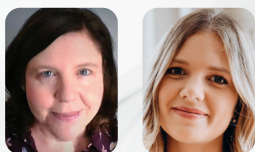


ACBS Consultation on Oral Nutritional Supplements



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Nutritional products, such as Oral Nutritional Supplements (ONS), are included as a key part of management strategies in the treatment and prevention of malnutrition.¹

Dietitians are ideally placed to lead on recommendations for the prescribing of nutritional products, ensuring continuity of care and cost-effective management of malnutrition across all care settings. It is important that dietitians have full access to a wide range of prescribed products in order to meet patients' differing nutritional and clinical needs.

On 19th April (2021), an open consultation document outlining proposed changes to the Advisory Committee for Borderline Substances (ACBS) policy on liquid (often referred to as ready-to-drink [RTD]) ONS was published by the UK Government.² Dietitians should be made aware of this consultation document as these changes will have an impact on dietetic prescribing practices, and on the management of malnutrition in their patients.

This article will highlight the importance of ONS in the treatment of disease-related malnutrition and explain the role of the ACBS in the prescribing of borderline substances for use in NHS primary care. We will also discuss key considerations for dietitians relating to the recently published ACBS open consultation on ONS before concluding with information on how healthcare professionals (HCPs) can engage in the consultation process.

Keeping the spotlight on malnutrition

It is estimated that more than 3 million people in the United Kingdom (UK) are malnourished or at risk of malnutrition.³ If not effectively managed, malnutrition can lead to physical and functional decline, poorer clinical outcomes and greater healthcare use.^{1, 4} If not treated effectively in the primary care setting, malnutrition can extend to other settings – for example, around 29% of adults admitted to UK hospitals are malnourished or at risk of malnutrition.⁵

The cost of malnutrition in the UK is estimated at £23.5 billion,¹ representing more than 15% of the total expenditure of health and social care.³ The cost of treating a malnourished patient is more than 2-3 times greater than treating a well-nourished patient, driven largely by poorer outcomes leading to increased healthcare needs.³

However, the prescribing costs for ONS remain low.^{1, 6} Subsequently, identifying, preventing and addressing malnutrition has potential benefits in terms of patient outcomes and healthcare cost-savings.^{3, 7}

The dietitian's role

Dietitians possess the necessary expertise to identify, assess, manage, monitor, and review individuals to achieve patient-centred outcomes for the prevention and treatment of malnutrition.⁸ As such, they should have professional freedom and autonomy to be able to make the best choices for their patients. This includes determining the most suitable ONS products. Dietitians are best-placed to use ONS products appropriately and effectively, reducing inappropriate ONS prescriptions in primary care by 30%.⁹

Not all patients at risk of malnutrition will need to see a dietitian. However, dietitians play a crucial role in leading the implementation of appropriate evidence-based malnutrition management pathways (such as the *Managing Adult Malnutrition in the Community Pathway*),¹⁰ in order to support GPs and other primary care professionals to effectively address malnutrition through early intervention.

Funding of additional dietetic posts in primary care to support such activities is available via the Additional Roles Reimbursement Scheme by which GPs can apply for specific funding to support recruitment within Primary Care Networks (PCNs).¹¹ This recent scheme is re-shaping the way primary care services are delivered, based on local population needs (including frailty and other conditions that may be associated with malnutrition). The British Dietetic Association (BDA) is supporting this with activities to highlight the positive impact of dietitians in primary care.⁹

Evidence-based benefits of ONS

ONS are a clinically and cost-effective way of managing disease-related malnutrition, with the vast majority of the evidence being for RTD ONS (see **Table 1**).^{1, 4, 7, 12}

An introduction to ACBS

The Advisory Committee on Borderline Substances (ACBS), established in 1971, is responsible for advising on the prescribing of nutritional (and dermatological) products for use in NHS primary care. The ACBS reviews applications for borderline substances (i.e. those specially formulated by manufacturers to manage medical conditions) and assesses

their efficacy, safety and pricing. Products approved and recommended by the ACBS are listed in Part XV of the Drug Tariff.

Nutrition borderline substances on prescription

Prescribed nutritional borderline substances (NBS) (including ONS) are often referred to within legal frameworks as Medical Foods, or Foods for Special Medical Purposes (FSMPs). They are *'specialised foods designed for the dietary management of patients, including those affected by, or at risk of, malnutrition, due to a disease, disorder or medical condition whose dietary management cannot safely, practically or for clinical reasons be achieved by modification of the normal diet alone'*.²³

For reimbursement purposes, FSMPs are defined as NBS and are approved for reimbursement in the community by the ACBS. NBS are typically prescribed in the same manner as other prescription drugs – by HCPs registered as independent or supplementary prescribers. There are a range of factors which must be taken into consideration when devising the nutritional management of a patient, including their medical condition, nutritional and fluid needs, appetite, presence of dysphagia or other limitations on physical capabilities, as well as the patient's preferences in terms of taste and style of ONS.

Unlike most prescribed drugs, palatability and choice of ONS products is critical in meeting different patient preferences and supporting patient compliance and, as such, dietitians require access to a wide range of different product styles, flavours and volumes.^{24, 25, 26}

Overview of the ACBS consultation

The ACBS has launched an open consultation on proposed changes to their policy on liquid ONS listed in part XV of the Drug Tariff. The proposed changes cover:²

- The standardisation of pack sizes of ready-to-drink (RTD) ONS to 125 ml and 200 ml. The ACBS states this will improve prescribing and reduce prescribing errors
- Restricting the presentation of the same RTD ONS formulation to one size only. The ACBS states that there is no need for the same ONS product to be presented in more than one volume
- Restricting the clinical indications of RTD ONS providing 1 kcal/ml to intestinal failure only
- Removing RTD ONS products manufactured or marketed to provide daily requirements in one bottle; unless they are presented in one of the standardised sizes (125 ml or 200 ml), provide a minimum of 500 kcals per bottle, and provide all other nutrients in appropriate amounts
- Removing the use of the word 'complete' in brand names and product descriptions (e.g. on pack or in HCP data cards)
- Removing the use of the word 'fibre' in brand names and product descriptions (e.g. on pack or in HCP data cards).

Clinicians, manufacturers and other interested parties are invited to respond to the consultation by completing a survey (see later section for website link), which closes at **11.45 pm on 27 June 2021**. It is crucial that dietitians present their views on these proposed changes.

Table 1: Reported clinical benefits of ONS

Clinical outcomes	Reduction in clinical complications (e.g. pressure ulcers, poor wound healing, infections) and reduced mortality (in acutely ill older people), fewer hospital readmissions, and shorter length of stay. ^{7, 13, 14, 15, 16} Improved body weight and reduction of malnutrition risk in community settings. ⁷
Dietary outcomes	Improved energy and protein intakes, with little reduction in normal food intake across a range of settings and health conditions. ^{7, 13, 17}
Functional	Improvements for handgrip strength, physical functioning, and quality of life. ^{13, 18} Reduction in functional limitations in community settings. ^{19, 20}
Cost benefit	Cost-effective way to manage malnutrition, especially in patients with a low body mass index (BMI), living in the community setting. ²¹ Reduced healthcare use (i.e. fewer consultations with GPs and reduced antibiotic prescriptions, reduced hospital readmissions and length of stay) when used in primary care settings. ^{7, 22}

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ACBS Open Consultation: Considerations

It is worth taking the time to consider the potential impact of these proposed changes on clinical practice. Possible concerns that could be raised in response to the consultation include:

- 1. Reduction of dietetic choice** – Dietitians may question their freedom to exercise professional judgement, choosing suitable ONS products and volumes based on individual patient needs. Appropriate prescribing is very different to restrictive prescribing and whilst prescribing policies are required to ensure the cost-effective use of ONS, they must be based on improving patient outcomes and the value they bring to the whole health economy.
- 2. Challenging the evidence** – As an evidence-based profession, dietitians may wish to request the evidence and rationale underpinning the consultation and how this would influence their response.
- 3. Risks to patient safety** – The removal of important front-of-pack labelling information, including from a brand name, e.g. Fibre; Complete, could potentially lead to prescribing errors and confusion. HCPs may be required to determine themselves whether an ONS product is nutritionally complete or a source of fibre, resulting in additional workload pressures.
- 4. Impact on patient care and patient preferences** – The standardisation of pack sizes and restrictions (one presentation size and 1 kcal/ml) will result in the removal of some product formulations from the market, impacting choice and disrupting patient care for those currently established on them. Offering a variety of different ONS products has been linked to improved patient compliance.^{24, 27}
- 5. Limiting ability of industry to innovate** – The medical nutrition industry listens to HCPs to understand patients' needs. Many key innovations are industry-led and based on research, dietetic and patient feedback. It would be disappointing if future innovations were led by ACBS criteria and not patient need.

How can you engage in the ACBS consultation?

There are a number of ways dietitians can engage in the ACBS consultation.

Clinicians, manufacturers, and other interested parties may make representations about the policy to the ACBS Secretariat by completing and submitting the survey found on the consultation website: www.gov.uk/government/consultations/oral-nutritional-supplements-acbs-policy

We would encourage you to make the most of the open-ended questions to address your concerns/implications. The ACBS state that they will consider any responses and may amend the proposed policy accordingly. They state that the final policy, including the ACBS' considerations to representations, will be published at a suitable time.

Dietitians can also support any response made to the consultation made by their BDA specialist group or may wish to contact the ACBS secretariat directly by email: acbs@dhsc.gov.uk or by post ACBS Secretariat: Room 2S07, Department of Health and Social Care, Quarry House, Leeds, LS2 7UE.

Conclusion

ONS are a clinically and cost-effective way of managing disease-related malnutrition. As clinical experts in nutrition, dietitians should maintain their autonomy in being able to make the best decisions for their patients. The new ACBS consultation on ONS is at risk of limiting dietitian autonomy, impacting patient safety and care and limiting the ability of industry to innovate.

As members of an evidence-based profession, dietitians should seek to critically analyse the evidence base underpinning the consultation and should carefully consider how proposed changes would influence their clinical practice. Dietitians should engage in the consultation process to inform the future of dietetics.

About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow-on formula, young child formula and complementary weaning foods), medical nutrition products for diseases, disorders and medical conditions, including oral nutritional supplements, enteral tube feeding and parenteral nutrition, as well as companies who aseptically compound chemotherapy, parenteral nutrition and CIVAS.

