Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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Circular No 48/16 10 October 2016

Dear Pharmacist,

The HSE has carried out a review of the administrative arrangements pertaining to the Discretionary Hardship Arrangements and has introduced a National Framework to ensure uniformity of administration across the country. Pharmacists were informed of those changes in Circular 014/16. These changes were effective from 1st April 2016.

The HSE have developed a set of Frequently Asked Questions in order to assist you in implementing the new arrangements.

Enclosed with this Circular is the list of medicinal products that are not approvable by the Local Health Offices under any circumstances. This will be updated and published from time to time.

It should be noted that those products which are undergoing formal Pricing and Reimbursement Assessment or remain 'Not recommended for reimbursement' by the National Centre for Pharmacoeconomics or have been rejected by the Drugs Group cannot be approved. There will be no exceptions.

I trust these clarifications assist you in your management of Discretionary Hardship Arrangements.

Yours faithfully,

Anne Marie Hoey

Anne Marie Hoey
Primary Care Reimbursement & Eligibility

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Health Service Executive

FAQ's re:
The New National Framework for the Administration of Discretionary Hardship Arrangements

The HSE has carried out a review of the administrative arrangements pertaining to the Discretionary Hardship Arrangements and has introduced a National Framework to ensure uniformity of administration across the country.

This may have resulted in changes for some areas to the approval process. The reimbursement rules around Hardship Arrangements were outlined earlier this year in circular 014/16. These changes were effective from 1st April 2016.

Enclosed with the Circular is the list of medicinal products that are not approvable by the Local Health Offices under any circumstances. This will be updated and published from time to time. The HSE has updated for use nationally the application and appeal forms. The HSE PCRS have prepared this FAQs sheet to provide support to pharmacists in implementing the new arrangements. All documentation relevant to the Hardship Arrangements is available at www.hse.ie or www.ipu.ie > HSE Contract > Schemes & Initiatives > Hardship Arrangements.

Q.1 Will items included on the list of *'items which are not approvable at local level under discretionary Hardship arrangements'* be reimbursed for existing patients?

Yes, if a patient received approval for reimbursement support for an item under the Hardship Arrangements prior to implementation of the new rules, they will continue to be approved until further notice.

Macushield and like Lutein Products have been reviewed by the Medicines Management Programme (MMP) and a recommendation has been made to the HSE that reimbursement support should not be continued. The manufacturer appealed citing further clinical evidence available. The MMP has reviewed the additional evidence presented and is satisfied to uphold its original recommendation. No new patients will be approved and existing approved patients will no longer receive reimbursement support from 1 January 2017.

Q.2 Will items included on the list of *'items which are not approvable at local level under discretionary Hardship arrangements'* be reimbursed for new patients?

These items are *'not approvable'* by the Local Health Offices. The Medicines Management Programme was integral to the development of the list. Items included on this list will not be approved for new patients, and appeals will be rejected as the evidence of cost effectiveness or therapeutic value has not been established. You can find the *'not approvable'* list here for ease of reference.

Q.3 How long does approval last?

Approval lasts a maximum of six months, being the maximum validity of a prescription unless shorter periods have been specified by the PCRS. This will be the case until the HSE can make Hardship approval status visible for individual patients on the enhanced visibility system in the way that NOAC approvals currently are.

Approval may be granted for shorter periods on an occasional basis e.g. specialised dressings (not normal nursing needs) for patients in nursing homes may be approved for a maximum of three months where significant quantities are prescribed.

Q. 4 I want to know if it is worthwhile going through the application process on behalf of a patient. Can you clarify why a product may not be approved if it is not on the *'not approvable'* list?

In relation to applications for other products, there are a number of reasons why the Local Health Office may not grant reimbursement support for a product for a GMS patient under the National Framework for the administration of the Discretionary Hardship Arrangements:

(i) Where the application is not based on a hospital / consultant prescription;
(ii) Where there is a comparable / alternative item available on Reimbursement List particularly where it is a non-drug item offering an equivalent technical solution;
(iii) Where the product is a 'new chemical entity' and / or not recommended for reimbursement by the NCPE following a pharmacoeconomic assessment;
(iv) Where there is limited clinical evidence of patient benefit; or
(v) Where the price is too high when compared with therapeutic alternatives.

In addition, the Local Health Office is required to consider whether or not the product comes under one of the *'approvable categories'*:

(i) Is it an Exempt Medicinal Product for which there is 'unmet clinical need'?
(ii) Is it a vitamin or mineral supplement for the treatment of a serious disease?
(iii) Is it a non-drug product where no suitable alternative is available and the product is required to retain the patient in the community setting or enable discharge to the community setting?

If you can identify any of the grounds for refusal in relation to the product you are considering seeking approval for, and if the product does not come under one of the *'approvable categories'* it may be worth contacting the Local Health Office to see if there is any merit to preparing and submitting an application at all. Your local HSE Pharmacist or the relevant Area Medical Officer should be able to assist in this regard.

Q. 5 Consultant Initiated in Certain Circumstances.

Melatonin, Vitamins and Minerals including thiamine are the most frequently requested for patients, and are 'approvable' where consultant initiated, in specific circumstances as outlined in the list. These requests must be supported by a hospital prescription.

Q.6 Circular 14 / 16 sets out a requirement for confirmation of Hospital Initiation for products that are not on the Reimbursement List. Is this necessary in all cases?

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. There are however a number of situations where the HSE will approve applications supported by a GP prescription:

a. **Liquid line extensions** of products already on the Reimbursement List can be submitted for Hardship approval supported by a GP prescription e.g. liquid formulations of omeprazole for peg feed children

b. Where a **shortage of a product on the Reimbursement List** occurs. In these circumstances, a GP prescription for the Exempt Medicinal Product to provide continuity of supply for the patient will be accepted by the local office

c. Palliative Care / End of Life – see Q9.

d. Elastic Stockings

e. Peg Giving Sets and Accessories (where local direct provision is not in place)

f. Copper IUDs

g. Dressings
While Dressings are not available to patients on GMS scripts, certain dressings are listed on the Reimbursement List for GP Stock orders.
Where there are no local arrangements to make supplies through the Public Health Nurse network at local level, applications can be submitted for Hardship approval supported by a GP prescription. Approval as per Q3 may be for shorter periods than the maximum validity of the prescription.
N.B Normal Nursing Needs as per Appendix A are not supported for patients in Nursing Homes.

Pricing of products in relation to (a) to (g) above may not be acceptable to the HSE and therefore products will not necessarily be approved in all circumstances

Q.7 What about Non-Drug Products other than Dressings e.g. Ostomy Products?

There are a range of reimbursable alternatives available on the Reimbursement List, in many cases providing an equivalent technical solution. Therefore, a Hospital Prescription is necessary before approval on an exceptional basis will be considered.

Q.8 What about Elastic Stockings? Is a Hospital Script necessary where these are prescribed?

No. A Hospital Script is not necessary for Elastic Stockings. Reimbursement Support is provided for two pairs per calendar year.

Q.9 What about my patients who are in palliative / 'end of life' care? Do they need a Hospital Prescription in all cases?

Where the patient is on opioid medication and is attended or supervised by the Palliative Care Team, there are a range of medicines that can be provided supported by a GP prescription. These are (i) Senna Products (ii) Bisacodyl preparations (iii) Dioctyl preparations (iv) Kin mouthwash (v) Bioxtra Products (vi) Phosphate and Arachis Oil enemas. Duraphat can also be approved but only for patients with Head and Neck Cancers.

While recognising the importance of respecting the privacy of the patient, where the HSE is made aware that a patient is at 'end of life', it will 'fast track' decisions as expeditiously as possible.

Q.10 My patient has been approved previously for a product on the 'Non Approvable' List? Will the product be approved in future for my patient?

Where patients have been approved previously in line with New / Novel Arrangements, their existing approval continues unless and until the Medicines Management Programme makes an adverse recommendation in relation to continued reimbursement for any patients. However, those products which are undergoing formal Pricing and Reimbursement Assessment or remain 'Not recommended for reimbursement' by the National Centre for Pharmacoeconomics or have been rejected by the Drugs Group cannot be approved. Please refer to the NCPE website for further information.

Q. 11 My patient who was previously approved at local level does not have a current Hospital script? Will there be a problem when the current approval period expires?

No. Local offices have been directed not to discontinue any approvals for existing patients so long as there remains a valid prescription supporting the application. Local offices have been given the timescale of one year as the appropriate span for 'look back' in this regard. Where an approval has not been requested within a year for a patient, the patient is deemed a 'new' patient and a Hospital script is required

to support the application. Pharmacies should make arrangements to retain a copy of any Hospital script for Hardship audit purposes in the future.

Q.12 Are there any changes to the claims process?

With effect from April 2016, claims for 'approved items' must be submitted on a monthly basis to the Local Health Office. The claim must include:

(i) A properly completed HD2 Form;
(ii) A copy of the hospital prescription for patients approved after the 1st April 2016;
(iii) An invoice for all claims; and a
(iv) Unified claim form signed by the patient or their agent.

Q.13 Where can I get more HD1 and HD2 forms?

A Copy has been circulated to all pharmacies (ref Circulars 010 /10 and 014 /6). Local offices also have received copies and it is intended to publish the form as a pdf at www.hse.ie or www.ipu.ie

Q.14 The new HD1 form outlines a requirement to insert the VAT element in the pricing of the product? How do I calculate VAT?

Vat is applied on the total price to the HSE i.e. ingredient cost plus fee. VAT is not applicable to oral preparations.

Q.15 Has there been any change in the HD2 form?

There is no change in the HD2 form previously circulated in 2010 with Circular 10/10

Q.16 My patient has been prescribed a licensed medication by a consultant. The medication is not approved on schemes; will this be approved on Hardship?

Unless it is a chemical entity that was previously available on the Reimbursement List and has now been discontinued on the Reimbursement List, it will not be approved.

Q.17 My patient has been prescribed a new medication by their consultant, on checking the NCPE website I see that the medication is currently being reviewed, will this be approved on Hardship?

No.

Q.18 Are fees for Phased Dispensing paid under Hardship?

No.

Q.19 A product was not approved, how does the patient appeal?

If a patient wishes to appeal a decision, the patient's hospital clinician or a member of their team can complete an individual reimbursement form for the purposes of lodging an appeal. The appeal form should be sent to the PCRS for review.

Q.20 How does the patient appeal a decision of the HSE PCRS?

When the appeal process has been exhausted within the PCRS, the patient's clinician can make direct representations to the Medicines Management Programme. The

National Appeals office has no role in access to Medicines through the GMS / Discretionary Hardship Arrangements or Community Drugs Schemes

Q.21 Do I have to provide Discretionary Hardship Arrangements in my pharmacy?

As the name suggests, these are discretionary 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. However, in complex situations, many pharmacists will want to assist their patients in this regard.

Q.22 How do I claim for Exempt Medicinal Products?

The HSE has recently updated the Administrative Codes for those Exempt Medicinal Products (Circular 39 /16) which satisfy unmet clinical need and are at a price that the HSE is prepared to pay. This should reduce workload for local offices as the number of applications for these products through the local offices should be vastly reduced.

My question has not been answered, where can I get further information?

Further Information is available from the HSE on their website or alternatively at novelhardship@hse.ie.

There is also further information available at www.ipu.ie.

Appendix A
Normal Nursing Needs

The following Dressings and aids for Wound Management are considered Normal Nursing Needs and therefore should not be approved under Discretionary Hardship Arrangements as they would be expected to be available as stock items in the residential setting. Examples include

Conforming Bandages
Disposable Aprons
Dressing Packs
Wound Cleansing Agents eg Normasol, Sterile Water
Face Masks
Gauze Swabs
Surgical Tapes
Melolin and similar simple dressings
Surgipad Dressings
Mepore and similar simple bandages
Opsite and similar simple dressings
Jelonet Dressings
Tubular Support Bandages
Gloves
Alcohol Swabs
Oral Swabs
Blood Collection Sets
Hibiscrub
Milton

However, Dressings of a more complex nature e.g. Granuflex, Kaltostat, Actilite etc can be approved under Discretionary Hardship Arrangements. It should be noted that the Expert Group convened for the National Review of Wound Management Products do not consider there is any need for specific conformable Sacral Dressings or Heel Dressings. Their expert opinion is that flat dressings can be moulded at the point of dressing the wound or pressure point to fit appropriately.

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 / Ocuvite 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. Camoflage 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
26. Nintedanib / Ofev / Vargatef – undergoing Pricing and Reimbursement Assessment
27. Teduglutide / Revestive – undergoing Pricing and Reimbursement Assessment
28. Abbott Libre Free Style Monitoring System – undergoing Pricing and Reimbursement Assessment

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

29. Melatonin (under 18 years) – where recommended by a consultant within Child and Adolescent Services
30. Vitamins and Minerals where Consultant initiated for patients with Cystic Fibrosis or other serious illness
31. Thiamine where consultant initiated for people with alcohol dependency

* Where supported by a Hospital Prescription

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