North Central London Health and Care
Integrated Care System

North Central London Integrated Care Board (NCL ICB) Commissioned National Health Service Payment Scheme (NHS PS) Excluded Drugs & Devices Policy

For inclusion in NHS Provider contracts as a document

Policy Year 2025/26
Issue date: May 2025

Contents

Related documents

Documents
NHS England Drugs and Devices List: Version 20.0
NCL ICB Commissioned High Cost Drugs List 2025/26
NHS Payment Scheme: 2025/26 Prices Workbook (Annex A)
NCL ICB Interface Prescribing Guidance (April 2024)
NCL ICS Consensus on the NCL Primary & Secondary Care Interface: Version 1.1 (December 2023)
NCL Red List

Document control

Date	Version	Amendment	Amendment approved by
06/10/2015 – 22/02/2017	1.0	Medicines Management Schedule 2015/16 updated: • Draft Clinical Commissioning Group Commissioned National Tariff Payment System (NTPS) 2017/19 (Formerly Payment by Results (PbR) excluded Drugs & Devices Policy).	NEL CSU
20/1/2016 – 22/02/2017	2.0	NCL prescribing Guidance changes • NCL prescribing Guidance	NEL CSU
16/10/2015 – 22/02/2017	3.0	Red List Changes • Red list V18	NEL CSU
08/10/2015	4.0	Addition of current commissioner required TBF to Appendix 1	NEL CSU
14/10/2015	5.0	Addition of Risk share data requirements.	NEL CSU
27/02/2019	6.0	Update to fit 2019/21 contract requirements.	NEL CSU
12/04/2024	7.0	Update to fit 2024/25 contract requirements.	NTeD team
15/05/2025	8.0	Update to fit 2025/26 contract requirements. (Acknowledgement to NEL ICS Team for sharing 'NEL ICS Collaborative contract: Management of HCDs excluded from the NHS PS – 2024/25' which has supported this update)	NCL Medicines Clinical Reference Group (mCRG)

Glossary & Definitions

Term	Definitions
Actual drug acquisition costs	The actual price the Trusts pays for the HCD. This should be in line with the agreed medicines procurement and supply chain (MPSC), patient access schemes (PAS) or commercial access arrangements (CAA).
Blueteq®	A web-based platform, providing prior approval forms to ensure eligibility for the initiation and continuation of NCL ICB-commissioned HCDs
Bundled price	The medicines framework price, which includes drug acquisition, homecare delivery and nurse training fees as a single price
CIP	Cost Improvement Plan
DrPLCM	Drugs Patient Level Contracting Monitoring
HCD	NHS PS excluded high cost drugs, for which NCL ICB is the responsible Commissioner
HCD Working group	The high cost drug working group supports the ICB Chief Pharmacist in providing oversight, assurance, compliance and recommendations for the delivery of HCD functions
IFR	Individual Funding Requests
IMOC	Integrated Medicines Optimisation Committee
MFVG	The Medicines Finance and Value Group provides financial oversight, scrutiny and assurance on primary and secondary care medicines expenditure across NCL ICS
NCL ICB	North Central London Integrated Care Board
NHS PS	National Health Service Payment Scheme, which replaces the National Tariff Payment System.
NHS PS prices	NHS PS unit and guide prices has replaced the national tariff; however, still provides a national price list for secondary care activity from which HCDs are excluded
NHSE	National Health Service England
NICE IPG	NICE Interventional Procedures Guidance
NICE TA	National Institute for Health and Care Excellence Technology Appraisal
Red List drug	A medicine that is on a hospital formulary but owing to their specialist, safety or monitoring requirements, GPs should not be asked to prescribe.

1. Introduction

1.1 The 2022 Health and Care Act established Integrated Care Systems (ICS) and formalised them as legal entities with statutory powers and responsibilities. Integrated Care Boards (ICBs) form part of an ICS and are responsible for the planning and funding of most NHS services in their allocated area.

1.2 This policy has been developed by the NCL High Cost Drug (HCD) team (with acknowledgment to NEL ICS HCD Team) and the NCL Provider Chief Pharmacists (Appendix 1) and applies to the following Providers:

University College London Hospitals NHS Foundation Trust [UCLH]	Moorfields Eye Hospital NHS Foundation Trust [MEH]
Royal Free London Group [RFL] (Barnet, Chase Farm, Royal Free & North Middlesex Hospitals)	Royal National Orthopaedic Hospital NHS Trust [RNOH]
Whittington Health NHS Trust [WH]	Great Ormond Street Hospital for Children NHS Foundation Trust [GOSH]
North London NHS Foundation Trust	Central and North West London NHS Foundation Trust (CNWL)*

*CNWL provide community health services in Camden and sexual health services across NCL.

1.3 It intends to support good clinical and financial management, compliance to policy and pathways and assurance of HCDs and devices, delivered by the Providers, to ensure the optimum patient outcomes and value for money.

1.4 NCL ICB is the host Commissioner for contracts held with NCL Provider Trusts.

1.5 The NCL ICB is accountable for funding and managing the expenditure on HCDs and devices for NCL patients. However, decisions agreed by NCL ICB, will impact all patients treated at NCL Providers and associate ICB Commissioners.

1.6 NCL ICB will adopt a collaborative and consistent approach with NCL Providers when commissioning and funding NHS PS excluded HCDs and devices in 2025/26.

2. Scope

2.1 This policy applies only to HCDs and devices excluded from the 2025/26 NHS PS and are the commissioning responsibility of NCL ICB i.e. within the NHS PS: 2025/26 Prices Workbook (Annex A).

2.2 This policy details the specification and arrangements for clinical and financial management of HCDs and devices excluded from the NHS PS from April 1st 2025 to March 31st 2026.

3. Medicines Governance

3.1 The NCL Integrated Medicines Optimisation Committee (IMOC) and its sub-groups, were developed during 2024/25 (Appendix 2) with the purpose of 'providing oversight and assurance on the ICB's statutory functions on medicines', including, safety, clinical outcomes and best value for money.

3.2 As part of the governance review, the NCL Medicines Finance & Value Group (NCL MFVG) was established to provide financial oversight, scrutiny and assurance on primary and secondary care medicines expenditure across NCL ICS to the IMOC.

3.3 HCD pathways will be developed collaboratively by the ICB and NCL Providers via the NCL HCD working group and the Medicines pathway group to ensure consistent clinical practice across the ICS and equity of access to medicines. These pathways will be predominantly based on NICE TAs but may also include non-NICE indications and will include information on clinical effectiveness, cost implications, safety, entry and exit points for patients and dose escalation rules.

3.4 All HCDs prescribed by the Providers must be approved as being clinically appropriate by the NCL Joint Formulary Committee (JFC) or the Provider's Drug and Therapeutics Committee and included in the NCL Netformulary platform or Provider's formulary (only applicable to MEH and GOSH).

3.5 The JFC approves the NCL Red List (a list of medicines that GPs should not be asked to prescribe owing to their specialist, safety or monitoring requirements). The responsibility for prescribing these medicines should remain with the hospital trust consultant unless, shared care has been agreed.

4. General Commissioning Principles

4.1 HCDs and devices specifically excluded from the 2025/26 NHS PS will only be reimbursed by NCL ICB, where use is in line with a recommended NICE TA or a NCL ICB agreed HCD pathway (for use not in line with a NICE TA).

4.2 NCL Principles for Commissioning HCD pathways for ICB commissioned indications have been agreed by NCL ICB IMOC and are detailed in Appendix 3.

4.3 HCDs listed in Annex A of the 2025/26 NHS PS will be agreed (commissioned) for specific indications by the ICB and will be published in the NCL ICB High Cost Drugs List.

4.4 Devices listed in Annex A of the 2025/26 NHS PS will be agreed for specific indications in the ICB.

4.5 Out-of-sector patients (i.e. those registered with a non-NCL GP) treated at a NCL Provider will be treated in line with NCL ICB approved HCD pathways.

4.6 Providers should comply with principles contained in local, national and professional guidance including but not limited to:

Publications:	
NICE - Technology Appraisal Guidance	Department of Health and Social Care
NICE - Clinical Guidance	NHS England
Medicines and Healthcare products Regulatory Agency	UK Health Security Agency

4.7 NCL ICB will only commission and reimburse HCDs and devices excluded from NHS PS prices at actual drug and device acquisition cost. Any costs charged above acquisition cost, Trusts will be expected to reimburse the ICB.

4.8 NCL ICB and the Provider will always aim to promote good quality medicines management in accordance with the NCL Interface Prescribing Guidance and NCL ICS Consensus on the NCL Primary & Secondary Care Interface.

5. Budget Planning

5.1 Finance and activity plans will be set as part of the annual contract negotiation process based on historic activity based on acquisition costs and adjusted in accordance with national planning guidance. Medicines horizon scanning outputs will be used to inform ICS growth costs with HCD and devices.

5.2 NCL ICB and Providers will work collaboratively to identify cost pressures and CIPs for HCD and devices expected in 2025/26, which will need to be agreed as part of the 2025/26 planning round.

5.3 HCDs and devices (excluded from the NHS PS prices) recommended within a NICE TA are mandated for commissioning from day 30 or 90 of its publication date.

5.4 HCDs and devices (excluded from the NHS PS prices) where use is not in line with a NICE TA, a locally agreed HCD pathway needs to be financially approved by the NCL MFVG (if over £200k per annum, will be referred to the Finance Recovery and Investment Board (FRIB)) or other appropriate finance governance committees.

5.5 HCDs and devices recommended by a NICE TA will be considered as part of horizon scanning and will be funded in year.

5.6 For HCDs and devices not recommended by a NICE TA, these will only be considered by the MFVG in exceptional circumstances and only if expected to be cost neutral or saving to the ICB HCD budget.

6. Funding and Reimbursement

6.1 The proposed contract model for HCDs and devices for 2025/26 will be within the variable element (i.e. cost and volume).

6.2 Providers must ensure HCD and devices are charged to NCL ICB at the **actual drug acquisition costs**, in line with the agreed medicines procurement and supply chain (MPSC), patient access schemes (PAS) or commercial access arrangements (CAA). This will represent the maximum that NCL ICB will reimburse. This supersedes any historic tariff arrangements. Any costs charged above acquisition cost will be expected to be reimbursed to the ICB.

6.3 No additional (on-costs or other) charges applied to HCDs or devices added by Providers will be reimbursed. The HCDs and devices costs are directly 'passed through' to the ICB. Providers should note that all cost pressures have to be managed within the overall ICB funding allocation as there is no additional in-year funding for ICB-commissioned HCD and devices (pass through) from NHSE.

6.4 The only exceptions for 2025/26 are:

- MEH package price (this is expected to be reviewed in year)
- Homecare unbundled price (see section 9.5).

6.5 Service Condition 39 (SC39) of the NHS Standard Contract 'If an NHSE Medicines Framework Product is clinically appropriate for use in the provision of the Services and is at the time of purchase available for timely supply via an NHSE Medicines Framework Agreement, the Provider must purchase that product via the relevant NHSE Medicines Framework Agreement'. The Provider will not be entitled to reimbursement for any medicine purchased in breach of SC39 where that medicine is listed in the HCD tab in Annex A of the 2025/26 NHS PS.

6.6 Excluded HCDs and devices recommended within a NICE IPG or NICE clinical guideline will not be routinely funded unless endorsed within a national clinical commissioning policy or locally agreed pathway.

6.7 HCDs and devices that are not NICE recommended or within a local HCD/devices pathway can be considered via an Individual Funding Request (IFR). IFRs are only applicable to patients with exceptional clinical circumstances and where there is no identified cohort. IFRs must be made in accordance with the NCL Individual Funding Requests IFR Policy.

7. Assurance & Audit

7.1 Treatment will be funded by NCL ICB upon receipt and approval of an initiation or continuation (where appropriate*) form via Blueteq®. *Required Blueteq® forms are listed in the NCL ICB HCD List.

7.2 The Provider will provide all relevant information to validate use in line with NICE TA or local HCD pathways via Blueteq® and submit within 5 days of the first treatment dose.

7.3 MEH do not currently submit Blueteq® forms and work is underway to review the assurance process for growth hormones in NCL.

7.4 A monthly report on HCDs and devices expenditure will be required as set out in the Information Schedule of the NHS Standard Contract including the minimum data set (MDS) (Appendix 4).

7.5 The ICB may seek validation of the use of some HCDs and devices from Providers.

- Validation queries may be raised on a monthly basis in line with national payment timetables. Where further action is required validation meetings may be convened.

7.6 NCL ICB reserve the right to audit Provider HCD and devices PLCM charges to demonstrate compliance with this schedule. Any audits will be designed using a collaborative approach.

- The ICB and the Provider will agree, the drugs, indications and timescales for completion of the post verification audits in 2025/26. Potential areas for audit may include audit against NICE TA or HCD pathways criteria or where projected spend varies significantly from that predicted.

8. Efficiency schemes

Best value medicines

8.1 Best value medicines, including biosimilars, must be considered as first line for patients in line with the NCL principles for commissioning HCD pathways for ICB commissioned indications (Appendix 3).

8.2 In line with NHSE's biosimilar medicines commissioning framework (April 2025), when the originator biologic loses market exclusivity and biosimilars first enter the market:

- 100% of new patients should be commenced on the 'best value' biologic within 3 months.
- At least 80% of existing patients should be switched to the 'best value' biologic medicine within 10 months.

8.3 When a procurement contract awards a new 'best value' version of a medicine, all new patients should be commenced on the 'best value' biologic within 3 months.

8.4 Best value generics should be adopted as per 8.2.

8.5 The NCL Joint Formulary Committee have agreed to support all biosimilars approved by the European Medicines Agency (EMA), therefore, future biosimilars do not need to be reviewed by the Joint Formulary Committee, provided the originator biologic is already on the NCL Joint Formulary.

'Invest to save' opportunities (incentivisation)

8.6 The ICB and Providers will be expected to work collaboratively to agree a Cost Improvement Plan (CIP) for HCD and devices to ensure best value for the ICS.

8.7 There may be a case to be made for temporary additional investment, in order to, realise specific savings in exceptional circumstances. Such circumstances are limited and require a clear description of the resource required and an explicit benefit realisation plan. So-called 'invest to save scheme', if approved, will create a commitment from the budget holder to a future reduction in the identified budget, as a result of, delivering the described project.

8.8 'Invest to save' opportunities will be considered, where they are in line with national principles and endorsed by the MFVG and meet the criteria set out below. Note that 'invest to save' business cases must be identified as part of the annual planning cycle.

8.9 'Invest to save' business case criteria:

- Any 'invest to save' funding required outside of allocated budget amounts will need to conform with the ICB's governance policy and in some instances, at the discretion of the ICB CFO, be required for submission to ICB FRIB for approval.
- All 'invest to save' business cases must clearly set out why the required expenditure cannot be identified from within the existing trusts' directorate budget.
- All 'invest to save' business cases must provide a detailed explanation of the proposed cashable savings to the ICB or additional income to the ICB generated by the scheme proposed.
- All 'invest to save' business cases must clearly set out the payback period (the time it will take to recover the initial additional investment) and the specific detail of the impact of the scheme over at least the next 3 financial years.
- All 'invest to save' business cases must clearly set out how savings are expected to be managed with the expectation that these are tracked through the year to ensure delivery.
- Any risks of non-delivery must be disclosed and mitigated within the 'invest to save' business cases and managed and reported upon as part of in-year monitoring.

- All 'invest to save' business cases must include an assessment of value for money and be in accordance with ICB's Standing Financial Instructions (SFIs).

8.10 Where national reference prices are recommended by NHSE, these will be adopted.

9. Homecare

9.1 When providing medicines to patients through homecare arrangements, Providers should be able to demonstrate that they are delivering on compliance with policy or guidance published in accordance with Royal Pharmaceutical Society of Great Britain (RPS) Professional Standards for Homecare Services and the House of Lords Public Services Committee's report on Homecare medicines services: an opportunity lost.

9.2 The NHS PS 2025/26 states the following: 'Homecare services (drugs, devices and their related costs) are also excluded from core payment mechanisms or prices. For these items and their related costs, local funding arrangements must be agreed by the commissioner and Provider, in accordance with the excluded items pricing rule set out.'

9.3 The Provider must hold all homecare contracts and ensure the following governance processes:

- All homecare transactions and prescribing should be recorded through the Provider pharmacy system.
- Providers' Chief Pharmacist or deputy should be designated as the responsible officer for clinical and financial governance.
- Providers will work collaboratively to ensure cost effective procurement and alignment of homecare contracts.

9.4 During the financial year 2025/26, work will be undertaken across NCL ICS to understand the resourcing and charging for homecare arrangements.

9.5 There is an expectation from the ICB that the Providers should ensure funds for homecare services are provided and that the pharmacy departments of each Trust are adequately resourced to provide homecare services to their patients.

9.6 For excluded drugs via homecare, purchasing the drug via the framework's 'bundled price' (bundled price covers drug acquisition, homecare delivery and nurse training fees) typically provides the lowest net acquisition cost. NCL ICB recognises that rare situations may arise where an unbundled arrangement (i.e. purchasing the drug from the framework at the 'NHS direct price' with separate homecare delivery /nurse training costs) may provide the lowest net cost for a cohort of patients.

9.7 Any unbundled arrangements will be reviewed by the HCD working group and recommendations for approval made to the MFVG. Providers must demonstrate a financial benefit to the Commissioner.

9.8 In year approvals may require a contract variation.

10. Clinical Trials

10.1 The ICB will not fund a patient's drug treatment commenced as part of any clinical trial. Any excess treatment costs related to non-commercial research studies will be funded in line with the NHS England *"*Guidance on Excess Treatment Costs*"* (updated March 2022).

10.2 Patients participating in a clinical trial must be made aware that there is no guarantee that the medicine will be continued irrespective of the results. In line with the Medicines for Human Use (clinical trials) regulations 2004, and the Declaration of Helsinki (1964 updated 2013), the responsibility for ensuring a clear exit strategy from a trial, and those benefiting from treatment and ongoing access to treatment, lies with those conducting the trial. The Provider must manage patients and their expectations through this process.

10.3 The local Research Ethics Committee must ensure that financial implications of trials are considered and resolved before agreement is given for trials.

11. Expanded Access Schemes

11.1 Expanded access schemes can include: 'free of charge' or discount medicines schemes.

- A free of charge 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.
- All FOC medicines schemes should be appropriately managed to safeguard both patients and the NHS.

11.2 NCL has agreed a guidance highlighting the necessary principles when reviewing FOC medicine schemes for individual patients or before inclusion onto local/regional formularies for an identified cohort, to ensure a consistent and equitable approach (NCL FOC medicines Schemes).

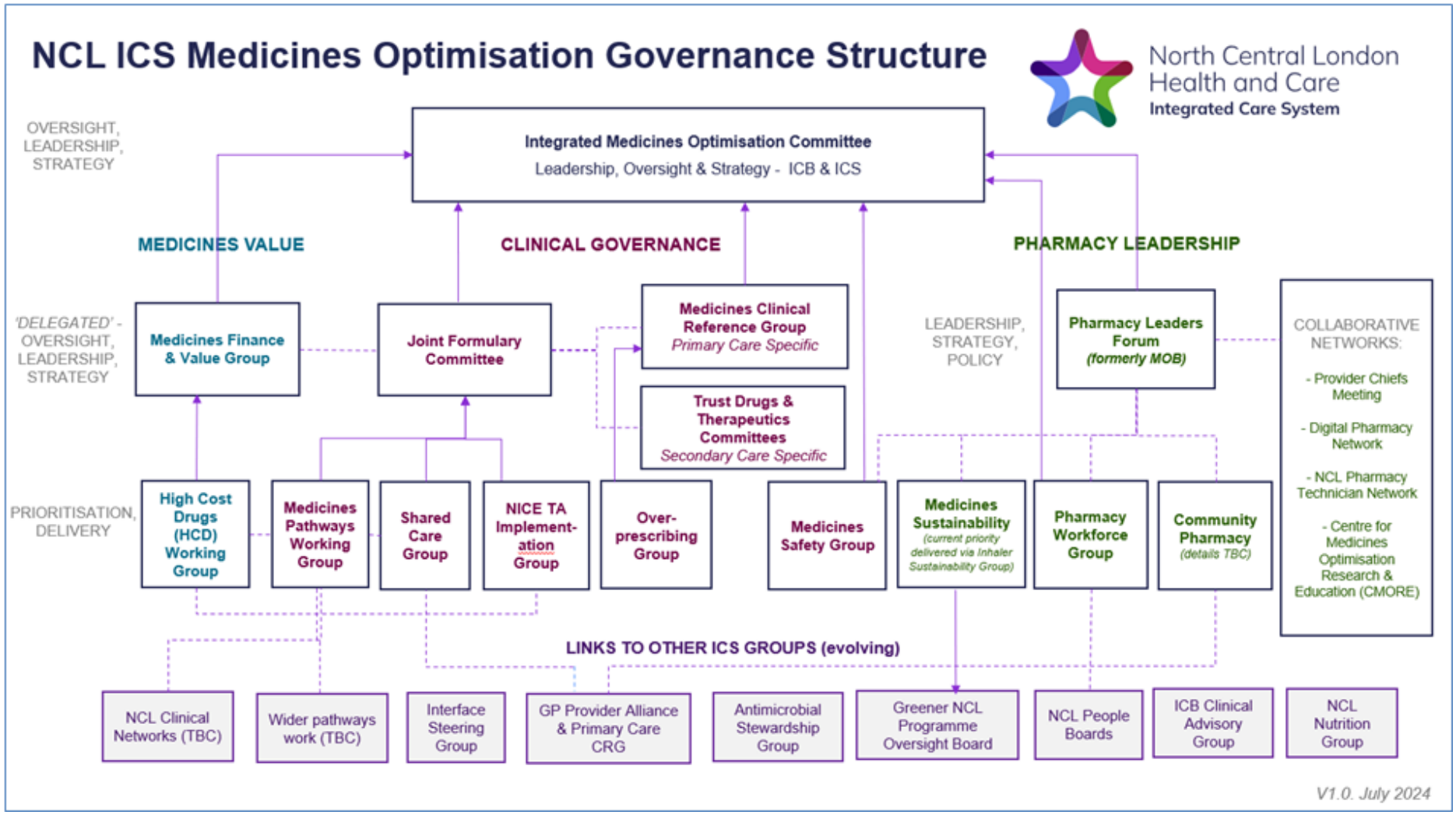
11.3 The ICB will not automatically fund, or support expanded access schemes where treatment has been initiated without prior agreement. This includes but is not limited to:

- Where free of charge stock is supplied to Providers for use in anticipation of a positive NICE TA.
- Free of charge and discount schemes, where the HCD use would not fall within current agreed HCD pathways.

Appendix 1: Stakeholder Engagement List

Provider Trust	Chief Pharmacist	Contracting lead
University College London Hospitals NHS Foundation Trust	Jatinder Harchowal	Nick Wright
Royal Free London NHS Foundation Trust	Wendy Spicer	Kim Sanderson
Whittington Health NHS Trust	Stuart Richardson	Rael Gamsu
Moorfields Eye Hospital NHS Foundation Trust	Naheed Phul	Richard Allen
Royal National Orthopaedic Hospital NHS Trust	Ashik Shah	Stephen Marshman
Great Ormond Street Hospital for Children NHS Foundation Trust	Jayne Ballinger	Rim Rahimtulla
North London NHS Foundation Trust	Lucy Reeves	Chris Blackburn
Central and North West London NHS Foundation Trust	TF Chan	Meenu Lakhani

Appendix 2: NCL ICS Medicines Optimisation Governance Structure



Appendix 3: Principles for commissioning HCD pathways for ICB commissioned indications

1) High-cost drug pathways should be updated by the NCL High Cost Drugs team within 90 days of publication of a positive NICE TA (or 30 days if MHRA Early Assess to Medicines Scheme or NICE Fast Track appraisal):
   a) All pathways should permit:
      i) 1 drug per mechanism of action, PLUS
      ii) A second biosimilar anti-TNF for patients who experienced secondary loss-of-response to the first anti-TNF (assuming the originator is recommended by NICE, and the biosimilar is available at a significant discount)
   b) All drugs with a NICE TA will be made available, however the expectation (supported by a traffic light system) is that
      i) Lower cost drug classes are used preferentially to higher cost classes
      ii) Where two or more drugs have the same mechanism of action, the drug with the lowest acquisition cost is used preferentially
   c) Where there is a claim of superiority of a given drug (vs. biosimilar or a lower cost drug) the NCL JFC will evaluate whether the more expensive drug is cost-effective. For the avoidance of doubt, NCL JFC will not make an assessment on affordability.
   d) Where there is a claim that more than one drug per mechanism of action should be made available the NCL JFC will evaluate whether this is cost-effective.
   e) For patients who experience an immediate ADR [within 1 month] or have responded to treatment but experience an ADR within 6 months of treatment initiation, another treatment option within the same mechanism of action (if available and appropriate) can be accessed. Where the ADR is likely to be a drug class effect, an alternative mechanism of action is preferable.
2) Drug costs should include drug acquisition price plus any fee associated with drug administration e.g. infusion costs, homecare costs.
   High-cost drug pathways are to be approved clinically by NCL Joint Formulary Committee and NCL Integrated Medicines Optimisation Committee, and financially by the NCL Medicines Finance and Value Group, within the implementation period.
3) Contracting and finance arrangements between ICBs and Trusts should not delay the provision of NICE TA treatments.
4) Where an updated high-cost drug pathway is clinically but not financially approved within the NICE TA implementation period, the new drug can be used in line with the wording of the TA (i.e. any patient who meets eligibility criteria, regardless of locally optimised place in therapy or prior mechanisms of action).
5) **Dual biologic therapy for the same disease** is not routinely commissioned; for individual cases, please consider RMOC advisory statement, discuss at MDT and contact Trust formulary teams for advice re IFR submission.
   Concurrent biologic treatment for different co-morbidities, is permissible provided NICE eligibility criteria for both treatments are met and there is MDT agreement across both specialities that dual therapy is appropriate and a single drug which is active against both co-morbidities is not available.

Appendix 4: Minimum Data Set (MDS) for Invoices

The Provider must provide the following complete data set to NCL ICB in accordance to the Drugs Patient Level Contracting Monitoring (PLCM) Specification and monitoring report deadlines to request payment for NHS PS excluded drugs prescribed in line with criteria agreed between NCL ICB and the Provider.

Minimum Data Set (MDS) for Invoices
Financial month
Financial year
Date and time data set created
Organisation identifier (code of provider)
Organisation identifier (gp practice responsibility)
Organisation identifier (code of commissioner)
General medical practice code (patient registration)
Withheld identity reason
NHS number
Local patient identifier (extended)
Postcode of usual address
Person birth date
Age at activity date (contract monitoring)
Person stated gender code
Activity treatment function code
Hospital provider spell number
Attendance identifier
Clinical intervention date (drug administered)
Therapeutic indication code (snomed ct)
High cost tariff excluded drug code (snomed ct dm+d)
Dm+d taxonomy code (high cost tariff excluded drug)
Drug name (high cost tariff excluded drug)
Route of administration (snomed ct dm+d)
Drug strength (high cost tariff excluded drug)
Drug volume (high cost tariff excluded drug)
Drug pack size (high cost tariff excluded drug)
Drug quantity or weight proportion (high cost tariff excluded drug)
Unit of measurement (snomed ct dm+d)
Dispensing route (high cost tariff excluded drug)
Provider reference number
Commissioned service category code
Specialised service code
Point of delivery code
Point of delivery further detail code
Point of delivery further detail description
Contract monitoring additional detail (1-5)
Contract monitoring additional description (1-5)
Unit price (supplier)
Unit price (commissioner)
Home delivery charge (high cost tariff excluded drug)
Value added tax charged indicator (contract monitoring)
Total cost