



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Feidhmeannacht na Seirbhíse Sláinte
Seirbhís Aisíocaíochta Cúraim Phríomhúil
Bealach amach 5 an M50
An Bóthar Thuaidh
Fionnghlas
Baile Átha Cliath 11
D11 XKF3

Health Service Executive
Primary Care Reimbursement Service
Exit 5, M50
North Road
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Dublin 11
D11 XKF3

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Circular No. 014/16

31 March 2016

Dear Pharmacist,

The HSE has developed a national framework for the administration of Discretionary Hardship Arrangements. The HSE is satisfied that all requirements can be ordinarily met through the Reimbursement List maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013 except in very particular circumstances where the patient is attending the Hospital setting.

Pharmacists should continue to submit claims previously approved by the LHO under the 'Hardship' arrangements to their LHO until further notice. In recent weeks, local offices have been informed of a range of products which are not within their authority to approve from March 16. PCRS will not reimburse these products for newly initiated patients and a copy is enclosed for your information. Please ensure that all relevant staff are aware of the new arrangements.

The Medicines Management Programme will review categories of products currently reimbursed in the months ahead and publish their recommendations on their website. If the HSE makes a decision to cease reimbursement support for products currently approved, you will be informed.

The Application form for reimbursement support has been updated to capture more information including a section for VAT (copy enclosed). You will note the requirement to provide a copy of the Hospital prescription. Approval will not be forthcoming for new patients in the absence of confirmation of Hospital Initiation. Approval for any product pertains for a maximum of six months in line with the maximum legal validity of a prescription.

There are a number of reasons why a product will not be approved under Discretionary Hardship Arrangements. One or more of the following may apply

- a. Not Consultant / Hospital Initiated
- b. Comparable / Alternative item available on Reimbursement List (particularly where Non Drug)
- c. For a 'New Chemical Entity' – Pharmacoeconomic Assessment by National Centre of Pharmacoeconomics (NCPE) where the product is not recommended for reimbursement
- d. Limited clinical evidence of patient benefit
- e. Price too high – when compared with alternatives.

If a patient wishes to appeal a decision of the HSE, an individual reimbursement form (copy attached) can be completed by the patient's hospital clinician outlining the exceptional circumstances which may apply.

With effect from April 2016, claims for 'approved items' must be submitted using the HD2 form (ref Circ.010/10) on a monthly basis to the local office as set out below:

- a) Pharmacy number
- b) Patient Forename, Surname
- c) Medical Card Number, Patient Code Letter
- d) Product Description
- e) Quantity dispensed
- f) Date dispensed
- g) Ingredient Cost
- h) Copy of Invoice for all claims
- i) VAT
- j) Dispensing Fee
- k) Unified Claim form signed by the patient or their agent.

I trust this clarifies the position and look forward to your cooperation within the standardised framework.

Yours faithfully,



Anne Marie Hoey
Primary Care Reimbursement & Eligibility

Items which are not ‘approvable’ at local level under Discretionary Hardship Arrangements

1. Nanny Goat Milk
2. Cariban – unlicensed medicine
3. Vaccines
4. Flexiseq – OTC item – No drug component
5. Coagucheck Strips (new patients)
6. Macushield / Ocuville Lutein (new patients)
7. Emollients (new patients)
8. Xenical – removed from Reimbursement list in Sept 12
9. Glucosamine Products – removed from Reimbursement list in Sept 12
10. Gluten Free Products – removed from Reimbursement list in Sept 12
11. Omega 3 Products – removed from Reimbursement list in Sept 12
12. Souvenaid food supplements
13. Symprove food supplements
14. Restore products
15. Herbal products other than Alforex (licensed product) in patients with CF
16. Camouflage Make - Up
17. Daxas – not recommended for reimbursement by HSE Drugs Group
18. Prilogy – not recommended for reimbursement by HSE Drugs Group
19. Plenadren – not recommended for reimbursement by HSE Drugs Group
20. iPort Device – not recommended for reimbursement
21. Braun Iry Pump set – equipment not reimbursed under Schemes
22. Britofex – outside of the established State Addiction Service
23. Ataluren / Translarna – undergoing Pricing and Reimbursement Assessment
24. Apremilast / Otezla – undergoing Pricing and Reimbursement Assessment
25. Tadalafil / Sildenafil etc – extra amounts for non approved indications

Items which may be reimbursed where Consultant initiated in certain circumstances.*

26. Melatonin – where recommended by a consultant within Child and Adolescent Services
27. Vit and Minerals where Consultant initiated for patients with Cystic Fibrosis or other serious illness
28. Thiamine where consultant initiated for people with alcohol dependency

* Where supported by a Hospital Prescription. These products form a significant proportion of the lower cost items that are requested regularly.



Section A should be completed and signed by the patient. Section B should be completed by the Doctor and Pharmacist. The form should then be sent to your H.S.E. Local Health Office.

SECTION A: *To be completed by the patient:*

First Name:

Surname:

Address / Eircode:

Medical Card No:

Expiry Date: / /
month year

Date of Birth: / /
month year

PPSN:

Personal Public Service Number (available from your Tax Cert, P60, P45, payslip or Social Welfare book)

DATA PROTECTION NOTICE:

- The information on this form will be used by the Health Services Executive (H.S.E.) to assess the suitability of the items listed below, to be provided free (subject to the prescription charge) to the person named on the form.
- Details of prescription items dispensed to the named person may be notified to the H.S.E. by the dispensing Pharmacist to ensure that the named person receives the items required free of charge subject to the relevant prescription charge.
- The named person may access information relating to themselves only, on prescription claims processed in their name by the H.S.E.

I wish to apply for the cost of the drugs below to be paid for by the H.S.E.,

Signature of Patient:

Date: / /
Day month Year

• **SECTION B: *To be completed by the Doctor and priced by the Pharmacist:***

I hereby certify that is under my care for the treatment of

..... and requires the following item/s which are not on the Reimbursement List:

Item Required	Weekly / Monthly Quantity as per Rx	Weekly / Monthly Ingredient cost	VAT (for non-oral medicinal products only)
1.			
2.			
3.			

To be completed by the Doctor / Pharmacist as appropriate

Patient Name and Address	
Nursing Home Patient Y / N	
De Novo Application Y / N	
Renewal Application Y / N	
Has the Product been initiated in the Hospital Setting Y / N	
If Yes, Please state the Hospital and the Name and MCRN of the Prescriber.	
Is the product an Exempt Medicinal Product (Unlicensed Medicine)* *Please ensure that the patient is aware of the unauthorised status of the medicine	
Additional Information (Please highlight any areas of unmet clinical need and why therapeutic alternatives on the Reimbursement List are unsuitable for this patient.)	

Doctor's Signature.....

Pharmacist's Signature

DOCTOR'S STAMP

PHARMACY STAMP

For the Pharmacist:

Please attach a copy of the prescription – preferably the Hospital Prescription if available. Unless the product is a line extension of an existing product on the Reimbursement List, approval is unlikely in the absence of a Hospital Prescription or letter of support from Hospital Clinician.

For Office Use Only

Approved/Refused:Date:.././.....

Expiry of approval...../...../.....

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<i>For Use on Appeal</i>	
<i>Case Reference</i>	<i>Date Received</i>

Individual Reimbursement Request Application Form

Name of Prescribing Consultant	
Contact Details:	Address:
	Telephone:
	Email:

Name of person completing form	
Contact Details:	Address incl Eircode:
	Telephone:
	Email:

Patient Details

Patient name			
Date of birth			
GMS / DPS / LTI Number <small>(Please tick and insert number)</small>	<input type="checkbox"/> GMS	<input type="checkbox"/> DPS	<input type="checkbox"/> LTI
	Number:		
Co-morbidities and other relevant factors			

Requested Treatment Details

Generic Name	
Brand (if relevant)	
Form	
Strength	
Planned duration of therapy	

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Indication for treatment	
Rationale for use	
Do you wish to highlight any areas of unmet need	
Additional Information <small>(Please add separate sheet if more space is required)</small>	

Purchasing Details

Cost	
Supplier	

Conditions of Reimbursement

- There is published clinical evidence as set out above to support the proposed treatment for the patient.
- Prescription has been initiated by a Consultant Medical Doctor
- I confirm that I have ensured that the details on this form are correct and that the above conditions of reimbursement have been understood.

Authorisation of request

Signature of prescribing consultant	
Institution	

Completed forms should be submitted to:

Pharmacy Function Unit,
Primary Care Reimbursement Service
Exit 5, M50
Finglas
Phone: 01-8647100
Fax: 01-8647142
Email: novelhardship@hse.ie