An tÚdarás Árachas Sláinte
The Health Insurance Authority

Health Insurance (Amendment) Act 2024

Section 6A – High Cost Claims

This document should be read in conjunction with Section 6A of the Health Insurance Act, 1994 (principal Act) as amended

Last updated November 2024

Contents

Guidance Note on drugs eligible for inclusion in High Cost Claim Pool claims

1 Purpose of this guidance

The Authority is providing guidance on the interpretation of "Health Service Executive approved drugs" in the context of the Health Insurance Act, 1994 (as amended) (the Act) and what types of evidence may support a registered undertakings claim that a drug is Health Service Executive (HSE) approved.

The information in this document is provided as a guide only and is not professional advice, including legal advice. It should not be assumed that the guidance is comprehensive or that it provides a definitive answer in every case. If a Registered Undertaking, or other interested party, has reason to believe information in this guidance is inaccurate or out of line with the Act, please email the Head of Regulation and Compliance at: silehanley@hia.ie.

2 Publicly Available Lists

The Act sets out that drugs on certain publicly available lists are considered to be HSE approved. To be eligible for inclusion in a HCCP claim, the drug must have been eligible for reimbursement at the time the claim was incurred.

2.1 Reimbursement List

The Reimbursement List established and published by the Health Service Executive under section 17 of the Health (Pricing and Supply of Medical Goods) Act 2013 is also known as the Primary Care Reimbursement List (PCRS List). This list is maintained by the HSE for the purpose of making payments to healthcare professionals, like pharmacists, for the free or reduced costs drugs they provide to the public. This list is currently available here: https://www.sspcrs.ie/druglist/pub.

To be eligible for inclusion in a HCCP claim, the drug must have been eligible for reimbursement at the time the claim was incurred. Monthly updates to the list are available here: https://www.sspcrs.ie/libr/html/monthlyproductupdate.pdf.

2.2 National Cancer Control Programme

The National Cancer Control Programme (NCCP) list provides details of cancer drugs eligible for reimbursement by the HSE. Drugs eligible for reimbursement under this criteria are available on lists directly linked to from this page: https://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/cdmp/odms.html

2.3 HSE Access and Integration Drug Management Programme

The HSE Access and Integration Drug Management Programme is a web based, centralised funding and reimbursement system for high-cost drugs. Its primary goal is to ensure equitable access for all patients to specified high-cost drugs, regardless of their geographical location and to support hospitals in meeting the financial burden of providing these drugs to patients. They maintain a list of drugs approved for funding and use in acute HSE hospitals. This service was

previously known as the Acute Hospitals Drugs Management Programme. The drugs included in the clinical protocols developed by the HSE Access and Integration Drug Management Programme are eligible for inclusion in HCCP claims.

Drugs eligible for reimbursement under this criteria are available on lists directly linked to from this page:

https://www.hse.ie/eng/about/who/acute-hospitals-division/drugs-management-programme

Drugs on this list can only be considered eligible for inclusion in HCCP claims if the incurred date of the claim is on or after the publication date of the protocol. Drugs may be eligible for inclusion in HCCP claims by virtue of a different verification method before this date.

2.4 HSE Medicines Management Programme

HSE Medicines Management Programme has identified a list of "best value" medicines in specific areas.

Drugs eligible for reimbursement under this criteria are available on lists directly linked to from this page:

https://www.hse.ie/eng/about/who/cspd/medicines-management/

2.5 Normal Human Immunoglobulin

Drugs which are normal human immunoglobulin products assigned the code J06BA under the Anatomical Therapeutic Chemical classification system established by the World Health Organisation are eligible for inclusion in HCCP claims. Human normal immunoglobulin is a plasma derived blood product and is used in the effective treatment of a number of indications. Details of the Anatomical Therapeutic Chemical Classification are available here: https://www.who.int/tools/atc-ddd-toolkit/atc-classification#:~:text=In%20the%20Anatomical%20Therapeutic%20Chemical.

A description of the normal human immunoglobulin products eligible for inclusion in HCCP claims is available here: https://atcddd.fhi.no/atc_ddd_index/?code=J06BA&showdescription=no.

The Health Products Regulatory Authority website allows for an advanced search option that caters for Anatomical therapeutic chemical (ATC) including code J06BA. This may be of assistance to insurers in determining whether a drug meets this criteria.

https://www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine/results?showadv=true&list=HM

2.6 Marketing Authorisation

Drugs which were granted a marketing authorisation prior to the commencement of section 17 of the Health (Pricing and Supply of Medical Goods) Act 2013 are eligible for inclusion in HCCP claims. Marketing authorisation in the Act has the same meaning as within Regulation 3(1) of the Medicinal Products (Control of Manufacture) Regulations 2007 (S.I. No. 539 of 2007).

2.7 Other drugs approved in accordance with the Health (Pricing and Supply of Medical Goods) Act 2013

Certain drugs have been approved for funding and reimbursement in public hospitals having regard to the criteria set out in Part 3 of Schedule 3 to the Health (Pricing and Supply of Medical Goods) Act 2013. This category does not contain drugs that have been used based on a case-by-case clinical judgement for specific patients in individual hospitals. This category does include drugs that have been recommended for reimbursement by the HSE Drugs Group and accepted by the HSE Senior Leadership Team. This can be verified using published minutes of the HSE Drugs Group, available here: https://www.hse.ie/eng/about/who/cpu/drugs-group-minutes/.

In order to verify that an individual drug has been approved in this manner it is necessary to verify that the drug has been recommended in one set of minutes and that the recommendation was accepted in a subsequent set of minutes.

3 Evidence Requirements

Registered undertakings are required to retain evidence of how they verified that each drug included in each HCCP claim was deemed, by the registered undertaking, to be eligible for inclusion. Particular care should be taken with drugs deemed eligible by reason of Marketing Authorisation.

Where a drug appears on more than one source list, any relevant source list is acceptable.

Where a registered undertaking considers that an additional source meets the definition of Health Services Executive approved Drugs under the Act, they should contact the HIA.

When making a request and to accelerate the assessment process please include strong justification as to why the source should be added to the list above, with reference to relevant legislation.