IMPROVING
THE AVAILABILITY OF MEDICINES
FOR PATIENTS IN WALES

TOP-UP PAYMENTS

IMPLEMENTATION GROUP
REPORT

February 2011
Foreword

In May 2009 the Minister for Health and Social Services in Wales established a Group comprising clinicians, pharmacists, nurses, NHS managers, a health economist and trade union representatives to implement the 11 recommendations of a report to improve access to medicines for NHS patients (“*Routledge report*”). The Group submitted their report to the Minister in March 2010.

On receipt the Minister noted the report touched on issues in relation to top-up payments. The Group were subsequently invited, in July 2010, to “fully consider the legal and ethical framework, and to develop clarification on the procedures for patients wishing to fund private packages of care.”

This report is the outcome of discussions of the Implementation Group (Annex 1) with a wide range of clinicians, patients, NHS staff and members of the public (Annex 2) on combining NHS treatment with a top-up treatment package when NHS funding pathways have been exhausted. The principles explored relate to access to medicines but apply equally to other areas of health care.

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February 2011

1 NHS principles

The work of the Implementation Group was undertaken against a background that (i) NHS Wales would maintain its focus on ensuring timely, appropriate, evidence based access to cost-effective medicines for all; and (ii) the key principles of the NHS will be retained regardless of whether or not top-ups are introduced:

- The NHS will provide a comprehensive service and range of medicines available to all.
- Access to NHS services and medicines will be based on clinical need not an individual’s ability to pay.
- NHS services will meet the highest standards and reflect the needs and preferences of patients, their families and their carers.
- The main purpose of NHS organisations will be to provide NHS services and in a cost-effective manner making the most effective and fair use of finite resources.

2 Terminology

The terms top-up payments/fees and co-payments are often used interchangeably and inconsistently. There is no legal definition of the terms and they are not used in primary legislation, nor in regulations made pursuant to primary legislation. The term top-up payment has been defined by the House of Commons Health Committee. Their definition was adapted as follows and is used throughout this report:

\[
\text{Payment made by a patient for a medicine (and related care) not approved and funded by the NHS.}
\]

Using this definition a top-up payment gives access to a medicine that supplements or replaces other medicines the patient is receiving from the NHS for the treatment of a particular condition. This differentiates it from a co-payment which refers to a user charge where the patient must make a financial contribution to access a standard NHS service e.g. the levy of a prescription charge in England.
Over the past decade the NHS has repeatedly come under criticism for not funding certain medicines. There are real challenges for NHS bodies in developing robust processes to ensure new, expensive but cost-effective medicines are available without unnecessary delay. In Wales the principal routes of access to new, expensive medicines are (i) the standard appraisal route which ensures medicines are routinely available to all for their approved indication; and (ii) an individual patient funding request which may permit access to a medicine on a case by case basis.

The access to a medicine via a top-up payment will accommodate the situation where, for clinical reasons, an individual clinician believes a medicine that has not met the criteria for approval by the standard route or an individual funding request may, nevertheless, benefit the patient in question.

3.1 Standard appraisal route

Licensed medicines are approved for use in Local Health Boards (LHBs) by the National Institute for Health and Clinical Excellence (NICE), the All Wales Medicines Strategy Group (AWMSG) or area medicines committees. Many new medicines, particularly those considered high-cost, normally undergo an appraisal of clinical effectiveness and cost-effectiveness by NICE or AWMSG. The medicines approved by NICE or AWMSG must be funded by Local Health Boards. Until October 2010 area medicines committees have considered those medicines that have not been appraised by NICE or AWMSG but from October, AWMSG will appraise all medicines not on the NICE work programme.

3.2 Individual patient funding request

An individual patient funding request (IPFR) is normally directed to a LHB or the Welsh Health Specialised Services Committee (WHSSC) to fund an intervention that falls outside the range of treatments the LHB or WHSSC normally provide.

The IPFR process is currently undergoing extensive review to ensure a robust, rational, timely, open, transparent, consistent, and fair process is in place that is accessible and understood by all. If a request for individual patient funding is successful costs are met by the NHS.

Details of individual patient funding requests for medicines in the 12 months to September 2010, for each LHB in Wales, are shown in Table 1.
Table 1  Outcome of individual patient funding requests (IPFRs) in Wales (October 2009 – September 2010)

<table>
<thead>
<tr>
<th><strong>Total IPFRs</strong></th>
<th><strong>3922</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>IPFRs for medicines</td>
<td><strong>907</strong></td>
</tr>
<tr>
<td>IPFRs for medicines approved</td>
<td><strong>663</strong></td>
</tr>
<tr>
<td>IPFRs for medicines refused</td>
<td><strong>149</strong></td>
</tr>
<tr>
<td>IPFRs for medicines approved after appeal</td>
<td><strong>3</strong></td>
</tr>
</tbody>
</table>

Supplementary data, an outline of how the information was gathered and a list of the medicines involved in this process can be found at Annex 3. Over the study period 149 individual patient funding requests for medicines across Wales were initially unsuccessful. It is these unsuccessful funding requests that are likely to be candidates for top-up payments in the future.

### 3.3 Top-up

When an individual funding request has failed on grounds of cost-effectiveness it is proposed that as long as the medicine can be shown to have a favourable benefit to harm profile for that individual patient, private payment may be permitted to allow an individual to access the medicine. This may supplement or replace other medicines the patient is receiving from the NHS for the treatment of their particular condition. The top-up treatment package will be delivered as a separate, discrete episode of care* but the patient will continue to be an NHS patient for all other ongoing episodes of care.

### 3.4 Private

Patients with sufficient resources or private health insurance may opt for private treatment at a location of their choice that can provide appropriate resources and clinical expertise. All treatment and care costs are funded by the individual or their private health scheme. Private patients can choose to revert back to being NHS patients at any time but not normally within the same treatment episode.

* An episode of care is a package of treatment and care provided for a specific medical problem or condition. It may be continuous or it may consist of a series of treatment and care episodes.
4 Why are top-ups required?

In the past criticism has been directed at NICE, AWMSG and LHBs on how and when they decide on which drugs to fund. Factors such as the length of time it takes to reach a decision, an overly bureaucratic process, a perceived emphasis on cost but not efficacy, inappropriate evaluation of the worth of medicines used in the end of life setting, and variations in decision making, particularly between the former LHBs in Wales, have all been concerns in the past.

Whilst steps have been taken to address the issues mentioned above there remains a need to improve understanding and improve public confidence in the various appraisal and decision making processes used across the NHS.

During our discussions with individual patients, patient representative groups and key charities, a range of concerns were raised. Most voiced frustrations in understanding, contributing to, or navigating current procedures and expressed a lack of confidence in the decision making process. As a consequence of these perceptions there is a tendency to assume that the decision making process does not take into account all the relevant information or have the interest of patients at heart. From time to time individual clinicians also share these views. There is no quick fix to this. AWMSG has made significant progress in further improving their process and the individual patient funding request procedure is currently under review. An integral part of the individual patient funding request process is the need to ensure that individuals who make unsuccessful funding requests receive clear information on why the medicine they have requested has not been funded. Perhaps if this information was more readily available it would help the individual in their decision as to the next steps, particularly where concerns about the benefit/harm ratio have been identified.

In April 2010 NHS Scotland produced a leaflet that summarised details of the various bodies responsible for access to new medicines together with essential contact details (Annex 4). Those with whom we have shared this information have encouraged the provision of similar information, in both online and hard copy formats, for use within Wales.

In addition to those new medicines that have been appraised but for which NHS funding has not been supported, there will also be a small number of new medicines that have not been appraised for use in the NHS but which an individual and their clinician consider could bring significant clinical benefit. In other situations a patient and clinician may wish to use a new medicine which has not been licensed (and therefore not appraised by NICE or AWMSG), or a licensed medicine for an indication that is “off-label” and again for which it will not have been appraised.

The number of medicines that will have evidence of effectiveness but which fall outside the standard appraisal route and fail to secure individual NHS funding will be candidates for top-up payments. The use of a top-up payment to access a medicine should be seen as the option of last resort.
4.1 Potential inappropriate use

The introduction of top-up payments will permit choice for the individual but may present opportunities for exploitation beyond the scope of this review. Areas of potential concern include:

- Insurance companies that provide private health care may attempt to exploit top-ups to their commercial advantage.
- The involvement of the pharmaceutical industry in the direct or indirect promotion of a new medicine, or a medicine with a new indication, whether intentional or unintentional, may drive demand for top-ups.
- NHS managers may consider the availability of a top-up payment option allows them to provide a two tier system whereby, for example, the NHS supplies generic medicines and the individual pays a top-up to access the branded equivalent.
- A GP may be drawn into the care of an individual contemplating a top-up or receiving a top-up treatment package initiated by a hospital consultant. They therefore need to be clear about their obligations. GPs can refuse to refer for a top-up treatment package if they consider it is not clinically necessary; they can refuse to prescribe if they consider it is not clinically necessary; they can refuse to prescribe where they feel they have insufficient expertise or where complex monitoring is involved.

The Implementation Group focussed on top-up payments for high cost medicines in secondary care. Utilisation in other settings and for alternate purposes will require further, careful consideration.

5 Legal framework

The view, overall, is that there is no legal barrier to an individual patient utilizing a top-up payment to access a medicine within NHS Wales. For example, where a medicine that has not been approved for use in Wales by NICE, AWMSG, WHSSC and has been subject to an unsuccessful individual patient funding request, it would be lawful for the LHB or Trust to provide the medicine and associated services as a top-up treatment package. A range of legal issues relating to the possible introduction of top-up payments in Wales have been considered and some of these are set out in detail in Annex 5. In summary:

- Where a top-up treatment package is provided, accommodation and services may only be provided if provision does not interfere with the performance by the LHB or Trust of its NHS functions.
- There is an obligation on LHBs to consult before offering accommodation and services as part of a top-up treatment package. There is no express obligation on a Trust to consult, but it would be good practice for them to do so.
• Before considering the provision of a medicine as part of a top-up treatment package it should be a requirement that all are submitted to individual patient funding request panels. This is not a legal requirement but will ensure all NHS avenues for funding are exhausted and allow LHBs and/or a Trust to capture and review the necessary data.

• Where a patient purchases a medicine as part of a top-up treatment package they should not lose their entitlement to NHS treatment. Scotland and England have already revised their policy position and issued detailed guidance to make it clear that NHS organisations in these countries should not withdraw NHS care simply because a patient opts to purchase a top-up treatment package. Welsh Ministers have the power to issue similar guidance in relation to Wales.

• Where an NHS body has the power to make a charge for the “principal” medicine that is the subject of the top-up, it can be argued that any follow up care required solely as a result of receiving that medicine should be paid for by the patient. For example, if the NHS was to pay for tests solely required because a patient had received a non NHS funded drug this would mean the NHS was effectively subsidising the cost of a patient’s private treatment. Local Health Boards or a Trust have the power to charge for associated monitoring and care. Whilst predictable costs should be clearly set out and agreed with the patient before treatment commences, the charge must not include managing unpredictable events. The cost of managing unpredictable events should be met by the NHS.

• There is no absolute legal requirement for a top-up treatment package and NHS care to be delivered separately. There are, however, definite advantages to introducing a policy that require, as far as possible, physical and temporal separation of the two types of care. The most important advantage from a legal perspective is that separation of care should make it clear to all of those involved in the provision of care, and to the patient himself, which aspects of care are being provided privately and which are being provided as part of the NHS. The clearer this distinction the less likelihood there is of the NHS charging for services that it does not have the power to charge for and, conversely, the less chance there is of a private patient not being charged for a service for which he should properly be required to pay. Issues surrounding liability for negligently provided treatment may also be clearer if there is separation in the provision of care.

• During discussions the issue was raised as to whether an NHS organisation would accept vicarious liability for non-medical staff providing treatment and care as part of a top-up payment package. Under current arrangements where there are private beds staffed by nurses and junior doctors employed under a normal NHS contract the Welsh Risk Pool provide indemnity for their acts and omissions. This scenario is not directly applicable to the delivery of top-up packages.
as these will be considered to be part of NHS care with regard liability for all medical and non-medical staff.

6 Lay perspective

The ethical considerations for top-up treatment packages involve the need to balance autonomy and patient choice with justice and equity. Some of these complex issues were discussed with individual lay representatives in face to face meetings or with members of Community Health Councils (CHCs). Some CHCs facilitated their own discussion groups or distributed our core list of questions to members. Feedback was received from over 80 individuals. A summary of the various responses can be found at Annex 6. The views of the majority who provided feedback were as follows:

- There were concerns about the introduction of top-ups and whether this was a step to a two tier NHS. However, the right of the individual patient to choose to pay for a medicine, as long as they had the support of their clinician, was clearly recognised.

- Whilst there was support for the notion that top-ups were acceptable if no NHS patient was disadvantaged, it was unclear whether this would always be the case in practice.

- Individuals who pay for a top-up package of care should have the right to return to NHS care as, and when, the need arises if they so wish.

- Whilst it was considered desirable that clinicians should not discuss the details of private care during an NHS consultation, individuals did want to be informed about all available treatment options that may be of benefit, including those medicines for which they may need to pay.

- There was a wish to receive clear, specific details of the cost of a top-up together with details of the treatment they would receive.

- The charge for a given medicine accessed via a top-up should be the same across Wales.

- Those consulted were uncomfortable with the idea the NHS should make a profit out of a top-up. There was, however, support for the NHS to recover costs as incurred.

- There was support to monitor the number, nature and outcome of top-up treatment packages and make this information available for the benefit of subsequent patients.
7 Procedural framework

If top-up treatment packages are to be introduced a number of key procedural issues need to be considered.

- Clinicians must demonstrate excellent communication skills when conveying information to patients. The need for these skills is important when discussing top-ups. Individuals need to be fully informed about their condition and the likely benefits and risks of the principal medicine(s) in the top-up.

- All treatment options (NHS and top-up) should be discussed with the patient during the NHS consultation. Clinicians do, however, need to comply with paragraph 2.9 of their Code for Private Practice: “In the course of their NHS duties and responsibilities, consultants should not initiate discussion about providing private services to NHS patients, nor should they ask other NHS staff to initiate such discussions on their behalf”.

- Clinicians and managers should be required to exhaust all options for securing NHS funding prior to proposing a top-up.

- Potential top-ups should be submitted as IPFRs to the appropriate panel. The NHS processes that deal with these must not be overly complex or bureaucratic and should be capable of dealing with requests in a prompt and timely manner. Where an IPFR is unsuccessful there is a need for the panel to clearly communicate the reasons to the patient.

- If an individual funding request is unsuccessful and subsequently proceeds to a top-up the individual patient funding panel should be notified prior to commencement of treatment by the responsible consultant.

- Patients considering a top-up should receive a second medical opinion to specifically ensure they are being offered appropriate advice and are clear about the benefits, risks and safety of the treatment in question. The second opinion will normally be obtained at the expense of the NHS and provided in a timely manner, but not necessarily by a senior clinician working in the same specialist area.

- Local Health Boards should also have arrangements in place to ensure the patient receives all reasonable, necessary information and are aware of the options available to them regarding the top-up. Local Health Boards may wish to ensure clinician’s use a checklist (Annex 7).
• Local Health Boards offering top-up payment packages should have written Standards of Practice for all NHS staff.

• While NHS treatment and top-up treatment should ideally be delivered as separate episodes of care in separate facilities, there may be particular logistical problems in Wales because separate (NHS and private) facilities may not always be available. To avoid restriction of access to a top-up in an affected area, a more pragmatic approach will sometimes be required.

• Non-emergency complications, essential monitoring and predicted consequences of the top-up treatment should be paid for by the patient. Patients should be adequately informed, acknowledge the risk of complications and be prepared to take financial responsibility for the management of non-emergency complications before commencing the top-up payment treatment.

• The NHS should not subsidise any element of a top-up treatment package and this must be made explicit to the patient at the outset, and before the top-up treatment starts. Likewise, individuals should be clear they will receive no advantage with regard any subsequent position on a NHS waiting list. The individual’s position on an NHS waiting list will be the same as a patient who has opted for NHS care in entirety.

• The NHS or NHS staff should not make additional profit from the provision of a top-up treatment. Charges and payments should be calculated on an appropriate commercial basis, be consistent across Wales and take into account a range of factors that include staff time, expertise, training, equipment, laboratory monitoring, use of other resources, bed occupancy and overhead costs etc.

• There should be ongoing monitoring/audit of both the operation of top-up payment packages of care in Wales and requests for individual patient funding.

• Health outcome data should also be monitored, collated and made available for the benefit of other patients.
Implementation Group
Towards improving the availability of medicine for patients in Wales

Membership
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Legal Services, Welsh Assembly Government
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Towards improving the availability of medicines for patients in Wales

Groups and individuals consulted between August and October 2010

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Chief Officer, Cardiff Community Health Council

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Consultant Oncologist & Medical Director, Academic Breast Unit Velindre Cancer Centre

Dr Idris Baker
Chair, Clinical Ethics Committee, Abertawe Bro Morgannwg University Health Board

John Bowles
Welsh Health Legal Services

Dr Andrew Edgar
Director, Centre for Applied Ethics, Cardiff University

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Director in Wales, British Dental Association Wales

Dr Rick Greville
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Dr Jonathan Kell
Clinical Director of Haematology, Cardiff & Vale University Health Board

David Kenny
Gwent Community Health Council

Cath Linley
General Manager, Macmillan Cancer Support

Professor Marcus Longley
Director, Welsh Institute for Health and Social Care, University of Glamorgan

Eric Low
Chief Executive Myeloma UK

Isabel Puscas
Library and Knowledge Manager, Public Health Wales
Annex 2

Lesley Radley
Chair, Velindre Cancer Centre Patient Liaison Group

Helen Rainbow
UK Policy Lead, Macmillan Cancer Support

Dr Cerilan Rogers and executive team
Welsh Health Specialised Services

Kathryn Thomas
Private Patient Manager, University Hospital Wales

Dr David Webb
Vice Chair, Clinical Ethics Committee, Abertawe Bro Morgannwg University Health Board

Dr Hugo van Woerden
Consultant in Public Health Medicine

- Age Concern
- Alzheimer’s Society
- All Wales Medicines Strategy Group (AWMSG)
- Aneurin Bevan Community Health Council
- Association of British Pharmaceutical Industry (ABPI)
- British Medical Association
- British Dental Association
- Breast Cancer Care Cymru
- British Lung Foundation
- Cancer UK
- Cardiff Community Health Council & Healthwatch
- Carers Wales
- Citizens Advice Bureau
- Community Health Councils – across Wales and Board
- Drug Aid
- Expert Patients Programme – National Leadership and Innovation Agency for Healthcare (NLIAH)
- Health Boards
- Help the Aged
- Macmillan
- Mencap
- Myeloma UK
- NHS Direct
- Older Peoples Network
- Patients Association
- Public Health Wales
- Welsh Health Specialist Services Committee
- Welsh Legal Services
Individual patient funding requests

October 2009-September 2010

Approach

Each Local Health Board in Wales was asked to provide details of the number and type of individual patient funding requests (IPFRs) they had received during the period 1\textsuperscript{st} October 2009 to 30\textsuperscript{th} September 2010.

Velindre NHS Trust was included in the exercise as their process for dealing with IPFRs is separate from that of Cardiff and Vale University Local Health Board.

Results

Over the 12 month period studied there were a total of 3922 IPFRs to Health Boards and Velindre NHS Trusts.

Of the 3922 requests made 907 (23\%) requests were for medicines.

When the data was adjusted per 100,000 population a marked variation across Local Health Boards in Wales was noticeable in the number of requests for medicines and in the number of these requests approved.

Betsi Cadwaladr University Local Health Board received 83 requests per 100,000 population compared with 3 per 100,000 population in Cwm Taf Local Health Board.

Over 70 different medicines were approved by the various individual patient funding request processes in place across Wales.
## Results

**Table 1:** Individual patient funding requests (IPFRs) across Wales for a 12 month period

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Total IPFRs</th>
<th>Abergavenny</th>
<th>Aberdare Bro Morgannwg</th>
<th>Aneurin Bevan</th>
<th>Betsi Cadwaladr</th>
<th>Cardiff &amp; Vale</th>
<th>Cwm Taf</th>
<th>Hywel Dda</th>
<th>Powys</th>
<th>SUB TOTAL</th>
<th>Velindre</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Total IPFRs adjusted per 100,000 population</td>
<td>377</td>
<td>893</td>
<td>2046</td>
<td>254</td>
<td>155</td>
<td>90</td>
<td>28</td>
<td>3843</td>
<td>79</td>
<td>3922</td>
<td></td>
</tr>
<tr>
<td></td>
<td>adjusted per 100,000 population</td>
<td>75</td>
<td>159</td>
<td>302</td>
<td>57</td>
<td>54</td>
<td>24</td>
<td>21</td>
<td>692</td>
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<tr>
<td>Q2</td>
<td>IPFRs for medicines adjusted per 100,000 population</td>
<td>52</td>
<td>149</td>
<td>561</td>
<td>21</td>
<td>8</td>
<td>34</td>
<td>5</td>
<td>830</td>
<td>77</td>
<td>907</td>
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<tr>
<td></td>
<td>adjusted per 100,000 population</td>
<td>10</td>
<td>27</td>
<td>83</td>
<td>5</td>
<td>3</td>
<td>9</td>
<td>4</td>
<td>140</td>
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<td>Q3a</td>
<td>IPFRs for medicines approved adjusted per 100,000 population</td>
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<td>622</td>
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<td></td>
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<td>20</td>
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<td>7</td>
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<td>103</td>
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<tr>
<td>Q3b</td>
<td>IPFRs medicines refused adjusted per 100,000 population</td>
<td>19</td>
<td>23</td>
<td>77</td>
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<td>4</td>
<td>8</td>
<td>0</td>
<td>142</td>
<td>7</td>
<td>149</td>
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<tr>
<td>Q3c</td>
<td>IPFRs for medicines withdrawn / cancelled</td>
<td>0</td>
<td>4</td>
<td>9</td>
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<td>2</td>
<td>19</td>
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<td>Q3d</td>
<td>IPFRs for medicines pending</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>41</td>
<td>5</td>
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<tr>
<td>Q4</td>
<td>Total IPFRs appeals</td>
<td>3</td>
<td>0</td>
<td>15</td>
<td>0</td>
<td>0</td>
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<td>18</td>
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<td>Q5</td>
<td>Total IPFRs approved after appeal</td>
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<td>4</td>
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<td>0</td>
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<td>Q6</td>
<td>IPFRs for medicines approved after appeal</td>
<td>0</td>
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<td>3</td>
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<td>0</td>
<td>0</td>
<td>3</td>
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</table>
Medicines approved by Health Boards and Velindre NHS Trust (individual patient funding requests) between 1st October 2009 and 30th September 2010

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Brand Name</th>
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<tr>
<td>3,4 Diaminopyridine</td>
<td>Grazax®</td>
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<tr>
<td>Abraxane®</td>
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<tr>
<td>Adalimumab</td>
<td>Immunoglobulin</td>
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<tr>
<td>Anakinra®</td>
<td>Infliximab</td>
</tr>
<tr>
<td>Antithymocyte globulin</td>
<td>Irinotecan, cisplatin and Avastin®</td>
</tr>
<tr>
<td>Antithymocyte globulin and oral ciclosporin A</td>
<td></td>
</tr>
<tr>
<td>Antituberculosis therapy</td>
<td>Lanreotide</td>
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<tr>
<td>Avastin®</td>
<td>Lapatinib</td>
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<td>Avonex®</td>
<td>LDL apheresis</td>
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<tr>
<td>Azacitidine</td>
<td>Lenalidomide</td>
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<tr>
<td>Aztreonam lysine</td>
<td>Leukine</td>
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<tr>
<td>Bendamustine</td>
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<td>Bexarotene therapy</td>
<td>Lucentis®</td>
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<td>Bortezomib</td>
<td>Methotrexate subcutaneous</td>
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<td>Bosentan</td>
<td>Nilotinib</td>
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<tr>
<td>Botox</td>
<td>Omalizumab</td>
</tr>
<tr>
<td>Botulinum toxin</td>
<td>Panitumumab</td>
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<tr>
<td>C1 esterase inhibitor</td>
<td>Posaconazole</td>
</tr>
<tr>
<td>Calcium sulphate</td>
<td>Ranibizumab</td>
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<tr>
<td>Capecitabine</td>
<td>Rituximab</td>
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<tr>
<td>Cefotaxime syringes</td>
<td>Romiplostim</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Sirolimus</td>
</tr>
<tr>
<td>Cetuximab</td>
<td>Sodium oxybate</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Sorafenib</td>
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<tr>
<td>Colesevelam</td>
<td>Subcutaneous immunoglobulin</td>
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<tr>
<td>Copaxone®</td>
<td>Sunitinib</td>
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<tr>
<td>Dasatinib</td>
<td>Tacrolimus and mycophenolate</td>
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<tr>
<td>Docetaxel</td>
<td>Temozolomide</td>
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<tr>
<td>Duodopa®</td>
<td>Teriparatide</td>
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<td>Eltrombopag</td>
<td>Thalidomide</td>
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<td>Erlotinib</td>
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<tr>
<td>Everolimus</td>
<td>Topotecan</td>
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<tr>
<td>Faslodex®</td>
<td>Vinorelbine</td>
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<tr>
<td>Gefitinib</td>
<td>Vitamin E oral drops</td>
</tr>
<tr>
<td></td>
<td>Voriconazole</td>
</tr>
</tbody>
</table>
New medicines in Scotland – who decides what the NHS can provide?

What is this factsheet about?
This factsheet explains the process that medicines go through before NHS doctors in Scotland can routinely prescribe them.

The person prescribing a medicine must make sure the patient knows how to use it safely. Medicines are usually prescribed by a doctor. In this factsheet, we use the word “doctor” to describe the person prescribing the medicine. The doctor is responsible for choosing the medicine used.

If you have questions about the medicines you have been prescribed or you wish to discuss any part of your NHS treatment, you can ask the doctor in charge of your care.

What happens before a medicine can be prescribed?
- In Scotland, a medicine usually has to have a licence (also known as a marketing authorisation) before it can be prescribed to treat people.
- A licence will only be granted if there is evidence from a clinical trial that the medicine is safe, of good quality, and worked for those people taking part in the trial. Medicines are usually licensed for use in adults who have a particular illness or condition.
- As well as being licensed, a medicine usually needs to be recommended for use by the NHS in Scotland before it can be prescribed by your doctor.

Who gives a licence to new medicines?
Two agencies license medicines:
- The Medicines and Healthcare products Regulatory Agency (MHRA) licenses medicines for use in the UK.
- The European Medicines Agency (EMA) licenses medicines for use in all countries of the European Union.

The pharmaceutical company that developed the medicine has to apply to one of these agencies for a licence. Before granting the licence, experts at the agency look at the research to check the medicine’s safety and quality, and make sure it works in the way it is supposed to.

Can my doctor prescribe a medicine that doesn’t have a licence?
- Unlicensed medicines may not have gone through the full licensing process.
- Normally your doctor will only prescribe a medicine that has a licence.
- However, your doctor can prescribe a medicine that doesn’t have a licence if he or she thinks it will benefit you (or your child). But your doctor must let you know that the medicine doesn’t have a licence, and get your agreement. And your doctor must take responsibility for the prescription and your (or your child’s) care during the time you are taking the medicine.

Can my doctor prescribe any newly licensed medicine?
Usually your doctor will prescribe a licensed medicine only after it has been;
- Recommended for use in Scotland by the Scottish Medicines Consortium, and
- accepted by your local NHS board for use in your board area.

What is the Scottish Medicines Consortium?
The Scottish Medicines Consortium (SMC) advises on the use of new medicines in the NHS in Scotland.

Before the SMC accepts a medicine for use by the NHS in Scotland, it needs to find out:
- how effective the medicine is
- which patients would benefit
- whether it is as good as or better than medicines the NHS already uses to treat the particular condition
- what it costs and
- whether it is good value for money.

The SMC looks at detailed information from the pharmaceutical company about the medicine. This includes any evidence from clinical trials, and research from countries where the medicine is already being used. The SMC does this as soon as possible after the medicine is licensed.

If the SMC accepts the medicine for use by the NHS in Scotland, it will publish this on the SMC website (www.scottishmedicines.org.uk). NHS boards and doctors take account of this advice when deciding which medicines should be prescribed.

Sometimes the SMC accepts more than one medicine for treating a certain condition or disease. Your NHS board can decide which of them your doctor should normally prescribe.

When NHS boards decide which medicines can be used in their area, they make a list of them. This list is called a ‘local formulary.’
Are other organisations involved in approving medicines for use?

- The National Institute for Health and Clinical Excellence (NICE) advises the NHS in England and Wales about the use of medical devices and medicines. It does not give official advice to Scotland on medicines.

- However, in Scotland an organisation called NHS Quality Improvement Scotland (NHS QIS) considers some of the advice that NICE gives the NHS in England and Wales. If NHS QIS thinks the advice is relevant to patients in Scotland, they will publish it on their website. NHS boards in Scotland must consider this advice when deciding what medicines to recommend.

- The Scottish Intercollegiate Guidelines Network (SIGN) is part of NHS QIS. It writes guidelines for health professionals on the best tests and treatments available. Generally SIGN advises on groups of medicines but it does occasionally recommend a specific medicine. The SMC and SIGN work together to make sure the NHS in Scotland receives the same advice on new medicines.

So if the SMC or NHS QIS accepts a medicine for use by the NHS in Scotland, will my doctor prescribe it for me?

- Your doctor will usually only prescribe medicines that have been accepted by your NHS board, and are included in the board’s ‘local formulary’.

- Even if a medicine is not on the board’s ‘local formulary’, your doctor might still be able to prescribe it if he or she feels it is the best treatment for you.

Can my doctor prescribe a licensed medicine if it hasn’t been accepted for use in Scotland?

- If your doctor believes you would benefit from a medicine that has not been accepted by the SMC or NHS QIS, he or she can ask your NHS board if they will provide it.

- Your doctor will need to tell your NHS board how and why you are likely to benefit from the medicine. Your NHS board will consider your doctor’s request and make a decision.

- You can ask your NHS board to direct you to a source of help and support through this process.

- If your NHS board decides to provide the medicine, you will not need to pay for it.

- If your NHS board decides not to provide the medicine, your doctor will explain the reasons for this and advise you whether there are grounds for an appeal.

If I cannot get a medicine from the NHS, can I pay privately for it instead?

- Yes, you can pay privately for a medicine that is not available to you from the NHS.

- However, there are likely to be particular reasons why your NHS board has refused to give you the medicine. Your doctor should explain these to you before you decide whether to pay privately for the medicine.

Is it possible to get NHS and private care at the same time?

- If you pay privately for your medicine, you will continue to receive the NHS care you are entitled to, and you will not be charged for it as long as it can be kept separate from your private care.

- Your doctor will tell you if it is not possible to keep your NHS and private care separate. In this case, your doctor will explain your treatment options.

- If you do decide to pay privately for the medicine, you should discuss this with your doctor or someone at your NHS board. They will be able to advise you on how to arrange this (see the section ‘Need more information?’ for contact details).

What if I’m unhappy about a decision by my NHS board or my doctor?

- If you are unhappy with a decision, you can ask for a second opinion. If you are still unhappy, you can make a complaint. The leaflet ‘Making a complaint about the NHS’ explains how to do this.

- You can get a copy from:
  - GP and dental surgeries, hospitals and other places where you get NHS care
  - the NHS helpline on 0800 22 44 88 (textphone 0800 22 44 88) for information on health conditions and services
  - contacting your local citizens advice bureau for free, confidential and independent advice on many things, including NHS services and your rights.

Need more information?

This factsheet gives guidance only. If you want to know more about your right to get a new medicine, please speak to your doctor.

You can also get more information by:

- contacting your local NHS board – each NHS board has someone who can offer you help and advice.

- To find contact details for your local NHS board:
  - phone the NHS helpline on 0800 22 44 88, or
  - look on the internet at www.nhs.org.uk

- phoning the NHS helpline on 0800 22 44 88 (textphone 0800 2000 2448) for information on health conditions and services

- contacting your local citizens advice bureau for free, confidential and independent advice on many things, including NHS services and your rights.

- To find your nearest branch, book in your phone book or on Citizens Advice Scotland’s website (www.cas.org.uk).

Medicines and Healthcare products Regulatory Agency (MHRA)

10-12 Market Towers
1 Nine Elms Lane
London
SW8 3NQ
Phone 020 7084 2000
(Monday to Fridays, 9am to 5pm)
Phone 020 7710 3000
(outside office hours)
Email info@mhra.gov.uk
Website www.mhra.gov.uk
Email ask@hris.org.uk to ask for this information in another language or format.

We have tried our best to make sure this information is correct. However, it is for guidance only so you should not rely on it as a complete statement of the law. If you are thinking about taking legal action, you should contact a solicitor, a citizens advice bureau or another advice agency.

This information is available on the Scottish Government website (www.scotland.gov.uk) and on the Health Rights Information Scotland website (www.hris.scot.uk).

Produced by Health Rights Information Scotland, a project of Consumer Focus Scotland on behalf of the Scottish Government Health Directorates.
Top-up payments: the legal framework

Background

- Section 1(1) of the NHS (Wales) Act 2006 (the Act) places a duty on Welsh Ministers to continue the promotion in Wales of a comprehensive health service designed to secure improvement (a) in the physical and mental health of the people in Wales; and (b) in the prevention, diagnosis and treatment of illness.

- Section 1(2) states that Welsh Ministers must for that purpose provide or secure the provision of services in accordance with the provisions of the Act.

- Section 1(3) specifically states that “the services provided must be free of charge except insofar as the making and recovery of charges is expressly provided for by or under any enactment”.

Raising charges

- Part 9 of the Act covers charging for NHS services. Essentially, unless the Act or Regulations made under powers contained in the Act (such as the NHS (Charges for Drugs and Appliances (Wales) Regulations) or other relevant enactment, allow an NHS body or primary care practitioner to charge for the provision of drugs, appliances or services, such drugs, appliances or services must be provided free of charge. Examples of instances where the NHS is allowed to charge are prescription charges (although that power is not exercised in Wales); charges for dental and ophthalmic services and charges for appliances (such as wigs and spinal supports).

- There are powers in the Act which allow Local Health Boards and NHS Trusts in Wales to provide accommodation and services to patients and to make charges for such accommodation or services. These powers would allow a LHB or Trust to provide services and drugs which are not available on the NHS in Wales to patients and to charge them for the provision of such accommodation and/or services.

Powers to raise charges for services and/or accommodation

It is necessary to consider powers available to both LHBs and NHS Trusts as, in Wales, NHS hospitals are vested in Local Health Boards, with the notable exception of Velindre Hospital which is vested in Velindre NHS Trust.
LHBs

- Paragraph 15(1) of Schedule 2 to the Act gives Local Health Boards the power to make available, at any hospital for which it has responsibility, accommodation or services for patients who give undertakings to pay charges imposed by the LHB in respect of such accommodation or services. LHBs also have the power to make and recover charges in respect of such accommodation and services. Charges are to be calculated on what the LHB considers to be the “appropriate commercial basis”.

- Paragraph 15(2) makes it clear that a LHB may only make such accommodation and services available provided that doing so does not interfere with the performance by the LHB of its functions under the Act (ie its function of arranging for and providing NHS services to patients) and does not operate to the detriment of persons who need to be admitted to hospital for NHS treatment.

- There is an obligation to consult before making such services and accommodation available.

- Paragraph 15(4) also makes it expressly clear that a LHB may allow services or accommodation which it makes available in accordance with paragraph 15(1) to be made available to a medical or dental practitioner serving (in an honorary or paid capacity) on the staff of a health service hospital for the treatment of private patients.

NHS Trusts

- Paragraph 19(1) of Schedule 3 to the Act gives NHS Trusts the power to make accommodation or services available for patients who give undertakings to pay any charges imposed by the NHS Trust in respect of the accommodation or services.

- Paragraph 19(2) provides that an NHS Trust may provide such accommodation and services provided that such provision does not interfere with the performance by a Trust of its NHS functions or its obligations under NHS contracts.

- In addition, NHS Trusts in Wales have powers which enable them to generate additional income in order to enable them to better perform their functions. Paragraph 20(1) of Schedule 3 to the Act provides that NHS Trusts have the powers available to Welsh Ministers under section 7(2) of the Health and Medicines Act 1988. Powers under section 7(2) of that Act include acquiring, producing, manufacturing and supplying goods; supplying accommodation to any person; supplying services to any person and supplying new services; and making such charges as it considers appropriate for anything done in the exercise of such powers.
The section stipulates that such charges are to be calculated on any basis that it considers to be the appropriate commercial basis.
**Public engagement exercise**  
**September – October 2010**

**Approach**

A public engagement exercise was carried out over a four week period ending mid-October 2010. The exercise was facilitated by Patient and Public Involvement Officers from Community Health Councils (CHCs) across Wales.

A presentation was made to a meeting of CHC Patient and Public Involvement Officers and it was agreed they would work with their patient and public networks to disseminate a series of key questions on top-up payments. Responses were received from Abertawe Bro Morgannwg CHC, Cardiff and Vale of Glamorgan CHC and Aneurin Bevan CHC.

Abertawe Bro Morgannwg (ABM) CHC disseminated the questions through their networks. Aneurin Bevan CHC held two meetings, one of which was facilitated (RW). Individuals submitted their individual responses at the end of the meeting or forwarded them later. Aneurin Bevan CHC also disseminated the key questions to members unable to attend the meeting. Cardiff and Vale of Glamorgan CHC held one Healthwatch meeting at which a facilitated session was run (RW/SE). They also disseminated the key questions via their networks. Individuals submitted their individual responses at the meeting or forwarded them later.

**Results**

A total of 85 responses were received.

**Table 1.** Question: *Is it only acceptable if the patient paying for the medicine/ treatment and care can benefit without the prospect of any NHS patient being disadvantaged?*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABM CHC</td>
<td>12</td>
<td>1</td>
<td>0</td>
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<tr>
<td>Cardiff &amp; Vale of Glamorgan CHC</td>
<td>13</td>
<td>6</td>
<td>2</td>
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<tr>
<td>Aneurin Bevan CHC</td>
<td>37</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>TOTAL</td>
<td>62</td>
<td>14</td>
<td>9</td>
</tr>
</tbody>
</table>

**Table 2.** Question: *Do you agree that future NHS care should not be withdrawn from a patient who purchases a medicine / treatment?*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
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<th>Unclear response</th>
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</thead>
<tbody>
<tr>
<td>ABM CHC</td>
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<tr>
<td>Aneurin Bevan CHC</td>
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<tr>
<td>TOTAL</td>
<td>65</td>
<td>14</td>
<td>6</td>
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</tbody>
</table>
**Table 3.** Question: Are you happy with the following statement?

“In the course of their NHS duties and responsibilities, consultants should **not** initiate discussion about providing private services to NHS patients

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
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<tr>
<td>ABM individual response</td>
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<td>9</td>
<td>2</td>
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<tr>
<td>Cardiff &amp; Vale of Glamorgan CHC</td>
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<td>11</td>
<td>3</td>
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<tr>
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<tr>
<td><strong>TOTAL</strong></td>
<td>13</td>
<td>50</td>
<td>22</td>
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</tbody>
</table>

**Table 4.** Question: Is it important that individuals who purchase a medicine/treatment package be given information that includes details of the treatment they will receive, the cost of the medicine/treatment and details of debt?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
</tr>
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<tbody>
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<tr>
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<tr>
<td>Aneurin Bevan CHC</td>
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<td>12</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>71</td>
<td>2</td>
<td>12</td>
</tr>
</tbody>
</table>

**Table 5.** Question: Should there be the same charge across Wales for any given medicine/treatment package when purchased i.e should a patient in South Wales be charged the same as a patient in North Wales and vice versa?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
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<tbody>
<tr>
<td>ABM individual response</td>
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<td>6</td>
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<tr>
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<tr>
<td>Aneurin Bevan CHC</td>
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<td>17</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>59</td>
<td>8</td>
<td>18</td>
</tr>
</tbody>
</table>

**Table 6.** Question: Should the NHS be able to make a reasonable profit when charging for a medicine and the associated care and monitoring require?

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
</tr>
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<tbody>
<tr>
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<td>Cardiff &amp; Vale of Glamorgan CHC</td>
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<td>18</td>
<td>1</td>
</tr>
<tr>
<td>Aneurin Bevan CHC</td>
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<td>28</td>
<td>12</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td>18</td>
<td>56</td>
<td>13</td>
</tr>
</tbody>
</table>
**Table 7.** Question: *Should the number and nature of copayment packages be monitored?*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
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<tbody>
<tr>
<td>ABM individual response</td>
<td>13</td>
<td>0</td>
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<td>Cardiff &amp; Vale of Glamorgan CHC</td>
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</tr>
<tr>
<td>Aneurin Bevan CHC</td>
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<td>1</td>
<td>17</td>
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<tr>
<td><strong>TOTAL</strong></td>
<td><strong>70</strong></td>
<td><strong>2</strong></td>
<td><strong>13</strong></td>
</tr>
</tbody>
</table>

**Table 8.** Question: *Should outcomes (of medicine/treatment packages) be made available to all?*

<table>
<thead>
<tr>
<th></th>
<th>Yes</th>
<th>No</th>
<th>Unclear response</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABM individual response</td>
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<td>Cardiff &amp; Vale of Glamorgan CHC</td>
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<td>1</td>
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<tr>
<td>Aneurin Bevan CHC</td>
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</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>62</strong></td>
<td><strong>5</strong></td>
<td><strong>18</strong></td>
</tr>
</tbody>
</table>
## Top-up checklist

### Patient Details

<table>
<thead>
<tr>
<th>Name:</th>
<th>Details of proposed top-up treatment/package</th>
<th>NHS provider:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of Birth:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospital No:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

This form **MUST** be completed for all patients choosing to receive a top-up treatment package alongside their NHS treatment.

<table>
<thead>
<tr>
<th>The patient (or their representative) has received written information about the proposed treatment in addition to a face to face consultation.</th>
<th>Clinician</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient (or their representative) has been given full information about the potential benefits, risks, burdens and side effects of the treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>This information has been recorded on the consent form for the patient's treatment. Informed consent has been obtained in line with GMC guidance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient has received a second clinical opinion.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding options within the NHS for the proposed treatment have been exhausted.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The proposed treatment has been considered by an Individual Funding Request Panel.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The outcomes of this treatment will be contributed to relevant national monitoring programmes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The outcomes of this treatment will be discussed at multi-disciplinary clinical governance meetings.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient understands that the additional medicines and any associated costs (eg. extra tests, monitoring, days in hospital etc) are not being funded by the NHS.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient (or their representative) has received written information about the proposed treatment costs and payment plan</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient understands that if they become unable to fund their top-up package (i.e. ‘run out of money’) the treatment will stop. The NHS will not provide the top-up treatment.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The patient understands that if the NHS decide to fund this treatment at a future date, the NHS will not normally refund the cost of treatment already given as part of a top-up treatment.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consultant responsible for patient’s NHS care</th>
<th>Consultant responsible for patient’s top-up treatment</th>
<th><em>patient's representative</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Print name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Signature</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date</td>
<td></td>
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</tbody>
</table>