



TOP-UP MEDICINES PAYMENTS POLICY AND PROCEDURE

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Documents to read alongside this Policy , Procedure etc (delete as necessary)	All Wales Policy making decisions on Individual Patient Funding Requests (IPFR) Improving the Availability of Medicines for Patients in Wales (WG Implementation Group Report 2011). Code of Conduct for Private Practice (DoH 2004).
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SECTION A

Policy Framework

1. Background/Introduction

In August 2008, the Minister for Health and Social Services asked Professor Philip Routledge, Chair of the All Wales Medicine Strategy Group (AWMSG), to look at the broader issues of improving the availability of medicines for patients in Wales. Professor Routledge led an Expert Group to consider these issues and the resulting report was published in March 2009, "The Routledge Report". In May 2009, the Minister established a group comprising clinicians, pharmacists, nurses, NHS Managers, a health economist and trades union representative to implement the 11 recommendations within the report.

The Minister asked the Implementation Group (IG), to fully consider the issue of top-up payments and urgently examine the legal and ethical framework, and to develop clarification on the issues and their implications for patients in Wales. The Cardiff and Vale University Health Board (the UHB) is required to adopt the new procedures for introducing Top-up Payments as outlined in the Implementation Group Report. (Dated February 2011).

2. Policy Statement and NHS Principles

It is the policy of the UHB to ensure that it has appropriate arrangements in place to ensure that patients can make Top-up Payments as appropriate and in accordance with the requirements of The Routledge Report.

This policy will be implemented at all times in accordance with the following key principles:

- 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 and 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 in a cost-effective manner making the most effective and fair use of finite resources.

Clinicians and managers are required to exhaust all options for securing NHS funding prior to proposing a top-up payment. Where a top-up payment is to be made, it must be made prior to the commencement of treatment.

3. Terminology

In Wales the principal routes of access to new, expensive medicines or treatments are via

- (i) standard appraisal and treatment routes which ensures medicines are routinely available to all for their approved indication; and
- (ii) an individual patient funding request (IPFR) which may permit access to a medicine not normally provided or commissioned on a case by case basis where clinical benefit and exceptionality can be evidenced.

If the request and any subsequent IPFR appeal for the medicine is rejected on the grounds of cost or clinical effectiveness, but on balance the benefits of treating the individual patient outweigh the risks, funding the medicine by top-up payments can be considered.

The term 'top-up payment' has been defined by the House of Commons Health Committee as follows:-

- *“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 or treatment that supplements or replaces other medicines the patient is receiving from the NHS for the treatment of a particular condition.

The Implementation Group report “Improving the availability of medicines for patients in Wales” –Top-Up Medicines Implementation Group (February 2011), has further defined a 'top-up payment' as:-

‘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.’

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 treatments and care episodes.

The full costs of providing the discrete episode of care will be recharged. These include any medicines, prosthetics, diagnostic procedures, medical staff, nursing staff, and all ancillary and accommodation costs associated with the care episode.

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.

4. Responsibilities

4.1. UHB Responsibilities

The Minister has required the UHB to ensure that the new procedures recommended by the Implementation Group report are implemented.

The UHB therefore wishes to ensure that there is a procedural framework in place for managing top-up payment cases, including the identification, management and recovery of charges.

The senior management team in each respective Clinical Board within the UHB, in conjunction with the relevant consultant have been designated as the administrative lead for managing patients who are considered appropriate for top-up payments.

This responsibility should be led by the nominated lead within each Clinical Board, as appropriate, and be supported by:-

- The respective Clinical Board's finance support team
- The respective Clinical Board's Head of Medicines Management
- The Medical Director's Office
- The IPFR team to process IPFR applications and to log any top-up treatments progressed
- The Contracting team (Central Finance) for, help with IPFR applications to external health commissioners.
- The Private Patient team (Central Finance) for the issue of invoices and recovery of funds in advance of treatment

4.2. Lead Director

The Director of Public Health is responsible for ensuring that the UHB has approved a policy and associated procedures to facilitate top-up payments.

4.3 Consultant's responsibilities

The UHB depends on the co-operation of the Consultants in the early identification of patients that may wish to consider treatments funded by top-up payment once all options for securing NHS funding have been exhausted.

The Consultant should raise the application with the relevant patient. This assists the UHB in ensuring all avenues available for providing the treatment on the NHS have been explored. It also allows the UHB to obtain the necessary undertaking from the patient to pay the relevant charges as appropriate.

Consultant / NHS Staff should conduct their practice in accordance with the Procedural Framework. (Section B of this policy and procedure).

The UHB has prepared an aide memoire to assist consultant staff in considering that they have addressed the key issues relating to a proposed 'top-up' medicine or treatment. This includes completion of the checklist contained in the Welsh Government Implementation Group guidance and the logging of all top-up treatments progressed with the UHB IPFR office.

4.4. Top-up Payment Arrangements

The delivery of care will be assessed on an individual patient basis following consideration and assessment of clinical need and requirements.

Each Clinical Board in the UHB will ensure the procedure within this policy is adopted with details specific to ensuring:

- Application is made to the relevant IPFR panel on behalf of the patient
- Estimated costs for the provision of the 'top up' episode of care are identified and clearly communicated to the patient before a decision is taken to proceed. It should be made clear that the costs are estimated and invoices will be issued 'on account'. The difference between the estimated costs and the actual costs will be invoiced or repaid once the Top Up treatment episode has been completed.
- The apportionment of resources amongst UHB service areas is clearly identified and agreed.
- Liaison with the Private Patients Office to arrange the invoicing and recovery of funds in advance of Top Up treatment commencing..
- That after the top-up treatment has taken place confirmation of actual resource consumption arising from the episode is provided to enable the Private Patients Office to invoice or reimburse the patient as appropriate.

5. Legal Framework

There is no legal barrier to an individual patient utilising 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 National Institute for Health and Clinical Excellence (NICE), All Wales Medicines Strategy Group (AWMSG) and Welsh Health Specialised Services Committee (WHSSC) and has been subject to an unsuccessful Individual Patient Funding Request, it would be lawful for the Health Board to provide the medicine and associated services as a package subject to top-up payments.

6. Professional Liability and Indemnity Responsibilities

The UHB will be indemnified by the Welsh Risk Pool with regard to liability for all medical and non medical staff undertaking activities relating to top-up payments as these activities are considered to be part of their NHS duties.

The Welsh Risk Pool scheme covers all risk relating to NHS activity subject to Welsh Health Circular (2000) 04, Revised Welsh Risk Pool Management Arrangements from 1 April 1999 and WHC (2000) 12 and 51, Insurance in the NHS in Wales.

For information regarding private patient activities please refer to the Cardiff and Vale UHB Private Patients Policy as the liability and indemnity arrangements are different for private patient activity.

7. Equality Impact

We have undertaken an Equality Impact Assessment and received feedback on this policy and procedure and the way it operates. We wanted to know of any possible or actual impact that this policy and procedure may have on any groups in respect of gender, maternity and pregnancy, carer status, marriage or civil partnership issues, race, disability, sexual orientation, Welsh language, religion or belief, transgender, age or other protected characteristics. The assessment found that there was no impact to the equality groups mentioned. Where appropriate we have taken the necessary actions required to minimise any stated impact to ensure that we meet our responsibilities under the equalities and human rights legislation.

8. Resources

No additional resource is required to implement this Policy.

9. Advice

Support to Consultants and individual staff members will be provided through the Pharmacy Department, Private Patient Office and the IPFR team.

10. Implementation

Awareness will be raised through the Clinical Boards and Directorates and by means of UHB communication networks.

11. Audit

Local use of this Policy will be subject to periodic audit review and top-Up payments will be monitored centrally by Public Health Wales (Appendix V).

Each quarter the UHB IPFR co-ordinator will complete the data collection form on IPFR requests and top-up payments. The completed data collection forms will be sent to Public Health Wales for collation.

12. References

Routledge Report March 2009, Implementation Group Report - Improving the availability of Medicines for patients in Wales, February 2011.

13. Distribution

This policy and procedure will be made available on the UHB intranet, internet and the clinical portal. It will also be specifically brought to the attention of the Clinical Boards.

14. Review

This policy and procedure will be reviewed every three years or sooner if appropriate.

Acknowledgements

This policy and procedure was based on the contents of the Routledge Report, Velindre NHS Trust Top-up Policy, and Betsi Cadwaladr Top up payments for Medicines: Policy and Procedures, sources are gratefully acknowledged.

Additional References/Further Information

Further information can be obtained on request from the office of the Director of Public Health.

SECTION B

Procedural Framework

For the Health Board to effectively manage and monitor top-up payment work that is being undertaken, the following procedural framework must be adopted and adhered to by those involved in top-up payment activity.

1. Prior to Considering Top-up Payment

Clinicians and managers are required to exhaust all options for securing NHS funding prior to proposing a top-up payment. This involves applying for NHS funding via the Individual Patient Funding Request Panel (IPFR) relevant to the patient's care. This may be in Cardiff and Vale UHB, WHSSC or an external commissioning organisation.

Stage 1 – Individual Patient Funding Request (IPFR) Application

The consultant will apply for individual patient funding by completing the All Wales IPFR application form. Please refer to the [All Wales IPFR policy](#) for further guidance

The IPFR will be submitted to the relevant IPFR Panel for consideration. If the request and any subsequent IPFR appeal for the medicine is rejected on the grounds of cost-effectiveness, but on balance the benefits of treating the individual patient outweigh the risks, funding the medicine by top-up payment can be considered.

Where an individual funding request is unsuccessful and subsequently proceeds to a top-up payment the Cardiff and Vale UHB IPFR Office should be notified to maintain the log of all Top Up Treatment commenced.

2. Proceeding to Top-Up Payments

Once all avenues for NHS funding have been exhausted, the consultant may wish to discuss the top-up payment option with the patient.

Stage 2 – Communication and Patient Information

Clinicians must demonstrate excellent communication skills when conveying information to patients. The need for these skills is important when discussing top up payments. Patients will need to be fully informed about their condition and the likely benefits and risks of the principal medicines funded by the top-up payment. All treatment options (NHS and top-up) should be discussed with the patient during the NHS consultation. The Implementation Group Report advises however that Clinicians do need to comply with paragraph 2.9* of the Code of Conduct for Private Practice, Recommended Standards of Practice for NHS Consultants (DoH 2004).

***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**.*

The Health Board should ensure that the patient receives all reasonable and necessary information and is aware of the options available to them. Clinicians must provide the patient with a Patient Information Leaflet outlining the procedure for top-up payments (appendix I).

The consultant should ensure the checklist included in Appendix II is completed for all cases where top-up payment is being considered and a copy should be lodged with the Cardiff and Vale UHB IPFR Office. Consultants should not charge private patient fees for any consultations regarding top-ups. The entire cost of the treatment episode must be identified, communicated and agreed with the patient up front before treatment commences. The costing should include all reasonably identifiable discrete costs relating to the top up episode including, clinicians, nurses, ancillary staff, bed costs, medical and surgical equipment, drugs and diagnostics specifically relating to the top up treatment, including frequency of inputs. This will need to be identified in conjunction with the Clinical Service Board's management and finance support team and be based on recovery of costs at standard NHS pay and procurement rates.

The Private Patient's Office and the Central Finance team can assist with the costing of specific components once inputs to the top-up treatment plan have been identified.

The patient will not be required to meet the cost however, for managing unpredicted events. It should be explained to the patient that non-emergency complications, essential monitoring and predicted consequences of the top-up medicine will need to 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 top-up payment treatment.

The Health Board will not subsidise any element of top-up medicine package save for the obligation of the Health Board to meet the cost of managing unpredicted events. This must be made explicit to the patient at the outset and before the top-up treatment is commenced. Likewise, patients should be clear that they will receive no advantage with regard to any subsequent position on an NHS waiting list.

The patient's position on an NHS waiting list will be the same as a patient who has opted for NHS care in its entirety.

Stage 3 - Second Medical Opinion

Patients considering a top-up payment should be provided with a second medical opinion concerning the treatment to ensure they are being offered appropriate advice and are clear about the benefits, risks and safety of the treatment in question. The second opinion is to provide assurance that the top-up medicine is a reasonable option for the patient and is not intended as full clinical second medical opinion.

The second opinion will normally be provided by NHS clinicians within the Health Board's commissioned services and provided in a timely manner, but not necessarily by a senior clinician working in the same sub-specialist area.

If the clinician providing the second opinion does not agree with the treatment plan for the patient then he/she must contact the referring clinician and discuss and agree a way forward.

Once the clinician providing the second opinion is satisfied and has completed and signed the Top-up Payment Checklist (Appendix II), he/she must then contact the patient's consultant so that they can make arrangements for top-up payment medicine to commence.

Stage 4 – Notification to Patient, IFPR

Once receipt of funds has been confirmed by the Private Patients Office the Consultant will notify the patient and the appropriate UHB IPFR Panel prior to top-up payment medicine commencing.

3. Charges to the Patient

The consultant will explain the procedure and the charges to the patient or the accompanying person, give them the details of charges and the relevant top-up payment leaflet. This leaflet should have been given to the patient by the consultant before the second medical opinion.

The patient must be presented with a schedule detailing the estimated cost of the top-up treatment. If the patient agrees to the top-up treatment costs then they will be required to complete and authorise the Top-Up Payment patient estimate/agreement Form (Appendix IV) and send it to the consultant.

This form should be lodged with the Private Patients Office together with the treatment costing. The Private Patients Office will raise an invoice in respect of the top-up treatment and liaise with the patient to facilitate recovery of funds as early as is practical. The Private Patients Office will maintain close communication with the consultant to confirm receipt of funds to allow treatment to commence.

A detailed estimate of all costs including tests and procedures will be sent to the patient prior to the second medical opinion. In the event of a request being made on behalf of a patient lacking mental capacity, all standard UHB Procedures are to be followed.

All patients will be asked to make full payment for all projected costs associated with the treatment. Any over recovery of costs will be returned to the patient.

It is a requirement before treatment commences that the patient completes an "undertaking to pay" form specific to top-up payments (Appendix IV). Signature of this form is regarded as evidence of the patient's decision to

receive this aspect of their treatment as a top-up payment. The top up payment must be paid before the treatment commences.

The Health Board will look to recover its costs but will ensure that they do not profit from the provision of the treatment for which a top-up payment is made. Charges and payments should be calculated on an appropriate tariff and be consistent across Wales.

4. Monitoring and Audit

Top-up payments will be monitored centrally by Public Health Wales (Appendix V).

Each quarter the UHB IPFR co-ordinator will complete the data collection form on IPFR requests and top-up payments. The completed data collection forms will be sent to Public Health Wales for collation.

5. Probity Standards of Practice for all NHS Staff

All staff will adhere to their professional code of conduct at all times and comply with UHB policies, procedures and standards of behaviour to include:

- Ensure that the interest of the patient is paramount at all times
- Be impartial and honest in the conduct of their official business
- Use Health Board funds delegated to them to the best advantage of the service, always ensuring value for money
- Health Board staff are expected to ensure that they do not abuse their official position for the benefit of themselves, family or friends, seek to gain advantage for a business or other interest during the course of their official business.

APPENDIX I

Information about 'Top-up Payments'

This leaflet provides information for patients about 'top-up payments' in NHS Wales. It will explain what 'top-up payments' are and describe the process for arranging to receive your treatment under this system.

Details of how to obtain further information on 'top-up payments' are given at the end of this leaflet.

What is a 'Top-up Payment'?

'Top-up payments' are made by patients for medicines and related care not approved and funded by the NHS in Wales.

What is related care?

Related care includes all the additional aspects of your care which are needed because of the medicines that you are paying for as a 'top-up payment'. For example, this includes the blood tests, scans, doctor, nurse and pharmacy time.

You will only be expected to pay for related care which is expected and planned. It does not include unexpected care which you receive because of your 'top-up payment' medicine. For example:

You will be asked to pay for all the additional routine blood tests which are associated with a 'top-up payment' medicine. However, if because of the medicine you were unexpectedly admitted into hospital, for example with an infection, you would not be expected to pay for any of those costs incurred.

What are the costs?

We will give you a written estimate of how much the 'top-up payment' medicine and expected related care will cost.

How do I organise a 'top-up payment' medicine?

Before you can have medicines using a 'top-up payment' a number of steps must have been followed.

At Cardiff and Vale University Health Board this means:

- 1) The request for funding must have been considered and refused by the Health Board Individual Patient Funding Request (IPFR) Panel.
- 2) Your doctor will explain the reasons why the requests have been refused and discuss with you the option of 'top-up payments'.
- 3) If you still want to fund the medicines through a 'top-up payment' system, your doctor will obtain a second opinion.

- 4) Once you are satisfied with the second opinion, your doctor will commence the process to arrange the top up treatment.

Where will I receive the ‘top-up payment’ medicine?

You can choose to receive the ‘top-up payment’ medicine at your local hospital or possibly at your home using a commercial homecare provider. Your doctor will discuss this with you.

What happens if I run out of money?

Top up payments must be paid before the treatment commences. If the costs are high than estimated and you become unable to fund the ‘top-up payment’ treatment (i.e. you run out of money) the treatment will stop. The NHS will continue to make available treatments to which you are entitled as an NHS patient.

What if the NHS in Wales funds the treatment in the future?

At this present time the NHS in Wales has no plans to refund the cost of ‘top-up payment’ medicines already given as part of treatment.

Further information

If you have any questions about ‘top-up payments’ or want further Information, please discuss this with your doctor.

APPENDIX II

Top-up Payment Checklist

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

Patient Details Name: Address: Date of Birth: Hospital No:	Details of proposed top-up treatment/ package	NHS provider:
		Top-up provider:

Tick if completed

The proposed treatment has been considered by an Individual Funding Request Panel. Funding options within the NHS for the proposed treatment have been exhausted	
The patient (or their representative) has been given full information about the potential benefits, risks, burdens and side effects of the treatment.	
The patient (or their representative) has received written information about the proposed treatment in addition to the Top-Up Payment Leaflet.	
This information has been recorded on the consent form for the patient's treatment. Informed consent has been obtained in line with GMC guidance.	
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.	
The patient has received a second clinical opinion.	
The patient (or their representative) has received a detailed estimate of the proposed treatment costs.	
The Patient understands that if they become unable to fund their top-up package (ie. 'run out of money') the treatment will stop. The NHS will not provide the top-up treatment.	
The patient understands that if the NHS decides 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	
The Patient understands that the outcomes of this treatment will be discussed at multi-disciplinary clinical governance meetings	

	Consultant responsible for patient's NHS care	Consultant responsible for patient's top-up treatment	Patient (or patient's representative)
Print name			
Signature			
Date			

APPENDIX III

Top up Payment estimated costs

TOP UP TREATMENT ESTIMATED COSTS				
This form should be completed by the clinician who is responsible for the care of the patient receiving Top-Up treatment. This form will be used to provide the patient with a detailed estimate of costs for top-up treatment.				
Drug (including supportive drugs)	Dose	Frequency	Treatment Length	
Additional Tests				
Test	Cost	Frequency	Total Number	
FBC				
U & E				
LFT				
TFT				
Tumour marker				Specify
EGFR				
HER 2				
Immunochemistry				
Other				Specify
Additional Scans/Procedures				
Test	Cost	Frequency	Total Number	
CT Scan				
PET-CT				
MRI				
Ultrasound				
X-ray				
Biopsy				
Lumbar Puncture				
Other				Specify
Hospital Costs				
Test	Cost	Frequency	Total Number	
OPD appointment				
Day Case				
In-patient bed				
Other				Specify

APPENDIX IV

Top-up Payment — Undertaking to Pay Form

PATIENT AGREEMENT TO PAY FOR TOP- UP TREATMENT

PART A:

Name of Patient..... IPFR Number.....

Date of Birth: ____/____/____

Hospital Number

Address.....

Post

code..... Telephone Number.....

Insurance Company Policy Number

Authorisation Number

PART B:

I confirm that I have agreed to self-fund for:.....

I have received the estimated cost of 'top-up payment' medicine and I fully understand, and have had explained to me that the full costs of providing the discrete episode of care will be recharged. These include any medicines, prosthetics, diagnostic procedures, medical staff, nursing staff, and all ancillary and accommodation costs associated with the care episode. Any other treatment will be provided on the NHS and not chargeable to myself or any third party, I undertake to pay Cardiff and Vale University Health Board for the cost of 'top-up payment' medicine and associated tests and consultations.

I understand the responsibility for settlement of all invoices from Cardiff and Vale University Health Board in advance of the commencement of treatment rests with me. Any monies not used in my treatment will be repaid back to me after treatment.

PART C: I consent to disclosure by the University Health Board of clinical information on my condition and treatment to other healthcare providers, in order to provide the medical treatment and ensure the continuity of medical care that I require.

Signed :

(Patient/Representative)

Date :

Consultant :

Date

APPENDIX V – Process for monitoring Top up Payments
[Process for monitoring top-up payments 2013-2014](#)