



Holly Cairns, T.D.
Dáil Éireann,
Leinster House,
Kildare Street,
Dublin 2.

1st March 2022

PQ: 10121/22

To ask the Minister for Health if he will provide a list of all medicines and food supplements which are currently subject to patient specific arrangements; and if he will make a statement on the matter. -Holly Cairns

Dear Deputy Cairns,

The Health Service Executive has been requested to reply directly to you in the context of the above Parliamentary Question (Reference 10121/22), which you submitted to the Minister for Health for response.

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.

Exceptional arrangements are considered under Section 23 of the Act:

Supply of items not on Reimbursement List. The HSE must be satisfied that:

(a) The patient requires that item for clinical reasons, and

(b) There is no listed item which is a suitable alternative for that item in so far as that patient is concerned.

A prescriber can apply for reimbursement support for any medicine/drug/appliance not on the Reimbursement List on behalf of their patient under Section 23 of the Act. There is no defined list of items.

Food supplements are not available under GMS and Community Drug Schemes. Under the 2013 Act, food supplements do not satisfy Schedule 3 – “Criteria Applicable to Items and Listed Items for Purposes of Executive Making Relevant Decision Under Section 18”:

Criteria Applicable to Medicinal Products

1. The medicinal product—

(a) must be suitable for use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use,
 (b) subject to paragraph 2, must not be advertised or promoted directly to the public,
 (c) must not be for the purpose of obtaining a cosmetic effect,
 (d) must be such that it is ordinarily supplied to the public only on foot of a prescription, and
 (e) must have a marketing authorisation referred to in paragraph (a) of the definition of “authorisation holder” in section 2(1).

Criteria Applicable to Medical Devices, Foodstuffs for Particular Nutritional Uses and Dietary Foods for Special Medical Purposes

1. The medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose—

(a) must be suitable for use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use,
 (b) subject to paragraph 2, must not be advertised or promoted to the public, and
 (c) must not be for the purpose of obtaining a cosmetic effect.

Due to the budget impact associated with certain items, PCRS introduced a reimbursement application system. The following products require prior-approval to be in place before patient specific reimbursement status is granted under Community Drug Schemes;

Product	Who can submit the application?
Fampridine (Fampyra®)	Consultant Neurologist
*Additional Blood Glucose Test Strips	Hospital (Consultant Endocrinologist or Diabetic Nurse Specialist) or GP
Lidocaine 5% Medicated Plaster (Versatis®)	Hospital Clinician or GP
Valsartan/Sacubitril (Entresto®)	The physician responsible for the initiation of treatment
*FreeStyle Libre (Flash Glucose Monitoring) Sensor	Consultant Endocrinologist
**Non-first line Standard Oral Nutritional Supplements	Hospital (Doctor or Dietician), HSE Dietician or GP
PrEP (Pre-exposure Prophylaxis)	PrEP prescriber approved by the HSE Sexual Health Programme
PCSK9- Inhibitors (High Tech Hub)	Prescribers (Consultants) approved by the HSE Medicines Management Programme
CGRP MABs (High Tech Hub)	Prescribers (Consultants) approved by the HSE Medicines Management Programme
Biologics for Dermatitis (High Tech Hub)	Prescribers (Consultants) approved by the HSE Medicines Management Programme

* Medical Device

** Food for Special Medical Purposes

Approval can be confirmed by the dispensing pharmacist through the ‘Secure Scheme Checker’ under ‘Patient Specific Arrangements’.

Yours sincerely,



Suzanne Doyle
 Primary Care Eligibility & Reimbursement Service