

Department of Health & Social Care gluten-free consultation

Background

Dietary adherence is key to the successful management of coeliac disease. However, adhering to a gluten-free diet (GFD) is challenging with rates varying between 42-91%¹. Recent research has shown that a gluten-free (GF) prescription supports adherence to the diet², which in turn helps to reduce the risk of associated long-term complications such as osteoporosis, bowel cancer, functional hyposplenism and vitamin D deficiency. For children, non-adherence can also result in complications such as faltering growth and delayed puberty³.

National Consultation

Since 2011, Clinical Commissioning Groups (CCGs) have increasingly sought to restrict and remove gluten-free food (GFF) on prescription, with an impact on both product type and quantity of GFF prescribed, driven by the need to achieve budgetary savings. This has resulted in considerable prescribing variation, a postcode lottery for patients with coeliac disease, prompting the recent Department of Health and Social Care (DHSC) consultation on the availability of GFF on prescription in primary care in England⁴. The consultation considered a number of options including making no changes to provision; restricting prescribing to bread products and mixes only or complete removal of GFF from prescription⁵. The consultation received almost 8,000 responses from a range of stakeholders including patients, healthcare professionals, professional and patient associations, NHS organisations and industry bodies.

In addition to a review of the evidence base, a comprehensive impact assessment (IA) and a fully costed Quality-Adjusted Life Year (QALY) assessment was undertaken as part of the consultation and led the DHSC to conclude that GF prescribing should be restricted to bread products and mixes for all age groups in England⁵. This decision recognises the importance of ongoing support in the management of this life-long autoimmune condition, offering an equitable solution whilst helping to mitigate the risk of poor adherence to a GFD related to accessibility, availability and cost issues. If all CCGs adopted the consultation outcome, the IA calculated it would deliver estimated savings to the NHS of £4.1 million⁵.

Task and Finish Group

Following the DHSC consultation, a Task and Finish Group was convened. The group was made up of key stakeholders including Coeliac UK, the British Dietetic Association (BDA), NHS Clinical Commissioners and the British Specialist Nutrition Association (BSNA), of which Glutafin is a member, to assist in the development of the process used to establish which products will remain on prescription. A decision was made to retain a range of bread products and mixes to allow for patient choice and dietary variety.

As part of this process, GF manufacturers were invited to resubmit their ACBS-approved GF bread products and mixes, to the Advisory Committee on Borderline Substances (ACBS), for re-approval. All GF manufacturers have now been informed regarding the outcome of their product applications, enabling them to confirm which ACBS-approved products they will be able to offer to patients going forward. It is anticipated that the new list of GFF will appear in the Drug Tariff from November 2018, followed by an amendment to the Prescribing Regulations to only allow prescribing of bread products and mixes in December 2018. All other GFF will no longer be prescribed and will be blacklisted within the amended Regulation. This Regulation will only apply in England.

Which products fall within the bread products and mixes categories?

Bread Products - including loaves, rolls, baguettes, ethnic breads. Products can be fresh, ambient or part-baked. Pizza bases will no longer be available on prescription in England.

Mixes - including multi-purpose/all-purpose mixes and bread mixes. This will allow patients to make a range of different foods to help support dietary variety. Within the new regulation mixes are defined as a 'food mix' rather than a 'flour mix'. Simple flours will no longer be available on prescription.

NB: Some low-protein products also bear the claim 'gluten free'. These products are not within the scope of these changes as they are intended for a different clinical indication.

What does this mean for prescribing in Scotland, Wales and Northern Ireland?

Scotland, Wales and Northern Ireland all utilise 'Gluten-Free Foods: a revised prescribing guide' as a basis for their national policy on gluten-free prescribing, specifically in relation to products and unit allowance⁶. However, once the amended Prescribing Regulations come into force in England, only GF bread products and mixes will appear on the English Drug Tariff. The devolved administrations have sought to understand the implications of this change in policy in England, and have been working with the DHSC to ensure continued access to the full list of previously approved ACBS products in these countries going forward.

Whilst there will be a reduced demand for items other than GF bread products and mixes, Glutafin is pleased to confirm minimal changes to its product range in Scotland, Wales and Northern Ireland.

Why are CCGs continuing to undertake local consultations following the outcome of the DHSC consultation?

The DHSC consultation outcome has been acknowledged by a range of stakeholders including NHS England, Coeliac UK and the British Dietetic Association (BDA). Whilst NHS England has recognised that CCGs have autonomy in making decisions for local populations, it has stated that it anticipates CCGs will take into account the outcome of the DHSC consultation. A guidance document to facilitate implementation of the amended Regulations is planned.

Both Coeliac UK and the British Dietetic Association (BDA) are supportive of the national recommendations to continue to prescribe GF bread products and mixes, however, there is concern around the decision of some local CCGs to progress with local consultations when a national position has been agreed. Coeliac UK will continue to submit formal responses to these local consultations in support of aligning local policies on GF prescribing with the national recommendations. The BDA also recently announced that providers in England should, as a minimum, adhere to the outcome of this national consultation. Further information on how you can help support patients in an area under consultation can be found under 'Making the case for Gluten-Free' on the BDA website:

https://www.bda.uk.com/professional/influencing/making_case_for_gluten_free

What do these changes mean for Glutafin?

As a dedicated manufacturer of specialist GF products and supporter of the coeliac community for over 30 years, Glutafin is committed to continuing to provide both products and additional services to help support both patients and healthcare professionals who are involved in their care.

Our range of bread products and mixes will continue to be available on prescription in England (depending on local CCG policy), Scotland, Wales and Northern Ireland. In addition, we can confirm we are able to continue to supply a range of additional Glutafin products for the devolved nations (table 1). For more detailed information on Glutafin product availability, please refer to the Filofax-compatible product guide provided in this issue of Dietetics Today.

Table 1

Product category	Available in England*	Available in Scotland**, Northern Ireland & Wales
Bread loaves (fresh & ambient)	●	●
Bread rolls	●	●
Bread mixes (white and fibre)	●	●
Multipurpose flour mixes (white and fibre)	●	●
Pizza bases		●
Crackers		●
Cereal		●
Biscuits		●

*Availability dependent on local CCG policy. **Availability dependent on local health board formulary

For further information regarding Glutafin products and services, or to order your free supply of Glutafin patient starter cards for newly diagnosed patients living in areas where prescription products are available, please email: institute@drschaer.com, or call our careline 0800 988 8470.

Sign-up to receive our monthly healthcare professional newsletter and access free professional resources, research summaries and expert webinars by visiting: www.drschaer-institute.com/uk

References: 1. Hall NJ et al. Systematic review: adherence to a gluten-free diet in adult patients with coeliac disease. *Aliment Pharmacol Ther*, 2009; 30(4): 315-30. 2. Muhammad, H.; Reeves, S.; Ishaq, S.; Mayberry, J.; Jeanes, Y.M. Adherence to a Gluten Free Diet Is Associated with Receiving Gluten Free Foods on Prescription and Understanding Food Labelling. *Nutrients* 2017, 9, 705. 3. Murch S et al. Joint BSPGHAN and Coeliac UK guidelines for the diagnosis and management of coeliac disease in children. *Arch Dis Child*, 2013 98(10): 806-11. 4. Walker AJ, Curtis HJ, Bacon S, et al Trends, geographical variation and factors associated with prescribing of gluten-free foods in English primary care: a cross-sectional study. *BMJ Open*. 2018; 8:3. 5. Department of Health and Social Care. 2018. Availability of gluten-free foods on NHS prescription. Available at: <https://www.gov.uk/government/consultations/availability-of-gluten-free-foods-on-nhs-prescription> Last accessed: September 2018. 6. Coeliac UK. Gluten-Free Foods: a revised prescribing guide. 2011. <https://www.coeliac.org.uk/document-library/378-gluten-free-foods-a-revised-prescribing-guide/?return=/gluten-free-diet-and-lifestyle/prescriptions/national-prescribing-guidelines/>. Last accessed: September 2018