



# Gluten Free Prescribing

April 2019

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# 1 Why a focus group?

In November 2018, Healthwatch Milton Keynes (HWMK) facilitated two focus groups aimed at those with gastro-related conditions. The purpose was to explore participants' experiences of gastro-related services in Milton Keynes with a view to understanding how the gastro pathway could be improved, and to explore the impact of changes to gluten-free prescribing on participants.

The focus groups were conducted in response to the two core issues raised with us:

- Milton Keynes Clinical Commissioning Group (MKCCG) spoke to us about the high numbers of emergency hospital admissions for gastro-related conditions in Milton Keynes, and their wish to talk to patients to better understand the reasons for using Accident and Emergency services.
- Patient and voluntary sector groups concerns raised with us about recent changes to gluten free prescribing, introduced by the MKCCG in 2017 following the NHS led consultation on items which should not be routinely prescribed in primary care.

Whilst the first focus group focused primarily on participants' experiences of gastro related services, and the latter primarily on the changes to gluten free prescribing there was some crossover in themes that emerged from discussions. Where appropriate, this report therefore draws on the experiences of participants from both focus groups.

## 2 Why the focus on Gluten Free?

Coeliac disease is not an allergy or an intolerance, it is an autoimmune disease where eating gluten triggers the immune system to react and causes intestinal malabsorption. This is characterized by inflammation of the small intestine, loss of microvilli structure, failed intestinal absorption, and malnutrition.

Currently, the only medical treatment for Coeliac Disease is strict adherence to a Gluten Free diet for life. According to NICE, Patients who do not follow a strict Gluten Free diet are at a higher risk of long-term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. The British Society of Gastroenterology identifies Coeliac patients as being at increased risk of osteoporosis and bone fracture.<sup>1</sup>

In 2017, the MKCCG launched the '*Clinical Priority and Best Value Consultation*' which sought local people's views on proposals on changes to podiatry services, adult hearing services, supply of medicines, procedures of limited clinical value and inpatient community services. The NHS consultation guidelines at that time advised Clinical Commissioning Groups (CCGs) that there would be a separate national consultation on Gluten Free (GF) prescribing at a later date but allowed each CCG to decide individually whether to include Gluten Free prescribing in their local consultations.

As a result of the feedback received during the consultation, the MKCCG felt that they had suitable support from the people of Milton Keynes to stop the prescribing of Gluten Free foods. On the 13<sup>th</sup> of June 2017, the MKCCG published the following advice on their website:

**"Following the consultation, the CCG's Board has agreed to make the following changes:**

**Cease prescribing gluten free foods on NHS Prescription, but a patient's GP will be able to apply for prescription in exceptional circumstances, where they believe a patient is at real risk of dietary neglect, for whatever reason."**<sup>2</sup>

In March 2017, the Department of Health and Social Care (DHSC) launched the first of its two national public consultations into Gluten Free Prescribing. The first proposed changes to the availability of GF foods and presented three options:

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<sup>1</sup> <https://www.england.nhs.uk/medicines/medicines-optimisation/prescribing-gluten-free-foods-in-primary-care-guidance-for-ccgs-faqs/#what-are-the-implications-of-not-following-a-gluten-free-gf-diet>

<sup>2</sup> <http://www.miltonkeynesccg.nhs.uk/news/2017/public-consultation-helps-ccg-decide-on-health-service-proposals/>



- make no changes,
- restrict all GF foods or,
- restrict to certain GF products.

This consultation received almost 8,000 responses from a range of stakeholders including General Practitioners (GPs) 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.<sup>3</sup> In their second consultation, which shared the draft revised regulations and asked whether they would work in practice, 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.<sup>4</sup>

As a result of the analysis of the responses to both of these consultation exercises, the Government decided to restrict GF prescriptions to certain bread and mixes. This option delivers savings to the NHS and mitigates the risk that those on lower incomes would not be able to afford to buy their own GF foods from retail outlets where prices are often higher and availability more limited.<sup>5</sup>

*The National Health Services (General Medical Services Contracts)(Prescription of Drugs etc.) (Amendment) Regulations 2018 for the prescribing of gluten-free (GF) foods* were amended and came into force on the 4<sup>th</sup> of December 2018. Amendments were also made to the made to the *Prescribing Gluten-Free Foods in Primary Care: Guidance for CCGs* 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.<sup>6</sup>

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<sup>3</sup> Page 7, <https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf>

<sup>4</sup> Page 8, <https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf>

<sup>5</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/753733/responses-to-the-consultation-on-gluten-free-food-regulations.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753733/responses-to-the-consultation-on-gluten-free-food-regulations.pdf)

<sup>6</sup> Page 5, <https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf>

While the DHSC were clear that restricting GF prescribing to certain products was the Government's preferred option, they were not the only ones. In the second consultation, to the question: "Do you think that the proposed Amendment Regulations as drafted, will achieve the desired changes; to provide a staple list of GF bread and GF mixes to patients on NHS prescription?", 70% of responding GPs said yes. So did 69% of other Health professionals including other approved Prescribers, Dietitians, Registered Nutritionists, Nurses, Pharmacists, Scientists, Pharmacy Technicians, Practice Managers, and Primary Care Pharmacists, who responded to this question.<sup>7</sup>

In the *Responses to the consultation on the gluten free food regulations* document, it states quite clearly :

"The GF food list as published in Part XV of the Drug Tariff will be smaller and mean that patients with established gluten sensitive enteropathies will retain access to GF bread and mixes on NHS prescription.

GF products that fall outside the category of a bread or a mix will no longer be prescribed at NHS expense. Prescribing regulations will be amended to reflect these changes."

And:

Availability of GF foods on NHS prescription varies according to local CCG policy. Some follow guidelines that are provided by the charity for patients with coeliac disease, Coeliac UK, whilst others have restricted prescribing to certain products and/or patient groups, or have restricted GF products all together. The new regulations are intended to reduce variation.

And furthermore that:

The amended regulations are intended to reduce the variation in the provision of GF foods on prescription. All GF food, other than bread and mixes, will be included in Schedule 1 of the "National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. CCGs are encouraged to align their local policies with the amended regulations.

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<sup>7</sup> Page 23,

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/753733/responses-to-the-consultation-on-gluten-free-food-regulations.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/753733/responses-to-the-consultation-on-gluten-free-food-regulations.pdf)



NHS England's approach is somewhat mixed. On their Frequently Asked Questions webpage for the GF Guidance they state that the aims of the changes are to “make savings through restricting the prescribing of GF foods to a more limited list of products, whilst maintaining adherence among patients and so avoiding detrimental health effects. The savings mean the NHS will be able to invest more in other treatments”<sup>8</sup>.

The amended guidance capitulates somewhat even though it refers to the DHSC analysis of responses and the decision made 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.”<sup>9</sup>

The guidance states that the purpose of the amended regulations is to reduce much of the prescribing variation across the country, and acknowledges what the public and press tend to refer to as a ‘postcode lottery, by noting that “We know that across England there is significant variation in what is being prescribed and to whom.”<sup>10</sup> However, the guidance goes on to say that “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.”<sup>11</sup>

This ambiguity in the NHS England Gluten Free Prescribing Guidance does highlight the difficulty facing MKCCG in ensuring that they deliver services in a financially responsible manner, and how this difficulty is passed on to GPs who are, as a result, unable to continue to prescribe the clinically recognised and appropriate treatment to a group of patients. It is important to remember that Coeliac Disease (CD) is unique as it is the only long-term gastrointestinal disorder that can be effectively treated by diet alone. Unlike those conditions requiring long-term drug intervention, the only treatment for CD is lifelong adherence to a strict gluten free diet. A gluten free diet requires significant dietary change to remove all sources of gluten from the diet and still meet the Eatwell Guide recommendations advocated by Public Health England.

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<sup>8</sup> <https://www.england.nhs.uk/medicines/medicines-optimisation/prescribing-gluten-free-foods-in-primary-care-guidance-for-ccgs-faq/#why-are-changes-being-made-to-the-availability-of-gf-foods>

<sup>9</sup> Page 6, <https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf>

<sup>10</sup>Page 5, <https://www.england.nhs.uk/wp-content/uploads/2018/11/prescribing-gluten-free-foods-primary-care-guidance-for-ccgs.pdf>

<sup>11</sup> <https://www.england.nhs.uk/medicines/medicines-optimisation/prescribing-gluten-free-foods-in-primary-care-guidance-for-ccgs-faq/#will-all-ccgs-prescribe-gf-bread-and-mixes>

The British Specialist Nutrition Association Ltd (BSNA) pointed out, in their response to the DHSC consultation that:

“It is important to recognise that the detrimental health outcomes associated with CD [Coeliac Disease] are long-term and may result in a much higher financial burden to the NHS than the lifetime cost of treatment itself. To highlight this point, it costs approximately £195 a year to support a patient with a gluten-free prescription, yet the average cost to the NHS of an osteoporotic hip fracture is £27,000 (equivalent 138 years of prescribing cost). This is significant as, at diagnosis, osteopenia and osteoporosis is found in 40% of adult patients and that significant improvement in bone health is observed in the first twelve months following initiation of a gluten-free diet. Therefore, without any long-term data on the impact of such a policy on patients, the true financial and personal burden of these policy proposals cannot be adequately estimated at this point in time.”<sup>12</sup>

The British Medical Association outlines the General Practitioners responsibility to prescribe:

“Under the NHS regulations your GP must prescribe for you any drugs that he or she feels are needed for your medical care. A patient is entitled to drugs that the GP believes are necessary, not those which the patient feels should be prescribed. GPs are responsible for all prescribing decisions they make and for any consequent monitoring that is needed as a result of the prescription given.

The Department of Health lists all drugs that the NHS is prepared to pay for in a list called the Drug Tariff. It is likely that most, if not all, the drugs you need are available through the NHS, however the Drug Tariff does have exceptions. Some drugs, listed in Schedule 11 will only be offered on the NHS to patients suffering from specified conditions. Similarly, some products other than drugs, such as gluten free foods or sunblocks, are listed as ‘Borderline Substances’ and may only be prescribed at NHS expense in defined circumstances.”<sup>13</sup>

The defined circumstances are very clear in the case of Gluten Free Food Prescribing; the NHS Drug Tariff for April 2019 states the products are for Coeliac Disease and Dermatitis Herpetiformis.

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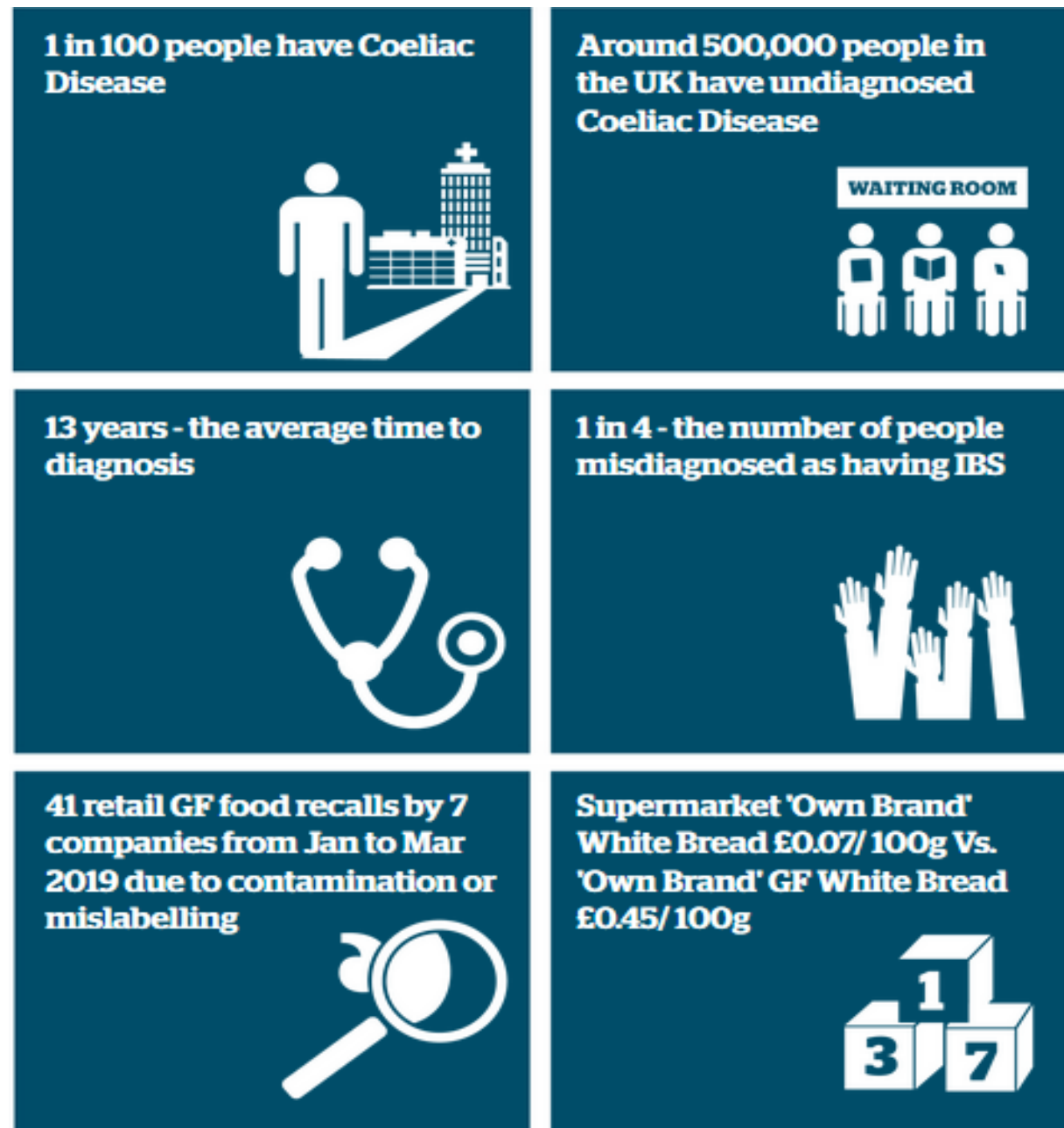
<sup>12</sup> 3.2, page 5, <https://bsna.co.uk/uploads/banners/DH-Consultation-BSNA-Supplementary-Information-Final.pdf>

<sup>13</sup> <https://www.bma.org.uk/advice/employment/gp-practices/service-provision/prescribing/prescribing-in-general-practice>





### 3 By the numbers



- Supermarket Price Comparison made online 15/03/2019

## 4 Milton Keynes GF Prescribing Policy

Our research led us to look, from a patient perspective, for information on the MKCCG GF prescribing policy and the exemption process (also referred to as an Individual Funding Request or IFR) which proved difficult as it is not contained on the MKCCG website. Using the search term 'Gluten' on the MKCCG website brings up information on the original consultation and a MKCCG Board report prompted by Healthwatch Milton Keynes to review/reconsider local prescribing arrangements following the outcome of the national consultation.

We eventually found the information on the MK Formulary which is produced, according to the website, as a joint venture between primary and secondary care to be a tool to assist in promoting safe, cost effective prescribing within the Milton Keynes area.

It was challenging as a member of the public to easily search for information about GF prescribing and the exemption process.

In 'Chapter 9' which is concerned with Nutrition and Blood, Coeliac Disease comes under 9.9: Nutrition (Oral), and specifically referred to under the section 'Nutrition in special diets' and says:

### Coeliac disease

*Milton Keynes CCG does not routinely fund gluten free foods on prescription for coeliac disease and dermatitis herpetiformis.*

*If a clinician considers that a patient's specific circumstances mean that they could be at risk of dietary neglect then they can request that their case is considered by MKCCG.*

*You will need to complete this proforma [See Appendix A] and include as much information as possible so that the case can be fully reviewed by the team.*

*If a patient is approved for NHS prescriptions, the only products that can be prescribed are bread and flour mixes as listed in the Drug Tariff.<sup>14</sup>*

<sup>14</sup> [https://www.formularymk.nhs.uk/99-Nutrition-\(oral\)/](https://www.formularymk.nhs.uk/99-Nutrition-(oral)/)



## 5 Individual Funding Requests (IFR)

It was evident from experience shared with us at the two focus groups HWMK held, that people affected by the changes to GF prescribing were largely unaware that there is an option to ask their GP for an IFR. This could be an issue, if a low number of applications for this type of appeal process being sought were to be used as evidence that the removal of gluten free prescribing is not having a negative effect on people's care or their health.

Using the IFR process for assessment of need regarding access to gluten free food on prescription was seen by participants as an unnecessary burden on GPs and on the CCG. It is important to allow healthcare professionals to make decisions about what is best for their patients, thereby enabling use of clinical judgement to identify and support patients where there is clinical need.<sup>15</sup>

Gluten free foods are a relatively low cost item on prescription. IFRs take time as they require a GP appointment, extra GP time for completing the IFR form, and also a clinical panel to convene to review the cases/ applications. While some individuals may require access to gluten free food on prescription in the long term, others may require short term support. This may mean that the CCG would need to re-evaluate IFRs on a regular basis, adding to the administrative cost, over and above the annual reviews.

Defining set parameters to provide a safety net for individual cases of need is challenging and there is no clear framework to ensure that all vulnerable patients are identified and supported.<sup>16</sup> MKCCG has not adopted an approach that is able to consistently or fairly, identify vulnerable patients and relies on patients presenting to their GP.

Participants told us that the IFR process should be advertised more clearly in GP practices. HWMK asked the MKCCG to improve information about patients' rights to ask for an IFR on posters in GP waiting rooms. They told us posters would be reviewed, following the outcome of the national consultation, but this review has not been actioned to date. However, in this specific case, HWMK recognises that MKCCG has recently undergone restructures to its leadership and therefore one of our recommendations will readdress this, now that the new leadership structure is in place.

A big issue with IFRs is that they are expected to show, according to NHS England's IFR guide for patients, that a patient's clinical circumstances are exceptional. The application must show all available clinical evidence for why your clinician believes you would benefit more from the treatment than other patients with the same condition. As part of the impartial, and non-discriminatory IFR process, the NHS states that non-clinical factors are not to be considered. This is directly opposed to the MKCCGs policy statement: 'for

<sup>15</sup> <https://www.coeliac.org.uk/document-library/4509-department-of-health-consultation-response/>

<sup>16</sup> <https://www.coeliac.org.uk/document-library/4509-department-of-health-consultation-response/>



whatever reason' (referenced on page 4 of this report) about the ability to apply for a prescription. However, it is what is being experienced by patients who are being refused IFRs applied for, on financial grounds.

## 6 Health Inequality

Wiltshire CCG noted on their local GF Prescribing consultation webpage that "Gluten-free prescribing began in the 1960s when no gluten-free foods or products were readily available. Today gluten-free foods are found in most supermarkets, shops and many cafes ... and competition has driven pricing down meaning they are affordable dietary alternatives."<sup>17</sup> However, one participant at our focus group described paying £13.50 for 500g of GF flour.

We have been told by people who have been through the IFR panel process that low income was not viewed as grounds for an exemption in their specific cases. There was widespread concern amongst participants that the changes to GF prescribing are contributing to health inequalities. Participants spoke of family and friends who would not be able to finance GF products.

Participants also highlighted that the inequality is amplified further, given that CCGs across the country are inconsistent in their approach to GF prescribing. Individuals with the same need, living in different areas, are likely to have very different experiences. Indeed, within our own Integrated Care System (ICS), Luton CCG decided to follow the recommendations of the DHSC, as have the Buckinghamshire, Oxford, and Nene CCGs.

"I have a young grandchild who is coeliac . Their single parent is struggling to manage to afford the food needed to control their condition. An appeal to the CCG was initially turned down as, apparently, low income is not a reason for exemption despite the clinical need for gluten free food. They were advised to appeal again as the parent is also disabled and therefore at a double disadvantage. They have heard nothing. I understood that nationally it has been agreed that coeliacs can continue to be prescribed bread and flour. I was wondering what is happening here in MK?" - HWMK Member feedback.

<sup>17</sup> <http://www.wiltshireccg.nhs.uk/news-2/have-your-say-on-a-new-approach-to-gluten-free-prescribing>

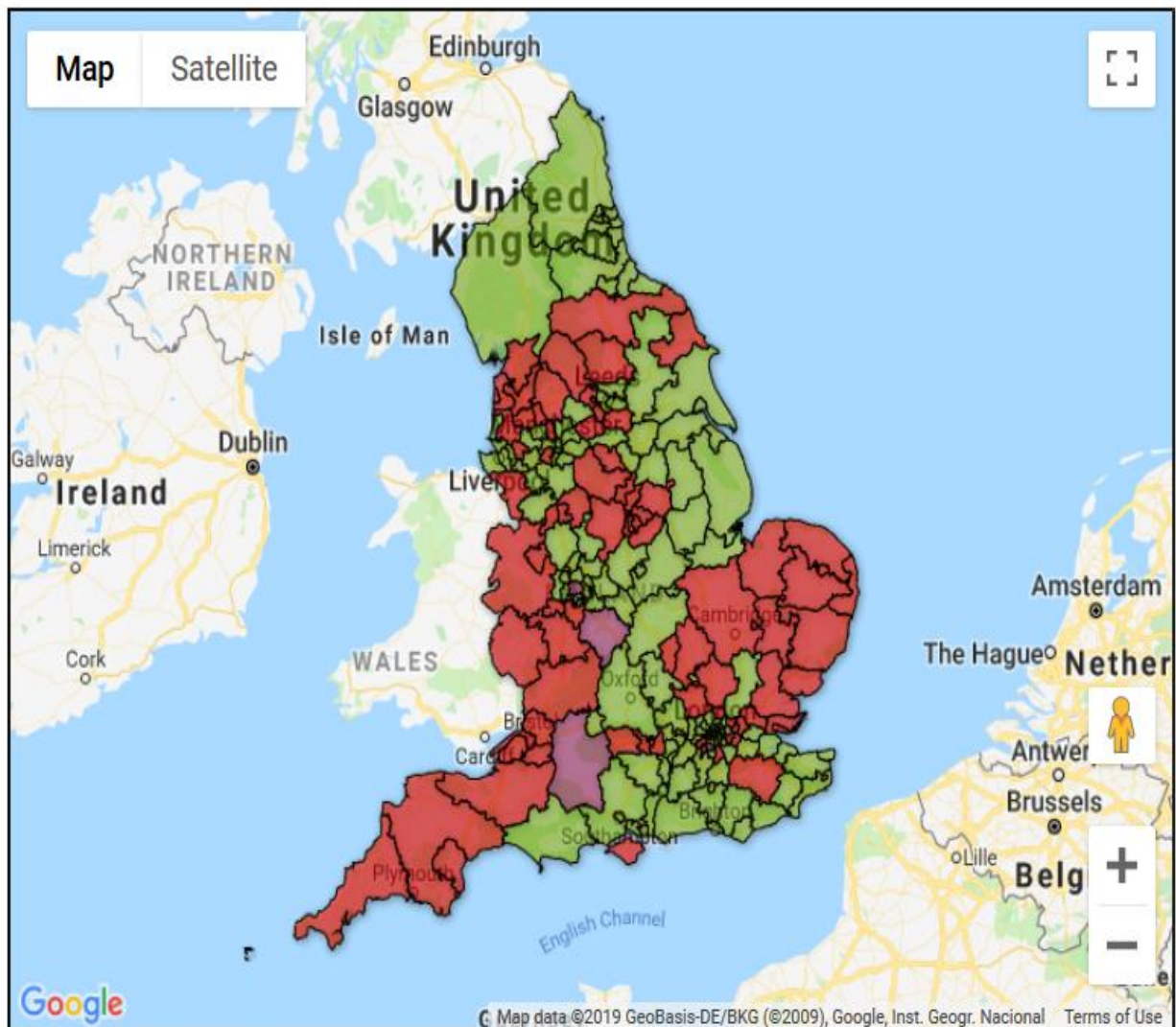


## 7 Prescribing Policy Across England

Gluten free prescribing map of England courtesy of Coeliac UK

### Map key

- Bread and flour mixes available on prescription
- Policy on gluten free prescribing under review
- Partial or complete withdrawal of prescriptions



CCG boundary data © NHS England. Contains Ordnance Survey data © Crown copyright and database right [2013]



<https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/>

# 8 Access to GF Foods

Participants at the focus group raised issues they were experiencing around accessibility to shops selling gluten free foods. Pharmacies can still order the gluten free products that were available through the NHS but can add a mark-up price when ordering them as a non-prescription item and this varies from pharmacy to pharmacy.

There is now only one supermarket chain stocking the fortified breads that were available through the NHS, but only in three of its stores across Milton Keynes. The only other supermarket chain to have stocked these items has recently decided to discontinue this brand.

A 9-year-old with coeliac disease was brought to the event by their parent who told us about their experience, as a family, dealing with a long-term condition which, if not treated appropriately now, will have severe health consequences as the child ages. They told us that the child used to receive a fortified breakfast cereal on prescription. Since the changes were introduced, they have not been able to find a nutritious alternative in shops. This child is also unable to have school provided lunches because of the risk of cross contamination.

All of the group participants were concerned and disappointed to discover that children were not automatically exempt from the changes to gluten free prescribing.

One person described being housebound during the bad weather last year. During this time the participant was unable to get to larger stores which sold gluten free products, making them reliant on the gluten free staples they got on prescription.

All participants expressed their concerns that those who are less mobile or live in more rural areas, especially in the winter weather, may not be able to access larger stores with reliable and plentiful stocks of gluten free products.





## 9 Recommendations

- HWMK would like Milton Keynes Clinical Commissioning Group to consider taking a consistent approach to prescribing, in line with *The National Health Services (General Medical Services Contracts)(Prescription of Drugs etc.) (Amendment) Regulations 2018 for the prescribing of gluten-free (GF) foods* so Milton Keynes residents have equality of access.
- We recognise that the CCG have reviewed their position in light of the National Survey, but would ask that they consider this report, and its recommendations, in the prescribing group.
- Ensure that patients have easy access to information about their right to request their GP make an IFR and are not discouraged from doing so.
- Add a link to the Joint Trusts Formulary website to the CCG website.
- Review the IFR process to ensure GPs treat patients consistently and that the process itself is not a barrier to identifying and supporting genuine need.
- As all Coeliac patients require a Gluten Free diet, a main barrier to receiving treatment is the ability to afford GF Foods. HWMK would ask that, because of this, socio economic factors be allowed as part of the IFR.



## 10 CCG Response

This report provides an overview of the changes that have taken place with regard to gluten free foods. It reflects the tension between the national guidance encouraging CCGs to align local policies with the amended NHS regulations and the need for the CCG to deliver financial balance. This tension is acknowledged in the NHS England guidance for primary care so the CCG is not acting out with NHSE policy. Had NHSE wanted to see uniformity and remove local decision making, the policy could have been made mandatory.

In terms of variation across the country and STP, the report notes that Luton allows bread and flour mixes but does not state that Bedfordshire do not allow these. A survey on the Coeliac UK website indicates that 40% CCG restrict prescribing beyond the national guidance.

The report correctly states that the only treatment for CD is a GF diet but there are ways of achieving this without relying on GF foods. A natural GF diet may contain foods such as meat, fish, fruit and vegetables, rice, potatoes, lentils. The Coeliac UK website provides advice about GF diets on a budget. The report quotes a price of £13.50 for 500g GF flour. It is available in Lidl for £1.29 per kg and Tesco at £1.70.

Anything related to prescribing sits on the Joint Trusts Formulary Website so that there is only one place for prescribing advice that has to be kept up to date. We will create a link from the CCG internet site to the formulary.

Healthwatch makes the point that patients do not know that GPs can submit IFR requests. The CCG supplied posters for all GP practices and whilst it did not specifically mention IFR, patients generally discussed the change with their GP. The GPs were made fully aware of the process and were sent copies of the IFR templates.

The CCG has not received any IFR requests since August 2018.

There is a comment about difficulty in accessing foods in rural areas and poor weather. MK is not known for its rurality and there is a good spread of supermarkets. Everyone should be aware of winter weather and stock their fridges and pantries accordingly particularly if they have medical or dietary needs.

The availability of fortified breads is noted as a concern. We acknowledge that there may be a difference between supplier brands of Gluten Free foods and the content of various levels of vitamins and minerals. However, any supplementation of certain vitamins and minerals would be at a much lower dose than that needed to correct any actual deficiency. Patients with coeliac disease (particularly at diagnosis, and for some ongoing) may need additional supplementation for example of iron, calcium & vitamin D which should be assessed by a gastroenterologist or dietician and the requirement for supplements regularly reviewed. A general multi-vitamin and mineral supplement could also be purchased over the counter in discussion with their gastroenterologist/dietician.





# 11 Appendix A

## Funding Application for GLUTEN FREE FOODS



Milton Keynes Clinical Commissioning Group

Milton Keynes Clinical Commissioning Group's Governing Body has decided to stop providing gluten-free foods on the NHS unless there are specific circumstances whereby a **patient could be at risk of dietary neglect**. If you think that your patient's specific circumstances mean that they could be at risk of dietary neglect then you can request that their case is considered by MKCCG. You will need to complete this proforma and include as much information as possible so that the case can be fully reviewed by the team.

Patient NHS No.		Trust:		GP Name:	
Patient Hospital No.		Name of Dietitian /GP Making Request:		GP Practice:	
Patient initials & DoB:		Dietitian / GP Contact Details:			
<p>1. Please confirm diagnosis and explain why this patient could be at risk of dietary neglect. It is important to provide as much information as possible to inform the decision. <b>The application will be strengthened by including a testimony from the patient / carer setting out how the change in policy has impacted on them. This may be written in any format that the patient chooses and scanned / emailed along with this form. Alternatively you may wish to give the patient part 2 of this form to fill in and return to you.</b></p>					
<p>2. Please provide the patient's maximum units of gluten-free food allowable within MKCCG guidelines (based on Coeliac UK guidance). Please note that if approval is given it will only be for GF bread and flour mixes as specified in the drug Tariff.</p>					
<p>3. Please confirm that the (please tick):</p> <ul style="list-style-type: none"> <li>The patient's GP has been consulted and supports the application (if application being made by another healthcare professional)</li> <li>Patient will have an annual GP review and as part of that review an assessment will be made on whether there has been a change in circumstances which mean that the patient is no longer at risk of dietary neglect.</li> <li>CCG will be informed if the patient is no longer considered at risk of dietary neglect and so no longer requires gluten-free food at NHS expense.</li> </ul>					
<p>Dietitian / GP / Consultant contact e-mail in case of CCG query (secure nhs.net address):</p>					
<p>Dietitian / GP / Consultant signature (electronic signature acceptable):</p>					
<p>Date of application:</p>					

Only fully completed forms will be accepted for consideration by the CCG. Please send to [mkccgpharmacy@nhs.net](mailto:mkccgpharmacy@nhs.net)  
Statement from the Patient or their Carer

I would like the CCG to consider my case because

Please tick:

☐ This application is for gluten free foods on prescription for myself

☐ This application is submitted for (insert patient's name if not the person filling in the form) ..... and I have their permission to act on their behalf.

Signed

Print name

Date



## 12 Appendix B

Statutory Instruments  
2018 No. 1134

National Health Service, England  
The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018

Made	1st November 2018
Laid before Parliament	6th November 2018
Coming into force	4th December 2018

The Secretary of State for Health and Social Care makes the following Regulations in exercise of the powers conferred by sections 88 and 272(7) and (8) of the National Health Service Act 2006(1).

### Citation and commencement

1. These Regulations may be cited as the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) (Amendment) Regulations 2018 and come into force on 4th December 2018.

Amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

2.—(1) The National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(2) are amended as follows.

(2) For regulation 2 substitute—

“Drugs, medicines and other substances that may not be ordered

2.—(1) The following drugs, medicines and other substances may not be ordered for patients in the provision of medical services under a general medical services contract—

(a) a drug, medicine or other substance which is listed in Schedule 1;

(b) any gluten-free food; or

(c) any very low gluten food.

(2) But—

(a) paragraph (1)(b) does not apply to gluten-free bread or a gluten-free food mix;

(b) paragraph (1)(c) does not apply to very low gluten bread or a very low gluten food mix.



(3) 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 crossbred varieties which have been specially processed to reduce the gluten content, and where it contains oats—

(i) it has been specially produced, prepared or processed in a way to avoid contamination by wheat, rye, barley or their crossbred 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.”.

(3) In Schedule 1 (drugs, medicines and other substances not to be ordered under a general medical services contract) omit the entries for—

Appleford’s Gluten-Free Rice Cakes;

Clara’s Kitchen Gluten-Free Porridge;

Ener-G Gluten-free and Soya-free Macaroon Cookies;

Ener-G Gluten-free Rice Peanut-Butter Cookies;

Ener-G Gluten-free Rice Walnut Cookies;

Glutafin Gluten-Free Chocolate Chip Cookies;

Glutafin Gluten-Free Custard Cream Biscuits;

Glutafin Gluten-Free Gingernut Cookies;

Glutafin Gluten-Free Milk Chocolate Biscuits;

Glutafin Gluten-Free Milk Chocolate Digestive Biscuits;



Glutafin Gluten-Free Shortcake Biscuits;

Glutano Gluten-Free Chocolate Hazelnut Wafer Bar;

Glutano Gluten-Free Muesli;

Glutano Gluten-Free Pretzel;

Glutano Gluten-Free Wafer;

Glutano Gluten-Free Wafer, Cream Filled;

Gratis Gluten-Free Tricolour Pasta;

Juvela Gluten-Free Mince Pies;

Juvela Gluten-Free Sage & Onion Stuffing Mix;

Rite-Diet Gluten-Free Baking Powder;

Rite-Diet Gluten-Free Banana Cake;

Rite-Diet Gluten-Free Bourbon Biscuits;

Rite-Diet Gluten-Free Christmas Pudding;

Rite-Diet Gluten-Free Coconut Cookies;

Rite-Diet Gluten-Free Date & Walnut Cake;

Rite-Diet Gluten-Free Gingernut Cookies;

Rite-Diet Gluten-Free Half Covered Chocolate Digestive Biscuits;

Rite-Diet Gluten-Free Lemon Madeira Cake;

Rite-Diet Gluten-Free Muesli Cookies;

Rite-Diet Gluten-Free Rich Fruit Cake;

Rite-Diet Gluten-Free Wheat-Free Mince Pies;

Schar Gluten Free Sponge Cake;

Sunnyvale Gluten-Free Rich Plum Pudding;

Sun Yums Gluten Free & Dairy Free Almond & Coconut Cake;

Sun Yums Gluten Free & Dairy Free Banana & Sesame Cake;



Sun Yums Gluten Free & Dairy Free Carob & Mint Cake;

Sun Yums Gluten Free & Dairy Free Ginger & Pecan Nut Cake;

Sun Yums Gluten Free & Dairy Free Jaffa Spice Cake.

Signed by authority of the Secretary of State for Health and Social Care.

O'Shaughnessy

Parliamentary Under-Secretary of State,

Department of Health and Social Care

1st November 2018

# EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (“the 2004 Regulations”) to restrict the circumstances in which gluten-free foods and very low gluten foods may be ordered on prescription under general medical services contracts.

Regulation 2 of the 2004 Regulations is substituted by regulation 2(2) of these Regulations. As substituted, regulation 2 of the 2004 Regulations:

provides that gluten-free and very low gluten foods can no longer generally be ordered on prescription under general medical services contracts, with exceptions for gluten-free bread and food mixes, and for very low gluten bread and food mixes (paragraphs (1) and (2))

defines a food as “gluten-free” or as “very low gluten” by reference to its ingredients and its gluten content measured in milligrams per kilogram (paragraph (3))

defines other terms used in the regulation (paragraph (4)).

Schedule 1 to the 2004 Regulations is amended to remove entries relating to gluten-free foods as a result of the substituted regulation 2 (regulation 2(3) of these Regulations).

An impact assessment relating to this instrument has been prepared and copies can be obtained from the Department of Health and Social Care, 39 Victoria Street, London SW1H 0EU. It is also available alongside this instrument on [www.legislation.gov.uk](http://www.legislation.gov.uk).

(1)

2006 c. 41.

(2)



S.I. 2004/629; as amended by S.I. 2004/1625 and 3215, 2009/2230, 2010/2389, 2011/680 and 1043, 2013/363 and 2194 and 2015/1862.

