NHS Norfolk

NHS Great Yarmouth and Waveney

New Medicines Policy:

A policy and procedure for introducing new medicines and indications across:
NHS Norfolk
NHS Great Yarmouth & Waveney

Policy date: July 2009

Review date: July 2010

Other related policies:

- Policy for non-routine treatments and treatment thresholds
- Individual Funding request Policy

A policy and procedure for introducing new medicines and indications across NHS Norfolk and NHS Great Yarmouth & Waveney
June 2009

1. Foreword

In November 1997, following wide consultation locally, the former East Norfolk Health Authority introduced the forerunner of this policy. For two years, the policy advised the Health Authority on those new medicines and indications which had been prioritised by the Health Authority's professional advisory group - the "Therapeutics Advisory Group" (TAG) - as being most worthy of introduction.

In November 1999, the East Norfolk Health Authority policy was formally adopted by the newly established Norfolk Health Authority pending an update which was adopted in January 2001.

The creation of Primary Care Trusts in 2002 necessitated a further update.

The reorganisation of PCTs in 2006 has necessitated a further update which also incorporated changes due to "Payment by Results" and guidance from judicial reviews.

In August 2008, the Exceptional Drug Policy (now called the Individual Funding Request Policy) for NHS Norfolk and NHS Great Yarmouth and Waveney came under review, and it was decided to have a separate policy to cover individual funding requests. This necessitated a review of this policy as well.

2. Technical update

The underlying principles of the original policy have not changed.

NHS Norfolk and NHS Great Yarmouth & Waveney have indicated their desire to work together to develop, maintain and implement policies on:

- the introduction of new medicines [or new uses for medicines – "indications"]
- their method of introduction,
- recommendations on the location of clinical and financial responsibility for prescribing the medicines.
- jointly commissioning a range of medicines which are excluded from the tariffs of "Payment by Results".

Both PCTs have agreed to continue the jointly-owned professional advisory group – the Therapeutics Advisory Group – from which they seek advice on matters relating to medicines.

3. Introduction

A new medicine, or a new indication for an existing medicine, can be a welcome addition to the formulary, providing a significant advance over current treatment in terms of its increased effectiveness or improved side-effect profile. However, many new medicines or formulations offer little of clinical significance over existing treatments. Furthermore, new medicines are usually more expensive than existing treatments - sometimes spectacularly so.

Having made provision for the cost of medicines within fixed budgets, the unexpected introduction of an expensive new medicine or indication upsets carefully laid plans. Budgets become overspent and resources may be diverted from other areas of patient care to fund the new medicine - perhaps to the detriment of the overall well-being of patients.

We need to know whether the additional benefit brought about by the new medicine or indication is worth the hardship imposed on other patients when resources are diverted from their care.

We need to incorporate guidance from the National Institute for Clinical Excellence (NICE) and consider how best to implement it within local circumstances. We need to estimate the financial and human resources necessary for implementation and secure appropriate funding, workforce and service development.

With these ethical, legal and financial implications, the introduction of new medicines must be undertaken in a considered fashion. This document describes the method used for the introduction of new medicines across NHS Norfolk and NHS Great Yarmouth & Waveney.

It assumes a ***complementary*** approach between NHS Trusts and PCTs.

3.1 Legal pointers

We need to incorporate the interpretation of relevant legislation by learning from the findings of judicial reviews and other legal advice:

> *"I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided of doctors were willing to give it, no matter how much the cost, particularly when a life is potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet. …. Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the court can make. In my judgment, it is not something that a health authority such as this authority can be fairly criticised for not advancing before the court."*[1]
>
> *"While a policy may be adopted for the exercise of discretion, it must not be adopted with a rigidity which excludes consideration of possible departure in individual cases*[2]*."*
>
> *"The line between individual consideration and inconsistency, slender enough in theory, can be imperceptible in practice*[2]*."*
>
> *"…it is an unhappy but unavoidable feature of state funded health care that regional health authorities have to establish certain priorities in funding different treatments from their finite resources. It is natural that each authority, in establishing its own priorities, will give greater priority to life-threatening and other grave illnesses than to others*

1 Sir Thomas Bingham, Former Master of the Rolls, R v Cambridge Health Authority ex parte B [1995] 906C.

2 R v Ministry of Agriculture Fisheries and Food ex parte Hamble Fisheries (Offshore) Limited [1995]

obviously less demanding of medical intervention. The precise allocation and weighting of priorities is clearly a matter of judgment for each authority, keeping well in mind its ***statutory obligations to meet the reasonable requirements of all those within its area*** *for which it is responsible. It makes sense to have a policy for the purpose - indeed, it might well be irrational not to have one - and it makes sense too that, in settling on such a policy, an authority would normally place treatment of transsexualism lower in its scale of priorities than, say, cancer or heart disease or kidney failure. Authorities might reasonably differ as to precisely where in the scale transsexualism should be placed and as to the criteria for determining the appropriateness and need for treatment of it in individual cases."*[3]

"The judge observed in paragraph 63 of his judgment that the Court of Appeal was there considering North West Lancashire's policy on the prioritisation of treatment because of scarcity of resources. He said that in that context it was to be noted that, as most people would expect, it gave the treatment of cancer as an obvious example of a top priority." (As quoted in [4])

"He concluded that to decide that unlicensed use would not be funded save in undefined exceptional circumstances was not of itself unlawful." (As quoted in [4])

In addition, where a decision has a significant adverse clinical impact:

"The court may not interfere with the exercise of an administrative discretion on substantive grounds save where the court is satisfied that the decision is unreasonable in the sense that it is beyond the range of responses open to a reasonable decision-maker. But in judging whether the decision-maker has exceeded this margin of appreciation the human rights context is important. The more substantial is the interference with human rights (i.e. significant adverse clinical impact)*, the more the court will require by way of justification before it is satisfied that the decision is reasonable in the sense outlined above."*[5]

If a *"case is concerned with a decision which may be a life or death decision for the appellant. In these circumstances, … it is appropriate for the court to subject the decision to refuse funding for the treatment (and thus in practice the treatment) to rigorous scrutiny."*[4]

3 R v North West Lancashire Health Authority [2000]

4 Ann Marie Rogers / R v Swindon PCT, Apr 2006.

5 R v Ministry of Defence ex p Smith [1996]

4. Key features of the policy

- Trust-based Drug and Therapeutics Committees (DTCs) will play a gatekeeper role for the introduction of new medicines or indications within the Trust. This includes medicines for clinical trials, which should be introduced in conjunction with R&D Governance Committees.
- The Therapeutics Advisory Group (TAG) will act as the professional advisory group for the Norfolk and Great Yarmouth & Waveney health economies. It will consider medicines or indications with a particularly high cost impact for which extra funding or guidance is sought, or of sufficient uniqueness that the PCTs will want to ensure equity of provision across Norfolk and Great Yarmouth & Waveney. It will consider all guidance on medicines from the National Institute for Clinical Excellence (NICE), NPSA and other national guidance (e.g. Better Care, Better Value indicators).
- In the case of medicines which are excluded from the tariffs of "Payment by Results", Trust-based DTCs will shortlist new medicines and indications for consideration by PCTs for possible inclusion in PCT Commissioning arrangements. This includes estimates of the likely impact of expected guidance from the National Institute for Clinical Excellence.
- The PCTs' prescribing advisers have a similar responsibility for primary care and have developed their own advisory groups.
- The decision on the suitability of prescribing a medicine in primary care as opposed to secondary care, should be made on grounds of clinical appropriateness and patient safety and will take account of guidance from NICE and NPSA. It should not be influenced by the likely source of funding for the medicine.
- The introduction of new medicines or indications should take into account the cost pressures in both the primary and secondary sector. Affordability and cost-effectiveness are important wherever the medicine is prescribed.
- The assessment of new medicines should prompt a comparison of existing medicines or treatments for the same or other conditions in order to determine their relative cost-effectiveness. Some introductions will only take place if resources are transferred from other, less valuable, activities.
- The assessment of medicines will be an **ongoing continuous process** throughout the financial year, but prioritisation for additional funding will only take place on an **annual basis** as part of the commissioning cycle. Medicines will be considered alongside all other proposals for development.
- The default position for new medicines and indications is that they are not routinely available until they have been assessed, prioritised and funded. Thus, as the financial year progresses, there will be a growing list of new medicines and indications awaiting prioritisation and possible funding in the next financial year.
- However, the PCTs will consider the more immediate use and funding of a medicine in individual patients on grounds of exceptionality – or, more widely, if there is national guidance or direction about a new medicine.
- NICE Technology Appraisals will be funded within three months of the date of publication.
- Funding to cover medicines excluded from tariff and "pass-through" payments will be agreed as part of the PCTs' Commissioning arrangements.
- The budget-setting process for primary care prescribing will take account of the likely impact of expected new drugs and recommendations from NICE.

5. A series of decisions

We answer a series of questions about a new medicine in order to determine its worth against other treatments. These questions are posed in the following order:

- Does it work and what does it achieve? ..... Effectiveness & Safety
- What is the proposed use of the medicine? ..... Guideline for use
- Where is the prescribing responsibility? ..... Clinical responsibility
- What is its cost and where does it fall? ..... Financial impact
- Is it worth the (extra) cost? ..... Economic appraisal
- How does it compare with our other priorities? ..... Priority status
- Can we afford it - or how do we afford it? ..... Financial ability
- Should we use it? ..... The final decision

In the light of the above, where available, we refer to the evaluations produced by the National Institute for Clinical Excellence (NICE) and their guidance for the NHS.

6. Funding aims

PCTs are committed to ensuring that medicines recommended for use by NICE are properly implemented and appropriately funded – including considering the funding of any consequential service developments.

Where there is no guidance from NICE, PCTs **aim to ensure** that medicines or indications which are funded meet the following criteria. (These are adapted from those developed by the US National Institute for Health Care Management[6]).

These medicines will **still have to be assessed alongside other priorities** in the local commissioning arrangements before a decision is made on a medicine's priority and affordability.

6.1 Criteria

1. The medicine is used for a medical condition.
2. There is sufficient evidence to draw conclusions about the medicine's effects on health outcomes.
3. The evidence demonstrates that the medicine can be expected to produce its intended effects on health outcomes.
4. The medicine's expected beneficial effects on health outcomes outweigh its expected harmful effects.
5. The medicine is a cost-effective method to address the medical condition and that we have clarified the financial impact of its introduction.

6.2 Definitions

- **Medical condition**: a medical condition is a disease, an illness, or an injury. A biological or psychological condition that lies within the range of normal human variation is not considered a disease, illness or injury.
- **Health outcomes**: health outcomes are outcomes of medical conditions that directly affect the length or quality of a person's life. (for example: evidence of lowered mortality, not just lowered cholesterol.)
- **Sufficient evidence**: evidence is considered to be sufficient to draw conclusions if it is peer reviewed, is well controlled, directly or indirectly relates the intervention to health outcomes, and is reproducible both within and outside of research settings. (For example: for a medicine to be used in primary care:- a randomised controlled trial of a medicine used in a typical primary care setting of sufficient duration to measure a number of health as opposed to intermediate outcomes.)
- **Cost-effective**: a medicine is considered cost-effective if there is no other available intervention that offers a clinically appropriate benefit at a lower cost.
- **Indication**: the condition which is treated by the medicine.

6 Eddy DM. Benefit language: Criteria that will improve quality while reducing costs. JAMA Feb 1996. 275(8):650-657.

7. The introductory sequence

7.1 Effectiveness

The starting point for the introduction of a medicine or indication is to consider the research-based evidence of its effectiveness. We will take into consideration the quality and "maturity" of the evidence, the choice of outcome measures evaluated and the setting in which the trial took place.

7.2 Guideline for use

Drawing on the evidence of effectiveness, clinicians should draw up a guideline for the proposed use of the medicine. The guideline will be considered alongside the evidence. The impact of a guideline will be improved if developed in accordance with standard guideline appraisal checklists.

Where a medicine is likely to be started, modified, monitored and stopped by specialists, prescribing responsibility rests with the specialist. However, if they would like to share clinical and prescribing responsibility with GPs, clinicians should propose a shared-care protocol. The protocol will be considered by Therapeutics Advisory Group.

7.3 Clinical responsibility

A key decision when introducing medicines within Norfolk is the assessment of whether a medicine is **appropriate for prescribing in primary care.** This is determined, in Norfolk, by the Therapeutics Advisory Group (TAG). Furthermore, hospital clinicians should only ask GPs to prescribe those medicines which have been approved for use by their Trust.

7.4 Financial impact

Drawing on the guideline for use, the estimated number of patients for treatment, and an estimate of uptake, it should prove possible to estimate the total cost of the proposed introduction. This cost can then be apportioned to the primary and secondary sectors depending on the decision on clinical responsibility. We can then assess the medicine's financial impact on existing agreements and primary care budgets. Most expenditure in secondary care will be within tariff.

7.5 Economic appraisal

An assessment of the cost-effectiveness of the proposed medicine or indication: This should take into account the additional costs needed for the introduction of the medicine in the setting in which it is proposed to be used - that is, to take into account any extra staff, equipment or monitoring needed.

7.6 Prioritising medicines for commissioning

The PCTs are legally required to fund the medicines and indications recommended by the technology appraisals from NICE. TAG will estimate the financial impact of upcoming appraisals to inform the commissioning process.

Otherwise, the Therapeutics Advisory Group will identify those medicines which are of highest priority for introduction. These are likely to be the medicines or indications with the greatest cost-effectiveness. TAG will take into account - and may need to review - previous decisions to ensure consistency and to make sure we use the medicines and indications of greatest value.

Technical factors which will influence the priority status of a medicine or indication include the quantity, quality and strength of evidence of effectiveness and cost-effectiveness, the availability of alternative treatments, safety, etc.

7.7 Commissioning priority

If additional funding is required, the PCTs will consider the medicines of highest priority alongside other funding priorities, including those not related to new medicines.

Thus, the PCTs' overall commissioning process will consider the professional advice on new medicines and will take into account other relevant factors include other national guidance, NHS policy, National Service Frameworks, local strategies and priorities, the state of development of other services for the disease and the importance and prevalence of the disease locally.

It may seek the views of relevant **disease-specific advisory groups**, such as those advising on cancer services, coronary heart disease and diabetes, and the views of **practice-based commissioning groups**, to assess a medicine's priority against other service developments recommended by those groups.

The PCTs' consider the affordability of their priorities in their local commissioning arrangements. The highest priorities are funded - and this may or may not include some or all of the medicines put forward for consideration. They will consult with a variety of stakeholders, including Professional Executive Committees and patient groups.

7.8 The final decision

The PCTs confirm their commissioning intentions towards the end of the financial year. If funding is approved, this will be made available during the next financial year - with funding for medicines or indications recommended by NICE technology appraisals being made available not more than three months after the date of publication.

8. Introducing medicines in Primary Care

With few exceptions, all medicines licensed in the UK can be prescribed by GPs. Even unlicensed medicines can be prescribed, although Prescribers are discouraged to do this.

Prescribers and PCTs consider both clinical appropriateness and affordability when using a medicine. The introduction of medicines within Norfolk should take into account cost-pressures in the primary care sector as well as the secondary sector. Cost-effectiveness is important whoever prescribes the medicine.

When new medicines are licensed which are likely to be prescribed mostly by GPs, these are proposed for assessment by the PCTs' Prescribing Support Team directly to Therapeutics Advisory Group. Recommendations made by Therapeutics Advisory Group are disseminated to all doctors and pharmacists through the Prescribing Support Team's monthly newsletter (Norfolk Prescriber).

The Therapeutics Advisory Group makes recommendations on whether the medicine is suitable for prescribing by GPs, by specialists or whether a shared-care arrangement is appropriate.

PCT prescribing leads, the Prescribing Support Team and Trust-based Drug and Therapeutics Committees are working together to harmonise formularies for medicines which are widely used in primary care. This activity is conducted through various working groups.

9. Introducing medicines within a Trust

Most new medicines or formulations have modest cost-impact and/or will join medicines of comparable clinical impact. Most decisions on the introduction of new medicines are appropriately made within a Trust. This will allow the Trust to take account of its specialty mix, clinical experience and expertise, work settings and financial status.

Trusts have developed suitable mechanisms for the assessment of new medicines and indications. Such mechanisms build upon the functions of existing Drug and Therapeutics Committees.

A typical mechanism involves Clinical Directors who make submissions to their D&T Committee or equivalent professional advisory body. Submissions address the issue of the medicine's effectiveness - and its cost-effectiveness when compared to other treatments for the same condition.

D&T Committees validate these submissions and then take the decision-making process further in order to consider:

- the medicine's cost-effectiveness compared to other treatments,
- its affordability,

- and then to make the recommendation on its use in the Trust.

The Committee would take into consideration advice provided to GPs by the PCTs' prescribing advisors and decisions made by the Therapeutics Advisory Group.

The ongoing review of new and existing medicines will revitalise the Trust formulary and identify areas where savings can be made. These savings (and those made elsewhere) can be applied towards the additional cost of new medicines if deemed appropriate.

Resources can be transferred from:

- the medicine budget for the directorate;
- the directorate budget;
- medicine budgets for other directorates;
- budgets for other directorates.

9.1 Responsibilities of Trust D&T Committees[7]

In respect to the introduction of new medicines or indications, this policy endorses the following responsibilities:

- the sole gateway advising on the introduction of new medicines or indications within the Trust;
- evaluating the effectiveness and assessing the cost implications of new medicines or indications;
- horizon scanning for new medicines or new indications;
- consideration of guidance developed by Therapeutics Advisory Group;
- collection and preparation of business cases for consideration by the Authority's Therapeutics Advisory Group;
    - Where a NICE technology appraisal is awaited for a new medicine or indication, a business case should be prepared sufficiently in advance so that, if such a medicine or indication is recommended for use by NICE, funding can be made available no later than three months after publication of the guidance;
- agreeing protocols for the use of a medicine or indication within the Trust;
- monitoring medicine use within the Trust.
- considering and endorsing requests for exceptional funding in individual patients.

7 Or equivalent professional advisory body.

10. Therapeutics Advisory Group (TAG)

Whilst it is expected that most decisions on the introduction on new medicines, formulations or new indications in secondary care will be made by Trust D&T Committees, there is an important role for submissions to Norfolk and Great Yarmouth & Waveney's Therapeutics Advisory Group (TAG) when ***guidance*** or ***additional funding*** is sought.

10.1 Tasks

The role of the Therapeutics Advisory Group is to provide informed professional advice across Norfolk and Waveney on the clinical use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc. This includes:

- advice on the managed introduction and implementation of new medicines and indications into practice – including on the most appropriate method of introducing medicines recommended by NICE;
- advice on the prescribing responsibility across the Primary / Secondary care interface
- advice on non-medical prescribing issues.

10.2 Terms of Reference

These are appended as an annex.

10.3 What medicines are considered by TAG?

1. All medicines for which NICE has published Technology Appraisals.
2. Medicines for which guidance is needed on ***use in the primary care setting***, including the approval of ***shared-care guidelines***.
3. Medicines for which there is uncertainty over ***clinical and prescribing responsibility*** across the primary secondary care interface.
4. Medicines which are ***excluded from the tariffs*** of "Payment by Results" or are used in Healthcare Resource Groups which are ***excluded from tariff***.
5. Medicines or new indications for which a Trust is seeking ***additional funding*** e.g. as a "pass-through" payment - or ***guidance*** e.g. because of impact in primary care.
6. Medicines for which we need an assessment of their ***therapeutic value*** or ***cost-effectiveness***, including:
    - Medicines which open up ***new therapeutic avenues***, e.g. the "first medicine for a condition".
    - Medicines which operate through ***new mechanisms***, e.g. the first of a new class of medicine.
    - Medicines with a ***high cost*** impact across primary and secondary care - indicative threshold: additional annual treatment cost of £3,000 per patient or £50,000 across the two PCTs.
    - New medicines or indications with proven effects of unusual clinical importance, unachievable through other means, but achievable only at high additional cost.
7. Medicines possessing particular qualities of uniqueness for which the PCTs seek to ensure ***equitable provision*** across the two PCTs and four NHS Trusts.

8. Medicines which are subject to investigation in trials and which may require significant investment in excess treatment costs.

Other points

- It is important not to overburden the process, so ***medicines with a high cost impact will be evaluated preferentially***.
- Submissions from a Trust should be made and have been considered by the Trust D&T Committee.
- Submissions should justify the requirement for ***additional*** expenditure on the treatment.

10.4 Taking forward TAG recommendations

The Therapeutics Advisory Group is a professional advisory group. It gives advice and makes recommendations.

Most recommendations made through the Therapeutics Advisory Group can be implemented through small changes in clinical and administrative practice. Recommendations for Prescribers are disseminated and supported by the PCTs' Prescribing & Medicines Management Teams. Clinical recommendations affecting hospital Trust staff can usually be taken forward by Trust-based Drug and Therapeutics Committees and considered by usual internal mechanisms.

However, some recommendations will need to be handled through commissioning arrangements - particularly those medicines which are excluded from Tariff. In the event, some recommendations may not be implemented due to competing priorities and unaffordability.

Thus, the final outcome of many TAG recommendations is determined by commissioning decisions made by the PCTs.

The TAG will receive reports on the implementation and prescribing outcomes of its recommendations for consideration, and report to the relevant Boards where practice continues to differ from recommendations.

11. Commissioning new medicines

11.1 The annual commissioning cycle

As part of the annual commissioning cycle of the PCTs, a working group of the Therapeutics Advisory Group will assist the commissioning process by reviewing medicines which may become available during the next financial year.

Trusts will need to prepare business cases to support the introduction of a new medicine or indication.

> Where a NICE technology appraisal is awaited for a new medicine or indication, a business case should be prepared sufficiently in advance so that, if such medicine or indication is recommended for use by NICE, funding can be made available no later than three months after publication of any guidance.

The working group will review these alongside other sources of evidence and will attempt a prioritisation based largely on the ***technical aspects*** of a medicine – such as effectiveness and cost-effectiveness and will also estimate funding requirements.

> Where a technology appraisal is expected from NICE, the working group will estimate the likely financial impact so that the PCT commissioners can set aside a sufficient reserve. This enables the PCTs to discharge their requirement to fund NICE technology appraisals within three months.

The PCTs' commissioning process undertakes a further level of prioritisation to take account of the affordability of the recommendations when set alongside competing proposals for development. This prioritisation takes into account other relevant factors such as national guidance and strategies, local strategies and priorities, the state of development of other services for the disease and the importance and prevalence of the disease locally.

It is quite probable that PCTs will not be able to commission all the new medicines and indications recommended by TAG – thus ***the final outcome of many TAG recommendations is determined by the commissioning decisions of PCTs***.

Significant decisions, on the availability or otherwise of medicines, may be considered and ratified by the boards of PCTs in public session.

If a medicine is supported in the consultation process and ***if*** additional funding is necessary and available, this will be referenced in the annual service level agreement with the Trust starting the following April.

Beyond that, additional funding for new medicines or indications may only become available for the following April - a period of up to 14 months. Medicines will not ordinarily be funded "out-of-cycle".

The Therapeutics Advisory Group and D&T committees will continue to evaluate medicines throughout the year. This will result in a prioritised list of medicines which are deemed of value, but are not yet funded. The Therapeutics Advisory Group will periodically review the list to take account of:

- new guidance prepared for the NHS by NICE;
- newly introduced medicines or indications;
- new research information on existing or new medicines;
- new information on pricing or licensed indications;
- new information on medicine safety.

11.2 Non-tariff medicines

Technical guidance on Payment by Results states[8]:

> *"A number of high cost drugs, devices, procedures and products have been excluded from the scope of tariff. … The following criteria were used to identify the exclusions:*
>
> - *Costs are high relative to the rest of the activity within the relevant HRG or outpatient specialty*
> - *A sub-set of Trusts within the HRG or outpatient specialty disproportionately provides the high cost item.*
>
> *For all excluded drugs, devices, and blood products, commissioners and providers should agree local prices, and local arrangements for activity monitoring.*
>
> *These local prices should be paid as a supplement to the relevant HRG or outpatient tariff.*
>
> *In most cases, the supplement should cover only the cost of the excluded drug, product or device.*
>
> *In all cases, commissioners and providers will need to determine whether they wish to agree volumes and prices as part of SLAs, or to operate on a case-by-case basis."*

The list of "non-tariff medicines" may vary from year to year. Expenditure on this list of medicines and devices is subject to the local commissioning process.

The PCTs will need to agree clear implementation plans (as contained in a business case) for non-tariff medicines and in particular, they will need to be certain about the starting and stopping criteria before they commit resources. Alternative, extended or supplementary indications will not be funded without prior agreement.

The PCTs will also need to agree the appropriate associated service costs and HRGs.

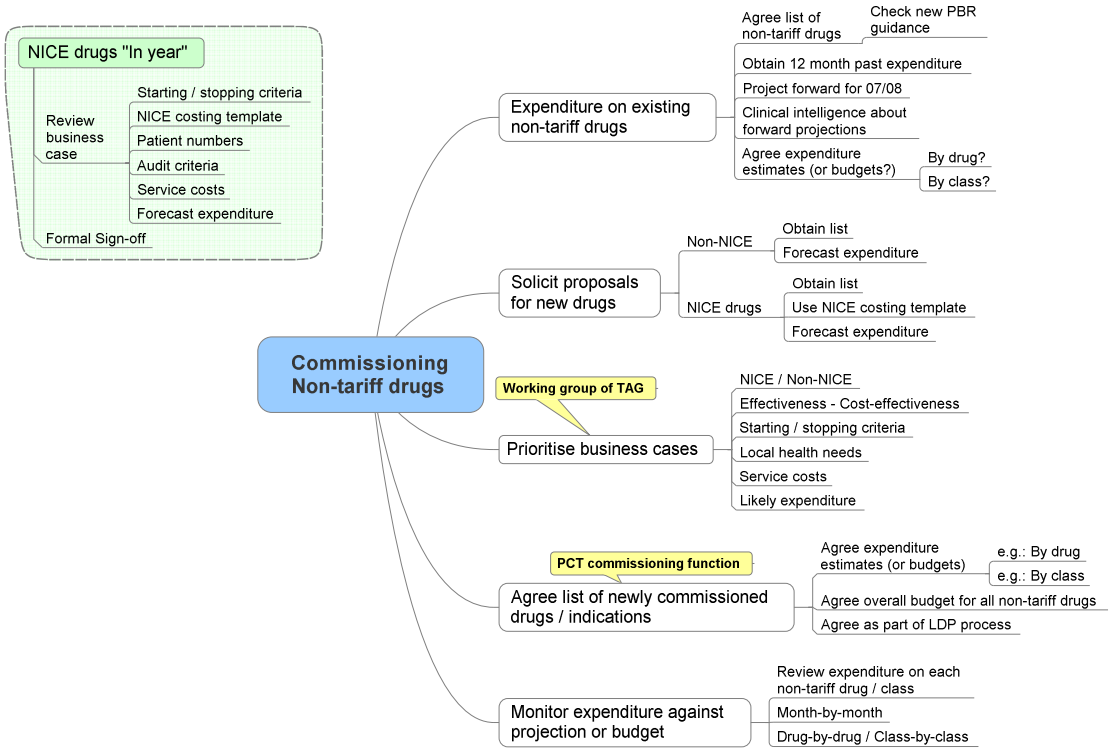
The PCTs may need assurance about the control mechanisms that Trusts establish to oversee the use of high cost medicines or devices and they will periodically expect to review audits of their use, as for example, using those audits recommended by NICE.

The PCTs may build in a "prior approval" mechanism for some medicines or devices for patients who meet agreed funding criteria - so called "Named patient funding".

Where PCTs and Trusts have agreed an expenditure estimate for the financial year for a medicine or device, the PCTs expect Trusts to review the forecast expenditure with them if there is a significant variance. The PCTs may need to establish different eligibility criteria before further expenditure is committed.

8 Implementing Payment By Results: Technical Guidance 2005/06, December 2004. The Technical Guidance for 2007/08, December 2006, continues this approach, but the wording is less detailed and the older wording is included for greater clarity.

The commissioning process for non-tariff medicines is summarised in the following diagram:



11.3 National Institute of Clinical Excellence

Three month rule

The 2003 Department of Health Directions to Primary Care Trusts and NHS trusts indicate that PCTs shall normally make funding available for health care interventions recommended by NICE Technology Appraisal Guidance within three months from the date of publication of the guidance. Subject to very limited exceptions:

> *"a Primary Care Trust shall, unless directed otherwise by the Secretary of State, in exercising those functions that it has been directed to exercise by the Secretary of State, apply such amounts of the sums paid to it under section 97C(1)(b) of the Act[9] as may be required to ensure that a health care intervention that is recommended by the Institute in a Technology Appraisal Guidance is, from a date not later than three months from the date of that Technology appraisal Guidance, normally available: (a) to be prescribed for any patient on a prescription form for the purpose of his NHS treatment[10]; or (b) to be supplied or administered to any patient for the purpose of his NHS treatment."*

Therefore PCTs should make funding available within three months of the guidance being published. The financial implications of upcoming NICE guidance be anticipated and a business case produced by each Trust and agreed with the PCT in good time.

In December 2006 in *"Good practice guidance on managing the introduction of new healthcare interventions"* and links to NICE technology appraisal guidance the Department of Health issued further guidance to clarify the three month rule. This provides in Part 2 under the funding direction that:

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9 (now section 228 of the National Health Service Act 2006)

10 NHS Act 1977, Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) of 1 July 2003.

"Each PCT should use its best endeavours to ensure that any new treatments recommended by NICE are available as soon as possible after NICE issues Technology Appraisal Guidance[11]. If it is possible for a PCT to make the necessary arrangements without utilising the full three month period stipulated in the Directions, it should do so."

Additional drug costs of implementing NICE guidance in primary care are factored into annual primary care budget-setting guidance by the National Prescribing Centre and PCT prescribing advisers.

Making "informed decisions" in the absence of NICE guidance

Department of Health guidance expects PCTs to take informed views about new technologies in the absence of NICE guidance:

"If a new intervention is not referred to NICE, this does not imply any judgement on whether the intervention(s) in question are clinically or cost effective. NHS bodies should continue to use existing arrangements to access the publicly available evidence and to determine local policies for the managed entry of the new intervention. The same principle should apply if an intervention has been referred to NICE but guidance is not yet available at the point at which the new intervention is first introduced."[12]

*"**Reiterating the Message of HSC 1999/176**: It is not acceptable to cite a lack of NICE guidance as a reason for not providing a treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established. … NICE does not exist to "kite mark" all the interventions which are introduced for use in the NHS. … Not all new interventions will be referred to NICE for appraisal and for those interventions that are referred to NICE there may be a time lag. … Therefore, the NHS will have to continue to make informed decisions about the use of these interventions under either circumstance."[13]*

11.4 Pass-through payments

The PCTs will consider whether a new medicine will be funded outside tariff under the "pass-through" payments system. By definition, this is a very rare occurrence. Where this is agreed, it must be for a period of two years or less and the Department of Health must be notified.

"Pass-through payments are additional payments for use of a particular device, technology or drug and can be made to providers over and above the relevant tariff reimbursement. PCTs and providers must agree payment is intended primarily for new devices, drugs, treatments or technologies or to new applications of existing technology. However, there may be a limited number of technologies which may not be new but are a) coded to a relatively high volume HRG where the activity within the HRG is heterogeneous in nature and b) delivered in a limited number of centres and c) of disproportionate cost relative to the HRG tariff."[14]

11 Gateway Ref: 7521

12 HSC 1999/176

13 Good practice guidance on managing the introduction of new healthcare interventions and links to NICE technology appraisal guidance. 14 Dec 2006. Gateway Ref: 7521

14 Payment by Results Guidance 2007/08, Dec 2006.

12. Possible decisions on introduction

The final outcome of many TAG recommendations is determined by commissioning decisions.

12.1 Double Red: Not recommended for routine use

- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their PCT if they chose to prescribe the medicine.
- Trust-based clinicians would not ordinarily be expected to use the medicine.
- Exceptional cases would still be considered initially via the chair of the Trust's DTC.

12.2 Red: Secondary care use only

- Agreed criteria to determine which patients are treated and guideline for use.
- Need to agree funding arrangements: e.g. within tariff, excluded from tariff, pass-through payment.
- Could act, as a probationary period for new medicines for which there is immature or emerging data on effectiveness or cost-effectiveness. Also, for medicines for which the proven effective outcome is of uncertain or limited relevance.
- GPs would not ordinarily be expected to prescribe the medicine.
- GPs would not ordinarily receive money from any contingency funds held by their PCT if they chose to prescribe the medicine.

12.3 Amber: Option for Shared care

- Assessment and initiation by a specialist.
- Typically requires a specialist to modify or terminate treatment.
- Clinical and prescribing responsibilities are detailed in an agreed shared-care protocol.
- Suitable for a GP to prescribe ongoing treatment following an initial period of supply by the specialist as detailed in the shared-care protocol.

12.4 Green: GP prescribable at the request of Consultant/Specialist

- GPs may prescribe following recommendation by a specialist.
- Shared care protocol not required as with Amber classification.
- Hospital to supply when immediately necessary as an outpatient and on discharge, otherwise supplied by GP.

12.5 Double Green: Medicines considered to be suitable for GPs to initiate and prescribe

- GPs may take full responsibility for prescribing these medicines.

Summarised as:

Double-Red:	Not recommended for routine use
Red:	Hospital only – Drugs for which the Trust is responsible for prescribing. GPs should not be expected or approached to prescribe.
Amber:	Shared care following hospital initiation under agreed shared-care protocol.
Green:	Specialist recommendation, GP prescribing.
Double Green:	GP prescribing

Terms of reference: Therapeutics Advisory Group (TAG)

Accountability

- The TAG is established by jointly by NHS Norfolk and NHS Great Yarmouth & Waveney and is accountable to them.
- The TAG will report to NHS Norfolk and NHS Great Yarmouth & Waveney on its recommendations on new medicines and indications.
- The TAG reports recommendations to relevant service development groups to assist those groups' commissioning roles.

Probity

- Members are expected to follow the guidance contained in *"Commercial Sponsorship – Ethical Standards for the NHS"*, Department of Health, November 2000.
- Members are expected abide by *"The Seven Principles of Public Life"* (Nolan Committee recommendations) attached.
- Members should take account of the principles described in the document *"Social Values Judgement: Principles for the development of NICE guidance"*.
- The TAG minutes will be made publicly available through local NHS websites.
- An annual report on TAG recommendations and activities will be provided for Boards.

Role

- The TAG will work within the NHS Norfolk and NHS Great Yarmouth and Waveney 'Ethical & Commissioning Principles' Framework[15].
- The role of the TAG is to provide informed professional advice after consideration of critically appraised evidence to NHS Norfolk and NHS Great Yarmouth & Waveney on the clinical and cost-effective use of medicines, dressings and other prescribable items such as those evaluated by the Advisory Committee on Borderline Substances (ACBS), herbal remedies etc. This includes:
    - advice on the managed introduction of new medicines and indications into practice – including the most appropriate method of implementing guidance produced for the NHS by NICE;
    - advice on the transfer of prescribing responsibility across the Primary / Secondary care interface.
- The professional advice will cover NHS Norfolk and NHS Great Yarmouth & Waveney.
- The TAG does not make recommendations on individual cases nor consider the application of TAG advice in individual circumstances.
- Priority will be given to issues which are of relevance to more than one Trust or Primary Care Trust.
- The TAG has no executive authority.

[15] See Appendix but also included in Individual Funding Request policy document

- NHS Norfolk and NHS Great Yarmouth & Waveney look to the TAG for advice to underpin their joint process for the introduction of new medicines and indications.

Process

- The TAG will consult with relevant parties when developing policies and advice.
- The TAG can solicit advice from external experts and local networks e.g. Cardiac network.
- The work of the TAG may be supported by *ad hoc* working groups.
- Advice and recommendations are agreed by a quorate TAG.
- TAG recommendations will be agreed by the development of a consensus. A small number of objections may be accepted and these should be recorded in the Minutes.
- TAG members should be mindful to represent a body of opinion, not merely their own opinion

Membership[16]

Members are nominated by their organisations to provide informed professional advice.

NHS provider organisations are represented by a pharmacist and a senior clinician with responsibilities in medicines management – typically the Chair of a Trust's Drug and Therapeutics Committee. These organisations are encouraged to nominate deputies to attend in their absence to ensure appropriate input and balance.

- A senior officer / non-executive director from a Primary Care Trust
- TAG Lead Pharmacist.
- Consultant/Specialist in Public Health Medicine or Director of Public Health.
- Senior medical representative from each member organisation.
- Senior pharmacist representative from each organisation.
- Nurse representative
- Mental Health Care Trust representative
- Local Medical Committee representative.
- Local Pharmaceutical Committee representative.
- Representation from Patients' Fora.
- Clinical Pharmacologist (Academic representative).
- 1 representative from the commissioning function of a PCT.

Quorum

- Seven members, or their deputies, to include the chair (or nominated deputy) and three from primary care organisations and three from secondary care organisations.

16 National Prescribing Centre Area Prescribing Committee Guide May 2007 http://www.npc.co.uk/apcguide/apc_guide_may_2007.pdf

Responsibilities of TAG members

- Accept ownership of TAG recommendations
- Undertake work as necessary between meetings
- Promote two-way communication between the TAG and relevant NHS colleagues / organisations
- Take specific views from the TAG back to the member organisations for comment, and then to feed back the responses to the TAG, as appropriate
- Commit to regular attendance of TAG meetings to ensure continuity and balance of input into decision-making
- Be an enthusiastic, motivated and active participant in the committee
- Declare prior to each meeting any outside interests, which might have a bearing on their actions, views and involvement in discussions within the committee

Remit

New medicines and indications

1. To consider the clinical and cost-effectiveness of new medicines and indications and others matters relating to prescribing responsibility (see below).
2. To consider guidance on medicines prepared for the NHS by NICE and NPSA.
3. To consider the resource implications (staff, services and financial) of new medicines and indications to the NHS Norfolk and NHS Great Yarmouth & Waveney health economies.
4. To receive and consider proposals for the use of new medicines and indications as endorsed by Trust-based Drug and Therapeutics Committees (focused on secondary care medicines) or as proposed through Norfolk and Great Yarmouth & Waveney Prescribing Support Teams (focused on primary care medicines).
5. To agree an estimate of the clinical and cost-effectiveness of a new medicine or indication and the extent to which this is supported by research-based evidence.
6. To agree advice on the place of a medicine in relation to the other methods of managing the proposed indication.
7. In relation to other medicines considered by the TAG and taking into account the prevailing circumstances, including financial circumstances and national recommendations and expectations:
    - To issue advice on the appropriate use of the medicine in NHS Norfolk and NHS Great Yarmouth & Waveney and the reasons for this view;
    - To indicate those medicines which are considered to be of highest priority for introduction in the current commissioning cycle and the reasons for this view;
    - To indicate those medicines which are not considered of sufficient priority to recommend their use in NHS Norfolk and NHS Great Yarmouth & Waveney and the reasons for this view.
8. To review policies in the light of changed circumstances, including new research evidence and guidance from the National Institute for Clinical Excellence and/or the Department of Health, the MHRA/CHM and the NPSA.

Primary–Secondary care interface

1. To consider matters which affect the clinical and prescribing responsibility of medicines by GPs and consultants, e.g. licensed and proposed indications, evidence to support use, alternatives, side-effects, monitoring requirements, follow-up by consultants, use in a clinical trial, etc.
2. To develop and update general guidance on clinical and prescribing responsibilities across the primary–secondary care interface.
3. To advise on the initial and subsequent prescribing responsibility for specific medicines and the clinical role of GPs and consultants in the supervision and monitoring of the patient.
4. To receive and consider shared-care protocols (which document the above) for adoption in NHS Norfolk and NHS Great Yarmouth & Waveney.
5. To advocate the preferred funding mechanism to support the implementation of TAG advice.
6. To review policies in the light of experience, changed circumstances, including new research evidence and guidance from the National Institute for Clinical Excellence and/or the Department of Health, the MHRA/CHM and the NPSA.

Clinical trials

1. To consider and issue advice on the clinical and prescribing responsibility of GPs who are approached to prescribe a medicine which is being used as part of a clinical trial.
2. To develop general principles, but also provide advice on specific trials when not covered by the general principles.

Sponsorship

- To develop and advise the local health economy on the probity of relationships between the pharmaceutical industry and the workings of the local health economy with a particular focus on ensuring that the choice of medicines used is not adversely influenced by such relationships.

Other issues

- In relation to the issues described above, to receive and comment on guidelines which contain therapeutic advice.

Complaints and other feedback

- Feedback on TAG advice should be made to the Chairman who will refer to the PCT's Prescribing & Medicines Management Teams for guidance on further handling.
- The TAG will reconsider its advice in the light of new information, new proposals for use, alternative interpretations or changed circumstances brought to its attention by informants or complainants.
- In the absence of such changed circumstances, TAG members will have their attention drawn to feedback or complaints by the Chairman.

Dissemination of advice

1. Through the meeting notes to members of the TAG.
2. Through the "Norfolk Prescriber" newsletter.
3. Through the "Traffic-light / TAG recommendations" document which is updated at least annually.
4. Through PCT intranets.
5. Through *ad hoc* communications where necessary.
6. Through reports to relevant groups involved in service development
7. Through contributions to guidelines produced by others.
8. In PCT strategic delivery plans when appropriate.
9. In response to queries made to PCTs.

Implementation of advice

1. Through the commissioning processes of Primary Care Trusts.
2. Through processes internal to PCTs and Trusts (e.g., Trust-based Drug and Therapeutics Committees, PCT prescribing committees, clinical governance processes, audits etc).
3. Through the work of NHS Norfolk and NHS Great Yarmouth & Waveney's Prescribing and Medicines Management Teams.

NICE: Social Value Judgements[17]

Summary of principles
These guidelines describe the social value judgements that should, generally, be incorporated into the processes used to develop NICE guidance and be applied when preparing individual items of NICE guidance. The Institute recognises, however, that there will be circumstances when – for valid reasons – departures from these general principles are appropriate. When departures from these principles are made, the reasons should be explained.

Principle 1
The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance.

Principle 2
For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations.

Principle 3
NICE guidance should not support the use of interventions[18] for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.

Principle 4
In the economic evaluation of particular interventions, cost–utility analysis is necessary but should not be the sole basis for decisions on cost effectiveness.

Principle 5
NICE guidance should explain, explicitly, reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio in excess of £20,000 to £30,000 per QALY.

Principle 6
NICE clinical guidance should only recommend the use of a therapeutic or preventive intervention for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups that cannot be identified by any other means.

Principle 7
In setting priorities there is no case for the Institute or its advisory bodies to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of preventative or therapeutic interventions.

Principle 8
In developing clinical guidance for the NHS, no priority should be given based on individuals' income, social class or position in life and individuals' social roles, at different ages, when considering cost effectiveness. Nevertheless, in developing its approach to public health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status.

Principle 9
NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention that cannot be identified by any other means.

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17 Social Value Judgements: Principles for the development of NICE guidance, December 2005

18 The term 'intervention' is used in these guidelines to encompass health technologies and any other measure used to influence the course of a particular condition.

Principle 10
NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account.

Principle 11
Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.

Principle 12
It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance. The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures.

Principle 13
Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses.

Assessing the qualities of a medicine

"If we can never know the answer, let us be honest and admit that we cannot. If we cannot produce proof, let us withhold the final stamp of intellectual approval until we do. It is better to be an agnostic forever than to worship false gods.[19]*"*

Valuing evidence on effectiveness

Medicines which are licensed for use in the UK or European Union have already undergone an assessment process which requires the manufacturers to prove safety, quality of manufacture and (at least some) element of effectiveness in one or more outcomes (not always those of greatest relevance). However, there is no requirement to demonstrate better effectiveness or cost-effectiveness against medicines of comparable clinical effect. This is a task undertaken at a national level by NICE, and locally by clinicians, Trusts and commissioners.

Thus, whilst for other health technologies, it may be possible to decide that there is insufficient evidence of effectiveness to justify its introduction at local level; this is less likely to be the case for new medicines.

Nevertheless, the evidence on effectiveness may be regarded as "immature" because:

- it refers to an intermediate outcome with an unproved prognosis;
- it refers to an outcome of uncertain relevance;
- the medicine was used in settings unlikely to be achieved in practice;
- data is from short-term follow up - which is of limited value for medicines taken for chronic diseases;
- it lacks information on adverse events which may become apparent only when the medicine is used widely;
- the research trial had flaws or was controversial;
- it lacks information on cost-effectiveness.

Assessing other qualities

Medicines may be considered to have value in other dimensions due to qualities such as: newness, uniqueness, ability to cure, ability to palliate terminal illness, ability to prolong life, ability to prevent illness, ability to save life immediately, etc.

NICE has reflected on the role these other dimensions should play in the development of its guidance in its publication *"Social Value Judgements"*[17]. The principles are included as an annex.

19 Murphy E. The logic of medicine. Baltimore. The John Hopkins University Press. 1979.

The Seven Principles of Public Life

From the: *"First Report of the Committee on Standards in Public Life (Nolan Committee) CM2850-1"*

Selflessness
Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity
Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their official duties.

Objectivity
In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability
Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness
Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty
Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership
Holders of public office should promote and support these principles by leadership and example.

These principles apply to all aspects of public life. The Committee has set them out here for the benefit of all who serve the public in any way.