For inclusion in NHS Provider contracts as a document relied on:

CCG Commissioned National Tariff Payment System (NTPS)
Formerly Payment by Results
Excluded Drugs & Devices Policy
2017/19
### Amendment history:

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<td>Medicines Management Schedule 2015/16 updated for review by CCGs changes</td>
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1. **Introduction**

1.1. This policy has been developed by the North and East London Commissioning Unit (NELCSU) on behalf of NHS North Central London (NCL) Clinical Commissioning Groups (CCGs).

1.2. NHS Barnet, Camden, Enfield, Haringey and Islington CCGs are the Commissioner or Coordinating Commissioner, known as the Commissioner, for contracts held with NHS provider trusts individually, known as the Provider.

1.3. It details the medicines management specification and arrangements for managing drug exclusions from the National Tariff after March 31st 2017.

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

2.1. All drugs, devices and technologies, including new drugs and technologies, should be provided within the scope of National Tariff unless specifically excluded in the NTPS guidance.

2.2. Drugs, devices and technologies specifically excluded from National Tariff will only be funded where the use is in line with criteria agreed with the Commissioner.

2.3. The drugs and their respective indications that the Commissioner commission from the Provider, is set out in Appendix 1 - Provider List of Excluded Drugs. This list will be updated to reflect any changes detailed in the final published NHSE drug list.

2.4. Providers should comply with principles contained in local, national and professional guidance including NICE Technology Appraisal Guidance, Department of Health, NHS England and Medicines and Healthcare products Regulatory Agency publications, National Service Frameworks, relevant Health Service Circulars and Guidance, Executive Letters, Audit Commission reports, Lord Carter’s Reports & Hackett Report.

2.5. The Provider will provide all relevant information to validate use in line with NICE or local commissioning policies using agreed London-wide tick box notification proformas or web-based forms via Blueteq.

2.6. New drugs, devices or technologies identified during 2017/19 will be considered by the Commissioner when a business case is submitted by the Provider. 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, devices or technologies that have received a recommendation under a NICE Technology Appraisal or NHS England Clinical Commissioning Policy.

2.7. The Commissioner will not fund a patient’s treatments undertaken as part of a commercially sponsored clinical trial. Any excess treatment costs related to non-commercial research studies will be funded in line with the DH guidance (HSG (97) 32).

2.8. The Commissioner will only reimburse drugs, devices and technologies excluded from National Tariff at acquisition cost, notwithstanding any local agreements (see 3.4 below).
2.9. The Commissioner will agree an annual saving plan for drugs with the Provider, including local and national Quality, Innovation, Productivity, Prevention (QIPP) initiatives.

2.10. Risk Share opportunities should be presented to commissioners by providers and will be considered where they are in line with national or local principles and endorsed by the Commissioner. Where risk share is agreed, it should be clearly identifiable in the data submitted to the Commissioner as ‘Risk share’.

The Commissioner and the Provider must work in accordance with the principles within the NCL Medicines Optimisation Network (NCL MON) Prescribing Guidance at Appendix 2 which aims to promote good quality medicines management.
3. Commissioning and procurement

3.1. 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.

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

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

3.4. Providers must provide NCL CCGs with assurance that medicine charges reflect actual acquisition costs, except where a local agreement has been reached. No additional (on-costs or other) charges applied to medicines or technologies added by Providers will be recognised or reimbursed unless specifically agreed otherwise.

3.5. These drugs and devices are directly ‘passed through’ to the Commissioner as the responsibility of CCGs.

3.6. Legacy patients i.e. those patients started on NTPS-excluded medicine prior to NICE guidance or local agreement will be managed through a process agreed with Commissioners, with the Providers ensuring they are reviewed on an individual basis over the course of the year.

3.7. Treatment for these patients will be funded by NCL CCGs subject to receipt of a continuation form that includes:

3.7.1. Current clinical status as defined by NICE or local agreement criteria e.g. DAS scores;

3.7.2. and Baseline scores if available;

3.7.3. or Valid clinical reason for continuing and definition of treatment failure in the individual patient.
4. **Payment**

4.1. Drugs as detailed in the current Commissioner excluded drug list will be commissioned in line with the Commissioner’s commissioning policies and NICE Technology Appraisals (TA). [http://guidance.nice.org.uk/TA/Published](http://guidance.nice.org.uk/TA/Published)

4.2. NICE approved drugs/devices recommended within a NICE Technology Appraisal, which are excluded from tariff, will be automatically funded from day 90 of its publication.

4.3. Some approved drugs and devices may be funded before this time at the discretion of the Commissioner.

4.4. NCL CCGs use a series of standard tick box forms (TBFs) for medicines commissioned by CCGs. The TBFs detailed in Appendix 4 must be used to request medicines indicated as ‘TBF’ on the “Provider List of Excluded Drugs 2017/19 Medicines not reimbursed through national tariff prices funded by NHS England and NCL CCGs” (Appendix 1) where applicable. Note, the term TBF relates to paper and electronic (Blueteq) forms.

4.5. Providers are expected to meet the requirements of NICE Technology Appraisals and be able to demonstrate compliance through completion of prior notification London-wide tick box forms, electronic forms via Blueteq or provision of all the same data in a local database. This is detailed in the Provider List of Excluded Drugs 2017/19 (Medicines not reimbursed through national tariff prices funded by NHS England and NCL CCGs” document (Appendix 1).

4.6 The current tick box notification forms can be obtained from the IFR team and must be sent to the Commissioner in line with the NELCSU Individual Funding Requests (IFR) policy.

4.7 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, if there is evidence that the patient has clinically exceptional circumstances in comparison with other patients with the same condition presenting at the same stage of the disease. However, where the intervention relates to a cohort, a business case will be required for review by the Commissioner.

4.8 Individual Funding Requests (IFR) must be made in accordance with the NELCSU Individual Funding Requests IFR Policy.

4.9 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.
4.10 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 ratification 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.

5 Financial Assumptions

5.6 Excluded drugs and device costs charged to the Commissioner will be reflective of actual product costs to providers. The commissioner will reserve the right to audit provider costs to demonstrate compliance with this term. 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.

5.7 The Provider should use the most cost effective drug treatment where there is more than one drug choice.

5.8 NELCSU 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.

5.9 If Providers obtain better value than this national price then the Provider should be offered the national, London-wide or local funded level on the condition that it joins the appropriate programme so that the programme achieves this benchmark level.

5.10 Risk share opportunities will be considered where they are in line with national principles and endorsed by the Commissioner. This may also include on-going costs for delivery of safe and appropriate homecare.

5.11 All existing risk sharing arrangements must be identified by 30 April 2017 to the NEL CSU Acute Services Medicines Management lead and will be reviewed against national principles developed by the Medicines Optimisation Network.

5.12 Where agreement cannot be reached on share of gains or proposals offer limited value, the full value of best price and best prescribing practice will be passed through in line with national guidance.

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

5.14 Non-excluded drugs prescribed concurrently with the excluded drugs are not chargeable as these are covered within national tariff.

5.15 No additional charges above cost will be accepted.

5.16 The only exception to this will be for those specifically identified in 2017/19 Payment by Results guidelines, explicitly agreed with NCL CCGS and specifically agreed within the contract.
5.17 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. A list of existing patient access / rebate schemes can be found at:

https://www.nice.org.uk/about/what-we-do/patient-access-schemes-liaison-unit/list-of-technologies-with-approved-patient-access-schemes

5.18 The Commissioner will not fund a patient's treatment undertaken as part of a commercially sponsored clinical trial, the ending of an expanded access scheme or withdrawal of compassionate funding by a pharmaceutical company.

5.19 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 Act 2004, and the Declaration of Helsinki, the responsibility for ensuring a clear exit strategy from a trial and those benefiting from treatment will have on going access to it, lies with those conducting the trial.

5.20 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.

5.21 Excess treatment costs related to non-commercial research studies will be funded by the Commissioner in line with the DH guidance (HSG (97) 32) and DH Guidance on funding Excess Treatment Costs related to non-commercial research studies and applying for a subvention that can be found respectively at:


6 Performance Monitoring

6.1. All providers will be required to fully populate electronic NCL-wide tick box notification forms or web-based forms using Blueteq to ensure drugs are being used safely within the commissioned NICE or local criteria. This includes indication, product name and strength, dose and date of dispensing

6.2. A monthly report on drugs and devices expenditure will be required as set out in the Information Schedule of the NHS Standard Contract (see Appendix 3 Minimum data Set for Invoices).

6.3. Validation of the use of excluded drugs and devices will be requested by NCL CCGs where there is a reported overspend or an area of concern identified by Commissioners. This will normally be in the form of an audit.

6.4. Any use of a drug/device outside the agreed criteria without express authority from NCL CCGs will not be funded.
6.5. Validation queries will be raised on a monthly basis in line with national payment timetables. Where further action is required validation meetings will be convened on a quarterly basis.

7. CQUIN on Drugs and Devices Excluded from Tariff

7.1. NCL CCGs, in line with NHS England, will exclude all Payment by Results excluded drug and device budgets from the contract value to which CQUIN applies for all NCL CCG contracts.

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 in order to meet the requirements in the DH guidance *Innovation, Health and Wealth publication of NHS formularies (2012)*

8.3. The Provider will work with the Commissioner to identify cost pressures beyond March 31 2018 resulting from any new drugs, new indications or NICE guidance expected in 2018/19, by September 2017.

8.4. The NCL JFC shall prioritise and consider the clinical effectiveness of the identified interventions between October and December 2017 and the Commissioner shall consider prioritised cost pressures within the 2017/19 contracting round. All cost pressures must be identified by the Provider and prioritised by the Commissioner before 31 March 2018.

8.5. 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*.

8.6. The Provider must hold all home care contracts and ensure the following governance processes:

a) all homecare transactions and prescribing should be recorded through the Provider pharmacy system

b) the Provider Chief Pharmacist or deputy should be designated as the responsible officer for clinical and financial governance

c) the Provider and the Commissioner shall ensure the cost effective procurement and alignment of homecare contracts

8.7. The Commissioner / Coordinating Commissioner and the Provider will agree, as soon as possible and not later than end of June 2017, the drugs, indications and timescales for completion of the post verification audits in 2017/19. Potential areas for audit may include audit against NICE criteria or where projected spend varies significantly from that predicted.

9. QIPP and cost effective prescribing

9.1. The Commissioner will agree a Quality, Innovation, Productivity, Prevention (QIPP) and cost effective savings plan, including areas identified by the North Central London Medicines Optimisation Network, with the Provider.

9.2. The QIPP plan will include all prescribing by the Provider that have a direct or indirect effect on the Commissioner’s acute or primary care prescribing budgets.

9.3. This agreement will include how the saving to the baseline revenue of the Provider under this Contract will be shared between the Commissioner and the Provider as appropriate and where agreed.

9.4. The Medicines QIPP plan will be developed by the NCL Medicines Optimisation Network and implemented through the NCL Joint Formulary Committee work plan by longstop date.

Glossary

NCL North Central London, namely Barnet, Camden, Enfield, Haringey and Islington, CCGs

NICE National Institute for Clinical Excellence

National Tariff The list of prices published from time to time by the Department of Health and applied in line with Department of Health guidance relating to National Tariff construction and coding, charging and recording methodologies, in particular the NTIPS Rules and the Operation of Secondary Uses Services (SUS) to support Payment by Results, each as amended, re-issued or replaced from time to time.

PbR Payment by Results – the rules and core principles of the NHS financial system.

PbR exclusion A service, drug, technology or treatment for which the price is not specified in the National Tariff.

DH Department of Health
This is a request to fund, for an individual, an episode of healthcare that currently falls outside existing contracts where the patient falls outside generic or treatment specific policy where unusual circumstance apply to the individual. This does not include newly licensed drugs.

Service Development

Refers to any new developments including:
new treatments, including medicines
changes to treatment thresholds
use of drugs for unlicensed indications

Appendices

1. Provider List of National Tariff Payment System (NTPS) formerly NTPS Excluded Drugs 2017/19 (Medicines not reimbursed through national tariff prices funded by NHS England and NCL CCGs)

2. CCG PbR Excluded Drug List V11

3. NHSE drug list


3. Minimum Data set for invoices

4. Tick box forms or blueteq
Appendix 1

1.1 Provider List of NTPS (formerly PbR Excluded Drugs) 2017/19 (Medicines not reimbursed through national tariff prices funded by NHS England and NCL CCGs)

1.2 CCG PbR Excluded list 17-19 V11

1.3 NHSE drugs list V11
Appendix 2

NCL Medicines Optimisation Network (NCL MON) Prescribing Guidance v12

Red List V18
Appendix 3
Minimum Data Set for Invoices

The Provider must provide the following complete data set to the Commissioner in accordance with the provider monitoring report deadlines to request payment for NTPS excluded drugs prescribed in line with criteria agreed between the Commissioner and the Provider, detailed in appendix 1. The Minimum Data Set (MDS) for invoices must include:

- Provider code
- Provider name
- Financial Year and Month
- Drug Name
- Drug Strength
- Drug dose for new patients or changed doses (maybe supplied via relevant software or submission of tickbox notification form)
- Drug Indication
- Issue date
- Quantity supplied
- Acquisition cost after any rebate or patient access scheme applied, notwithstanding any local agreements
- CCG code
- CCG name
- Patient NHS Number
- Local Patient Code
- Date of Birth
- Post code
- Practice code
- Additional Information where specifically required e.g. Growth Hormone, Infliximab*, Risk share identifier.

*Additional information relating to patient weight, where required in order to verify dosage and or costs e.g. growth hormone, would be considered a minimum requirement.
Appendix 4
Tick Box Forms

Tick Box Forms or Blueteq

Current Tick Box Forms*
Updated forms will be available and added to the appendix as they are
developed

*Note: New NICE guidance or agreed indications for NTPS excluded drugs that occur in year
may result in the need for TBF revision or new TBF. The commissioner would expect these or Blueteq
to be used where such a development occurs as a ‘prior approval process’.