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PrescQIPP
Funded by the NHS for the NHS

Commissioning high cost drugs (HCDs) and devices 22/23

This bulletin provides summary information and guidance to Integrated Care Boards (ICBs) on arrangements for high cost drugs and devices that are excluded from the National Tariff in England and provides supporting tools for implementation.

This version is based on the NHS contract and National Tariff Payment system information for 2022-2023. It is anticipated that a new version of the NHS contract and payment system will be published and adopted for 2023-2025 and this bulletin will be updated to reflect any significant changes to national policy.

Different funding mechanisms are in place across NHS Scotland, NHS Wales and NHS Northern Ireland (NI) and information is included regarding the devolved nations, where applicable.

Recommendations

- Drugs and devices that are specifically excluded from the national tariff in England, or similar payment arrangements in the devolved nations, should not automatically be funded by local commissioners.
- Only drugs and devices with indications for use that are the responsibility of ICBs/Health Boards (HB), and which have been through the ICB/HB due governance process and received a positive funding decision should be commissioned. This includes drugs and devices which have been considered locally via submission of a business case or following a positive NICE Technology appraisal (TA) or reviewed by the Scottish Medicines Consortium (SMC) in Scotland.
- England: ICBs should ensure that arrangements for commissioning excluded HCDs and devices are specified in contracts with provider organisations. An example of a contract schedule specifying the commissioning arrangements between an ICB and provider organisation, and an appendix listing commissioning arrangements for all ICB commissioned and excluded high cost drugs and devices, is available via the PrescQIPP website for local adaption as schedule 2 contract addendums.
- Northern Ireland (NI): NICE TAs do not automatically apply to NI. Once NICE publishes a final appraisal determination, the local Department of Health assesses the guidance for applicability to NI and aims to publish endorsement decisions on its website, with links to appropriate caveats, where these apply, within 4 weeks of full publication. If the NICE guidance is not applicable to NI, then this is highlighted with an explanation and communicated to the Health and Social Care Trusts and other relevant stakeholders through a service notification from the NI Strategic Planning and Performance Group (SPPG). The applicability to NI of any patient access scheme is also assessed.
- Scotland: Drugs and devices should be considered for funding by HBs in accordance with the SMC recommendations in Scotland, or by local consideration via local due governance processes. NICE TAs do not automatically apply to Scotland.
- Wales: NICE TA guidance applies in Wales. Welsh HBs are expected to adopt these recommendations within 60 days of publication or either a NICE final appraisal determination (FAD) or Welsh Government ratification. The All Wales Medicines Strategy Group (AWMSG) will also conduct health technology assessments (HTA) for other medicines for consideration by the Welsh Government.

Introduction

A number of high cost or specialist drugs are available and used in the management of a variety of conditions, across the United Kingdom (UK). The contractual conditions and financial flows in relation to these are complex and their provision depends on a number of different national policies and systems.

Currently, it is estimated that approximately 60 percent of the cost of medicines used by providers of secondary and tertiary care may be accounted for by medicines which fall outside the scope of the usual healthcare resource groups or national tariffs. In England alone, the spend on medicines in hospitals in 2011 was around £4.9 billion, with the cost on high cost or specialist drugs estimated as £2.9 billion per year, with some trusts; especially tertiary care centres, reporting that their 'tariff-excluded" or HCDs account for significantly more than 60 percent of their total drug spend.[1]

NHS provider contract in England – the national tariff

The national tariff, (also known as the National Tariff Payment System or NTPS), is the payment system used by commissioners and providers of secondary healthcare in England and is a set of prices and rules used by commissioners to pay their providers (such as acute hospital trusts) for NHS Services. It is designed to deliver the most efficient, cost effective care to patients and relates to all forms of NHS healthcare, whether commissioned by Integrated Care Boards (ICBs), (formerly Clinical Commissioning Groups (CCGs)), NHS England (NHSE) or Local Authorities and whether it relates to physical or mental health.[2-4] The tariff in England accounts for around £76 billion of spending each year and an average of 60% of a hospital trust's income.[4] The NTPS replaced the previous Payment by Results (PbR) system in April 2014. However, the NTPS retains the vast majority of the PbR policy and consequently, the terms PbR and NTPS are considered to be interchangeable.[5] PbR provides a transparent, rules-based national tariff system, used to determine the reimbursement of NHS funded care in England. The tariff contains a set of rules that must be followed, as well as specifying the prices or currencies to be paid for units of healthcare activity, also known as spells or episodes.[3-7] The prices or units of currency are sometimes also referred to as Healthcare Resource Groups or HRGs and are used to ensure that NHS organisations use a common standard to report activity.[3,4] HRGs are currently used as a means of determining fair and equitable reimbursement for care services delivered by providers. These 'units of currency' support standardised healthcare commissioning across the service and provide a fair and consistent approach to hospital funding.[6] Payment is made to the organisation and not to individual departments.[4] Services which sit outside the scope of the tariff and are funded under different arrangements currently include: public health services (open access sexual health services, universal health visitors, screening programmes, sexual assault services and public health services for people in prisons); primary care services, such as general practice, community pharmacy, dental practice, and community optometry. Payment for these primary care services is covered by legislation relating specifically to primary care. Social care and care homes are also not covered by the tariff.[4]

Following a consultation process in the previous financial year, each new tariff and associated payment arrangements in England, is usually published so it takes effect from the 1st April.[7,8] However, if the publication is delayed, the tariff in place continues to apply. For example, the 2019/2020 tariff was in effect until the 2020/2021 tariff was published in November 2020.[3]

Several financial and payment methodologies may be utilised, although NHSE will indicate the preferred method as part of the contract consultation process for the next financial year. Until March 2020, payments to providers were linked to actual in year activity, known as activity based payments. This is also referred to as the traditional PbR mechanism. During the COVID-19 pandemic, the NTPS was suspended and all providers were reimbursed on a block contract basis, agreed locally. This was due to be changed with trusts and commissioners moving back to the NTPS tariff rules from October 2022.[4]

The latest version of the NTPS for 22/23 was available for use from 1st April 2022 and introduces the new financial approach to the contract management, known as the aligned payment and incentive

rules (API).[7-9] Local commissioners and providers can also agree local pricing arrangements for certain services and with NHSE approval.[4]

Information regarding the current national payment tariff and any future proposed tariffs in development are available on the NHSE and NHS Improvement website.[2]

Details of past tariffs and funding arrangements are available.[10]

The aligned payment and incentive rules in England

The revised national tariff introduced in 2021/2022, includes an additional payment approach to support Integrated Care System (ICS) development and achievement of financial balance and stability. The new aligned payment and incentive rules were introduced to cover most secondary care activity.[4]

Aligned payment and incentive rules comprise two elements:

- A fixed element payment, expected to cover funding for all expected activity and service costs, including:
  - The costs of delivering services within the agreed system plan.
  - Agreed levels of Best Practice Tariff (BPT) performance and full achievement of the Commissioning for Quality and Innovation (CQUIN) criteria.
  - ICB commissioned HCDs and devices and other items previously excluded from 2020/21 national prices, such as excess bed day payments.
- A variable element payment, which mean payments or deductions are made for:
  - Activity over or under a baseline elective activity.
  - BPT attainment above or below that assumed as part of the fixed element.
  - CQUIN indicator attainment less than 100%.[7,8]

Aligned payment and incentive agreements use a single currency, defined as all the services covered by the fixed payment and will eventually be based on patient level information and costing (PLICS) data collected by the trusts, whilst the PbR national and unit prices will continue to be based on HRGs or treatment function codes (TFCs).[7] Whilst it is anticipated that the vast majority of secondary care activity or service costs will be funded by the aligned payment and incentive approach, additional activity undertaken by trusts as part of the NHS Increasing Capacity Framework and any activity which is part of a subcontract will continue to use or be based on national or unit costs, as agreed by local negotiation.[11,12]

Health system management in Scotland, Wales and NI

The Scottish National Tariff is a list of standard average prices or HRGs, published as the Costs Book (NHS Scotland costs data). It includes all the inpatient and day care hospital admissions data (NHS Scotland acute hospital activity).[13] It was developed to help set service level agreements between NHS Scotland Providers provide a financial statement or annual return, known as the Scottish Financial Returns (SFRs) to their Scottish HBs for remuneration, which covers all hospital expenditure including drug costs.[13,14] Medicines costs are also a material part of all the HB budgets.[15]

In Wales and NI, HRGs are used as indicators of the unit costs of providing a range of hospital and community services at both trust and hospital level; they are based on information derived from electronic hospital activity systems and trust financial and information returns. HRGs are mainly used to monitor hospital and provider financial performance.[16-19]

HCDs, devices and innovative products

All existing and new drugs and devices should be provided within the scope of the national tariff, unless they are included in the national tariff HCD exclusions list (Annex A), used as part of an excluded services or where a locally determined additional payment or pricing arrangement, also known as an

uplift to the standard tariff price has been agreed. ICBs should not pay separately for any drug which is included in the unit price or HRG cost.

In general, HCDs are only commissioned and funded by commissioners (ICBs/HBs) following publication of a positive NICE TA, or equivalent assessment in the devolved nations. Drugs and devices not subject to a NICE TA, or equivalent, usually require submission of a full business case for consideration by the local area prescribing committee and associated system governance processes.

In England, the current list of HCDs, devices and innovative products, are included in Annex A – tabs 14a, 14b and 14c of the NTPS workbook. All are excluded from the associated HRG pricing.[3,20] The current tariff workbook should be consulted for the most up to date status of HCDs in relation to the NTPS.[20]

Where usage is predictable and relatively stable, the additional costs associated with these HCDs are calculated as a block payment by local negotiation and included in the fixed element.[3,8] Where usage is likely to be high or unpredictable, the high cost drug or device continues to be commissioned on a cost and volume basis, with a pass through payment to the trust.[8] In general, all HCDs and all high cost devices commissioned by NHSE are excluded from the fixed element and are paid on a cost and volume basis.[3,8] Whilst several HCDs commissioned by ICBs may be included and funded as a block payment in the fixed element, any drug commissioned on a cost and volume basis by NHSE should also be commissioned on a cost and volume basis by the ICBs.[8]

Several medicines, including botulinum toxin and somatropin, which historically have been listed as HCDs, have been removed from the HCD list for 22/23. In addition, funding for several HCDs, including romiplostim, eltrombopag and sodium oxybate, should now be included in the fixed element.[8]

Where BPTs are in place, drugs are generally considered to be included in that BPT unless listed as a specific exclusion in Annex A or within the applicable national tariff guidance in relation to that BPT.[3,21] Where an API contract is in place, funding for the agreed level of BPT is included in the fixed element with the variable element used to reflect the actual attainment for the BPTs.[8]

ICBs only commission for indications, services and excluded HCDs and devices that they are responsible for. A commissioner assignment flow chart and accompanying guidance is available to support decisions regarding who the responsible commissioner is for funding purposes.[22,23] Further information regarding management and funding of patients who change geographical locations and local commissioners is provided later in this bulletin.

For NHSE high cost devices, all 26 NHSE commissioned high cost device categories are excluded from the fixed element of API contracts. The Specialised Services Devices Programme (SSDP), formerly known as the High Cost Tariff Excluded devices programme, is a nationwide purchase and supply system for specific categories of high cost tariff excluded devices. Further details are available in Annex A and on the NHSE website.[3,8,24]

Local commissioners (ICBs) are currently responsible for funding four high cost devices, including insulin pumps and continuous glucose monitors (CGM).[20] These devices are not within the scope of the SSDP.

A new national insulin pump and continuous glucose monitoring contract procurement framework started on the 7th January 2022 and runs for 24 months ending on 6th January 2024. Further information is available on the NHS Supply Chain website.[25] Where devices are supplied via the provider trust, the associated costs should be reimbursed by the local commissioners (ICB) on a cost and volume basis.[3,20] Several intermittent CGM devices are also included in the primary care Drug Tariff and can be prescribed on an FP10 prescription.[26] All local supply arrangements in relation to prescribing of these devices should be agreed at system level and approved by the local area prescribing committees and associated system governance, prior to requests to GPs to prescribe in primary care. This is to ensure that appropriate patient training and follow up is in place as well as the necessary funding to support prescribing in primary care.

Homecare

A home care medicine delivery and services delivers ongoing medicines supplies and where necessary the associated care, initiated by the hospital prescribed, direct to the patient's home with their consent.[27]

A large proportion of the excluded HCDs are currently supplied via homecare delivery services with up to 200,000 patients in England at an overall estimated cost of £1.5 billion, of the £4 billion spent on medicines in secondary care.[28,29]

Homecare provision is convenient for the patient and ensures that all the necessary consumables, such as antiseptic swabs, needles and sharps containers are also supplied to the patient, as well as any other considerations such as waste disposal, patient training and ongoing support are available. There are different levels of homecare provision, ranging from simple supply to more complex arrangements involving intravenous administration and in some cases home adaptations.[28-30] Different levels of homecare support are generally associated with different levels of funding and usually confirmed in a regional homecare contract framework to support provision of this service within their region.[31] In addition, provider trusts will also have local policies to determine how homecare medicines are managed for their localities.[32] The National Homecare Medicines Committee advises the NHS on all matters in relation to medicines related homecare.[33]

In relation to the contract and funding flows, if the high cost drug is included in the fixed element, then any associated additional costs, such as homecare payments should be negotiated and included in the fixed element. If the high cost drug is usually reimbursed on a cost and volume basis, then the same applies to the additional costs.[34]

New drugs and devices and service developments

If the new drug or device is subject to a positive NICE TA recommendation, it should be treated as excluded from the fixed element of the NTPS and payment made to the provider on a cost and volume basis, until its NTPS status has been confirmed.[3,8]

Business cases for in-year developments on the use of new HCDs and devices, not subject to a NICE TA recommendation, should be considered in line with the ICBs prioritisation framework. Providers, as well as commissioners, can consider cost effectiveness and reject or defer introduction of new drugs and new uses for drugs, for use within their own organisations and in accordance with their corporate governance arrangements. Where a new medicine and device is likely to be implemented across multiple system sectors, consideration and collaborative agreement at the local area prescribing committee is warranted.

NHSE commissioned services, drugs and indications

Certain HCDs and devices, indications and services are solely commissioned by NHSE, under its remit as lead commissioner for specialised services.[35]

A list of NHSE Indications and associated drugs can be found on the NHSE website.[36] This list of NHSE commissioned drugs and indications is currently subject to frequent changes and should be consulted regularly for the most up to date NHSE commissioning position. ICBs should not fund drugs or devices that are solely commissioned by NHSE, or indications for drugs and devices that are commissioned by NHSE, or those that are part of NHSE commissioned services.

In some situations, NHSE commissions specialised and highly specialised services from specified specialist centres only. These centres are detailed in the provider eligibility lists in the Prescribed Specialised Services (PSO) tool 2020/2021 – guide to identification rules, which is available on the PSO tool application website.[37] Providers and local services who do not have a contract with NHSE to provide a specialist service and are not included in these lists, should avoid providing these services. The provider should transfer the patient to a NHSE commissioned specialist service, as they will generally not be paid for such activity and will need to absorb the associated costs if they do continue

to treat patients without the appropriate contract agreement. Alternatively, the provider can seek eligibility to provide the specialised or highly specialised service and obtain an NHSE contract in their own right.[37]

NHSE specialised commissioning, not ICBs, is the responsible commissioner for all chemotherapy services, including drug procurement and delivery across England. The exact scope is set out in the Manual for PSO.[35] All chemotherapy and certain supportive drugs, as specified in the NHSE list of supportive drugs for chemotherapy, are the commissioning responsibility of NHSE and are not the responsibility of ICBs.[35,38] Other adjunctive treatments that may be given in addition to primary chemotherapy, e.g. hormone treatments which are not excluded from tariff and drugs affecting bone metabolism, are not automatically funded by NHSE and ICBs should ensure that arrangements for commissioning these treatments are agreed locally.[35] Since July 2016, the Cancer Drugs Fund (CDF) has been a source of funding for cancer drugs in England.[39]

The Health and Social Care Bill 2022 enables NHSE to delegate to an ICB, any or all of its statutory functions for directly commissioning health care services and paying providers for them.[22,40] In each case where this happens, a delegation agreement will be put in place between NHSE and the ICB and the delegation will be communicated to affected providers.[22]

In May 2022, NHSE issued preliminary guidance in relation to the transfer of certain specialised services and indications to the ICBs by April 2023.[41,42]

Collaborative commissioning

NHSE strongly encourages commissioners to collaborate closely in negotiating and agreeing contracts with providers to enable a consistent approach to contracting which is more efficient for both commissioners and providers.[43] Neighbouring ICBs are encouraged to work together where possible for services across large geographical areas.[44] For provider contracts involving multiple commissioners, commissioners are encouraged to commission on a collaborative basis.[43] Providers and the co-ordinating commissioner for the particular contract should ensure the local associate or collaborating commissioners are consulted appropriately on in year service developments that impact upon them.[43,44] Individual ICBs remain responsible for making decisions relating to their own policy, for committing commissioning resources, and for making commissioning decisions for their health economy.[43,44] The co-ordinating commissioner must circulate details of the proposed action or variation, including for in-year developments, to all collaborating or associate commissioners in sufficient time to allow prior approval of that action or variation.[43] Where, any action or variation is in conflict with a decision made by a collaborating commissioner, the collaborating or associate commissioner should reserve the right to take its own decision. Where a collaborating or associate commissioner requires a provider to adhere to a different policy other than that agreed by the co-ordinating commissioner, this must be clearly communicated to the co-ordinating commissioner in writing, within the agreed timescales for the contract and this variation should be clearly specified in the provider contract documents.[43,44]

Patients transferring from one commissioner to another commissioner

The safety and wellbeing of patients is paramount. No essential assessment, care or treatment should be refused or delayed because of uncertainty or ambiguity in relation to commissioning arrangements.[45,46]

Transfer of patients from outside of designated geographical area

Where responsibility for providing NHS services to a patient has been transferred to another ICB/HB e.g. if the patient has moved into the area, the new ICB should normally honour funding commitments made by the patient's previous NHS commissioner.[22] However, where funding is required for NHS healthcare for individual patients which fall outside the range of services and treatment that a ICB has arranged to routinely provide, the ICB should reserve the right to seek a formal clinical review of the patient's future healthcare needs at the point of transfer. The ICB should consider whether the decision

to provide the patient with any further courses of treatment of the type previously provided, and of any other nature, is equitable and appropriate via the Individual Patient Funding Request policy (IPFR) route.[46] IPFRs and other forms of prior approval should not be required for emergency or immediately necessary treatment.[46]

This also applies to patients who become the responsibility of an ICB in England, having formerly been provided with healthcare under the NHS in Wales, Scotland or NI or vice versa.[22,45,46]

This principle does not apply where the patient would not have continued to receive the treatment in question, for whatever reason, as NHS commissioned treatment from the patient's previous responsible commissioning ICB. This also does not apply to patients who become the responsibility of the ICB having been formerly provided with healthcare under private healthcare arrangements or pursuant to a state healthcare system anywhere else in the EU or in a non-EU country.[46,47]

Transfer of responsibility from NHSE to ICBs

In circumstances where the commissioning responsibility for an excluded drug or device transfers from NHSE to an ICB, e.g. where a child who is being treated under NHSE responsibility transitions to adulthood, ICBs should 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, via the IPFR route. It would seem appropriate that the general principles, outlined above in relation to geographical movements should be applied.[45,46]

Patients transferring to and from the Health and Justice system

NHSE is responsible for commissioning health services, (excluding emergency care), for people in prisons and other Health and Justice sites. ICBs are responsible for commissioning emergency care including A&E and ambulance services as well as out of hours primary medical services for prisoners and detainees present in their geographical area. When a person who is prescribed a HCD or device is admitted into, transferred between or released from a Health and Justice site, prescribing responsibility and supply is retained by the current specialist prescriber until a formal transfer of care has been completed.

See attachments 1 and 2 for further information on commissioning arrangements and the principles for safe and continued access to care for people in the Health and Justice setting.

Contract monitoring and financial considerations

National tariff excluded drugs and associated activity charges

In line with national tariff guidance, once a drug or indication is agreed for commissioning by commissioners, commissioners should only pay the contract price (i.e. actual cost to the provider), unless a gainshare agreement is in place, along with any associated additional preparation costs provided this is undertaken outside the normal preparation arrangements in hospital and the agreed activity costs for drugs administered in provider settings.

For drugs administered in hospital, commissioners should only pay activity costs which have been locally negotiated and agreed; these should not usually exceed the activity costs used by NICE in its costing template calculation. Therefore, if a drug is delivered in an alternative setting, e.g. inpatient setting, rather than day case or outpatient, any additional costs not covered by the usual activity cost for that episode of care should be negotiated and agreed locally.

Commissioners should only make additional payments to providers on a cost and volume basis for drugs and devices which have been excluded from the fixed element of the NTPS. Costs associated with HCDs which are specified as included in the fixed element of the NTPS, should be agreed locally as part of the contract annual agreement process. Only drugs which have received a positive opinion from a NICE TA or after local consideration and agreement.

Gainshares

Incentive schemes such as gainshares have been used for several years, to incentivise providers to move to less expensive alternatives, where clinically appropriate or to use more effective procurement strategies to benefit the whole NHS.[1,48] They have been widely used across the NHS to support the implementation of biosimilar monoclonal antibodies. Risk/gain/loss share models provide an opportunity for providers and commissioners to establish a network to identify and distribute financial gains or losses. Comparisons are drawn between the estimated and actual contract spend, with any surplus or deficit then being shared between the provider(s) and commissioner(s). Models can also be used to share risk and loss between stakeholders if necessary to establish improvements in clinical pathways.[48,49]

In the Department of Health (DH) commissioned report 'Homecare Medicines: Towards a Vision for the Future', it was recommended that commissioners should ensure that as part of national or regional procurement arrangements for medicines, there are clear, up-front agreements on the share of financial savings with both commissioners and providers.[27]

NHSE have also produced a list of basic principles which should be considered when implementing any such scheme, along with a commissioning framework for biological medicines including biosimilars.[1,50]

Where co-ordinating commissioners have agreed local discount schemes or gainshare for excluded drugs that result in an additional saving on the national available Patient Access Scheme (PAS)/ Commercial Access Agreement (CAA) price, or the Commercial Medicines Unit (CMU) price, these prices should be made available to all commissioners purchasing services from that provider.

Contract monitoring and invoice data validation

All NHS contracts are monitored using the national data standards.[51-53] A revised information data standard for providers and commissioners has been published by NHS Digital. The contract monitoring information standards are a set of standards being introduced by NHSE to enable national consistency of the flow of cost and activity information from providers to commissioners. The contract monitoring standards became national data standards in April 2021 and had an implementation date of September 2021 for reporting of activity from October 2021.[53]

Providers should provide commissioners with accurate information on the use of HCDs and devices in accordance with a minimum data set for invoices, which either complies with the current national standards or as agreed locally.

Invoice data validation and payment mechanisms should adhere to all national reporting standards. Further information regarding invoice validations is available on the NHSE website.[53,54]

At present, Group Prior Approval (GPA) is currently an integral part of the monthly invoice data validation and contract monitoring process for many localities. A GPA form or notification, which confirms the patient meets the clinical criteria for the treatment either in accordance with the relevant NICE TA or the locally agreed criteria, is completed and signed by the responsible Consultant/Specialist, prior to the start of treatment. This is submitted or registered via an electronic automated reconciliation system (BluTeq), which as part of the monthly contract monitoring process, is used to cross check the invoice data against the patient prior approval notifications and flag patients who may have been miscoded and allocated to the wrong commissioner/ healthcare payer. Only patients for whom approval has been given are funded If the system flags an unknown patient, this can be referred back to the Provider for investigation as part of the monthly contract invoicing process and allow the provider to submit the notification for the patient or re-code the patient to re-assign the commissioner. Where a notification form has not been submitted for approval or where any outstanding invoice queries have not been resolved, payment is withheld by the commissioner, in accordance with the agreed NHS contract process. The content and design of the GPA forms must be agreed between the commissioner and provider but must focus on ease of use, only incorporate the minimum information required to

confirm eligibility to the relevant prescribing policy avoid inclusion of any data that are not critical for the intended purpose and avoid unnecessary administrative burden.[55] Example prior approval forms can be found on the PrescQIPP website.

Clinical audit of HCD or device use by specialism is an alternative methodology to ensure appropriate allocation of public monies. Clinical audit can also be used for post payment verification to confirm usage detail in the event of over or under performance of activity. Where a proportion of the sample audited does not meet the commissioner's criteria for funding, local commissioners should agree local arrangements for ongoing payments with their providers.

National recommendations and policies

NICE Technology Appraisals

In England, drugs that have a positive TA from the National Institute for Health and Care Excellence (NICE) are usually funded by local commissioners within 90 calendar days, from the date of publication, unless otherwise specified in the FAD.[56] A fast track technology appraisal (FTA) is now also offered to companies, with a funding timescale of 30 days following publication of a positive recommendation.[57] An FTA is also applied to Innovative Medicines Fund medicines with an Early Access to Medicines Scheme (EAMS) designation.[58] NICE TAs are either single TAs (STA), assessing a single drug and usually new pharmaceutical products or license extensions, or a multiple TA (MTA) for more complex topics or for reviews of published appraisals.[57] Full details of the NICE TA evaluation process can be found in the process manual.[59]

The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE TAs.[56] Where NICE finds that the case for routine use in the NHS has not been met, a managed access approach may be included as a recommendation in the appraisal outcome.[59]

For any medicine NICE recommends with managed access, a managed access agreement (MAA) is put in place between NHSE and the company. MAAs consist of two parts: a time limited data collection agreement (DCA) that outlines the data to be collected to address the evidential uncertainties, as defined by NICE, a patient access scheme and/or a CAA to ensure the MAA offers value to the taxpayers during the managed access period.[59] In a similar way to the Cancer Drug Fund, the new Innovative Medicines Fund, will provide funding to the managed access programs and operate within a fixed budget of £340 million. At the end of the MAA, all medicines that enter the Innovative Medicines Fund should be re-evaluated by NICE to confirm final recommendations regarding routine use in the NHS. If a medicine is not recommended for routine commissioning at the NICE guidance update, patients who started treatment during the period of managed access should continue to receive the medicine until such time that the patient and the treating clinician determines it is no longer clinically appropriate. No further funding is available from the Innovative Medicines Fund, and the company must meet the ongoing cost.[58,60] The Commercial Framework for New Medicines gives more detail regarding how NHSE work in partnership with NICE and companies on commercial medicines activity.[61]

Where a high cost excluded drug or device has not been commissioned but the drug could be beneficial to an individual patient, then an IPFR could be made by the clinician on behalf of the patient. In general, this process should be reserved for patients with unique clinical circumstances.[62]

In Wales, an agreement is in place that all NICE Guidelines and quality standards are available to use in Wales, but their use is not mandatory. Adoption of NICE TAs is mandatory and Welsh HBs must ensure that the medicine or device is available within 60 calendar days of publication of the FAD. In Wales, a new treatment fund is provided by the Welsh Government to support HBs and trusts with implementation of NICE TAs.[63] The All Wales Medicines Strategy Group (AWMSG) advises the Welsh Government about the use, management and prescribing of medicines in Wales.[64]

A circular issued by the NI Health Department in April 2022, confirms that NICE guidance is designed principally for use in England and, as such, does not automatically apply in NI. However, once NICE

releases the FAD approximately six weeks prior to final publication, the local department review process assesses the applicability of the NICE TA to NI. This review is expected to be complete within four weeks of the final publication by NICE. Once the local review is complete the NI Department of Health publish endorsement decisions on its website, with links to appropriate caveats, where these apply. If a piece of NICE guidance is not applicable to NI, then this is highlighted with an explanation. This is then communicated to the Health and Social Care Trusts and other relevant stakeholders through a service notification from the NI strategic planning and performance group (SPPG).[65] The applicability to NI of any PAS is also assessed. The guidance also states that where there is a PAS, a drug should not be used without achieving the appropriate financial savings.[65] Details of endorsed NICE TAs are included on the NI Health and Social Care Board website.[66]

In relation to NHS Scotland, NICE single and multiple technology appraisals (MTAs) have had no official status in NHS Scotland since August 2016 and October 2017 respectively. Advice from NICE MTAs adopted prior to October 2017 continues to apply and a list of these MTAs are available on the Healthcare Improvement Scotland website.[67] NHS HBs in Scotland are required to consider and adopt Scottish Medicines Consortium (SMC) advice. The SMC decides whether new medicines ought to be routinely available for prescribing by the NHS in Scotland.[68] If a medicine has been accepted for use by the SMC, then the Scottish Government expects the NHS Scottish boards to implement the SMC recommendations, however along with local formulary submissions this is ultimately a decision for individual NHS Scottish Health Boards and their area Drug and Therapeutic Committees (ADTC).[69]

Clinical guidelines

ICBs are not mandated to routinely fund recommendations from NICE Clinical Guidelines or NICE Clinical Knowledge Summaries which provide guidance for decisions about person centred care.[70,71] A full business case with supporting evidence and the proposed change in pathway should be requested for consideration by the ICB governance processes. This requirement should also apply to guidance and recommendations issued by other national committees or bodies, such as the Regional Medicines Optimisation Committee (RMOCs), or professional bodies, such as the Royal College of General Practitioners (RCGP) etc.[72]

NHS Wales have an agreement that all NICE guidelines and quality standards are available to use in Wales, however their use is not mandatory.[63]

In NI, NICE Clinical Guidelines are screened by the NI Department of Health for endorsement and within eight weeks of publication for subsequent adoption by health boards. If the clinical guidance is not applicable to NI, then this is highlighted with an explanation to the NI health boards.[73]

The Scottish Intercollegiate Guidelines Network (SIGN) produces clinical guidance for Healthcare Improvement Scotland, which is then considered for implementation by the Scottish Health Boards. SIGN also works collaboratively with a number of other organisations on guideline development, including NICE and the British Thoracic Society (BTS).[74,75]

MedTech Funding Mandate

The MedTech Funding Mandate (MTFM) launched on 1 April 2021, is an NHS Long Term Plan commitment in England only. In its first year, 2021/22, the policy supported four NICE-approved, cost saving technologies.[76] Support for these technologies has been continued into 2022/23, although it is anticipated that in future, supported technologies will be reviewed annually to ensure that they continue to meet the policy criteria.[76]

To be considered for the MTFM 2022/23 policy, technologies needed to be:

- Effective: demonstrated through positive NICE Medical Technology Guidance (MTG) or Diagnostic Guidance (DG), published by 30 June 2021.

- Cost-saving within three years of implementation: as demonstrated by NICE modelling and published in a NICE resource impact template.
- Affordable to the NHS: the NICE budget impact analysis total costs should not exceed £20 million in any of the first three years.[76]

All items subject to the MTFM innovative products list are specified in Annex A, tab 14c of the national tariff workbook and are excluded from the fixed element of the payment tariff and funding should be made available on a cost and volume basis.[3,4,20]

Innovative Licensing and Access Pathway (ILAP) & Early Access to Medicines Scheme (EAMS)

The MHRA currently administer two schemes which aim to accelerate the time to market for new medicinal products and facilitate patient access.[77-79]

The Innovative Licensing and Access Pathway (ILAP) supports innovative medicinal products through all stages of the design, development, and approvals process, from pre-clinical trial stage to the mid development programme point.

To be eligible for the scheme the medicinal product must either be for a life threatening or seriously debilitating condition or there is a significant patient or public health need and fulfil at least two of the following criteria, as well has have the potential to offer benefits to patients:

a. Innovative medicines such as an advanced therapy medicinal product (ATMP) or new chemical or biological entity or novel drug device combination
b. Medicines being developed in a clinically significant new indication for an approved medicine
c. Medicines for rare disease and/or other special populations such as neonates and children, elderly and pregnant women
d. Development aligning with the objectives for UK public health priorities such as the Chief Medical Officer, Department of Health and Social care (DHSC) or Life Sciences Sector Deal, including those in the devolved administration where appropriate.[77]

The Early Access to Medicines Scheme (EAMS), was launched in April 2014 and comprises stakeholders from industry, government and healthcare. Under the scheme, Pharmaceutical companies apply for, and must be granted, Promising Innovative Medicine (PIM) designation for their product. Pharmaceutical companies can then submit an early portfolio of evidence for consideration by the MHRA.[78,79]

Under the scheme, the MHRA will publish an EAMS scientific opinion on the benefit/risk balance of the proposed new medicine, based on the data available when the EAMS submission was made. The EAMS scheme is voluntary for companies making submissions to the MHRA. The scientific opinion from the MHRA does not replace the normal licensing procedures for medicines.[79]

A core principle of the scheme is that the company provides the medicine free of charge to the NHS during the EAMS period; defined as from the award of a positive EAMS scientific opinion and up to the granting of a positive funding policy, by NICE or equivalent national body. The scheme also suggests that patients receiving a free of charge medicine during the EAMS period should continue to do so up to the point of a positive funding policy (NICE TA).[79]

Innovative products can be registered on both the ILAP and EAM schemes.[79]

Full details of both schemes are available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

Commissioners should not be expected to automatically fund treatment initiated under the Early Access to Medicines Scheme (EAMS) on licensing of that drug, unless it is subject to a positive NICE TA.[79] Providers should discuss any patients included in the scheme as soon as possible and in the absence of a relevant positive NICE TA, SMC or AWMSG recommendation, submit a business case for

consideration and approval via the local commissioners.[78-80] If the medicine concerned has been funded in part by the Innovative Medicines fund, as part of a NICE agreed MAA and then receives a negative endorsement by NICE at re-evaluation, the company concerned should continue to fund the treatment for as long as the patient and treating clinician consider it to be clinically appropriate.[60,61]

Free of charge (FOC) medicine schemes are often offered by the pharmaceutical industry. A FOC medicines scheme is defined as an arrangement where a UK licensed or unlicensed medicine is provided free of charge by the company to an individual patient or an identified cohort of patients. Advice has been compiled and issued by the Regional Medicines Optimisation Committee (RMOC). Commissioners and providers should only undertake a free of charge scheme if the principles outlined in the advice produced by the RMOC is followed. Any such scheme should only be for direct patient benefit and should not be for the purpose of increasing market access. All locally proposed FOC schemes should be considered and agreed through the agreed ICB medicines governance process.[81]

Research studies, clinical trials, novel and uncertain treatments

Novel or uncertain treatments, including unlicensed drugs or drugs and devices used outside their licensed indications (off label) that clinicians consider necessary for the treatment of patients, which are not part of a commercial or non-commercial trial, should be managed through the provider's internal governance processes, e.g. the local Drug and Therapeutics Committee and research governance systems. ICBs should not pay for treatments that are novel or for treatments of uncertain efficacy and safety, unless this has been agreed through the current arrangements overseen by National Institute for Health Research (NIHR) or the proposed treatment or off label indication has been considered and approved for use by the local area prescribing committee following submission of an appropriate business case. Funding for novel or uncertain treatments, for example, new, rarely used, unlicensed and/or investigational drugs outside of a research trial, should remain the responsibility of the provider, until such time as a local business case has been considered and agreed via the ICB medicines governance and finance processes.

Further information regarding funding of medicines and associated or excess treatment costs in relation to research studies or clinical trials is provided below.

Unless listed as an excluded drug or device specifically for an unlicensed (off-label) condition, drugs that are used outside their licensed indications by providers are usually included in the fixed element of the national tariff or locally agreed prices. Use of excluded drugs or devices for off-label indications should not be funded unless approved for use for the off-label indication by the local area prescribing committee, following submission of a business case.

Research studies, clinical trials and Excess Treatment Costs (ETCs)

The Health Research Authority and the Health Departments in England, NI, Scotland and Wales have defined a UK wide policy framework which defines the principles that should apply to all health and social care research across the UK and the responsibilities of individuals and organisations.[82] It replaces the seperate Research Governance Frameworks. The policy framework reflects the relevant legislation in the UK and takes account, where relevant, of the application of this legislation in each individual UK devolved administration while supporting UK-wide compatibility and consistency and enabling cross-border research.[82]

A research study may result in care that differs from standard treatment in the NHS or is delivered in a different location. The associated NHS treatment cost may be less than or greater than the cost of standard NHS treatment. If greater, the difference between the NHS treatment costs and the cost of standard treatment is referred to as the NHS excess treatment costs (ETCs).[83,84]

The costs of non-commercial research are met by different funders depending on the type of cost and the type of research.[85]

Commercial clinical trials (including commercial trials conducted within the NHS)

The funding arrangements for commercial contract research are straightforward. The NHS is required to recover, from industry, all costs over and above standard NHS treatment cost (i.e. all excess treatment costs).[85] The ABPI have produced a model clinical trial agreement and associated guidance for use in commercial clinical trial agreements between the parties involved. The specific financial details and agreement are usually included as an addendum to the agreement.[86] Four versions of the model clinical trial agreement have been developed to ensure compliance with the law and to reflect regional institutional arrangements across the UK.[86]

Commissioners should not provide funding for patients to continue medication/treatment commenced as part of a commercial clinical trial unless previously agreed at the start of the trial. Medicines which are part of the EAMS or Innovative Medicines Fund scheme should be funded by the appropriate company until the publication of a positive NICE TA. For patients who wish to continue a treatment, which subsequently receives a negative NICE TA recommendation, the ongoing costs should be met by the marketing authorisation holder.[60]

Where possible funding uncertainty at the end of a clinical trial exists, Providers should discuss the financial implications with commissioners at least 12 months before the trial ends and funding may be required to support patients to continue clinically effective and safe care.

The NIHR highlight that the financial implications and excess treatment costs associated with any trial should be considered prior to the start of the trial.[83] At the time of writing, local research governance committees would ensure that the financial and clinical implications of trials are considered and resolved before approval is granted and also liaise with local medicines governance arrangements where needed. If ongoing treatment costs in relation to commercial trials are not prioritised for ongoing funding by local systems, these costs remain the responsibility of the trial investigators. Patients should be made aware that funding of new drugs and devices they are receiving as part of a clinical trial may not be available once the trial ends.

Non-commercial research studies

The NIHR was established in 2006 and is funded by the Department of Health and Social Care. NIHR acts as the research funder and research partner of the NHS, public health and social care and complements the work of the Medical Research Council.[87]

Guidance from the DHSC for the Attribution of Costs for Research and Development (AcoRD) sets out the principles for determining who pays for the different costs. Slightly different rules apply across the four home nations.[85]

ETCs in relation to non-commercial research are paid for by service commissioners in England.[83,84] Research studies are not automatically considered to be commercial contract research simply because they attract industry funding. Commercial companies also work collaboratively with NHS bodies or non-NHS research funders to support non-commercial research. If a study is primarily for the public benefit, rather than the direct commercial benefit of the company concerned, it may be considered as non-commercial by NIHR.[85]

Following a previous consultation with the NIHR, DHSC and Health Research Agency (HRA), NHSE published policy guidance on the management of ETCs for implementation from April 2022 and which applies to newly recruiting studies. For non-commercial studies, NHSE and ICBs have responsibility to meet the costs of ETCs through normal commissioning arrangements, which meet the eligibility criteria for NIHR Clinical Research Network (CRN) support as defined by the DHSC.[84,88]

To meet these criteria studies must:[88]

- Meet the definition of research (as outlined in the DHSC Eligibility Criteria).

- Have appropriate ethical approval (e.g. NHS, Social Care research ethics committee (REC), or Ministry of Defence REC; and Health Research Authority (HRA) where required).
- Have full research funding (i.e. funding to meet all research costs in compliance with AcoRD guidance).

Whilst this policy is aimed at non-commercial studies, the policy provides the following clarification regarding the types of non-commercial studies which would be considered eligible for NIHR CRN support:[84]

- Investigator-initiated commercial collaborative studies (industry funded, non-industry sponsored studies).
- Non-commercial studies funded by overseas governments.
- Non-commercial studies funded by overseas charities.
- Certain other high quality studies, which meet the eligibility criteria.

NHS ETCs are paid for either by NHSE as the direct commissioner, for example in Specialised Commissioning, or by NHS ICBs, depending on the service under study. ETCs are paid to the organisations that have recruited the participants. These organisations will normally be expected to hold a NHS contract to provide clinical care.[85]

Providers incurring ETCs should be delivering routine NHS services.[83,84]

Payments for studies for which NHS ICBs are the responsible commissioner are made to recruiting organisations through the NIHR Local Clinical Research Networks (LCRNs). Payments for studies for which NHSE is the responsible commissioner are made to the recruiting organisations directly by NHSE via the normal contractual route.[84,85]

Only studies which received research funding approval after 1 October 2018 are subject to the new national process – any studies funded before this date will continue to use the historic process and will not be transitioned. For these studies using the historic process, ETC approval sits with the relevant commissioning team (e.g. local/regional specialised commissioning team(s)), as budget holders for clinical activity commissioned from local trusts and other commissioned providers.[84,85] The contact details for regional/local specialised commissioning teams can be found on the NHSE website.

The schedule of events cost attribution template (SoECAT) has been developed and implemented across the UK, to ensure that the site level costs of non-commercial research studies are appropriately attributed according to AcoRD principles at the time of application for research funding.[89]

Details of proposed non-commercial research trials including possible ETCs should be notified to the commissioners and approved prior to the start of the study.[84] Non-commercial studies which are not subject to NIHR approval, would need to be considered and approved by local medicines governance processes including research ethics approval.

Each of the four UK health administrations have developed their policies for their respective national research portfolios. Details of the eligibility criteria for Scotland, Wales and NI can be found at –

- Scotland: NHS Research Scotland (NRS) – formed from a partnership of the Scottish Health Boards and the Chief Scientist Office (CSO) of Scottish Government.[90]
- Wales: Health and Care Research Wales (HCRW).[91]
- NI: Northern Ireland Clinical Research Network (NICRN).[92]

Health Boards in the respective devolved nations provide funding for the ETCs once the research study has been approved and included on the research register. In Scotland, the NRS permissions co-ordinating centre (PCC) manages the approval process. In Wales, it is the Support and Delivery Centre and in NI by the NICRN.[91,93,94]

Further information is available on the National Institute for Health and Care Research (NIHR) website.

Additional resources to support HCD commissioning

PrescQIPP host a High Cost Drugs Pharmacist Virtual Professional Network. The purpose of the group is to connect pharmacists working in the area of HCDs and to allow sharing of resources, challenges and solutions. The group is facilitated by quarterly teleconferences and a High Cost Drugs online forum where members can post questions to their peers across the community. The group is open to all PrescQIPP subscribers.

An example of an additional contract schedule specifying the HCD and device commissioning arrangements between an ICB and provider organisation, and an appendix listing commissioning arrangements for all ICB commissioned and excluded high cost drugs and devices, is available via the PrescQIPP website for local adaption as schedule 2 contract addendums – see attachments 3 and 4 to this bulletin.

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Acknowledgements

This document is based on the East of England CCG, (now ICBs) Collaborative Commissioning Arrangements for High Cost Drugs and Technologies (to include devices) 2022/2023. Further resources are available on the PrescQIPP website and can be adapted for local use.

Additional PrescQIPP resources

Briefing	https://www.prescqipp.info/our-resources/bulletins/bulletin-309-commissioning-of-high-cost-drugs-and-devices/
Implementation tools	

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Support with any queries or comments related to the content of this document is available through the PrescQIPP help centre https://help.prescqipp.info

This document represents the view of PrescQIPP CIC at the time of publication, which was arrived at after careful consideration of the referenced evidence, and in accordance with PrescQIPP's quality assurance framework.

The use and application of this guidance does not override the individual responsibility of health and social care professionals to make decisions appropriate to local need and the circumstances of individual patients (in consultation with the patient and/or guardian or carer). Terms and conditions

Glossary/Definitions

Excluded high cost drugs and devices	Drugs and devices that are not included in the fixed element of the national tariff aligned payment rules and are therefore excluded from the tariff. All high cost drugs which are excluded from the tariff in this way are specifically listed in Annex A National Prices and national tariff workbook.
Best Practice Tariffs (BPTs)	Designed to encourage providers to deliver best practice care and to reduce variation in the quality of care or incentivise new ways of working. There are currently 21 BPTs: for details, see Annex C of the 2021/22 national tariff. When a BPT is set up for a HRG it will often contain two prices: one for those meeting the BPT criteria and a lower price for those that do not. Some BPTs do not have different prices but trigger an additional payment for meeting the criteria. BPTs are also used in the aligned payment and incentive agreements, with the fixed payment including agreed levels of BPT achievement. If actual achievement differs from the agreed levels, a variable payment would then be paid/deducted.
Co-ordinating or lead Commissioner	An NHS body which commissions care from an acute care provider by means of a contract under which it acts on its own behalf and on behalf of one or more other NHS bodies, known as associate commissioners.
Collaborating or Associate Commissioner	An NHS body which commissions care from another body, including an acute care provider, by means of a contract or service agreement under which another NHS body is the coordinating commissioner.
Novel treatment	A drug or treatment that is new and different, i.e. a change to current practice where there is a level of evidence for its use that can be considered, the quality of which may be variable. The evidence, ethical and governance considerations are evaluable but have not been evaluated through local NHS processes at the current time.
Uncertain treatment	A drug or treatment for which there is no/little evidence. Uncertain treatments may constitute a variation in a treatment pathway or a major change to an established therapy. The difference compared with a novel treatment is that the evidence, ethical and governance issues cannot be evaluated through a local NHS process.
MedTech Funding Mandate	The MedTech Funding Mandate policy, introduced on the 1st April 2021, is an NHS Long Term Plan commitment that gives patients access to selected NICE approved cost saving devices, diagnostics and digital products more quickly.
Notification	Providers need to ensure that treatment is only commenced in line with agreed criteria and commissioners must be notified of commencement preferably right at the start of treatment, but alternatively before the time of first invoicing. All invoices must be supported with minimum data set as defined.
Prior Approval	Prior Approval is a process by which a commissioner approves treatment funding prior to that treatment being commenced. For a group of patients who meet a standard set of clinical criteria, i.e. meet the thresholds for treatment as specified in a NICE TA, this process uses a group prior approval system, whereby as long as the patient meets the minimum criteria for treatment, funding will be agreed and provided by the commissioner. Historically, this process has used group prior approval forms as agreed between the commissioner and provider and utilised a computerised system known as Blueteq.

Individual Patient Funding Request (IPFR)	An individual funding request can be made for a treatment that is not routinely offered by the NHS when a clinician believes that their patient is clearly different to other patients with the same condition or where their patient might benefit from the treatment in a unique way to other patients. This is known as "clinical exceptionality." The term Exceptional Treatment Arrangements (ETAs) is no longer in use.
Excess Treatment Costs	A research study may result in care that differs from standard treatment in the NHS or is delivered in a different location. The associated NHS treatment cost may be less than or greater than the cost of standard NHS treatment. If greater, the difference between the NHS treatment costs and the cost of standard treatment is referred to as the NHS excess treatment costs (ETCs), which is reimbursed from pooled centralised budget with contributions from each local commissioner (ICBs/HBs).
Locally Determined Prices	Where there are no national prices, local prices must be agreed between commissioners and providers. National prices can sometimes be adjusted through local variations or, where they do not adequately reimburse efficient costs because of certain issues, through local modifications. The national tariff documents set out the principles and rules that apply to all locally determined prices and local variations.
Early Access to Medicines Scheme (EAMS)	The Early Access to Medicines Scheme (EAMS) gives access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need.
Patient Access Scheme (PAS)	Is an agreement between pharmaceutical companies and the NHS which offer a lower acquisition costs to the NHS enabling patients to gain access to high cost medicines. Most positive NICE TAs for excluded high cost drugs are conditional on a PAS being in place.
Commercial Access Agreement (CAA)	A Commercial Access Agreement (CAA) is a confidential price agreed between pharmaceutical companies and the NHS for medicines which are already in use but are being used for a new indication. For drugs which have an existing simple discount PAS in place, the CAA has two parts: • Part 1 is a replacement for the PAS for all supplies/indications. • Part 2 is a 'top-up' by rebate, only for the indication in the CDF. This price is confidential. The CAA (part 1) mirrors the existing simple discount (i.e. is the same as the PAS price for all existing indications) and applies to all current and future indications, including those in baseline commissioning. A technology cannot have a PAS and a CAA.
Full Business Case	A full business case (FBC) is a written document that brings together the arguments for a preferred planned investment, including current and future service requirements, affordability, the organisation's competitive service position and the ability to complete the project within budget and time scale.
Gain/Loss/ Risk share	Risk/Gain/Loss Share models provides an opportunity for providers and commissioners to establish a network to identify and distribute financial gains or losses. Comparisons are drawn between the estimated and actual contract spend, with any surplus or deficit is then shared between the Provider(s) and Commissioner(s). Models can also be used to share risk and loss between stakeholders if necessary to establish improvements in clinical pathways.

Area Prescribing or Formulary Committees	Area Prescribing Committees (APCs) exist across the UK and consider and advise on medicines use, medicines safety and prescribing for their localities. Their membership usually includes healthcare professionals, including senior clinicians and pharmacists from primary and secondary care organisations, as well as other key stakeholders such as patient representatives, public health colleagues and other local experts as needed. It allows a common approach to be agreed across a system, rather than each organisation within that system deciding by itself. APCs will consider and adopt recommendations from national bodies such as NICE or the RMOCs but will also commission their own local assessment for topics which have not been assessed elsewhere. In some localities, this committee may be known as the medicines optimisation committee or MOC.
Secondary Uses Service (SUS)	The Secondary Uses Service (SUS) is the central repository which supports the flow of Commissioning Data Sets (CDS) between providers and commissioners. When a patient or service user is treated or cared for, information is collected which supports their treatment. This information is also useful to commissioners and providers of NHS-funded care for 'secondary' purposes – purposes other than direct or 'primary' clinical care – such as: • Healthcare planning • Commissioning of services • National Tariff reimbursement • Development of national policy
Payment by Results (PbR)	Payment by Results (PbR) provides a transparent, rules-based national tariff system, used to determine the reimbursement of NHS funded care in England. The two fundamental features of PbR are nationally determined currencies and tariffs. Currencies are the unit of healthcare for which a payment is made and can take a number of forms covering different time periods from an outpatient attendance or a stay in hospital, to a year of care for a long-term condition. Tariffs are the set prices paid for each currency. PbR currently covers most of the acute healthcare in hospitals, with national tariffs for admitted patient care, outpatient attendances and accident and emergency. This activity is submitted using Commissioning Data Sets (CDS).
National Tariff Payment System (NTPS)	Following the handover of responsibility for the NHS Payment system from DH to NHS England and NHS improvements (formerly Monitor) in April 2013, PbR was effectively replaced by the National Tariff Payment System (NTPS) in April 2014. This new payment system currently retains the vast majority of PbR policy.
Coding	When a patient is discharged, a clinical coder translates their care into codes. Two classification systems, ICD-10 for diagnoses and OPCS-4 for procedures (interventions) are used. When a patient attends an outpatient clinic, their Treatment Function Code (TFC) is similarly recorded.
Health care Resource Groups (HRGs)	The currency for admitted patient care, outpatients and A&E is Healthcare Resource Groups (HRG). HRGs are clinically meaningful groupings of diagnoses and interventions that consume similar levels of NHS resources. Grouping the extensive and growing number of clinical codes into HRGs allows tariffs to be set at a sensible and workable level. For admitted patient care, also known as APC, each HRG covers a spell of care, from admission to discharge.