

Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs

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Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the recommendations set out in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

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1 Background

1.1 Who is this guidance for?

This guidance is addressed to Clinical Commissioning Groups (CCGs) to support them to fulfil their duties around appropriate use of their resources, taking account of revised prescribing legislation for gluten-free (GF) food. We expect CCGs to take the proposed guidance into account in formulating local policies, and for prescribers to reflect local policies in their prescribing practice. The guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties.

This guidance is issued as general guidance under sections 14Z10 and 2 of the NHS Act 2006 (as amended) and is addressed to CCGs to support them to fulfil their duties around appropriate use of prescribing resources. The objective of this guidance is to support CCGs in their decision-making by setting out the reasons for the changes made to prescribing legislation for GF food, with the wider objective being to address unwarranted variation across England in terms of CCG prescribing policies, and to provide clear national advice to make local prescribing practices more effective (see appendix 1 for prescribing data variation).

1.2 Why have we developed this guidance?

Last year 1.1 billion prescription items¹ were dispensed in primary care at a cost of £9.2billion². This growing cost coupled with finite resources means that it is important that the NHS achieves the greatest value from the money that it spends. We know that across England there is significant variation in what is being prescribed and to whom.

This guidance helps CCGs to review their local prescribing policies of GF foods in light of revisions to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 (“the Amendment Regulations”).

The Amendment Regulations are intended to promote consistency across all CCGs. Currently, the availability of GF foods on NHS prescription varies according to local CCG policy. Some follow guidelines provided by the national charity for patients with coeliac disease (Coeliac UK) whilst others restrict prescribing to certain products and/or patient groups, or restrict GF products altogether. The Amendment Regulations reduce much of this variation as they allow only for GF bread and mixes to be prescribed at NHS expense. CCGs may further restrict the prescribing of GF foods by selecting bread only, mixes only or CCGs may choose to end prescribing of GF foods altogether.

This guidance follows work done by the Department of Health & Social Care (DHSC) as part of the Department’s wider role in optimising the use of medicines in the NHS.

¹ An item is anything which can be prescribed on an NHS prescription. More information on what is prescribed on an NHS prescription is available in the Drug Tariff.

² NHS Digital Prescription Cost Analysis 2017

In March 2017, DHSC published a consultation proposing changes to the availability of GF foods on NHS prescription. The rationale for change was the increased availability of these products in supermarkets and other food outlets at a time when the annual cost to the NHS of prescribing such items was £15.7 million.

The consultation exercise presented three options for changing the availability of GF foods so that savings could be achieved and funds used elsewhere in the NHS. The options in question were to make **no changes**, **restrict all GF foods** or **restrict to certain products**.

Following an analysis of responses, DHSC decided to restrict GF prescriptions to certain bread and mixes. This delivered savings to the NHS and helped mitigate the risk that those on lower incomes would not be able to purchase their own staple GF foods.

Following on from this, DHSC carried out a second consultation in August 2018. The purpose of this second consultation was to seek feedback on the draft revised Regulations and to ensure they would work in practice. The August consultation received over 900 responses from a range of stakeholders including patients and carers of patients, members of the public, dietitians, pharmacists and CCGs. The majority of respondents agreed that the revised Regulations would be understood by the service and would provide a staple list of gluten-free bread and mix products.

Further background to this work is available on GOV.UK at the links, below.

www.gov.uk/government/consultations/availability-of-gluten-free-foods-on-nhs-prescription

<https://www.gov.uk/government/consultations/gluten-free-foods-on-nhs-prescription>

1.3 How have the recommendations in this guidance been developed?

Over the past few years, DHSC has undertaken a detailed programme of work to examine whether the prescribing of GF foods can be restricted so that savings to the NHS can be achieved without detrimental health outcomes to patients. Key pieces of work undertaken include:

- Research into the different GF prescribing policies adopted by CCGs and a sense of their impact;
- A 2017 national consultation exercise proposing 3 options for change which received almost 8,000 responses;
- An economic assessment of the 3 options, exploring their impact on patients and the NHS;
- An Equality Impact Assessment to mitigate the risks of particular groups being negatively impacted by any decision to restrict prescribing;

- A literature review of the latest publications from the National Institute for Health & Care Excellence and the British Society of Gastroenterology, both of which provided intelligence on the management of patients with coeliac disease; and
- A 2018 national consultation exercise to share a draft of the revised Regulations with stakeholders to gauge how they will work in practice.

These pieces of work helped DHSC to develop a sound understanding of the issues at play and informed the national recommendations, which are set out in part 4 of this Guidance. These recommendations were developed to communicate changes in the Regulations to CCGs and to support them with the review and development of their local GF food prescribing policies.

The recommendations in this guidance have been clinically reviewed by the Low Priority Prescribing (LPP) clinical working group. The LPP clinical working group was established by NHS England and NHSCC. The group is chaired by representatives of these two organisations, with membership including GPs and pharmacists, CCGs, Royal College of General Practitioners, National Institute for Health and Care Excellence (NICE), Department of Health & Social Care, the Royal Pharmaceutical Society and others.

1.4 How have the recommendations in this guidance been developed following the results of consultation?

DHSC undertook two national consultations on the prescribing of GF foods in the NHS. The first of these proposed changes to prescribing arrangements and resulted in the Government's decision to restrict such foods to bread and mixes. The second consultation shared the draft revised Regulations and asked stakeholders how well these would work in practice.

In March 2017, DHSC published a consultation proposing changes to the availability of GF foods. This presented three options for changing the availability of GF foods so that savings could be achieved and funds used elsewhere in the NHS. The options in question were to **make no changes**, **restrict all GF foods** or **restrict to certain products**.

The consultation received almost 8,000 responses from a range of stakeholders including general practitioners and other approved prescribers, dietitians, pharmacists, patients, members of the public, national charities and manufacturers of GF foods. The majority of respondents were in favour of restricting to certain products as this struck a balance between achieving savings for the NHS and maintaining availability of GF foods for patients.

Feedback from **three groups** was particularly informative in helping DHSC to select bread and mixes for prescribing. **Parents or carers of children** requested that GF staple foods, especially bread, remained on prescription to prevent children feeling "different" to their peers e.g. the ability to take a packed lunch (sandwiches) to school. **The British Specialist Nutritional Association** indicated that in a survey they undertook of almost 4,000 patients with coeliac disease, 97% of respondents ate GF bread at least once a week with 76.6% consuming bread daily. **South Hertfordshire**

Coeliac Patient Group picked up on an early misconception that coeliac patients routinely consumed GF flour to manage their condition. In fact, GF mixes were commonly used and were helpful alongside naturally GF foods such as eggs and milk.

In their second consultation, DHSC received over 900 responses. The majority of these were from patients who were concerned by the variation in CCG prescribing policy of GF foods. As described above in section 1.2, the revised regulations will reduce the variation by allowing for a maximum of bread and mixes only to be prescribed at NHS expense.

Patients responded positively to the inclusion of bread in the revised draft regulations. Patients' experience was that bread products could be expensive to purchase in supermarkets and availability could vary, leading to some patients questioning whether this might reduce their adherence to a GF diet. The provision of bread and mixes on NHS prescription is expected to minimise any drop in adherence.

2 How will this guidance be updated and reviewed?

NHS England will clinically review the guidance at least annually (or more frequently if required), consulting the joint clinical working group on clinical matters where required, and taking a steer from DHSC in terms of changes to regulations that may need to be made. Prescribing data will be monitored to assess changes in prescribing activity and spend on GF food in primary care.

To help support the effectiveness of the guidance, DHSC's Advisory Committee on Borderline Substances (ACBS) will amend its processes accordingly. The ACBS is a national expert committee that advises GPs on the non-medicinal products, including GF foods, which can be prescribed for patients with medical conditions. ACBS advice takes the form of its national 'recommended list' which many prescribers follow.

Once the Amendment Regulations come in to force, ACBS's recommended list will only include GF bread and mixes and no other GF products.

3 Definitions

The Amendment Regulations define what is meant by gluten-free food and will come in to force in December 2018. The extract, below, is taken from the regulations:

For the purposes of this regulation -

(a) a food is gluten-free if the food, as sold to the final consumer -

(i) contains no more than 20mg/kg of gluten; and

(ii) where it contains oats has been specially produced, prepared and or processed in a way to avoid contamination by wheat, rye, barley, or their crossbred varieties:

(b) a food is very low gluten if the food as sold to the final consumer, contains no more than 100mg/kg of gluten and consists of, or contains, one or more ingredients made from wheat, rye, barley, oats or their cross bred varieties which have been specially processed to reduce the gluten content, and where it contains oats —

(i) it has been specially produced, prepared and or processed in a way to avoid contamination by wheat, rye, barley, or their cross bred varieties, and

(ii) the gluten content of the oats does not exceed 20mg/kg

(4) In this regulation -

“food mix” means a mixture of two or more ingredients which is to be –

(a) combined with any one or more additional ingredients, and

(b) baked or otherwise cooked;

“gluten” means a protein fraction from wheat, rye, barley, oats or their crossbred varieties and derivatives, which is insoluble in water and 0.5 M sodium chloride solution.”

4 Recommendations

Recommendation	<ul style="list-style-type: none"> Advise CCGs to support prescribers to prescribe in line with the revised regulations which allow for no gluten-free products to be prescribed at NHS expense, other than gluten-free bread and/or gluten-free mixes. Advise CCGs that patients in receipt of NHS prescriptions for gluten-free bread and/or mixes should be those diagnosed by their doctor as suffering from established gluten-sensitive enteropathies, including dermatitis herpetiformis and coeliac disease.
Exceptions and further recommendations	No routine exceptions have been identified.
Annual spend	£15.7 million (2017)
Background and Rationale	<p>GF foods are tolerated by people suffering from established gluten sensitive enteropathies, which include coeliac disease. When someone has coeliac disease, their small intestine becomes inflamed if they eat food containing gluten. This reaction to gluten makes it difficult for them to digest food and nutrients.</p> <p>Staple GF foods have been available on prescription to patients diagnosed with gluten sensitivity enteropathies since the late 1960s when the availability of GF foods was limited. GF foods are now readily available in supermarkets and a wider range of naturally GF food types are available, meaning that the ability of patients to obtain these foods without a prescription has greatly increased.</p> <p>Revised prescribing regulations allow for a maximum of GF bread and mixes only to be prescribed at NHS expense. CCGs can restrict further by selecting bread only, mixes only or can choose to end prescribing of all GF foods if they feel this is appropriate for their population, whilst taking account of their legal duties to advance equality and have regard to reducing health inequalities.</p>
Further Resources and Guidance for CCGs and prescribers	<p>www.gov.uk/government/consultations/availability-of-gluten-free-foods-on-nhs-prescription</p> <p>https://www.gov.uk/government/consultations/gluten-free-foods-on-nhs-prescription</p> <p>https://www.coeliac.org.uk/home/</p>

Appendix 1 – CCG prescribing policy variation

Trends in GF food prescribing across CCGs with different local policies, mean quarterly number of prescription items per CCG



Appendix 2 – Unintended Consequences

The following potential unintended consequences were considered:

Potential unintended consequences of issuing the proposed guidance	Response
<p>Compensatory prescribing</p> <p>Patients will request additional bread and mixes to compensate for those non-bread and non-mix formulated foods that are no longer available through prescription.</p>	<p>Published data from NHS Business Services Authority shows that those CCGs who are already restricting GF foods to some degree have not experienced this phenomenon.</p>
<p>Drop in adherence</p> <p>A change in the availability of gluten-free foods on prescription may result in a drop in the number of patients who adhere to a GF diet. Currently, the only medical treatment for Coeliac Disease (CD) is strict adherence to a GF diet for life. Patients who do not follow a strict GF diet are at a higher risk of long term complications, including osteoporosis, ulcerative jejunitis and intestinal malignancy.</p>	<p>A published DHSC Impact Assessment examines the issue of adherence in detail and concludes that adherence to a GF diet cannot be isolated to any single cause. Evidence shows that many factors are at play including product labelling, cost and information when eating out and managing social occasions. Adherence requires a range of knowledge and skills to avoid all sources of gluten. DHSC's decision to restrict GF prescribing to bread and mixes provides a balance between achieving savings for the NHS and supporting patients in their adherence to a GF diet.</p>
<p>Increase in retail price of GF foods</p> <p>National changes to GF prescribing might cause manufacturers to increase the price of GF foods in retail to make up the shortfall of any lost revenue from NHS sales. Respondents to DHSC's 2018 consultation asked for the Government to cap prices for GF food.</p>	<p>DHSC is unable to intervene in the market, in this way. Pricing is a matter for companies based on demand and supply of the market place.</p>