Medicines Management Programme

Preferred high-protein oral nutritional supplement(s)

Evaluation report

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List of Abbreviations

αTE	Alpha tocopherol
βHMB	Beta-hydroxy-beta-methylbutyrate
CDS	Community Drug Schemes
DP	Drugs Payment (scheme)
EPUAP	European Pressure Ulcer Advisory Panel
ESPEN	European Society for Clinical Nutrition and Metabolism
FSMP	Foods for specific medical purposes
G	Gram(s)
GMS	General Medical Services (scheme)
HCP	Healthcare professional
HSE	Health Service Executive
INDI	Irish Nutrition and Dietetic Institute
IrSPEN	Irish Society for Clinical Nutrition and Metabolism
Kcal	Kilocalorie(s)
LTI	Long Term Illness (scheme)
Mcg	Microgram(s)
Mg	Milligram(s)
Ml	Millilitre(s)
MMP	Medicines Management Programme
NPIAP	National Pressure Injury Advisory Panel

NPUAP	National Pressure Ulcer Advisory Panel
ONS	Oral nutritional supplement(s)
PCRS	Primary Care Reimbursement Service
PICO	Population, intervention, comparison and outcome
PPPIA	Pan Pacific Pressure Injury Alliance
QoL	Quality of life
RCT	Randomised controlled trial
VAT	Value-added tax

Definitions

For the purpose of this evaluation, the HSE-Medicines Management Programme considered high-protein oral nutritional supplements as oral nutritional supplements classified as high-protein on the HSE Reimbursement List and/or with greater than 20 % of the energy value provided by protein.

For the purpose of this document, the reimbursement price refers to the price as listed in the HSE Reimbursement List, available on the Health Service Executive-Primary Care Reimbursement Service website (www.pcrs.ie). Reimbursement prices are correct as of 1 May 2025.

Total expenditure includes ingredient cost and pharmacy fees, based on claims submitted by pharmacists.

The term supplier refers to a company that has submitted a high-protein oral nutritional supplement for inclusion in this evaluation process, and may include a manufacturer or distributor of, or agent for the high-protein oral nutritional supplement.

1. Executive summary

The Health Service Executive (HSE)-Medicines Management Programme (MMP) aims to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

In 2023, high-protein oral nutritional supplements (ONS) accounted for a total expenditure of approximately €14.88 million on the Community Drug Schemes (CDS).

The aim of this initiative is to identify preferred high-protein ONS. The review was carried out in accordance with the evaluation process outlined in the *HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s)*.

Following review of the submissions received, the MMP is currently unable to identify preferred high-protein ONS.

The MMP recommends that the following high-protein ONS be added to List B (non-preferred ONS):

High-protein ONS*	Supplier	Reimbursement code	Pack size
Ensure® Plus Advance 220 ml	Abbott Nutrition	81482	1
Ensure® Plus HP 200 ml	Abbott Nutrition	82412	1
AYMES® ActaSolve® Protein Compact 57 g sachet	Aymes International Ltd	83272	7
AYMES® ActaSolve® Protein Compact 57 g sachet (starter pack with shaker)	Aymes International Ltd	85032	5
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	82771	1
Fresubin® PRO Drink 200 ml	Fresenius Kabi Ltd	82772	1
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	82475	1
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	81121	1
Altraplen Protein 200 ml	Nualtra	82500	1
Altraplen Protein Daily 250 ml	Nualtra	85033	1
Cubitan® 200 ml	Nutricia	82430	1
Fortisip® Compact Protein 125 ml	Nutricia	85097	1
Fortisip® Extra 200 ml	Nutricia	85092	1

g: grams; ml: millilitres *Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List

The scope of the reimbursement application system in place for non first-line standard ONS should be broadened to include high-protein ONS, which will require prior approval for reimbursement on the CDS.

HSE-Primary Care and the MMP have previously published the *Standard ONS First-line Prescribing List for Adults Living in the Community (2017, updated April 2019)*. This list identified ONS to be included on the First-line Prescribing List (List A). There are products on List A that have similar energy and protein content to high-protein ONS, with a significantly lower reimbursement cost, i.e. List A powdered ONS. Therefore, the MMP recommends that List A powdered ONS should be considered first-line where appropriate for adults living in the community.

Powdered ONS are suitable for patients who require energy and protein supplementation, and offer patient choice in terms of the variety of flavour and volume options available. Powdered ONS require lower storage space compared with ready-to-drink sip feeds, and are reconstituted with fresh whole milk. As such, powdered ONS offer benefits to the health service and flexibility in terms of individual patient requirements.

A collaborative approach involving clinicians, dietitians, pharmacists, patients and the health service will be required to support utilisation of powdered ONS on List A for adults living in the community. Implementation of this recommendation will lead to savings for the health service while continuing to enable access to non-preferred ONS for patient cohorts where specific clinical requirements cannot be met with List A powdered ONS.

2. Purpose

The purpose of this evaluation is to review high-protein ONS with a view to identifying preferred products as part of the MMP's remit to support safe, effective and cost-effective prescribing in the Irish healthcare setting.

This evaluation document outlines information submitted to the MMP as part of an open consultation process, for the identification of preferred high-protein ONS. The document supports the MMP's evaluation process for the identification of preferred high-protein ONS.

3. Scope

This evaluation considers ONS on the HSE Reimbursement List with a high-protein content, which are not currently included on List A or List B Standard ONS and are currently available for supply to the Irish Market. List A and List B Standard ONS are available in Appendix A and B respectively. Comparisons may be made with preferred ONS that are included on List A Standard ONS.

This evaluation for the identification of a preferred high-protein ONS is limited to high-protein ONS:

- included on the HSE Reimbursement List as of 6 February 2024, and
- for which a submission was received from the supplier during the consultation as part of the *HSE-MMP roadmap for the identification of preferred high-protein ONS*.

Disease-specific ONS and pre-thickened ONS with a high-protein content were considered to be outside the scope of this evaluation to identify preferred high-protein ONS.

4. Background

4.1 Malnutrition

Malnutrition (undernutrition form) is a state of nutrition in which a deficiency of energy, protein and other nutrients causes measurable adverse effects on body structure, function and clinical outcome. Reduced food intake or reduced nutrient absorption, combined with acute or chronic inflammation leading to altered body composition and diminished function, characterises malnutrition associated with disease or injury.[1] Disease-related malnutrition encompasses malnutrition that arises in association with both acute and chronic disease.[2] In Ireland, it has been estimated that approximately 140,000 adults are suffering from disease-related malnutrition at any time.[3]

Oral nutrition support strategies aim to improve energy and protein intake through diet, dietary counselling, food fortification, provision of additional snacks or ONS.[1]

4.2 Oral nutritional supplements (ONS)

ONS are defined as products for use in oral nutrition support given with the aim to increase nutritional intake, provided as ready-to-drink liquids, puddings, or powders,[4] and are defined in EU legislation as "foods for specific medical purposes" (FSMP). FSMP are defined as "specially processed or formulated and intended for the dietary management of patients including infants, to be used under medical supervision".[5] Best practice indicates that patients who require nutrition support should always be given dietary advice in conjunction with an ONS prescription.[6]

ONS can be accessed on the CDS, as they are included on the HSE Reimbursement List.[7] For ONS to be included on the reimbursement list, they must have satisfied the criteria in accordance with the relevant HSE-Primary Care Reimbursement Service (PCRS) guidelines in place at the time of their addition to the reimbursement list. The current guidelines for this process are entitled *HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers (October 2024)*.[8] This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.[9]

4.3 Standard ONS First-line Prescribing List for Adults Living in the Community

HSE-Primary Care and the MMP have previously published a *Standard ONS First-line Prescribing List for Adults Living in the Community (2017, updated April 2019)*.[6] For the purpose of this prescribing guidance, standard ONS is defined as either powdered or readymade multi-nutrient (complete or incomplete) products providing a mix of macronutrients and micronutrients. The nutrition value for standard ONS is 1 kilocalorie (kcal) - 2.4 kcal per millilitre (ml) and less than 20% of the energy value is provided by protein.[10]

On 1 July 2019, the HSE introduced changes to the reimbursement of standard ONS on the CDS in line with the *Standard ONS First-line Prescribing List for Adults Living in the Community*. There was no change to the reimbursement of the standard ONS recommended on the *First-line Prescribing List* (List A). Non first-line standard ONS (List B) require prior approval for reimbursement on the CDS.

As of 1 May 2025, there are 14 products on List A consisting of six compact and mini-drink sip feeds and eight powdered ONS. A number of the powdered ONS are available as a starter pack with a shaker (see Appendix A). Powdered ONS require mixing with fresh whole milk. The range of energy and protein content, and reimbursement prices of standard ONS on List A are outlined in Table 1.

Table 1: Range of energy and protein content, and reimbursement prices of standard ONS on List A

	List A Powdered ONS		**List A Compact & mini-drink sip feeds**
Volume	Mixed with 100 ml whole milk*	Mixed with 200 ml whole milk*	125 ml
Energy content (per unit)	317 kcal - 319 kcal	374 kcal - 397 kcal	250 kcal - 300 kcal
Protein content (per unit)	13.7 g - 15.4 g	15.8 g - 19 g	11.9 g - 12.8 g
Reimbursement price (per unit)**	€0.56 - €0.74	€0.67 - €0.82	€1.38

g: grams; kcal: kilocalories
*Refer to manufacturer's instructions for information on which powders can be mixed with 100 ml and/or 200 ml whole milk
Note: there may be slight variations in total energy and protein content between different product flavours
**Reimbursement prices are correct as of 1 May 2025.

If a patient clinically requires a standard ONS, and they (or their carer) has the functional ability to mix a powder with milk, due consideration should be given to prescribing a powdered ONS on List A. If powdered ONS is not suitable for the patient, ready-to-drink compact and mini-drink sip feeds are also available on List A.

At the time of the establishment of List A and List B Standard ONS, high-protein ONS were considered outside the scope and therefore were not impacted by the reimbursement changes introduced on 1 July 2019. There has been a subsequent significant increase in the utilisation of, and expenditure on high-protein ONS on the CDS.

5. High-protein ONS – expenditure and utilisation

All FSMP on the HSE Reimbursement List, including ONS, enteral tube feeds, milk substitutes, thickening agents and products for the management of inborn errors of metabolism are included in the category *Clinical Nutritional Products.* The full list of products in this category is available on the HSE-PCRS website at

www.sspcrs.ie/druglist/pub. In 2023, total expenditure[i] by the PCRS on Clinical Nutritional Products on the General Medical Services (GMS), Drugs Payment (DP) and Long Term Illness (LTI) schemes was €48.28 million, €7.68 million and €8.56 million respectively.[11]

According to MMP analysis, there has been an increase in utilisation of, and total expenditure on, high-protein ONS on the CDS over the last five years. The total monthly expenditure increased from approximately €0.49 million in July 2019 to approximately €1.39 million in December 2023. The number of patients in receipt of high-protein ONS on a monthly basis increased from approximately 6,200 to approximately 16,500 over the same time period.[12]

6. Identification of preferred high-protein ONS

The review to identify preferred high-protein ONS was carried out in accordance with the evaluation process outlined in the *HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s).*

6.1 MMP roadmap

The MMP published the *HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s)* on 7 February 2024.

6.2 MMP evaluation process

As part of the evaluation process for the identification of preferred high-protein ONS, a period of consultation with stakeholders was undertaken between 7 February 2024 and 6 March 2024. Following requests from a number of suppliers of high-protein ONS, the consultation period was extended to 9 April 2024. Suppliers of high-protein ONS on the reimbursement list were notified of the publication of the roadmap and of the commencement of the evaluation process. The following suppliers were notified: Abbott Nutrition, Aymes International Ltd, Fresenius Kabi Ltd, Nualtra and Nutricia.

Information in relation to the evaluation process was published on the MMP website and on the MMP's X (formerly Twitter) account. Dietetic representative bodies, i.e. the Irish Nutrition and Dietetic Institute (INDI) and Irish Society for Clinical Nutrition and Metabolism (IrSPEN), were also notified of the publication of the roadmap and of the commencement of the evaluation process.

A copy of the roadmap published on 7 February 2024 and the updated version with the extended consultation period are available in Appendix C and D respectively.

[i] Total expenditure includes ingredient cost, pharmacy fees and value-added tax (VAT) where applicable, based on claims submitted by pharmacists.

7. Evaluation

7.1 Cover page

For a high-protein ONS to be considered for inclusion in the evaluation to identify preferred high protein ONS, suppliers were required to complete and sign a cover page, confirming compliance of the high-protein ONS with the published criteria in the *HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers 2023 (or previous versions).*

Suppliers were required to confirm that distribution arrangements are in place to enable the high-protein ONS to be dispensed by a pharmacist. A copy of the cover page is available in Appendix E.

7.2 Criteria

In line with the *HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s)*, the MMP considered the following criteria when reviewing the submissions received:

1. Reimbursement cost of the ONS
2. Nutritional content of the ONS
3. Robustness of supply to the Irish Market
4. Patient factors
5. Any other relevant factors

Comparisons may be made, as part of the evaluation process, with standard ONS included on List A.

Submissions were received from the following suppliers:

- Abbott Nutrition
- Fresenius Kabi Ltd
- Nualtra
- Nutricia.

No submission was received from Aymes International Ltd.

Table 2 outlines the ONS included in the submissions received from suppliers during the consultation period.

Table 2: ONS included in the submissions received from suppliers

Supplier	ONS*	Reimbursement code	Pack size
Abbott Nutrition	Ensure® Compact Protein 125 ml	83962	1
Abbott Nutrition	Ensure® Plus Advance 220 ml	81482	1
Abbott Nutrition	Ensure® Plus HP 200 ml	82412	1
Fresenius Kabi Ltd	Fresubin® PRO Compact Drink 125 ml	82771	1
Fresenius Kabi Ltd	Fresubin® PRO Drink 200 ml	82772	1
Fresenius Kabi Ltd	Fresubin® Protein Energy 200 ml	82475	1
Fresenius Kabi Ltd	Fresubin® Thickened Level 2 200 ml	85027	1
Fresenius Kabi Ltd	Fresubin® Thickened Level 3 200 ml	85031	1
Fresenius Kabi Ltd	Fresubin® 3.2 Kcal 125 ml	81121	1
Fresenius Kabi Ltd	Supportan® Drink 200 ml	81082	1
Nualtra	Altraplen Protein 200 ml	82500	1
Nualtra	Foodlink Complete 57 g Sachet	85067	7
Nutricia	Cubitan® 200 ml	82430	1
Nutricia	Fortisip® Compact Protein 125 ml	85097	1

g: grams; ml: millilitres
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List

Submissions were also received from healthcare professional (HCP) organisations which were given due consideration throughout this evaluation.

Clinical guidelines and recommendations on the use of high-protein ONS were also considered, as outlined in this document.

In line with the scope of this evaluation as defined in section 3, the following submitted ONS was not considered as part of this review as it is included on List A:

- Foodlink Complete 57 g Sachet.

Furthermore, for a high-protein ONS to be included in the review it must be available for supply to the Irish Market. Following confirmation of supply status with the suppliers, the following submitted ONS were not considered as part of this review:

- Ensure® Compact Protein 125 ml
- Fresubin® PRO Drink 200 ml.

Ensure® Compact Protein 125 ml was removed from the Reimbursement List on 1 December 2024.

The protein content of all the submitted ONS was considered for this review however a number of ONS were considered outside the scope for identification as preferred high-protein ONS due to the specialised nature of the products. The MMP consider pre-thickened sip feeds to be outside the scope of this evaluation to identify preferred high-protein ONS:

- Fresubin® Thickened Level 2 200 ml
- Fresubin® Thickened Level 3 200 ml.

The MMP also consider disease-specific ONS to be outside the scope of this evaluation to identify preferred high-protein ONS. Therefore, the following submitted ONS was not considered as part of the review to identify preferred high-protein ONS:

- Supportan® Drink 200 ml.

The MMP evaluated eight individual high-protein ONS from four suppliers for consideration as preferred high-protein ONS (outlined in Table 3) under the five criteria. The MMP reviewed information as submitted by individual suppliers. In cases where further information or clarification was required, this was requested from individual suppliers as part of the evaluation process. The individual product datasheets that were provided by suppliers were referred to as part of this evaluation.

Table 3: High-protein ONS considered in the evaluation to identify preferred high-protein ONS

High-protein ONS*	Supplier	Reimbursement code	Pack size
Ensure® Plus Advance 220 ml	Abbott Nutrition	81482	1
Ensure® Plus HP 200 ml	Abbott Nutrition	82412	1
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	82771	1
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	82475	1
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	81121	1
Altraplen Protein 200 ml	Nualtra	82500	1
Cubitan® 200 ml	Nutricia	82430	1
Fortisip® Compact Protein 125 ml	Nutricia	85097	1

ml: millilitres
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List.

7.2.1 Reimbursement cost of the ONS

The reimbursement cost of high-protein ONS submitted as part of the *MMP evaluation for the identification of preferred high-protein oral nutritional supplement(s)* were considered under this criterion.

Table 4 outlines the reimbursement price for each high-protein ONS (per unit) considered as part of this evaluation. One submission received during the evaluation process included a revised conditional reimbursement price for a high-protein ONS listed in Table 4. This revised conditional reimbursement price was given due consideration during the evaluation process.

Table 4: Reimbursement prices of high-protein ONS considered in the evaluation

High-protein ONS*	Supplier	Reimbursement code	Pack size	Reimbursement price per unit **
Ensure® Plus Advance 220 ml	Abbott Nutrition	81482	1	€1.76
Ensure® Plus HP 200 ml	Abbott Nutrition	82412	1	€1.60
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	82771	1	€1.60
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	82475	1	€1.60
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	81121	1	€2.40
Altraplen Protein 200 ml	Nualtra	82500	1	€1.60
Cubitan® 200 ml	Nutricia	82430	1	€1.60
Fortisip® Compact Protein 125 ml	Nutricia	85097	1	€1.60

ml: millilitres
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List
**Reimbursement prices are correct as of 1 May 2025.

For comparison, the reimbursement prices of standard ONS included on List A are outlined in Table 5.

Table 5: **Reimbursement prices of standard ONS on List A**

Product*	Pack size	Reimbursement		
		Code	Price**	Price per unit**
Powdered ONS				
Aymes Shake 57 g sachet	7	83254	€4.69	€0.67
Aymes Shake 57 g sachet (starter pack with shaker)	6	83268	€4.44	€0.74
Aymes Shake Compact 57 g sachet	7	83265	€3.89	€0.56
Aymes Shake Compact 57 g sachet (starter pack with shaker)	6	83277	€4.44	€0.74
Aymes Shake Fibre 57 g sachet	7	83270	€5.74	€0.82
Aymes Shake Fibre 57 g sachet (starter pack with shaker)	5	83271	€4.10	€0.82
Complan Shake 57 g sachet	4	85100	€2.96	€0.74
Ensure Shake 57 g sachet	7	83258	€5.18	€0.74
Foodlink Complete 57 g sachet	7	85067	€5.18	€0.74
Foodlink Complete 57 g sachet (starter pack with shaker)	5	83248	€3.70	€0.74
Foodlink Complete with Fibre 63 g sachet	7	85068	€5.74	€0.82
Foodlink Complete with Fibre 63 g sachet (starter pack with shaker)	5	81114	€4.10	€0.82
Fresubin Powder Extra 62 g sachet	7	83236	€5.04	€0.72
Compact & mini-drink sip feeds				
Altraplen Compact 125 ml	1	82510	€1.38	€1.38
Ensure Compact 125 ml	1	83956	€1.38	€1.38
Fortisip Compact 125 ml	1	82530	€1.38	€1.38
Fortisip Compact Fibre 125 ml	1	82532	€1.38	€1.38
Fresubin 2 Kcal Mini Drink 125 ml	1	85069	€1.38	€1.38
Fresubin 2 Kcal Fibre Mini Drink 125 ml	1	85093	€1.38	€1.38

g: grams; ml: millilitres
*Listed alphabetically within each section, with product name as per HSE Reimbursement List
**Reimbursement prices are correct as of 1 May 2025

As outlined in Table 5, the reimbursement price of the six compact and mini-drink sip feeds on List A is €1.38 per unit, while the reimbursement prices of powdered ONS (per unit) are significantly less, ranging from €0.56 to €0.82 per unit.

Recommendation

In relation to the criterion of reimbursement cost of high-protein ONS, the MMP is of the opinion that high-protein ONS with a lower reimbursement cost per unit should be considered for inclusion in the preferred list (List A), once

all other criteria have also been satisfied. The reimbursement cost should be a key consideration when recommending a high-protein ONS for individuals.

Based on reimbursement cost, the MMP was unable to identify high-protein ONS for inclusion in the preferred list, List A.

7.2.2 Nutritional content of the ONS

The nutritional content of the high-protein ONS submitted as part of the *MMP evaluation for the identification of preferred high-protein oral nutritional supplement(s)* was considered under this criterion. Protein content of the high-protein ONS was the principle consideration. Energy and fibre content were also considered and micronutrient content including amino acids, minerals, and vitamins, were reviewed based on the information outlined in the submissions.

7.2.2.1 Protein content

Table 6 outlines the protein content for each high-protein ONS considered in this evaluation to identify preferred high-protein ONS.

Table 6: Protein content of each high-protein ONS considered in the evaluation

High-protein ONS*	Supplier	Protein (per unit)	% Energy from Protein
Ensure® Plus Advance 220 ml	Abbott Nutrition	20 g	24.3 %
Ensure® Plus HP 200 ml	Abbott Nutrition	15.8 g	25.3 %
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	18 g	24 %
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	20 g	27 %
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	20 g	20 %
Altraplen Protein 200 ml	Nualtra	20 g	26.5 %
Cubitan® 200 ml	Nutricia	17.6 g	28.4 %
Fortisip® Compact Protein 125 ml	Nutricia	18.3 g	24 %

g: grams; ml: millilitres
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List
Protein content listed as per product information provided by supplier as part of evaluation

For comparison, the powdered ONS available on List A Standard ONS have a similar protein content, ranging from 15.8 g to 19 g when mixed with 200 ml whole milk as per manufacturer's instructions. For the powdered ONS on List A that can be mixed with 100 ml whole milk as per manufacturer's instructions, the protein content ranges from

13.7 g to 15.4 g. The protein content of the compact and mini-drink sip feeds on List A Standard ONS ranges from 11.9 g to 12.8 g per bottle (Table 1).

7.2.2.2 Energy content

Table 7 outlines the energy content for each high-protein ONS considered in this evaluation to identify preferred high-protein ONS.

Table 7: Energy content of each high-protein ONS considered in the evaluation

High-protein ONS*	Supplier	Energy (per unit)	Energy density
Ensure® Plus Advance 220 ml	Abbott Nutrition	330 kcal	1.5 kcal/ml
Ensure® Plus HP 200 ml	Abbott Nutrition	250 kcal	1.25 kcal/ml
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	300 kcal	2.4 kcal/ml
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	300 kcal	1.5 kcal/ml
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	400 kcal	3.2 kcal/ml
Altraplen Protein 200 ml	Nualtra	300 kcal	1.5 kcal/ml
Cubitan® 200 ml	Nutricia	248 kcal	1.24 kcal/ml
Fortisip® Compact Protein 125 ml	Nutricia	306 kcal	2.4 kcal/ml

ml: millilitres; kcal: kilocalories
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List
Energy content listed as per product information provided by supplier as part of evaluation

For comparison, the energy content of the powdered ONS available on List A Standard ONS ranges from 374 kcal to 397 kcal when mixed with 200 ml whole milk as per manufacturers' instructions. For the powdered ONS on List A that can be mixed with 100 ml whole milk as per manufacturer's instructions, the energy content ranges from 317 kcal to 319 kcal. The energy content of the compact and mini-drink sip feeds on List A Standard ONS ranges from 250 kcal to 300 kcal per bottle (Table 1).

7.2.2.3 Fibre content

Table 8 outlines the fibre content for each high-protein ONS considered in this evaluation to identify preferred high-protein ONS.

Table 8: Fibre content of each high-protein ONS considered in the evaluation

High-protein ONS*	Supplier	Fibre (per unit)
Ensure® Plus Advance 220 ml	Abbott Nutrition	1.7 g
Ensure® Plus HP 200 ml	Abbott Nutrition	0 g
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	0 g
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	0/1† g
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	0.5 g
Altraplen Protein 200 ml	Nualtra	0 g
Cubitan® 200 ml	Nutricia	< 0.5 g
Fortisip® Compact Protein 125 ml	Nutricia	0 g

g: grams; ml: millilitres †chocolate flavour
*Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List
Fibre content listed as per product information provided by supplier as part of evaluation

There are fibre-enriched powdered ONS and compact/mini-drink sip feeds available on List A Standard ONS.

Suppliers submitted information in relation to protein, energy and fibre content of individual products. This included information relating to pressure ulcer healing, compliance, and the role of fibre in preventing and managing constipation.

7.2.2.4 Micronutrient content

The high-protein ONS considered in the evaluation contain a variety of micronutrients. Vitamin C, Vitamin D, Vitamin E, calcium and zinc are present in all the high-protein ONS under evaluation, in varying amounts, in the region of; Vitamin C (26 mg - 250 mg), Vitamin D (2.2 mcg - 13 mcg), Vitamin E (4 mg alpha-tocopherol equivalents (αTE) - 38 mg αTE), calcium (206 mg - 499 mg), and zinc (2.2 mg - 9 mg) per unit. Arginine, leucine and Vitamin A are present in some of the high-protein ONS under evaluation. One high-protein ONS under evaluation contains beta-hydroxy-beta-methylbutyrate (βHMB).

Individual suppliers submitted information in relation to the micronutrient content of their individual products. This included information on Vitamin D, calcium, leucine and βHMB relating to effects on skeletal muscle mass and strength; information on Vitamin D and calcium in relation to bone strength to prevent fractures and osteoporotic bone loss and information on Vitamin A, Vitamin C and Vitamin E, arginine, zinc and βHMB in relation to wound healing.

The role of calcium and vitamin D in the prevention of fractures and bone loss is well established. More robust evidence is required to define the role of micronutrients in wound healing (Vitamin A, Vitamin C, Vitamin E, arginine, zinc and βHMB) and in increasing skeletal muscle mass and strength (βHMB, leucine).

Recommendation

In relation to the criterion of nutritional content of high-protein ONS, and the comparison with List A standard powdered ONS in terms of energy and protein content, the MMP is of the opinion that there are products already included on List A Standard ONS that offer similar energy and protein content as the submitted high-protein ONS. There are also fibre enriched powdered ONS options available on List A.

The MMP note the range of macronutrient and micronutrient content within the high-protein ONS category and that there may be specific clinical requirements to meet individual patient needs. Therefore, based on the information available for review, the MMP recommends that the category of high-protein ONS should be reserved for patient cohorts where specific clinical requirements cannot be met with a List A Standard ONS.

7.2.3 Robustness of supply to the Irish Market

The robustness of supply of high-protein ONS to the Irish Market, as outlined by suppliers of high-protein ONS that were submitted as part of the *MMP evaluation for the identification of preferred high-protein oral nutritional supplement(s),* was considered. Due consideration was also given to current and future supply of the high-protein ONS to the Irish Market. Information submitted by suppliers in relation to robustness of supply of high-protein ONS to the Irish Market outlined various processes demonstrating their individual capacity to supply high-protein ONS to the Irish Market.

In relation to the evidence of a suppliers' capacity to meet the ongoing needs of Irish patients, the MMP considered the market share of the high-protein ONS submitted as part of this evaluation. This involved an analysis of the PCRS pharmacy claims database. This analysis showed that in June 2024, Fortisip® Compact Protein had the highest market share of the high-protein ONS considered in the evaluation on the CDS, followed by Cubitan®.[12]

Recommendation

In relation to the criterion of robustness of supply of high-protein ONS to the Irish Market, the MMP is of the opinion that that there is a similar offering provided by suppliers of the high-protein ONS under consideration. The MMP is of the opinion that if preferred high-protein ONS are identified, it is preferable to have more than one supplier for the preferred high-protein ONS to mitigate potential risks from supply issues with an individual supplier.

7.2.4 Patient factors

Patient factors were considered as part of the *MMP evaluation for the identification of preferred high-protein ONS.* Due consideration was given to the following patient factors:

- range of flavours of the high-protein ONS, and
- volume of the high-protein ONS per unit.

7.2.4.1 Range of flavours of the high-protein ONS

The high-protein ONS considered in this evaluation are available in a variety of flavours, ranging from two flavours (Ensure® Plus HP 200 ml and Altraplen Protein 200 ml) to nine flavours (Fortisip® Compact Protein 125 ml). Powdered ONS and compact and mini-drink sip feeds on List A are also available in a variety of flavours.

7.2.4.2 Volume of the high-protein ONS

The high-protein ONS considered in this evaluation are available in presentations of 125 ml, 200 ml or 220 ml. Compact and mini-drink sip feeds on List A are available in a 125 ml presentation. There are powdered ONS on List A that can be mixed with 100 ml or 200 ml whole milk as per the manufacturers' instruction.

Suppliers submitted information in relation to product volume and available flavours for their products. This included information in relation to the benefits of higher volume (200 ml, 220 ml) and lower volume (125 ml) products, with higher volume contributing to a patient's fluid requirements and reducing risk of dehydration and lower volume increasing compliance. Information was also provided on the availability of additional flavours to enhance compliance in oncology patients.

7.2.4.3 Acceptability and compliance

For ONS to be included on the HSE Reimbursement List, they must have satisfied the criteria in accordance with the relevant PCRS guidelines in place at the time of their addition to the reimbursement list. The current guidelines *HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers (October 2024)*[8] includes the criteria for acceptability and compliance studies to be satisfied. Therefore, this information was not considered as part of the evaluation.

Recommendation

In relation to the criterion of patient factors, the volume and range of flavours of the high-protein ONS were considered. The MMP is of the opinion that it is preferable to have a variety of flavours and volumes available for patient choice.

7.2.5 Any other relevant factors

Any other relevant factors that were appropriate to consider as part of the *MMP evaluation for the identification of preferred high-protein oral nutritional supplement(s),* were included under this criterion. Due consideration was given to:

- submissions received from HCP organisations, and
- provision of a sampling service for the high-protein ONS.

7.2.5.1 Submissions received from HCP organisations

Submissions were received from HCP organisations during the consultation process. These submissions outlined a number of themes. For example, new estimates of malnutrition prevalence were provided indicating an increase nationally. Information was also provided on the National Malnutrition Screening Survey 2023. The need for continued availability of a range of products with a high-protein content to meet the breadth of patient needs was also outlined.

Due consideration was given to these submissions throughout the evaluation.

7.2.5.2 Sampling service

As part of the evaluation process individual suppliers outlined the following information regarding the provision of a free of charge sampling service for ONS, when samples are ordered by healthcare professionals for patients.

Abbott Nutrition

- **Ensure® Plus Advance 220 ml, Ensure® Plus HP 200 ml**

Abbott Nutrition outlined that they provide a next day delivery service for sampling packs of Ensure® Plus Advance and Ensure® Plus HP to patients.

Fresenius Kabi Ltd

- **Fresubin® PRO Compact Drink 125 ml, Fresubin® Protein Energy 200 ml, Fresubin® 3.2 Kcal 125 ml**

Fresenius Kabi Ltd outlined that they provide a sampling service for ONS via the website fresubinsamples.ie. Clinicians can order up to eight samples which can be delivered directly to the patient or to the clinician's place of work within 1-2 working days. Patient information leaflets are included with each sample order.

Nualtra

- **Altraplen Protein 200 ml**

Nualtra outlined that they offer a next day delivery service for direct-to-patient samples of Altraplen Protein via an online sample service nualtra.com/get-samples. HCPs can use this service to get samples delivered straight to

patients' homes. The service offers starter packs only. HCPs can also order specific flavours or starter packs to keep a stock of samples to give to patients directly.

Nutricia

- **Cubitan® 200 ml, Fortisip® Compact Protein 125 ml**

Nutricia outlined that they provide a sampling service for both Cubitan® 200 ml and Fortisip® Compact Protein 125 ml which enables HCPs to request a selection of flavours of a product to be provided to a patient, for the purposes of professional evaluation. Product samples can be delivered directly to the patient in their home the next day, or to the HCP to provide to the patient in their healthcare institution.

Recommendation

In relation to the criterion of other relevant factors, consideration was given to information submitted by HCP organisations throughout the evaluation process. Consideration was also given to information provided by suppliers regarding the provision of a patient sampling service for the high-protein ONS.

In relation to the provision of a sampling service for the high-protein ONS by the supplier, which allows patients to trial an ONS or different flavours, the MMP is of the opinion that there is a similar offering of such services available by the suppliers for the high-protein ONS under evaluation.

8. Clinical guidelines and recommendations

There is currently no national clinical guideline published in Ireland relating specifically to the use of high-protein ONS.

8.1 HSE National Wound Management Guidelines 2018

The nutritional requirements for optimal healing of all wounds are outlined in the HSE National Wound Management Guidelines (2018).[13] Of note, the guidelines state that due to lack of evidence for other wound types in clinical practice, nutritional requirements for pressure ulcers are typically used in the management of all non-healing wounds. The guidelines recommend the following in relation to ONS:

- For patients with established deficiency and pressure ulcers, offer fortified foods and/or high-calorie, high-protein ONS between meals if nutritional requirements cannot be achieved by dietary intake.
  NPUAP/EPUAP/PPPIA Recommendation: Strength of Evidence = B; Strength of Recommendation = Strong positive recommendation (NPUAP/EPUAP/PPPIA 2014:81)

In relation to nutritional status and the treatment of pressure ulcers, the guideline recommendations include:

- Consider using a supplement that contains high protein, arginine and micronutrients for adults who are malnourished with a pressure ulcer Category/Stage III or IV or multiple ulcers for at least eight weeks. *HSE Recommendation Evidence Grade: A*
- Do not offer nutritional supplements to treat a pressure ulcer in adults whose nutritional intake is adequate. *HSE Recommendation Evidence Grade: C*

Please refer to Appendix F for the process explaining the grading of evidence used in these guidelines.

8.2 ESPEN Guideline on Nutritional Support for Polymorbid Medical Inpatients 2023

This European Society for Clinical Nutrition and Metabolism (ESPEN) guideline provides 32 practical and non-disease specific recommendations to guide clinicians treating polymorbid patients hospitalised in medical wards.[14] For the purpose of this guideline, polymorbidity (also known as multimorbidity), is defined as the co-occurrence of at least two chronic health conditions in the same person.

In relation to high-protein ONS, the guideline states:

- In malnourished polymorbid medical inpatients or those at high risk of malnutrition, high-protein nutrient specific ONS should be administered, when they may help maintain functional status and muscle mass, reduce mortality and improve quality of life (QoL). *Grade of recommendation: B (Strong consensus 96% agreement).*

With regard to wound-specific ONS, the guideline states that the results of provisional studies examining their effectiveness in polymorbid patients in a rehabilitation setting are interesting and promising, however the available studies remain limited.

- In polymorbid medical inpatients with pressure ulcers, specific amino-acids (arginine and glutamine) and HMB can be added to oral/enteral feeds to accelerate the healing of pressure ulcers. *Grade of recommendation 0 (Strong consensus 92% agreement).*

Please refer to Appendix F for the process explaining the grading of evidence used in these guidelines.

8.3 European Pressure Ulcers Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: The International Guideline. EPUAP/NPIAP/PPPIA: 2019

The European Pressure Ulcer Advisory Panel (EPUAP), the National Pressure Injury Advisory Panel (NPIAP), and the Pan Pacific Pressure Injury Alliance (PPPIA) collaborated to produce an evidence-based guideline on the prevention and treatment of pressure injuries.[15]

With regards to nutritional supplementation specifically, the guideline recommendations include:

- Offer high-calorie, high-protein fortified foods and/or nutritional supplements in addition to the usual diet for adults who are at risk of developing a pressure injury and who are also malnourished or at risk of malnutrition, if nutritional requirements cannot be achieved by normal dietary intake. *(Strength of Evidence = C; Strength of Recommendation = Weak positive recommendation).*
- Offer high-calorie, high-protein nutritional supplements in addition to the usual diet for adults with a pressure injury who are malnourished or at risk of malnutrition, if nutritional requirements cannot be achieved by normal dietary intake. *(Strength of Evidence = B1; Strength of Recommendation = Strong positive recommendation).*
- Provide high-calorie, high-protein, arginine, zinc and antioxidant ONS or enteral formula for adults with a Category/Stage II or greater pressure injury who are malnourished or at risk of malnutrition. *(Strength of Evidence = B1; Strength of Recommendation = Weak positive recommendation).*

Please refer to Appendix F for the process explaining the grading of evidence used in these guidelines.

8.4 INDI Nutrition Support Reference Guide 2022

Chapter 17 – Nutrition and Wound Healing

The guideline recommends to provide high-protein, arginine, zinc and antioxidant ONS or enteral formula for adults with a Category/Stage II or greater pressure injury who are malnourished or at risk of malnutrition.[16]

- Improvement in healing should be seen between two and three weeks of commencing a high-protein, arginine, zinc and antioxidant ONS, but supplementation for at least eight weeks is recommended.
- Caution should be taken when using arginine containing supplements with patients in intensive care units.

8.5 Summary of clinical guidelines and recommendations

There is currently no national clinical guideline published in Ireland relating specifically to the use of high-protein ONS. The submitted clinical guidelines relate to the management of wounds, pressure ulcers and risk of malnutrition/malnutrition in polymorbid inpatients. The general consensus for patients with established deficiency and pressure ulcers, is to offer fortified foods and/or high-calorie, high-protein ONS between meals if nutritional requirements cannot be achieved by dietary intake. With regard to wound-specific ONS, the ESPEN guideline states that provisional studies examining the impact of wound-specific ONS to support wound healing in polymorbid inpatients in a rehabilitation setting are interesting and promising, however studies remain limited. The MMP note that the ESPEN guideline relates to the inpatient setting rather than the community setting.

In relation to nutritional status and the treatment of pressure ulcers, HSE and EPUAP/NPIAP/PPPIA guidelines recommend considering the use of a supplement that contains high protein, arginine and micronutrients for adults

who are malnourished with a pressure ulcer Category/Stage III or IV or multiple ulcers. Nutritional supplements are not recommended to treat pressure ulcers in adults whose nutritional intake is adequate.

9. MMP recommendations

Following review of the submissions received in accordance with the criteria outlined in the roadmap, the MMP is currently unable to identify preferred high-protein ONS.

The MMP recommends that high-protein ONS be added to List B (non-preferred ONS). The scope of the reimbursement application system in place for non first-line standard ONS should be broadened to include high-protein ONS, which will require prior approval for reimbursement on the CDS.

The high-protein ONS recommended for addition to List B are outlined in Table 9.

Table 9: High-protein ONS recommended for addition to List B

High-protein ONS*	Supplier	Reimbursement code	Pack size
Ensure® Plus Advance 220 ml	Abbott Nutrition	81482	1
Ensure® Plus HP 200 ml	Abbott Nutrition	82412	1
AYMES® ActaSolve® Protein Compact 57 g sachet	Aymes International Ltd	83272	7
AYMES® ActaSolve® Protein Compact 57 g sachet (starter pack with shaker)	Aymes International Ltd	85032	5
Fresubin® PRO Compact Drink 125 ml	Fresenius Kabi Ltd	82771	1
Fresubin® PRO Drink 200 ml	Fresenius Kabi Ltd	82772	1
Fresubin® Protein Energy 200 ml	Fresenius Kabi Ltd	82475	1
Fresubin® 3.2 Kcal 125 ml	Fresenius Kabi Ltd	81121	1
Altraplen Protein 200 ml	Nualtra	82500	1
Altraplen Protein Daily 250 ml	Nualtra	85033	1
Cubitan® 200 ml	Nutricia	82430	1
Fortisip® Compact Protein 125 ml	Nutricia	85097	1
Fortisip® Extra 200 ml	Nutricia	85092	1

g: grams; ml: millilitres *Listed alphabetically by supplier name and then alphabetically by name as appears on the HSE Reimbursement List

HSE-Primary Care and the MMP have previously published the *Standard ONS First-line Prescribing List for Adults Living in the Community (2017, updated April 2019)*. This list identified ONS to be included on the First-line Prescribing List (List A). There are products on List A that have similar energy and protein content to high-protein ONS, with a significantly lower reimbursement cost, i.e. List A powdered ONS. Therefore, List A powdered ONS should be considered first-line where appropriate for adults living in the community.

The MMP note that new estimates of malnutrition prevalence indicate an increase nationally, which will likely lead to increased demand for supports to manage this patient cohort. In light of this, and to optimise the resources available to the HSE, the MMP recommends that List A powdered ONS should be considered first-line where appropriate for adults living in the community.

Powdered ONS are suitable for patients who require energy and protein supplementation. Powdered ONS offer patient choice in terms of the variety of flavour and volume options available. Powdered ONS require lower storage space compared with ready-to-drink sip feeds, and are reconstituted with fresh whole milk. As such, powdered ONS offer benefits to the health service and flexibility in terms of individual patient requirements.

A collaborative approach involving clinicians, dietitians, pharmacists, patients and the health service will be required to support utilisation of powdered ONS on List A. Implementation of this recommendation will lead to savings for the health service while continuing to enable access to non-preferred ONS for patient cohorts where specific clinical requirements cannot be met with List A ONS.

Disease-specific ONS and pre-thickened ONS with a high-protein content were considered to be outside the scope of this evaluation to identify preferred high-protein ONS. The MMP will continue to monitor utilisation of these products on the CDS and a further review may be undertaken.

10. References

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International Guideline. Emily Haesler (Ed.). EPUAP/NPIAP/PPPIA: 2019. Available from: https://internationalguideline.com/2019 [Accessed on 03/04/2025].

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11. Appendices

Appendix A: Standard ONS List A

(As per HSE Reimbursement List on 1 May 2025)

Reimbursement code	Product	Pack size
Powdered ONS		
83254	Aymes Shake 57 g sachet	7
83268	Aymes Shake 57 g sachet (starter pack with shaker)	6
83265	Aymes Shake Compact 57 g sachet	7
83277	Aymes Shake Compact 57 g sachet (starter pack with shaker)	6
83270	Aymes Shake Fibre 57 g sachet	7
83271	Aymes Shake Fibre 57 g sachet (starter pack with shaker)	5
85100	Complan Shake 57 g sachet	4
83258	Ensure Shake 57 g sachet	7
85067	Foodlink Complete 57 g sachet	7
83248	Foodlink Complete 57 g sachet (starter pack with shaker)	5
85068	Foodlink Complete with Fibre 63 g sachet	7
81114	Foodlink Complete with Fibre 63 g sachet (starter pack with shaker)	5
83236	Fresubin Powder Extra 62 g sachet	7
Compact & mini-drink sip feeds		
82510	Altraplen Compact 125 ml	1
83956	Ensure Compact 125 ml	1
82530	Fortisip Compact 125 ml	1
82532	Fortisip Compact Fibre 125 ml	1
85069	Fresubin 2 KCal Mini Drink 125 ml	1
85093	Fresubin 2 KCal Fibre Mini Drink 125 ml	1

Appendix B: Standard ONS List B

(As per HSE Reimbursement List on 1 May 2025)

Reimbursement code	Product	Pack Size
85153	Altrajuce 200 ml	1
81776	Calshake 87 g sachet	7
83023	Enshake 96.5 g sachet	6
81485	Ensure 250 ml	1
81315	Ensure Crème Protein 125 g	1
81165	Ensure Plus 200 ml	1
83030	Ensure Plus Crème 125 g	1
81688	Ensure Plus Fibre 200 ml	1
83954	Ensure Plus Juce 220 ml	1
81153	Ensure Plus Yoghurt Style 220 ml	1
82501	Ensure TwoCal 200 ml	1
81342	Foodlink Extra Sachet 85 g	7
81343	Foodlink Extra Sachet 85 g (starter pack with shaker)	4
81152	Forticreme Complete 125 g	1
83710	Fortijuce 200 ml	1
85070	Fortisip 2 Kcal 200 ml	1
81170	Fortisip 200 ml	1
81316	Fortisip PlantBased 1.5Kcal 200 ml	1
81173	Fortisip Yoghurt Style 200 ml	1
82519	Fresubin 2 Kcal 200 ml	1
83959	Fresubin 2 Kcal Crème 125 g	1
82524	Fresubin 2 Kcal Fibre 200 ml	1
81180	Fresubin Energy 200 ml	1
81615	Fresubin Energy Fibre 200 ml	1
83712	Fresubin Jucy 200 ml	1
82341	Fresubin Original 200 ml	1
83961	Nutilis Fruit Level 4 150 g	1
83958	Nutilis Fruit Stage 3 150 g	1
83065	Nutricrem 125 g	1
81608	Nutrison Energy Multi Fibre 200 ml	1
83206	Scandishake Mix 85 g sachet	6

Appendix C: Initial roadmap published

HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s)

The HSE-Medicines Management Programme (MMP) provides sustained national leadership in relation to safe, effective and cost-effective prescribing. Oral nutritional supplements (ONS) are available under the Community Drug Schemes (CDS), as they are included on the Health Service Executive-Primary Care Reimbursement Service (HSE-PCRS) list of reimbursable items.

For ONS to be included on the list of reimbursable items, they must satisfy the criteria as outlined in the *HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers,* at the time of their application. This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.

HSE-Primary Care and MMP have previously published a *Standard ONS First-line Prescribing List for Adults Living in the Community*. On 1st July 2019, changes to the reimbursement of standard ONS on the CDS were introduced in line with the Prescribing List. High-protein ONS were outside the scope of this process.

According to MMP analysis, there has been an increase in utilisation of and total expenditure[ii] on high-protein ONS on the CDS over the last 4.5 years. The estimated total monthly expenditure increased from approximately €0.49 million in July 2019 to approximately €1.39 million in December 2023. The number of patients in receipt of high-protein ONS on a monthly basis increased from approximately 6,200 to approximately 16,500 over the same time period.

Evaluation Process

The MMP will undertake an evaluation to identify preferred high-protein ONS. Following the review, measures will be implemented to ensure appropriate and cost-effective prescribing of high-protein ONS.

A number of criteria relevant to high-protein ONS may be considered by the MMP in identifying the preferred high-protein ONS, including:

1. Reimbursement cost of the ONS
2. Nutritional content of the ONS
3. Robustness of supply to the Irish market
4. Patient factors
5. Any other relevant factors

Work Plan

The MMP will commence work on the identification of the preferred high-protein ONS using the process as outlined in this roadmap. This involves a consultation period where submissions are invited from all relevant stakeholders, including the suppliers of high-protein ONS. This process will include ONS with a high-protein content, which are not currently included on List A or List B Standard ONS. Products on the HSE-PCRS list of reimbursable items, or those that are the subject of an application for addition to the list of reimbursable items submitted to the HSE by close of business on 6th February 2024 will be considered in the review. In addition, the high-protein ONS must be available for supply to the Irish market.

Submissions can be emailed to mmp@hse.ie. Alternatively, the MMP can provide access to a secure file transfer system for submissions; please contact the MMP for further details. The MMP will issue confirmation of receipt of submission within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

[ii] Total expenditure includes ingredient cost and pharmacy fee, based on claims submitted by pharmacists.

The consultation period will open on 7th February 2024. The closing date for submissions is 6th March 2024 at 1pm.

Following consideration of submissions and internal review, the MMP will publish a recommendation in relation to high-protein ONS. The MMP will then engage with all stakeholders to introduce measures to support the implementation of the recommendation.

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Appendix D: Updated roadmap published

HSE-MMP roadmap for the identification of preferred high-protein oral nutritional supplement(s)

The HSE-Medicines Management Programme (MMP) provides sustained national leadership in relation to safe, effective and cost-effective prescribing. Oral nutritional supplements (ONS) are available under the Community Drug Schemes (CDS), as they are included on the Health Service Executive-Primary Care Reimbursement Service (HSE-PCRS) list of reimbursable items.

For ONS to be included on the list of reimbursable items, they must satisfy the criteria as outlined in the *HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers,* at the time of their application. This process is underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.

HSE-Primary Care and MMP have previously published a *Standard ONS First-line Prescribing List for Adults Living in the Community*. On 1st July 2019, changes to the reimbursement of standard ONS on the CDS were introduced in line with the Prescribing List. High-protein ONS were outside the scope of this process.

According to MMP analysis, there has been an increase in utilisation of and total expenditure[iii] on high-protein ONS on the CDS over the last 4.5 years. The estimated total monthly expenditure increased from approximately €0.49 million in July 2019 to approximately €1.39 million in December 2023. The number of patients in receipt of high-protein ONS on a monthly basis increased from approximately 6,200 to approximately 16,500 over the same time period.

Evaluation Process

The MMP will undertake an evaluation to identify preferred high-protein ONS. Following the review, measures will be implemented to ensure appropriate and cost-effective prescribing of high-protein ONS.

A number of criteria relevant to high-protein ONS may be considered by the MMP in identifying the preferred high-protein ONS, including:

1. Reimbursement cost of the ONS
2. Nutritional content of the ONS
3. Robustness of supply to the Irish market
4. Patient factors
5. Any other relevant factors

Work Plan

The MMP will commence work on the identification of the preferred high-protein ONS using the process as outlined in this roadmap. This involves a consultation period where submissions are invited from all relevant stakeholders, including the suppliers of high-protein ONS. This process will include ONS with a high-protein content, which are not currently included on List A or List B Standard ONS. Products on the HSE-PCRS list of reimbursable items, or those that are the subject of an application for addition to the list of reimbursable items submitted to the HSE by close of business on 6th February 2024 will be considered in the review. In addition, the high-protein ONS must be available for supply to the Irish market.

Submissions can be emailed to mmp@hse.ie. Alternatively, the MMP can provide access to a secure file transfer system for submissions; please contact the MMP for further details. The MMP will issue confirmation of receipt of submission within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

[iii] Total expenditure includes ingredient cost and pharmacy fee, based on claims submitted by pharmacists.

The consultation period will open on 7th February 2024. The closing date for submissions is 9th April 2024 at 1pm.

Following consideration of submissions and internal review, the MMP will publish a recommendation in relation to high-protein ONS. The MMP will then engage with all stakeholders to introduce measures to support the implementation of the recommendation.

References

1. HSE-Medicines Management Programme (MMP). Oral nutritional supplements. Available: https://www.hse.ie/eng/about/who/cspd/ncps/medicines-management/oral-nutritional-supplements/
2. HSE-Primary Care Reimbursement Service (PCRS) list of reimbursable items. Available: https://www.hse.ie/eng/staff/pcrs/items/
3. HSE-Primary Care Reimbursement Service (PCRS) database analysis – Utilisation and total expenditure on high-protein ONS. On file.
4. HSE-Primary Care Reimbursement Service (PCRS) Clinical Nutritional Products. Guidelines for Manufacturers/ Distributors/ Suppliers V3 December 2023. Available: https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-primary-care-reimbursement-service-pcrs-clinical-nutritional-products-reimbursement-guidelines-for-manufacturersdistributors/

Appendix E: Identification of preferred high-protein oral nutritional supplement(s): Cover Page for Submissions

For all submissions relating to a particular high-protein oral nutritional supplement (ONS), section A must be completed and included as the cover page for the submission. All high-protein ONS included in the submission must be listed in the table below.

In addition, suppliers of high-protein ONS must also complete section B, and include as the cover page for the submission.

Section A:

Product name	PCRS reimbursement code

Section B:

I, the undersigned, confirm compliance with the HSE-PCRS Clinical Nutritional Products Guidelines for Manufacturers/Distributors/Suppliers 2023[iv] *(or previous versions). I also confirm that distribution arrangements are in place to enable all products listed in the table in section A to be dispensed by a pharmacist.*

Managing Director Signature: _____

Managing Director Name: _____

Company name: _____

Date of submission: _____

Submissions can be emailed to mmp@hse.ie. Alternatively, the MMP can provide access to a secure file transfer system for submissions, please contact the MMP for further details. The MMP will issue confirmation of receipt of submission within 72 hours. Please contact the MMP if you do not receive confirmation of receipt after this time.

[iv] HSE-Primary Care Reimbursement Service (PCRS) Clinical Nutritional Products. Guidelines for Manufacturers/ Distributors/ Suppliers V3 December 2023. Available: https://www2.healthservice.hse.ie/organisation/national-pppgs/hse-primary-care-reimbursement-service-pcrs-clinical-nutritional-products-reimbursement-guidelines-for-manufacturersdistributors/

Appendix F: Grading of evidence used in submitted clinical guidelines
HSE National Wound Management Guidelines 2018

The recommendations in this guideline originate either directly from existing guidelines or were formulated by members of the Guideline Review Group, based on evidence gathered in response to PICO (population, intervention, comparison and outcome) questions posed. As per ADAPTE (2009) guidance for documents of this nature, an original grading scheme was developed and used to grade all recommendations, except recommendations in the pressure ulcer section which unless otherwise stated, were graded using the NPUAP/EPUAP/PPPIA (2014)* grading scheme.

The process used for grading the evidence throughout this guideline (except the pressure ulcer section) is as follows:

Level of Evidence	Source of the Evidence
A	Data derived from multiple randomised clinical trials (RCTs) or meta-analysis.
B	Data derived from a single RCT or large non-randomised studies.
C	Recommendation comes directly from an existing guideline.
D	Consensus of expert opinion and/or small studies, retrospective studies, registries.

This grading system was devised by members of the Guideline Review Group, and recommendations graded using this system are denoted as "HSE Recommendation Evidence Grade: A, B, C or D".

*The NPUAP/EPUAP/PPPIA 2014 grading scheme is outlined below:

Strengths of Evidence	
A	• The recommendation is supported by direct scientific evidence from properly designed and implemented controlled trials on pressure ulcers in humans (or humans at risk for pressure ulcers), providing statistical results that consistently support the recommendation (Level 1 studies required).
B	• The recommendation is supported by direct scientific evidence from properly designed and implemented clinical series on pressure ulcers in humans (or humans at risk for pressure ulcers) providing statistical results that consistently support the recommendation. (Level 2, 3, 4, 5 studies)
C	• The recommendation is supported by indirect evidence (e.g., studies in healthy humans, humans with other types of chronic wounds, animal models) and/or expert opinion.

Strengths of Recommendation	
👍👍	Strong positive recommendation: Definitely do it
👍	Weak positive recommendation: Probably do it
👈	No specific recommendation
👎	Weak negative recommendation: Probably don't do it
👎👎	Strong negative recommendation: Definitely don't do it

**National Pressure Ulcer Advisory Panel, European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers: Clinical Practice Guideline. Emily Haesler (Ed.). Cambridge Media: Osborne Park, Western Australia; 2014*

ESPEN Guideline on Nutritional Support for Polymorbid Medical Inpatients 2023

The process used for grading the evidence throughout this guideline is as follows:

Levels of evidence (SIGN grading system):

1++ High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias

1+ Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias

1- Meta-analyses, systematic reviews, or RCTs with a high risk of bias

2++ High quality systematic reviews of case control or cohort or studies. High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal

2+ Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal

2- Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal

3 Non-analytic studies, e.g. case reports, case series

4 Expert opinion

Grades and forms of recommendations (SIGN grading system):

a. Grades of recommendation

A At least one meta-analysis, systematic review, or RCT rated as 1 ++, and directly applicable to the target population; or a body of evidence consisting principally of studies rated as 1 +, directly applicable to the target population, and demonstrating overall consistency of results

B A body of evidence including studies rated as 2 ++, directly applicable to the target population; or a body of evidence including studies rated as 2 +, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1 ++ or 1 +

0 Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2 ++ or 2 +

GPP Good practice points/expert consensus: Recommended best practice based on the clinical experience of the guideline development group

b. Forms of recommendation

Judgment	Recommendation
Undesirable consequences clearly outweigh desirable consequences	Strong recommendation against
Undesirable consequences probably outweigh desirable consequences	Conditional recommendation against
Balance between desirable and undesirable consequences is closely balanced or uncertain	Recommendation for research and possibly conditional recommendation for use restricted to trials
Desirable consequences probably outweigh undesirable consequences	Conditional recommendation for
Desirable consequences clearly outweigh undesirable consequences	Strong recommendation for

European Pressure Ulcers Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: The International Guideline. EPUAP/NPIAP/PPPIA: 2019

The process used for grading the evidence throughout this guideline is as follows:

Strengths of Evidence	
A	• More than one high quality Level I study providing direct evidence • Consistent body of evidence
B1	• Level 1 studies of moderate or low quality providing direct evidence • Level 2 studies of high or moderate quality providing direct evidence • Most studies have consistent outcomes and inconsistencies can be explained
B2	• Level 2 studies of low quality providing direct evidence • Level 3 or 4 studies (regardless of quality) providing direct evidence • Most studies have consistent outcomes and inconsistencies can be explained
C	• Level 5 studies (indirect evidence) e.g., studies in normal human subjects, humans with other types of chronic wounds, animal models • A body of evidence with inconsistencies that cannot be explained, reflecting genuine uncertainty surrounding the topic
GPS	**Good Practice Statement** • Statements that are not supported by a body of evidence as listed above but considered by the Guideline Governance Group to be significant for clinical practice.

Strengths of Recommendation	
↑↑	Strong positive recommendation: Definitely do it
↑	Weak positive recommendation: Probably do it
↔	No specific recommendation
↓	Weak negative recommendation: Probably don't do it
↓↓	Strong negative recommendation: Definitely don't do it