Service User's GP or other primary care provider*.

In relation to provision of medication to day case patients, there will be no expectation to provide a supply of any routine medication that the patient was taking prior to admission to hospital.

The Trust should dispense in original manufacturer's packs whenever possible and supply a patient information leaflet (PIL).

** Exceptions to the supply quantity include treatment courses (antibiotics, steroids), "when required" medicines and those which are likely to change dose or be stopped (e.g. ace-inhibitors, laxatives, anti-emetics, etc.) In addition, due consideration should be given to provision of Controlled Drugs in patients with no prior history (should be reviewed after 2 weeks) and in patients with blister packs, since these may be subject to change.*

9.5 Outpatients

The provider will only supply medication where there is an **immediate and urgent clinical need, or the medication is designated as specialist only**. In such instances, at least 7 days of medication will be supplied. For Coventry and Warwickshire ICB, the local practice is 28 days of medication to be provided or adequate starter pack/ duration of treatment course. For all other by definition, routine, or non-urgent supplies, these should be communicated to the patients GP via a clinical clinic letter or appropriate electronic approved template. Patients will be informed of the non-urgent nature allowing the GP practice time to reconcile the appointment outcomes.

10. Discharge Medicines Service

10.1 When patients in hospital are identified as needing extra support with their medicines, they are referred through a safe and secure digital platform when they are discharged, for advice from their local community pharmacist.

10.2 This is an IPMO ICS work stream. Resource, reporting and sustainability will be accountable to the IPMO board.

11. Monitored Dosage System (MDS)

11.1 Where patients being discharged usually receive their medicines in a multidose-compartment aid, including but not limited to blister packs, the provider should liaise with the community pharmacy to organise for provision of discharge medication in the patient's usual multidose-compartment aid. Or alternatively seek prior agreement with patient, family, or carers towards a suitable/alternate plan.

12. Incidents Involving Medicines

12.1 The Provider has a standard operating procedure (or equivalent) for the reporting and severity classification of incidents involving medicines, which includes the sharing of learning in order to prevent recurrence.

12.2 Medication-related patient safety incidents are monitored, reported and actions taken where necessary.

13. Clinical Trials

See also see to section 2, reference to unlicensed, novel and uncertain treatments.

13.1 Please refer to the Coventry and Warwickshire ICB website with regards to policies relating to;

- Ongoing access to treatment following ICB funded trial.
- Ongoing access to treatment following industry trial.
- Ongoing access to treatment following non-commercial trial.
- Ongoing access to treatment following trial not sanctioned.

14. Private Patients and Patients Changing Commissioner

14.1 Please refer to the ICB website and APC website for policies regarding:

- Defining the boundaries between NHS and private healthcare
- Patients changing responsible commissioner

15. Early Access to Medicines Schemes (EAMS) & Free of Charge Schemes (FOCs)

15.1 **Early Access to Medicines Schemes (EAMS):** The scheme offers a way by which unlicensed medicines can be made available to patients before approval of a license, to benefit public health. It enables pharmaceutical companies to gain additional knowledge and the NHS to gain experience of these medicines in clinical use.

15.2 **Free of Charge Schemes (FOCs):** Commissioners will not automatically fund treatment initiated under an expanded access scheme or a 'Zero cost' scheme where free stock is supplied to providers in anticipation of a positive NICE TAG.

15.3 Commissioners do not automatically fund these and will require providers to submit supporting information and evidence base for consideration via the commissioners' due process.

15.4 Please refer to Trust Free of Charge Scheme for further information

16. Specialised Commissioning

16.1 A number of National Tariff excluded drugs are commissioned by NHS England. See link below for most up to date version. The ICB is not responsible for funding these drugs. Any repatriation from ICB to NHS England or vice versa, will only happen in consultation with the Provider, the ICB and NHS England. Where the transfer or repatriation creates resource

implications for the provider or commissioner, these will form part of the conversations before the change is implemented.

16.2 In cases whereby adolescents transcend from paediatric (NHS E funded) to adults (ICB funded), such cohorts of patients would require discussion with the commissioners and consideration required via the due process. If agreed, a commissioning policy would be required.

https://www.england.nhs.uk/publication/nhs-england-drugs-list/

16.3 Chemotherapy and associated supportive treatments fall under the commissioning responsibility of NHS England and not a responsibility of ICBs.

17. Individual Funding Requests (IFRs):

17.1 Integrated Care Boards will not consider IFRs for any drug and/or indication that is the commissioning responsibility of NHS England (NHSE) Specialised Services or is an output of a service commissioned by NHSE.

17.2 Providers must not use IFRs as means to circumvent Commissioner-wide due process. IFRs should only be made where the patient has exceptional clinical circumstances and in line with the Commissioner's Individual funding policy.

17.3 IFRs should not be used for cases that constitute a cohort of patients OR where it is deemed a service development since, by definition, other patients who would benefit have been defined and the Commissioner has agreed not to prioritise funding for that cohort.

Please refer to the ICB website for IFR policy.

Definitions:

National Tariff: The National Tariff Payment System (NTPS) is a set of prices and rules used by providers of NHS care and commissioners, designed to deliver the most efficient, cost effective care to patients. As set out in the Health and Social Care Act 2012, the national tariff covers the pricing of healthcare services provided for the purposes of the NHS.

The National Tariff specifies the prices to be paid for "currencies", which are defined units of healthcare activity such as a spell, episode or attendance.

Drugs and devices are included in the price for each currency unless they are specifically listed in the National Tariff as an excluded high-cost drug or device.

Excluded high-cost drugs and devices are drugs and devices that are not included in National Tariff prices. They are specifically listed in Annex A: The national prices and national tariff workbook.

Patient Access Scheme (PAS): Is an agreement between pharmaceutical companies and the NHS Commercial Medicines Unit, which offers a lower acquisition cost to the NHS enabling patients to gain access to high-cost medicine treatments. Most positive NICE TAs for excluded high-cost drugs are conditional on a PAS being in place.

Prior Approval: Prior Approval is a process by which a Commissioner requires to approve a device or drug funding for each patient in line with agreed clinical criteria prior to commencement of treatment. This process is in place to enable Commissioners to ensure only patients meeting the clinical criteria are approved, assess associated financial risk and monitor invoices.

Novel and uncertain treatments:

Novel is a drug or treatment that is new and different i.e. a change to current practice where there is a level of evidence for its use that can be considered, the quality of which may be variable. The evidence, ethical and governance considerations are evaluable but have not been evaluated through local NHS processes at the current time.

Uncertain is defined as a drug or treatment for which there is no/little evidence. i.e. there is confusion between whether it constitutes clinical innovation or a form of research/trial. Uncertain treatments may constitute a variation in a treatment pathway or a major change to an established therapy. The difference from a novel treatment is that the evidence, ethical and governance issues are not evaluable through local NHS processes

Individual Funding Request (IFR): An individual funding request can be made for a treatment that is not routinely offered by the NHS when a clinician believes that their patient is clearly different to other patients with the same condition or where their patient might benefit from the treatment in a different way to other patients. This is known as “clinical exceptionality”. NB The term Exceptional Treatment Arrangements (ETAs) is no longer in routine use.

Early Access to Medicines Scheme (EAMS): The early access to medicines scheme (EAMS) gives access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.

Expanded access schemes include **“free of charge”** medicines schemes and **“zero risk”** schemes.

A free of charge medicines scheme: Is an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the pharmaceutical company to an individual patient or an identified cohort of patients.

A “zero risk” scheme: Is where the cost of the treatment is refunded to the provider if treatment goals are not achieved.