North Central London Integrated Care System

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

Formerly Payment by Results Excluded Drugs & Devices or National Tariff excluded Drugs (NTeD)

For inclusion in NHS Provider contracts as a document

Policy Year 2024/25
Issue date 29/04/2024

Document control

Date	Version	Amendment	Amendment approved by
06/10/2015 – 22/02/2017	1.0	Medicines Management Schedule 2015/16 updated for Review by CCGs changes • 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

Related documents

Title
NHS England Drugs and Devices List: Version 19
NCL ICB Commissioned High Cost Drugs List 2024/25
National Tariff Prices Workbook 2024/25 (Annex A)
NCL ICB Interface Prescribing Guidance
NCL Red List

Glossary & Definitions

Blueteq®	Prior approval forms assuring eligibility for the initiation and continuation of ICB-commissioned HCD
CIP	Cost Improvement Plan
HCD	High cost drugs (ICB commissioned NHS PS excluded drugs only)
IFR	Individual funding requests
NCL ICB	North Central London Integrated Care Board
NHSE	National Health Service England
NHSPS	National Health Service Payment Scheme
NTeD	National Tariff excluded Drugs
NIEC TA	National Institute for Health and Care Excellence Technology Appraisal
Bundled price	The medicines framework price which includes drug acquisition, homecare delivery and nurse training fees as a single price.
Red list status	A medicine that GPs should not be asked to continue the prescribing.
NTeD Working group	National Tariff Excluded Drugs Working Group
Medicines Finance & Value Group	Provides financial oversight, scrutiny and assurance on primary and secondary care medicines expenditure across NCL ICS.
NICE IPG	NICE Interventional procedures guidance

Contents

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 (ICB) form part of the ICS and are responsible for the planning and funding of most NHS services in the area.

1.2 NCL ICB is the Commissioner or Coordinating Commissioner, known as the Commissioner, for contracts held with NHS provider trusts individually, known as the Provider.

1.3 NCL ICB will adopt a collaborative approach with NCL Providers when commissioning and funding new NHS PS excluded high-cost drugs and devices in 2024/25. The ICB must manage all of the financial risk.

1.4 The Commissioner has adopted a consistent approach across all trusts when commissioning and funding drugs and devices, including new drugs and devices, excluded from National Tariff.

1.5 Out of Sector patients should be treated the same as a patient who is registered with a GP practice within NCL ICB i.e. out-of-area patients should be treated in line with NCL ICB approved pathways.

2. Scope

2.1 This policy applies only to those NHS PS excluded drugs and devices that are the commissioning responsibility of NCL ICB. Excluded drugs are listed within the NCL high cost drugs list and devices within the National tariff workbook (Annex A).

2.2 This policy provides details of medicines management specification and arrangements for managing high cost drug excluded from NHS PS after March 31st 2024.

2.3 Providers and Commissioners in an ICS jointly agree on commissioning policies and formulary recommendations. To operate to the NHS Contract these are classified as host commissioner rules. Therefore, providers will apply these policies and recommendations to all patients undergoing treatment irrespective of the commissioner they are referred from. Including referring to the Provider Trust's local formulary position on medicines used in the service, red list status and prescribing arrangements.

3. General Commissioning Principles

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

- NICE Quality Standards
- NICE Clinical Guidance
- NICE Technology Appraisal Guidance
- Publications issued by the Department of Health and Social Care
- Publications issued by NHS England
- Publications issued by the Medicines and Healthcare products Regulatory Agency
- Publications issued by UK Health Security Agency (UKHSA)
- National Service Frameworks
- Regional Medicines Optimisation Committees or equivalent
- Royal Pharmaceutical Society

3.2 The Provider will provide all relevant information to validate use in line with NICE or local commissioning policies using agreed web-based forms via Blueteq.

3.3 All existing drugs and devices should be provided in accordance with NHS PS rules and will be considered as within the scope of the National Tariff unless listed explicitly as an excluded high cost drug or device in the National tariff workbook (Annex A) or as part of excluded services.

3.4 Drugs and devices specifically excluded from National Tariff will only be funded where the use is in line with criteria agreed with the Commissioner. The drugs and their respective indications that the Commissioner commissions from the Provider, is defined in the NCL high cost drug list. This list will be updated to reflect any changes detailed in the most recently published NHSE drug list. The Commissioner will only reimburse drugs and devices excluded from National Tariff at acquisition cost, notwithstanding any local agreements.

3.5 The Commissioner and the Provider will always aim to promote good quality medicines management in accordance with the NCL Interface Prescribing Guidance.

3.6 Although the ICB will manage the financial risk, a collaborative approach will be taken when the Commissioner and Providers agree Cost Improvement Plan (CIP) for high cost drugs. 'Invest to save' opportunities should be shared with the Commissioners by Providers and will be considered where they are in line with national or local principles and endorsed by the Commissioner.

3.7 Where 'Invest to save' is agreed, it should be clearly identifiable in the data submitted to the Commissioner as 'Invest to save'.

3.8 New drugs and devices identified during 2024/25 will be considered by the Commissioner when a business case is submitted by the Provider to the NTeD working group. Any changes will be made as contract variations in accordance with General Condition 13 Variation of this Contract. Note, this does not include new drugs or devices that have received a recommendation under a NICE Technology Appraisal or NHS England Clinical Commissioning Policy.

3.9 Providers and Commissioners will work collaboratively to agree a CIP with each Provider for high cost drugs, this may include recommendations by the North Central London Medicines Optimisation Network. The CIP should include how the saving to the baseline revenue of the Provider under this Contract will be shared within the ICS.

3.10 Detailed Principles for Commissioning high cost drug pathways for ICB commissioned indications have been agreed by NCL ICB IMOC and are detailed in Appendix 1.

4. Commissioning & Procurement

4.1 Finance and activity plans will be set as part of the contract negotiation process on an annual basis based on historic activity. Where appropriate this will be supplemented by the Provider's assessment of need through horizon scanning, and development of a business case following clinical review at the NCL Joint Formulary Committee (JFC). It is not anticipated that new excluded drugs and devices will be funded in-year unless approved by NICE and/or anticipated funding requirements have been previously identified.

4.2 Significant variation is experienced in the prices that commissioners pay for a range of drugs and devices that are provided to patients but are not covered by tariff.

4.3 The NHS is not obtaining best value from the opportunity to procure these at scale, with standard terms. ICB Commissioners have established a London-wide procurement framework for excluded drugs and devices, led by the London Procurement Program (LPP) that provides a local transparent price list that will be the maximum payable by Commissioners.

4.4 This price list will not include administration costs, and prescribing costs of aligned therapies will not be chargeable.

4.5 Providers must provide the ICB with assurance that medicine charges reflect actual drug acquisition costs, except where a local agreement has been reached. No additional (on-costs or other) charges applied to drugs or devices added by Providers will be recognised or reimbursed unless specifically agreed otherwise. These drugs and devices costs are directly 'passed through' to the Commissioner as the responsibility of the ICB.

4.6 Service Condition 39 (SC39) of the NHS Standard Contract *'If an NHSE Medicines Framework Product is clinically appropriate for use in relation to the Services and is at the time of purchase available 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 payment for any medicine purchased in breach of SC39 where that medicine is listed in the high cost drugs tab at Annex A of the NHS PS.

4.7 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. The Commissioner recognises that rare situations may arise where purchasing the drug from the framework at the 'NHS direct price' with the Provider arranging separate homecare delivery /nurse training may provide the lowest net acquisition cost. In exceptional circumstances, the Provider may wish to utilise an unbundled arrangement for a cohort of patients to mitigate the financial risk to the Commissioner. Any unbundled arrangements will have to be approved in advance by the Medicines Finance and Value group, whereby the Provider must demonstrate a financial benefit to the Commissioner. In these situations, the decision will be taken by the Medicines Finance and Value group and the need for a contract variation will be considered.

5. Payment

5.1 NICE approved drugs/ devices recommended within a NICE Technology Appraisal, which are excluded from tariff, will be funded from day 90 or 30 of its publication. Some approved drugs and devices may be funded before this time at the discretion of the Commissioner.

5.2 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 local clinical commissioning policy.

5.3 Treatment will be funded by NCL ICB subject to receipt of an initiation and continuation (where appropriate) form via Blueteq*, that captures required data:

- current clinical status as defined by NICE or agreed local criteria e.g. DAS
- baseline scores (if available)
- valid clinical reason for continuing

**Required Blueteq forms are listed in the NCL high cost drugs list for 2024/25.*

5.4 Providers are expected to meet the requirements of NICE Technology Appraisals, demonstrate compliance using prior notification forms via Blueteq and submit within 5 days of the first treatment dose.

5.5 Legacy patients, i.e. those patients started on high cost drugs prior to NICE guidance or local agreement will be managed on an individual basis over the course of the year. Treatment for these patients will be funded by NCL ICB, subject to receipt of a continuation form via Blueteq that captures the required outcome data.

5.6 Those excluded drugs and devices that are not NICE approved or endorsed within a local clinical commissioning policy can be considered via an Individual Funding Request (IFR).

5.7 IFRs must be made in accordance with the NCL Individual Funding Requests IFR Policy.

6. Financial Assumptions

6.1 Excluded drugs and device costs charged to the Commissioner will be reflective of actual product acquisition costs to Providers. The Commissioner will reserve the right to audit Provider costs to

demonstrate compliance with this schedule. Where national, London-wide or local procurement terms have been adopted and commercial best price obtained these will be applied by the Commissioner. The cost of these drugs should represent good value for money to the Commissioner.

6.2 In line with IMOC guidance if more than one treatment is suitable, the least expensive treatment should be used by the Provider.

6.3 NCL ICB will maintain a central repository of prices for all excluded drugs and devices that is updated as national, London-wide or local procurements are implemented. This will represent the maximum that the Commissioner will pay.

6.4 Providers are not expected to negotiate NHS PS excluded drugs prices outside of regional or national contracts. Any lower prices should be declared to the ICB.

6.5 Invest to save opportunities will be considered where they are in line with national principles and endorsed by the Commissioner. All existing 'invest to save' arrangements must be identified by June 2024 and will be reviewed against national principles identified and presented to and agreed by the NTeD working group.

6.6 Where drugs and devices are used outside of NCL ICB commissioned services, any consequential costs that are incurred will not be funded. This includes the costs associated with the entire treatment.

6.7 Non-excluded drugs prescribed concurrently with the excluded drugs are not chargeable as these are covered within national tariff, unless formally agreed by NCL ICB.

6.8 No additional charges above cost will be accepted. The only exception to this will be for those drugs specifically identified in 2024/25 NHS PS policy, explicitly agreed with NCL ICB and specifically agreed within the contract.

6.9 It is expected that all drugs subject to discounts, rebates or other such Patient Access Schemes (PAS) agreed as part of a NICE Technology Appraisal review will be charged to the Commissioner at full net cost unless by prior approval.

6.10 The Commissioner will not fund a patient's treatments undertaken as part of any clinical trial. Any excess treatment costs (ETC) related to non-commercial research studies will be funded in line with the NHS England *"*Guidance on Excess Treatment Costs*"* (updated September 2021).

6.11 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.

6.12 The Provider must manage patients and their expectations through this process. The local Research Ethics Committee must ensure that financial implications of trials are considered and resolved before agreement is given for trials.

6.13 The Commissioner will not fund a patient's treatment undertaken at the cessation of an expanded access scheme or withdrawal of compassionate funding by a pharmaceutical company.

7. Performance Monitoring

7.1 A monthly report on drugs 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 2).

7.2 The ICB may seek validation of the use of some drugs and devices from Providers. Any audits will be designed using a collaborative approach.

7.3 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.

7.4 The Commissioner / Coordinating Commissioner and the Provider will agree, as soon as possible and not later than 30th September 2024 the drugs, indications and timescales for completion of the post verification audits in 2024/25. Potential areas for audit may include audit against NICE criteria or where projected spend varies significantly from that predicted.

8. Medicines Governance

8.1 All drugs used by the Provider must be approved by the NCL JFC or the Provider's Drug and Therapeutics Committee as being clinically appropriate.

8.2 The Provider must publish clear, simple and transparent information that sets out which NICE Technology Appraisals are included in the Provider's formulary.

8.3 Providers and Commissioners will work collaboratively to identify cost pressures beyond March 31st 2025 resulting from any new drugs, indications or NICE guidance expected in 2025/26, by January 31st 2025.

9. Homecare

9.1 When providing medicines to patients through homecare arrangements, Providers should be able to demonstrate that they are working towards compliance with policy or guidance published in response to the findings of the Hackett Report on homecare medicines including professional standards issued by the Royal Pharmaceutical Society of Great Britain, and take account of the recommendations in the Lord Carter Review. Further issues regarding homecare medicines services, is highlighted in the Public Services Committee's report on Homecare medicines services: an opportunity lost.

9.2 The Provider must hold all home care 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 and Commissioner will work collaboratively to ensure cost effective procurement and alignment of homecare contracts.
- Providers shall implement all national and local homecare guidance including:
  - Royal Pharmaceutical Society: Homecare Services Professional Standards.
- Information on pathways currently available in NCL can be found on the NCL Health & Care website.

10. Biosimilars

10.1 In line with NHSE's biosimilar medicines commissioning framework, when the originator biologic loses market exclusivity and biosimilars first enter the market:

- 90% new patients should be commenced on the 'best value' biologic within 3 months
- switch plans need to be in place and started within 3 months
- and at least 80% of existing patients should be switched to the 'best value' biologic medicine within 12 months.

10.2 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.

Appendix 1: Principles for commissioning high cost drug 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; see **Error! Reference source not found.**) 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 2: Minimum Data Set (MDS) for Invoices

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