DERBYSHIRE JOINT AREA PRESCRIBING COMMITTEE
PRESCRIBING SPECIFICATION 2023-2024 version 1

Intentions of the prescribing specification

The prescribing specification is part of the healthcare services contract commissioners (ICB/) has with provider organisations. This document outlines the role and responsibilities of our provider trusts in ensuring a transparent and collaborative approach to the safe and effective management of medicines, seamless care of patients between NHS organisations and ensuring high quality prescribing. The document is updated annually for changes in process and best practice and taken to JAPC (with representatives from both commissioner and provider organisations across Derbyshire) to ensure that its requirements are both fair and reasonable. Once agreed by JAPC, the specification can then be included as part of the contract prescribing requirements from providers for the following contract year.

- Drugs and treatments commissioned by NHS England are not included into this prescribing specification
- Joined Up Care Derbyshire Integrated Care Board (ICB) require that the pharmaceutical services provided by the Trusts from which they commission services comply with national Service Specifications and Performance Indicators and all relevant national and regional circulars, examples include standards from the Royal Pharmaceutical Society, the NHS constitution, and recommendations by the Derbyshire Joint Area Prescribing Committee.
- The requirements set out in this prescribing specification applies to private providers of healthcare where patients treated privately transfer into the NHS. Patients moving into the NHS setting will be treated the same way as any other NHS patient and GPs will prescribe in line with local policies. Private patients prescribed non-Derbyshire formulary items will be counselled to expect NHS Derbyshire formulary drugs if moving into the NHS.
- Private providers contracted to treat NHS patients are required to follow the commissioning intentions of this specification

The provider trust will ensure that it has internal processes in place in order to meet 100% compliance, but commissioners recognise that there will be acceptable and appropriate exceptions. An exception report will be considered by appropriate D&Ts to ensure that a high level of clinically quality is continually maintained.

No	PERFORMANCE INDICATOR	THRESHOLD	METHOD OF MEASUREMENT	CONSEQUENCE OF BREACH
1.	There will be systems and policies in place to ensure the efficient management of medicines, including: - ✓ A multidisciplinary Drugs and Therapeutics Committee (MDTC) to include representation from primary care. o Where provider organisations operate without the full functions of a MDTC and adopt formularies and polices from the Joint Area Prescribing Committee, primary care representation on such groups may not be needed. As good practice timely minutes of their meeting will be made available to JAPC. ✓ Systems for formulary management and prescribing audit. ✓ A policy for the planned introduction of new drugs. ✓ A policy for the use of patients own drugs and their reissue to patients on discharge ✓ A policy for the safe and secure handling of medicines ✓ Sponsorship policies as agreed by Providers ✓ Collaborative relationships with pharma should be covered within the industry policy ✓ Management of Conflicts of interests ✓ Adequate quality assurance systems ✓ A control of infection policy ✓ The implementation of NICE recommendations Hospital Trusts should bring to the attention of the ICB any policies which are not compliant with NICE guidance. All providers should maintain adequate records to demonstrate compliance with NICE guidance.	100% compliance	An annual summary of activities undertaken in respect of this Performance Indicator to be considered by the JAPC Specific audit work	Referred to the Quality Management Group (QMG) for action and to the Contract Management Board (CMB) if necessary
2.	New Treatments and Interventions The Trust will ensure that its clinicians follow due process for the introduction of new drugs or therapies for individuals or groups of patients. This process will ensure: - • Consideration of the drug by the Trust's Drugs and Therapeutics Committee, followed, where appropriate, by • A paper to the JAPC for consideration or • A request to the ICB Non-Contract Treatment (Individual Case Review) Panel for consideration.	100% compliance	Exception reporting by GPs/ ICB	Unless specifically agreed by the JAPC/ ICB, new treatments and therapies introduced without following due process will not be funded

	Referrals to the Individual Funding Request (IFR) Panel should only be for patients whose circumstances are considered to be exceptional in accordance with the definition contained within the ICB Policy.			
3.	The Trust will ensure that its employees do not suggest to patients that a non-approved drug or treatment can be obtained from their GP.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
4.	Primary care and provider trusts will work to the policies, clinical guidelines, shared care agreements, patient group directions and position statements produced and agreed at JAPC	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
5.	Compliance with JAPC Traffic Light Classification for Prescribing i.e.: - • **RED** drugs/appliances/medical devices – Prescribing responsibility lies with a hospital consultant or specialist • **AMBER** drugs/appliances/medical devices – Initiated and stabilised within a hospital/specialist setting but suitable for shared care with GPs under a shared care arrangement • **GREEN** drugs/appliances/ medical devices– Regarded as suitable for primary care prescribing • **GREY** drugs/appliances/medical devices – not recommended for use or for use in restricted circumstances only. Drugs listed in the BNF are sometimes prescribed in an alternative, unlicensed formulation to meet the individual needs of a patient- these 'specials' are considered to be GREY drugs, and should only be prescribed on an exceptional basis when a licensed, cost-effective product is not available • **Do Not Prescribe (DNP)** drugs/appliances/medical devices – These are drugs not recommended or commissioned*. These include for example drugs classified by the BNF as 'less suitable for prescribing' *unless agreed through the individual funding request route.	100% compliance 100% compliance 100% compliance 100% compliance 100% compliance	Exception reporting by GPs/ ICB/ D&T JAPC to be informed by DTC minutes	Recharge the Trusts for the cost of drugs inappropriately passed on to GPs to prescribe, where the cost of the drugs would have been covered by national tariff prices or local contracts Provider trusts will be given a reasonable time period to resolve this by escalation to their DTC or equivalent Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required.

	For patients that are already on the medicine/treatment/medical device prior to the Do Not Prescribe (DNP) classification, this should not be withdrawn abruptly from patients, but should be continued until the next clinical review where their NHS clinician will decide whether it is appropriate to switch or stop treatment or submit an individual funding request if in exceptional circumstances on-going prescribing is considered clinically appropriate. To adhere to the definition of <u>initiation and recommendation (note: Do Not Prescribe (DNP) drugs should not be initiated or recommended by a clinician):</u> **<u>Initiation</u>** is when a consultant/specialist issues the first prescription because: *'the patient requires assessment before starting treatment and/or short-term assessment of the response to the drug is necessary and GPs will only be asked to continue prescribing when the patient is stable or predictably stable'* **<u>Recommendation</u>** is when a consultant/ specialist asks GPs to prescribe the initial and on-going prescriptions, but ensures that; *'There is no immediate need for the treatment and is in line with the outpatient policy and the patient's response to treatment is predictable and safe'* Where inappropriate requests are identified by primary care clinicians, DTCs will undertake a periodic review and act appropriately.			
6.	For all drugs started in a provider care setting the initiating clinician is responsible for the following: ✓ considering and advising on contraindications, side effects and interactions ✓ patient counselling ✓ baseline investigations ✓ where appropriate the provision of management plans and to inform GP when starting new medicines ✓ On-going monitoring e.g., blood test or ECGs and until requesting the primary care clinician takes responsibility for this as per JAPC traffic light classification or appropriate shared care agreement.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required

	Shared decision making (NICE NG197) ✓ Shared decision making is a collaborative process that involves a person and their healthcare professional working together to reach a joint decision about care. Shared decision making should be embedded into practice.			
7.	Undertake a periodic review when requested with primary care colleagues of "specials" to ensure appropriate and cost-effective use of NHS resources. Specials are individually prepared unlicensed formulations of existing drugs made for a specific patient. They are usually considerably more expensive than standard preparations	No target	Exception reporting by GPs/ ICB	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
8.	Shared care must always be subject to a proper written shared care protocol. In the transfer of management and prescribing responsibilities to the GP, it is essential that: - ✓ Prescribing responsibility will only be transferred when it is agreed by the consultant and the patient's GP that the patient's condition is stable or predictable following a period of initiation and review. ✓ Dissemination of sufficient information to the GP and other carers had occurred. ✓ Prior agreement has been reached between the GP and consultant before clinical responsibility is transferred. ✓ The GP is in a position to monitor treatment and adjust the dose if necessary. ✓ The drug has received approval by the JAPC. ✓ Communication between primary and secondary care clinicians should be facilitated with a copy or link to an up-to-date shared care agreement A GP has the right to refuse to enter into a shared care agreement, but to refuse on the grounds of drug cost alone is unacceptable. ICB must proactively support implementation of agreed shared care protocols to maximise uptake. Shared Care Guidelines	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required. Documented reasons for failure of GPs to accept shared care to be escalated to ICB and D&T groups

9.	Changes in clinical responsibility must be seamless and invisible and the patient or the patient's representative should not be involved in dialogue between clinicians or be required to act as a purveyor of information or policy. Any changes in responsibility transfer must be done at patient level in the patient's best interest and safely.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Involvement of Medicines Management and Hospital Pharmacists and ICB and Trust Management as required avoiding a reoccurrence.
10.	<u>Communication with patients and responding to queries</u> Providers take responsibilities for managing and responding to queries received from patients related to a spell with secondary care are required to: ➢ put in place efficient arrangements for handling patient queries promptly and publicise these arrangements to patients and GPs, on websites and appointment/admission letters and ensure that they respond properly to patient queries themselves, rather than simply passing them to practices to deal with; ➢ Communicate the results of investigations and tests carried out by the provider to patients directly, rather than relying on the practice to do so (except in the case of GP direct access diagnostic services). (Note that all clinicians, whether in primary or secondary care, retain clinical and medico-responsibility for the results of investigations which they personally request; sending a result on to another clinician does not absolve the original requester of that responsibility).	100% compliance	No exception reporting	Contractual requirement.

11.	**Outpatient attendance: provider organisation requirements** A clinic letter is not required after every single attendance but, **as a minimum, one must be sent after any clinical attendance where the secondary care health professionals need to pass information to the GP so that he/she can take action in relation to patient's on-going care.** Where required, providers must send clinic letters within 7 days of the patient's attendance (Clearly, if the GP does not receive a letter following an outpatient attendance, he/she will assume there is not action to be taken. And it is good practice, though not a specific contract requirement, for a letter to be sent where there is a material change in the patient's condition or its management, even where there is no need for the GP to take specific action as a result). Where a hospital clinician recommends that an out-patient goes to their GP for commencement of <u>new treatment, 5 working days from receipt of the letter</u> will be given for the GP to action the request and issue a prescription. Procedures will be in place to communicate this to the patient at the out-patient appointment. Information should be at the required standard as agreed in contractual quality schedules.	100% compliance	No exception reporting	Contractual requirement
	Urgent drugs i.e., those required within 5 working days will be supplied by the hospital pharmacy. 28 days will be supplied either through outpatient pharmacy services or on FP10HNC prescription unless a shorter course of treatment is indicated. Processes will be in place to ensure that the patient is aware to obtain non-FP10 prescriptions from the outpatient pharmacy service and not to request a GP transcription onto FP10. Mental Health outpatients may receive less than this dependent on clinical need and risk assessment. Medication information is by generic name, except for those agents where it is clinically necessary to indicate the brand prescribed for therapeutic or safety reasons as per JAPC recommendations. Trusts will ensure that whenever possible clinicians recommend a specific drug in accordance with current formularies. The prescribing of "special" formulations should only be considered when suitable alternative proprietary options have been exhausted.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required

12.	**Discharge: provider organisation requirements** Discharge summaries must be sent to the GP within 24hours after every discharge from inpatient, day case or A&E care. These must be sent electronically as structured messages of coded clinical information using standardised clinical headings. In-patients on discharge or transfer shall receive a minimum of 14 days treatment for all drugs and appliances unless otherwise indicated clinically (e.g., short courses or risk assessment). The 14-day treatment can be a reconciliation of medicines supplied by the trust and where appropriate medicines brought in by the patient, reducing unnecessary waste. Wherever possible patients will be encouraged to use their own medicines. A further exception to the 14 days is the supply of oral nutritional supplements whereby the provider will ensure 5-7 days is available. Patients attending for day case surgery will be provided with sufficient dressings/ antibiotics/ analgesia to meet their post-operative needs. On discharge, patients will be provided with clear written instructions outlining their personal drug regimen. Medication information is by generic name, except for those agents where it is clinically necessary to indicate the brand prescribed for therapeutic or safety reasons as per JAPC recommendations. Trusts will ensure that whenever possible clinicians recommend a specific drug in accordance with current formularies. The prescribing of "special" formulations should only be considered when suitable alternative proprietary options have been exhausted.	100% compliance	No exception reporting	Contractual requirement
		100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
13.	There must be ICB involvement in any significant developments concerning prescribing, and particularly changes in hospital prescribing practice which will impact on GP prescribing. This involvement may be via the Trust's Drugs and Therapeutic Committee and/or the JAPC depending on the nature of the change.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Any significant change will not be supported unless the ICB are fully engaged in discussions. All parties need to consider National, Regional and local QIPP plans in these developments

14.	Drug choice in the hospital or joint formulary will take into account differentials in the cost of drugs between primary and secondary care and reflect sound cost benefit analysis. Medicines will not be prescribed solely on the basis of advantageous pricing or other financial incentive. To include primary care commissioners in any procurement or rebate process that has the potential to impact on primary care or hospital prescribing budgets. The overall benefit to the health economy will be used as a guide to support provider trusts to compensate loss of income.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
15.	Primary and secondary care will not enter into local rebate schemes, and serve notice if appropriate, where a national procurement/ rebate scheme is recommended by NHSE&I. ICB will then consider cost-effective preferred options in local formularies and guidelines.	100% compliance	No exceptions	
16.	Where a non-formulary drug is recommended, the consultant will negotiate its supply from within the Trust. GPs should not be asked to prescribe drugs not approved for use in the Trust where the specialist works, unless by specific written agreement with an individual patient's GP. GPs may continue prescribing of concessionary drugs approved through a process of DTC if the exceptionality is agreed by the host commissioning ICB or local guidance of exceptionality.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
17.	If a medication dressing or appliance is not available on GP prescription and initiated by the Trust, it will continue to be supplied by the Trust.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
18.	Responsibility for the prescribing of unlicensed drugs or use of drugs off-label will not be transferred to GPs without their prior agreement (exceptions include recognised standards of prescribing practice e.g., paediatrics, dermatology and palliative care).	95% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
19.	Drugs being used as part of a hospital-initiated clinical trial will be supplied by the hospital.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required.

20.	Trusts and ICB will fully comply with Derbyshire ICB Research Forum recommendations for Funding of Clinical Trials	100% compliance	Exception reporting by GPs/ ICB/ D&T	ICB will not pick up post-trial prescribing or other financial implications unless the ICB have agreed prior to the commencement of the trial to do so.
21.	Clinical staff will be required to provide declarations of conflicts of interest when requesting new drugs / changes to the prescribing formulary; these will be documented in relevant minutes and are in addition to any declarations made under Standing Financial Instructions. Trusts should demonstrate that sponsorship has in no way affected purchasing decisions and is in accordance with Provider's sponsorship policies.	100% compliance	Details should be included in the annual report to JAPC	Referred to the Quality Management Group (QMG) for action and to the Contract Management Board (CMB) if necessary
22.	The Trust will agree with commissioners the introduction of any new drug, intervention or device, which is excluded from the national tariff, either recommended by NICE or otherwise, as to the appropriateness of its introduction and cost implications of such.	100% compliance	All such discussions to take place at the JAPC and the decision to be ratified by the ICB	The introduction of any new therapy without the prior agreement of ICB will not be funded.
23.	If the Trust has a particular problem with the cost of a drug or treatment not covered by NICE guidance, it will request the specific approval of commissioners for additional funding before commencement of treatment and without raising patient expectation, indicating the benefits of the drug and cost implications.	100% compliance	All such discussions to take place at the JAPC, and the decision to be ratified by the ICB, or via requests to the NCT (Individual Care Review) panels as appropriate.	In the absence of agreement from the commissioners, the Trust will absorb the costs if it elects to prescribe.
24.	The Trust should provide a medication reconciliation service on admission in accordance with NICE and National Patient Safety Agency guidance issued in December 2007	100% compliance	The availability of the service	
25.	Specific drugs under the QIPP agenda as performance indicators are listed in appendix 1	95% Compliance	Exception reporting by GPs/ ICB/ D&T	Decisions to be monitored by the JAPC and action taken to resolve any variances.
26.	Decisions reached by the JAPC with provider trusts throughout the year about the appropriate responsibility for the prescribing of pharmaceutical products will be implemented following an approved plan and monitored as agreed.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Decisions to be monitored by the JAPC and action taken to resolve any variances.

27.	Medication required for planned hospital procedures or investigations (for example, EMLA® cream before hospital dialysis, or MRSA eradication) will be prescribed by the hospital/provider and treating clinician.	100% compliance	Exception reporting by GPs/ ICB/ D&T	Decisions to be monitored by the JAPC and prescribing groups and action taken to resolve any variances.
28.	Trusts will horizon scan and engage with clinicians and medicines management in preparation for the uptake of biosimilars, Details of the uptake is given in the appendix of high-cost drugs.	100% compliance	No exceptions	Decisions to be monitored by the JAPC and prescribing groups and action taken to resolve any variances.
29.	To ensure that providers of commissioned services have arrangements in place for the safe management and use of controlled drugs	100% compliance	No exceptions	The ICB nominated lead for controlled drugs will evaluate the concern and escalate to NHSE CD Accountable Officer
30.	MHRA Early Access to Medicines scheme: Provider trusts will have a process within their organisation should they enter into MHRA EAMs schemes. Schemes that have the potential to impact on primary care will be notified to JAPC	100% compliance	No exceptions	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
31.	Provider trusts will implement and support the recommendations of JAPC on policies that affect the wider healthcare system. These include for example the decommissioning of gluten free products, self-care and vitamin D supplementation.	100% compliance	No exceptions	Direct contact between Medicines Management and Hospital Pharmacists to avoid recurrence, escalation to QMG if required
32.	Provider trusts/partners/commissioned services must comply with the Information Standard Notice (ISN) outlining new common standards for medicine data transfer which will support the transfer of medicines information between healthcare settings. From 1 October 2021, provider trusts/partners/commissioned services need to assess all of their systems that provide electronic transfer of patient medication and allergy/intolerance data to ensure compliance. IT systems used to send and receive medication and allergy/intolerance information must do so using either NHS Digital APIs or APIs created using the specifications. From 31st March 2023, provider trusts/partners/commissioned services must be compliant with the Information Standard Notice	100% compliance	No exceptions	Contractual requirement

High-Cost Drugs excluded from Tariff commissioned by ICB

High-Cost Drugs (HCDs) commissioned by specialised services and the NHS England are not included in this specification. JAPC will routinely classify these drugs as 'RED in line with NHSE commissioning intentions.' It will be the responsibility of the provider trust to establish with NHSE how and where it is commissioned. Reference of HCDs in this specification relate solely to those commissioned by ICB

Governance

1. Only drugs and devices with indications for use that are the responsibility of The Joined-Up Care Derbyshire ICBs, and which have been through the ICB due governance process and received a positive funding decision will be commissioned. The Joined-Up Care Derbyshire ICB will follow national guidance and recommendations where they exist on the use and incentives for the uptake of biosimilars.

2. The JAPC High-Cost drugs biosimilar working group will have oversight for how the ICB commission HCDs PBR excluded. The working group is to support Providers and Commissioner Organisations across the Derbyshire Integrated Commissioning System to work collaboratively on maximising the system benefits available from the introduction of biosimilar medicines and agreeing cost effective commissioning pathways. Appendix 1 and appendix 2 show the ICB governance arrangements that follow a new NICE TA or change in policy.

3. Where tariff rules are pass through payment (as opposed to block contracts) arrangements should be in place to follow the National tariff. Excluded drugs and device costs charged to ICB will be reflective of actual product cost to provider or the nominated supply cost, or any national reference price whichever is the lower. ICB reserve the right to audit provider costs to demonstrate compliance with this term.

4. Providers should have in place systems to ensure that medicines excluded from tariff are only charged to the ICB for those uses the ICB have agreed to commission. This includes where there are dual or multiple uses for medicines.

5. For High-Cost Drugs excluded from tariff the commissioning trust will only commission in line with NICE (National Institute of Clinical Excellence) Technologies Appraisal Guidance, ICB commissioning intentions or locally produced guidance. Commissioners and Providers should be mindful of the RMOC advice on 'sequential use of biologic medicines.' Further sequential use outside of the local commissioning algorithms should only be undertaken after advice from an MDT and in-line with Trust processes but limited by clinical appropriateness and safety.

6. Requests for use of combination biologics should be approved through an MDT meeting, and then presented at a D&T meeting with a ICB representative present (and NHSE view if applicable). Providers should ensure when prescribing combination biologics, consideration should be given to using biologics with different modes of action (e.g., use of an Anti-TNF and IL-inhibitor). When combining two biologics, safety concerns should be paramount, and patients should be monitored for adverse drug reactions and potential interactions. Information regarding use of combination biologics should be conveyed to the GP including potential adverse drug reactions, safety issues, any monitoring and potential interactions.

7. Any incentive schemes (financial and non-financial) offered to the Provider Trust from the manufacturers shall be disclosed to the Commissioner, whether they are accepted or not before any agreement. This will include offers made by pharmaceutical companies to pay for locally delivered/designed homecare services. Neither the Commissioner nor Provider will be disadvantaged from the acceptance of such schemes. For transparency and fairness any offers to the ICB will be declared to the relevant provider before any decision is made.

8. Commercial clinical trials and compassionate funding - Funding arrangements for the period following completion of the trial must be agreed with the commissioners prior to the trial commencing. It should be noted that Derbyshire does not routinely fund medicines that are part of a commercial clinical trial either during the trial period, following the completion of a clinical trial or after withdrawal of compassionate funding by a pharmaceutical company. Ethically, patients participating in a clinical trial must be made aware that there is no guarantee that the medicine will be continued at the end of the trial, irrespective of the results.

9. NICE in all their positive technology appraisals have a generic statement with the option to continue treatment until they and their clinician consider it appropriate to stop. Patients already treated privately, on a concessionary basis by the provider or through a clinical trial at a point of a positive appraisal relating to their treatment may wish to opt back into NHS. Continuation of treatment under the NHS should not be assumed unless there is evidence the patient meets or would have met the eligibility criteria of NICE initiation. No retrospective funding will be provided.

10. Excluded drugs/devices recommended within a NICE Interventional Procedures Guidance (IPG) and/or guideline will not be routinely funded unless endorsed within a national or locally agreed clinical commissioning policy.

11. JAPC considers free of charge schemes offered by pharmaceutical companies pre-NICE as a low priority for adoption. In exceptional circumstances patient specific cases may be considered, however, the request must be proposed by the treating clinician and accepted through relevant trust drugs and therapeutics committees which have representation from the ICB using an agreed decision-making framework. The ICB representative should liaise with the Clinical Policies and Decisions Team for this specialist area. Commissioners and providers should be mindful of the implication of such schemes and consider the advice and points raised by the Regional Medicines Optimisation Committee publications including principles to follow detailed in section 6 of the RMOC advice. See also Appendix 6 - RMOC Free of Charge (FOC) Supply (example template) – Request for approval template, which can be used by acute trusts when submitting an FOC application to its respective DTC/HCD meeting.

12. The Trust is required to provide assurance to commissioners that the management of sub-contracted services of supply, for example through homecare, is working towards compliance with the recommendations made in the Royal Pharmaceutical Society (RPS) Standards for Homecare Services and the RPS Handbook for Homecare Services in England and other relevant national standards. The Provider will demonstrate that National Key Performance Indicators (KPIs) are agreed and monitored for all homecare providers.

13. ICB reserve the right to recharge NHSE where prescribing of drugs has transferred to NHSE to ICB. Where local services do not have a contract with NHSE to provide a specialist service, the Provider should transfer the patient to a NHSE commissioned Provider or absorb the costs. Alternatively, the Provider can seek to obtain an NHSE contract for that specialised service.

14. Suppliers of biosimilars may offer early discounts to provider trusts that could be put in place before tendering prices become available. ICB ask providers not to sign up to these, or make any firm commitments, until details of tender outcomes are available, as it will be important not to encourage repeated switching of patients within the space of a few months.

Monitoring

15. For High-Cost Drugs excluded from tariff that are subject to a re-imbursement scheme between the DoH (Department of Health) and drug manufacturer, the provider trust will provide commissioners with monthly updates of new claims by drug name, patient numbers and value.

16. Where Coordinating Commissioners have agreed local discount schemes for excluded drugs that result in an additional saving on the national available Patient Access Scheme (PAS) or the Commercial Medicines Unit price, these prices should be made available to all **associate Commissioners** purchasing services from the Provider. (These may include incentive schemes such as vial sharing).

17. ICB when challenging treatments with HCDs may ask the provider to clarify their usage it believes falls outside commissioning intentions. The provider will respond to any challenges or queries relating to HCDs within 10 working days with an intention to resolve this issue.

Financial

18. For High-Cost Drugs excluded from tariff where costs are exceeding planned expenditure or where horizon scanning has identified a significant financial risk to the commissioning ICB it may decide upon the use of prior approval and/or proformas signed by the patient's consultant/specialist, in conjunction with the provider trust, to be sent to the ICB as part of the notification; prior approval; or group approval.

19. Provider trusts with a monitoring process will provide commissioners with a monthly update of use and expenditure of High-Cost Drugs outside tariff, by drug name against predicted spend and budget as set annually by ICB. For all High-Cost Drugs excluded from tariff the provider trust will provide patient level data for on-going quality assurance and validation. This will include the clinical criteria within the NICE technology appraisal or local policy. ICB will conform to the information governance requirements.

20. ICB can ask provider trust to undertake post-payment verification audits of the use of drugs outside tariffs and/or in non-PbR services.

21. ICB will reclaim payment (in line with current NHS financial regulations and contract arrangements) of High-Cost Drugs excluded from tariff for patients that do not meet commissioning policies.

22. Where drugs and devices outside of commissioned services or commissioning intentions any consequential costs that are incurred will not be funded. This includes the cost associated with the entire treatment.

23. In tariff drugs that prescribed concurrently with PBR excluded drugs are not chargeable as pass through payments. No additional charges above cost will be accepted unless explicitly agreed with ICB

24. High-cost treatments and interventions unless specified within contracts, not identified in the annual horizon scan or by exceptional circumstances (e.g., cost neutral or cost saving) will be considered low priority for funding in year. Additional resources may be considered for

treatments that are made available at short notice where there is a strong clinical impact on clinical outcomes supported by high quality studies.

25. Budgets for excluded drugs and devices will be set on an annual basis. This will be based on the provider's assessment of need through horizon scanning and agreed through confirm and challenge meeting by the host commissioning ICB with the provider.

26. There is an expectation that Provider Trusts will supply PBR excluded drugs via a safe and cost-effective route e.g., Homecare. Alternative supply routes may be considered where there are concerns regarding service delivery (this may include quality or resilience of the supply chain). No new in-tariff drugs should be supplied through Homecare without prior agreement between providers and commissioners. The written proposal should include for example, a scope where other arrangements have been explored and not feasible, the financial, safety and clinical implications are understood and accepted by the ICS/ICB and patient experience is not detrimental. Homecare should not be used or seen as a solution for addressing cost pressures by different budget holders (e.g., provider / commissioner).

Enablement Scheme

27. In the absence of national gainsharing agreements, the ICB will adopt the principles of an Enablement Scheme. An example of this would be to agree a fixed price which would drive the uptake of a biosimilar at a fair price. The enablement scheme price will consider additional nondrug costs (e.g., Barriers) of switching patients.

- Examples of barriers include patients requiring additional appointment to obtain consent for the switch, which would need to be met by the providers.

28. The enablement scheme price will only be agreed if it is unlikely that uptake will increase without additional financial enablers given the barriers to switching.

29. New patients initiated on the biosimilar should take no more time or incur additional costs compared to the originator. Switching from originator to the biosimilar will require a longer appointment to explain the change and get patient consent.

30. The Derby and Derbyshire ICB will follow national guidance and steer and those recommendations from regional procurement if in place.

31. Trusts are expected to plan for the introduction of biosimilar medicines into routine use, in conjunction with clinicians and medicines management when cheaper than the originator. It is essential for the NHS in Derbyshire, both commissioners and providers, that we maximise the financial benefits introducing these agents can realise. To this end we will require a joint improvement programme plan and for all Trusts to use treatments of the lowest acquisition cost or best price to the NHS system, in line with product licenses. This will be facilitated through the Derbyshire High-Cost drugs biosimilar working group.

32. The Derbyshire JAPC has determined that the starting point for discussing and agreeing a target for uptake will be 100%. This may be revised down with input from local clinicians (those expecting to use the treatment and from different specialties). JAPC will then set a realistic minimum target of achievement for all providers; there will be no variation of thresholds between providers. This process will occur for each biosimilar as they are launched.

There is an expectation of a minimum target of:

- ✓ 90% of new patients will be prescribed the best value biologic as determined by the regional procurement lead within three months of launch of a biosimilar medicine and
- ✓ at least 80% of existing patients within 12 months or sooner if possible.

In line with NICE TAs that include biosimilars in their updates to 'Start treatment with the least expensive drug….' new patients will be initiated on a biosimilar over the more expensive originator where indicated and excluded from any gain sharing agreements

* JAPC may decide to relax timelines in the event for example of another imminent biosimilar launch or the conclusion of a procurement process.

** Switching between biosimilars will be in agreement through JAPC with details of opportunity cost, patient safety and resource to switch as considerations

33. The collaborative approach for fast uptake of bio-similar is facilitated by 'Derby and Derbyshire ICB principles for sharing the benefits associated with more efficient use of medicines not reimbursed through national tariff prices' document and the newly formed Derbyshire Biosimilar Working Group. In the event of disagreement resulting in delay of biosimilar uptake the escalation process would be at director-to-director level to reflect the financial risk.

Patient monitoring

34. Concessions for drugs excluded from tariff which have been agreed internally within the provider trust, will not be funded by the ICB. Concession requests which provider trust wish the ICB to pay for should be referred into the commissioning trusts process for individual funding. The provider trust will regularly review concession requests to ensure these are evidence-based and rational – safe, clinical and cost effective - and will seek formulary inclusion if appropriate.

35. For assurance of High-Cost Drugs use excluded from tariff the commissioners require the minimum data set in point 7 to be recorded at patient level to ensure that treatment is in line with NICE or locally agreed guidelines or policies. This will be delivered by appropriate IT software such as Blueteq within a roll-out plan agreed annually with providers. Commissioners and Providers will be mindful of the RMOC 'Standard Principles for Medicines Prior Approval Forms' publication in the collaborative approach necessary for successful adoption of new and existing schemes.

36. The provider trust, in partnership with the commissioning trust, will undertake sample audits to give assurances of adherence to agreed guidance results of which will be shared with the commissioners where agreed.

Patients transferring from one commissioner to another commissioner

37. Where responsibility for providing NHS services to the patient has been transferred from another ICB, e.g., if the patient has moved into the area, the ICB should normally honour funding commitments made by the patient's previous NHS commissioner. Joined Up Care Derbyshire ICB reserve the right to seek a formal clinical review of the patient's future healthcare needs at the point of transfer, and to consider whether the decision to provide the patient with any further courses of treatment of the type previously provided, and of any other nature, are equitable and appropriate. This applies to patients who become the responsibility of a ICB, having formerly been provided with healthcare under the NHS in Wales, Scotland or Northern Ireland.

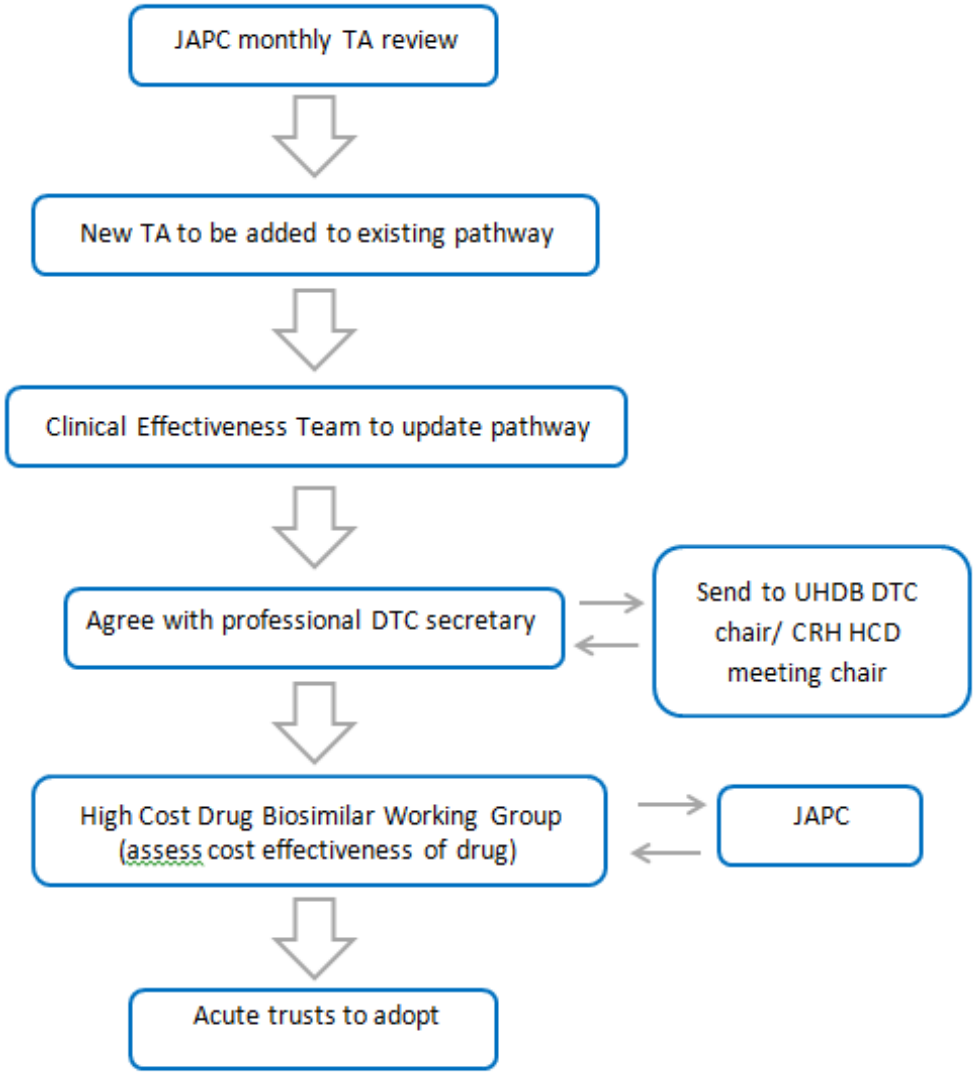
Transfer of responsibility from NHSE to ICB

38. In circumstances where the commissioning responsibility for an excluded drug or device transfers from NHSE to a ICB, e.g. where a child who is being treated under NHSE responsibility transitions to adulthood, ICB should reserve the right to seek a formal clinical review from the provider.

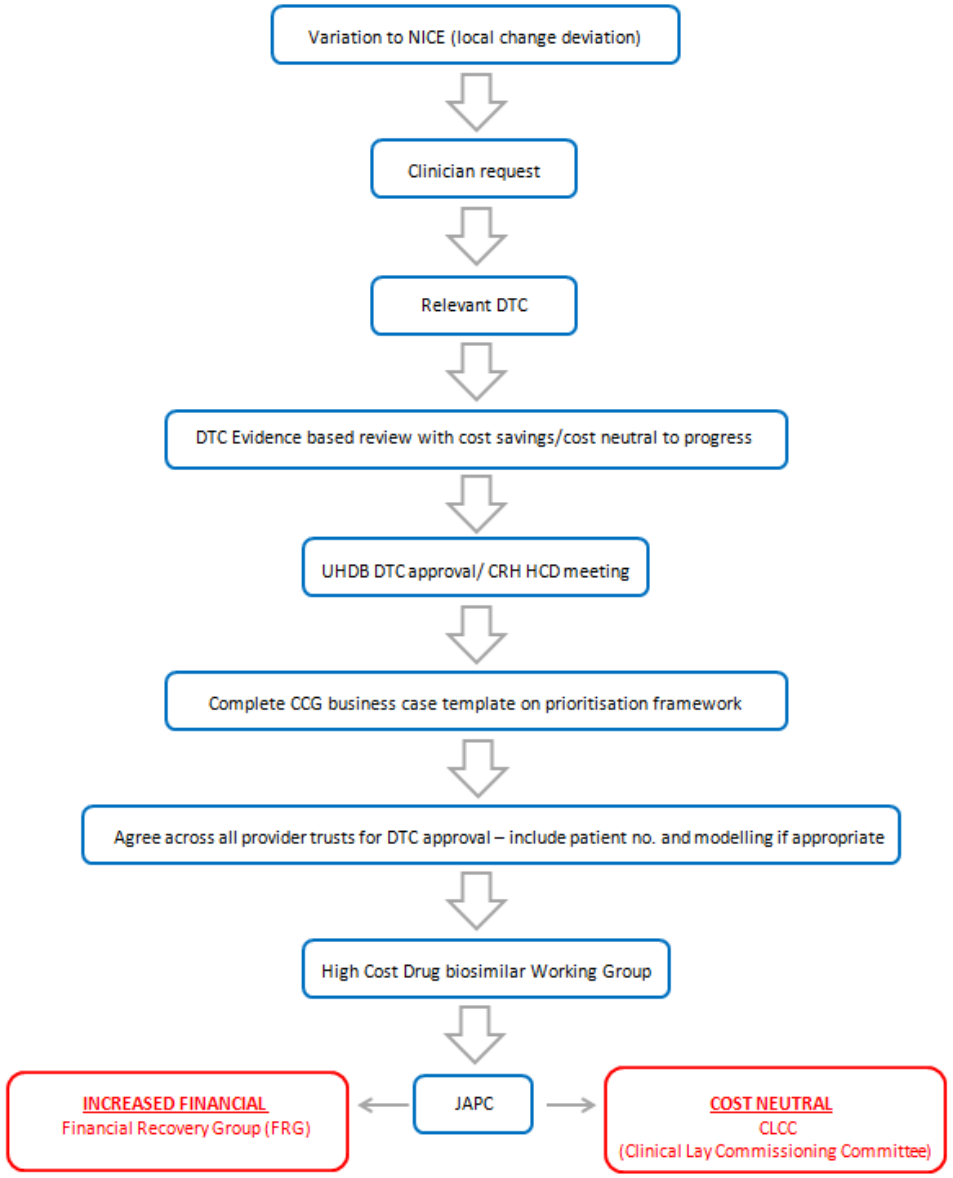
Transfer of budgetary responsibility from ICB to block contract

39. In exceptional circumstances (e.g., pandemic) NHSE will instruct a transfer of budgetary responsibility from the ICB to a block contract. Under these circumstances the block contract takes precedence over the prescribing specifications relating to high-cost drug commissioning (as listed above). The acute providers should continue to work with the ICB on budgetary spend versus modelling (allowing for capacity). Continuation of gain shares during this period will be the provider's risk. The financial and clinical risk associated with the block contract rest with the provider, including equity of treatments during and after the block contract. On completion of the block contract, ICB will revert back to the originally agreed commissioning intentions.

Appendix 1 - <u>High-cost drugs pathway for NICE compliant drugs</u>



Appendix 2 - <u>High-cost drugs pathway for non-NICE compliant</u>



Appendix 2 – <u>Supporting Medicines Optimisation between Provider Trusts and Commissioners</u>

Medicine's optimisation ensures people obtain the best possible outcomes from their medicines while minimising the risk of harm. Medicine's optimisation requires evidence-informed shared decision making between the patient and the professional(s) provide an individualised, person-centred approach to medicines use, within the available resources

Medicines management considers the systems of processes and behaviours determining how medicines are used by patients and the NHS, whereas medicines optimisation focuses on outcomes for patients obtained from their medicines. Medicines management is an important enabler of medicines optimisation and is a term that has been used historically in the NHS for managing people's medicines

NHS Provider Trusts to:

1. Improve medication error reporting and provide evidence quarterly of learning that could be shared across the Derbyshire health community through participation in a local Medicines Safety Officer network to facilitate learning. To share action/mitigation plans with their lead commissioner.
2. Develop mechanisms to support patients to safely use their medicines across secondary and primary care. Provide evidence of collaboration with other Derbyshire Trusts and Commissioners to maximise economies of scale. As a minimum to have an implementation plan in place.

Appendix 3 – RMOC free of charge (FOC) supply – Request for approval template (example)

Standard template for commissioner approval of free of charge medicines schemes

Completion of this form **<u>does not</u>** ensure future commissioning arrangements

Trust name	
Drug name – Approved (and generic / biosimilar – if known)	
Preparation (strength and formulation)	
Drug company	
UK license status	
Clinical indication	
Line in therapy and what this replaces (if any)	
Regimen (i.e., dose, route, duration and frequency, number of cycles. Include all anticancer drugs and supportive care medication used in combination with FOC drug)	
Estimated number of anticipated patients per financial year	
Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval	

Funding arrangements agreed with pharmaceutical company for existing patients if drug gains NICE approval, but the patient does not fit the funding criteria	
Funding arrangements agreed with pharmaceutical company for existing patients if the drug does not gain marketing authorisation / NICE approval	
Trust activity – please detail number of attendances (outpatient, inpatient, follow-ups) required for the use of the drug	
Any other information/supporting evidence (level of evidence, phase of trial, protocol etc.)	
Requesting clinician	
Completed by:	

References:

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4. PrescQipp Commissioning high cost drugs and devices August 2018: https://www.prescqipp.info/component/jdownloads/send/445-commissioning-high-cost-drugs-and-devices/4045-b156i-commissioning-high-cost-drugs-and-devices
5. NHSE Commissioning intentions: adalimumab September 2018: https://www.sps.nhs.uk/wp-content/uploads/2018/09/20180925-Contractual-Commissioning-Intentions-Adalimumab_corporate-template.pdf
6. Specialist Pharmacy Service Free of Charge (FOC) Medicines Schemes: https://www.sps.nhs.uk/articles/free-of-charge-foc-medicines-schemes-rmoc-advice-for-adoption-as-local-policy/
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