Briefing
September 2008

Top-up payments for drugs in England

Introduction

In June 2008 the government announced a review of their policy on whether people should be able to top up their NHS care with privately purchased drugs not available on the NHS. The government's existing policy, which prohibits individuals from funding prescribed drugs themselves while continuing a course of NHS care, has been subject to strong criticism following a number of high-profile cases in which terminally ill patients have had to either forego purchasing the drugs or to pay for the care that they would otherwise have received free on the NHS. Existing rules are being interpreted differently in different parts of the country, and the legislative basis for the government's position has been called into question.

This briefing describes how top-ups are distinct from other charges in the NHS and why they have become such a contentious issue now; outlines the relevant legislation and guidance in this area; and sets out the opposing positions on top-ups.

For a more detailed exploration of these issues, please see The King's Fund's submission to the government review (available at: www.kingsfund.org.uk/publications/consultation_responses/index.html). A statement outlining The King's Fund's position on top-up payments is also available (www.kingsfund.org.uk/media/index.html).

1. What are top-ups?

'Top-ups' are payments made by patients for drugs, devices or procedures that are not funded by the NHS. They are used to supplement other care the patient is receiving from the NHS for their particular condition.

Some top-ups are already permitted in the NHS. A dentist may provide a patient with both NHS and private treatment, including mixing the two in a single appointment, so long as this has been pre-agreed and the differently funded care is not on the same tooth in the same course of treatment (a rule developed to avoid patients unknowingly losing the right

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to free replacements of the NHS element of care). In optical care, top-ups are permitted in the case of those eligible for vouchers towards lenses or glasses.

Amenity beds, where patients pay to have a bed or room with more privacy and facilities while receiving their NHS treatment, also comprise a top-up.

Other types of NHS charges and public–private arrangements are not classed as top-ups. For example, prescription charges are effectively a co-payment for NHS care: they are compulsory contributions to the basic NHS package. There are also cases in which patients switch between NHS and private care. For example, an NHS GP appointment may be followed by an appointment with a private specialist. A couple who have had NHS-funded IVF treatment may purchase additional IVF cycles from the private sector, and still be eligible for any related NHS-funded antenatal and birthing care required as a result.

This briefing focuses on top-ups in relation to drugs, which is the focus of the current government review. Situations in which patients want to top up drugs arise when the drug is not approved for funding by National Institute for Health and Clinical Excellence (NICE) or by a patient's local primary care trust (PCT).

Drugs can be licensed for use in the United Kingdom by either the European Medicines Evaluation Agency or the UK's Medicines and Healthcare products Regulatory Agency. The Department of Health may then decide to refer new drugs to NICE, which will decide whether or not the drug should receive NHS funding on the basis of cost-effective analyses (how many additional quality years of life will be secured at what cost). Drugs are not routinely funded by the NHS if they are rejected by NICE, or if they have not yet been evaluated by NICE. Since NICE was established in 1999, it has assessed 56 treatments for cancer, of which 52 were approved for funding and only 4 rejected (Dillon 2008).

The options for clinicians and their patients in these cases are to apply for funding from their local PCT on the grounds that the patient's case is 'exceptional' in some way or for the patient themselves to purchase the drug. It has been estimated that in relation to cancer, approximately 800 patients a year apply unsuccessfully for exceptional funding and so may want to top up their care (Rarer Cancers Forum 2008). This may understate the numbers who would top up, because some patients may not be aware of the drugs concerned.

Existing government guidance indicates that clinicians and managers should not continue to provide free NHS treatment to a patient who is privately purchasing a drug for that condition, but the definitions around the circumstance when this prohibition applies, and its legal basis, are far from clear (see section 3 overleaf).

2. Why has this issue come up now?

The establishment of NICE in 1999 has made rationing decisions, about which drugs should and should not be available on the NHS, more transparent. Recently, a series of cases have come to public attention in which terminally ill patients have had to fund their NHS care because they have chosen to purchase a drug that NICE has either rejected or not assessed.

Media reports tell of different practices in different areas, with some PCTs withdrawing treatment from patients purchasing drugs, while others have permitted top-ups. Some patients have employed solicitors to challenge the legal basis for care being withdrawn in these circumstances, prompting PCTs in some cases to reverse their decisions and permit a top-up in these instances.

In addition, a recent audit conducted by the Rarer Cancers Forum found considerable variation in the practices and processes of PCT exception committees (Rarer Cancer Forums 2008). As a consequence the number of people finding themselves in a position where they may want to top up their care will vary from area to area.

In a YouGov poll of 2,000 adults conducted in June 2008, 78 per cent of respondents agreed that people should be able 'to pay the cost of cancer drugs that are not available to them… as part of their NHS care' (Western Provident Association 2008). The British Medical Association has called for a Royal Commission to be established to examine the issue after a motion was passed at their annual conference that patients should have the option of supplementing their care, though the conference stopped short of recommending that top-up payments should be permitted immediately (British Medical Association 2008).

In June 2008 the Secretary of State for Health Alan Johnson announced that he had commissioned the National Cancer Director, Professor Mike Richards, to 'examine current policy relating to patients who choose to pay privately for drugs that are not funded on the NHS and who, as a result, are required to pay for the care that they would otherwise have received free on the NHS', and 'to make recommendations on whether and how policy or guidance could be clarified or improved' (Hansard 2008 17 June; Department of Health 2008). The review, which covers all drugs, not just cancer drugs, will include assessing current law and guidance, trying to establish existing practices across the NHS, assessing experiences in comparable countries and engaging staff, patients, the public and stakeholders. Professor Richards is due to report in October.

The Conservative Party is also conducting a review of whether patients should be allowed to buy additional treatments not funded by the NHS. This review is broader than the government's, covering both drugs and services.

3. What does existing law and guidance say about top-ups?

Current legislation and guidance do not provide clear or well-defined directions to patients, clinicians or managers in the case of requests to purchase drugs privately to combine with NHS treatment.

The Health Minister Ivan Lewis has cited section 1 of the National Health Service Act 2006 (which replaced an identical clause in the National Health Services Act 1977) as the legal basis for the ban on mixing public and private care in the NHS. The section states:

> *'The Secretary of State must continue the promotion in England of a comprehensive health service designed to secure improvement … The services so provided must be free of charge except in so far as the making and recovery of charges is expressly provided for by or under any enactment whenever passed.'* (National Health Service Act 2006)

The Minister has interpreted this clause as preventing NHS organisations from allowing a patient to pay for a drug privately and have it administered on the NHS. In his words, this would constitute 'effectively charging for an NHS service' (Hansard 2008 10 June). As a consequence of this interpretation, patients must either forego the drug, or purchase the drug but lose their entitlement to NHS treatment for its administration.

However, a legal opinion produced by Nigel Griffin QC concluded that in the case of patients wishing to purchase non-NHS funded drugs and continue treatment on the NHS, this legislation would only prevent NHS bodies from buying the drugs and charging patients for them. Griffin concluded that it would not prevent a GP writing a private prescription and the patient purchasing the drug direct and having it administered as part of a course of NHS treatment (Griffin 2006).

The Secretary of State for Health Alan Johnson has cited a code of conduct for doctors, designed to regulate the boundary between the NHS and their private practice, as grounds for prohibiting top-ups (Hansard 2007). The Department of Health document *A Code of Conduct for Private Practice: Recommended standards of practice for NHS consultants*, issued in 2003 and updated in 2004 and in 2006 by the British Medical Association contains the provision that: 'a patient cannot be both a private and a NHS

patient for the treatment of one condition during a single visit to a NHS organisation' (Department of Health 2003, British Medical Association 2006). The same provision was contained in the 1986 guidance *Management of Private Practice in Health Service Hospitals in England and Wales*, which the 2003 guidance was designed to complement (Department of Health 1986).

In order to interpret this guidance, there needs to be clarity about what counts as NHS care and what as private. It is not clear how the administration of privately purchased drugs by an NHS clinician as part of a broader programme of NHS treatment should be categorised.

4. What are the options for change?

The public, professional and academic debate has presented the issue of top-ups as a clash between two views of fairness. Those opposing top-ups argue that to allow them runs counter to the principle of fairness underpinning the NHS – equal access for equal need. Allowing top-ups would create a two-tier NHS in which those who could afford to do so would be able to buy themselves additional levels of care.

Those in favour of top-ups argue it is not fair to withdraw NHS treatment, to which people have contributed financially through National Insurance and taxation, simply because someone chooses to make use of their own money to pay for additional treatment. Whereas the costs of opting out of the NHS to pay for the whole episode of care privately are unaffordable to most people, if top-ups were allowed the patient would only have to pay for the cost of the additional drug. It is likely that this would make the care more affordable to more people. (For a more detailed exploration of these issues see Weale and Clark 2008.)

Whichever of these two principles is followed, a number of more specific measures will need to be considered to make either option workable.

Permitting top-ups

- The government will have to identify and specify the circumstances in which top-ups are to be permitted. The current government review is focusing on drugs only, but there are other procedures and therapies that present similar if less emotive issues, such as requests for a more expensive artificial hip in the case of a hip replacement or more expensive lenses for patients with cataracts.
- It will be important to calculate associated costs – for example, the costs of administering a drug or fitting a device. If these costs were met by the NHS, this would mean resources being diverted from other NHS patients to support the delivery of a treatment that may have been judged to be not cost-effective by NICE. If these costs are to be met by the patient, then they will have to be carefully calculated.
- It will also be important to ensure that individuals understand the financial liabilities they may face if they top up their care. In the short term, individuals with a terminal illness may feel they have nothing to lose by risking their resources on an expensive drug with relatively low efficacy. But if the drug proves to extend their life, they may find themselves unable to finance payments in the medium or long term. One way in which costs to the individual could be capped and cost effectiveness to the NHS assured would be to introduce a time limit for each individual patient's use of a drug after which the NHS would pay, on the grounds that efficacy had been demonstrated.
- The government may also want to examine whether it is possible to enable those who cannot afford to pay for top-ups in full to have access to such drugs. One option would be to set top-up charges on a scale related to ability to pay, though this would mean using public money to subsidise cost-ineffective treatments.

Banning top-ups

- The legal basis of a ban on top-ups is currently unclear. In consequence current practice in the NHS varies between different geographical areas. Therefore if top-up payments for drugs are to be prohibited this would need to be established in law and clear guidelines and definitions would need to be developed to guide day-to-day, local application of these rules. This would be challenging given existing precedents for top-ups in other areas and more generally for mixing and matching public and private care.
- The government would need to frame any decision to ban top-ups within a broader, positive statement about what 'comprehensiveness' means in the context of the NHS, why all new drugs cannot be available to patients and why it is unacceptable that people within NHS facilities (or funded by the NHS but in private facilities) should receive different treatments.

5. Conclusion

The government is faced with a difficult choice. Whichever decision it takes, there will follow significant challenges and criticism.

In order to reduce the negative impact of any decision, the government is likely to examine how to reduce the proportion of drugs that have been licensed but not yet assessed by NICE – by, for example, extending NICE's remit to cover all new drugs (not only those referred to it by the Department of Health) and by speeding up NICE's decision-making processes, as recommended by Lord Darzi's NHS Next Stage Review (Department of Health 2008b). The government is also likely to consider how the cost of drugs might be reduced, so that they become more cost effective. Introducing financial risk-sharing schemes between the government and pharmaceutical industry is one option.

In addition, whether top-ups are permitted or prohibited, the government will need to ensure that there is a much greater degree of clarity than there is at present about individual rights and local and national decision-making processes.

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