Department of Health

# The Availability of Gluten Free Foods on Prescription in Primary Care 

Consultation on the Availability of Gluten Free Foods on Prescription in Primary Care

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Author: Medicines and Pharmacy Directorate/Medicines Regulation and Prescribing Branch/Prescribing Policy and Regulation Team/17090

## Document Purpose: Consultation

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Target audience:

- Professional and representative bodies
- GPs
- Clinicians
- Pharmacists
- Patients' Associations
- Members of the Public
- Managers
- Commissioners
- Directors of Public Health
- Clinical Commissioning Groups


## Contact details:

Prescribing Policy and Regulation Team
Medicines and Pharmacy Directorate
Department of Health
Room 2E14
Quarry House
Quarry Hill
Leeds
LS2 7UE
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# The Availability of Gluten Free Foods on Prescription in Primary Care 

# Consultation on the Availability of Gluten Free Foods on Prescription in Primary Care 

Prepared by the Prescribing Policy and Regulation Team

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## Executive summary

This consultation seeks views on Department of Health proposals on whether or not to make changes to availability of gluten free (GF) foods that are prescribed in primary care.

Staple GF foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, and have been 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 now available, so the ability of patients to obtain these foods without a prescription has greatly increased.
Changes to the prescribing of GF foods could save NHS resources and reduce the primary care prescription drugs bill by up to $£ 25.7$ million per annum ${ }^{1}$.
Many Clinical Commissioning Groups (CCGs) now have limited types or units of GF foods available on prescription. A number of CCGs provide only bread and flour; several have stopped prescribing all GF foods. CCGs were set up to ensure that their local populations receive the medicines and treatments they require, with locally managed resources. Differing approaches to the availability of GF foods is creating regional variations across England.

Any changes made would only apply to primary care prescribing, and would not impact secondary care.

The Minister for Health has agreed to launch this public consultation on whether to make changes to the prescribing legislation for GF foods. The options considered are:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.

Under this option GF foods would continue to be prescribed in primary care at NHS expense as now.

- Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care.

Under this option no GF foods would be available on prescription in primary care.

- Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care, by amending Schedule 1 of the above regulations.

Under this option only certain GF foods would be available on prescription in primary care.
The consultation will close on 22nd June 2017. Responses and comments can be submitted through a dedicated mailbox: GFprescribing@dh.gsi.gov.uk

[^0]
## 1. Introduction

1.1. The Department of Health (DH) is launching a public consultation to seek views on whether any changes should be made to prescribing legislation on gluten free (GF) foods. A range of options have been set out in this consultation document including ending the prescribing of GF foods by adding them to the Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004, or amending these Regulations. Schedule 1 is commonly known as the blacklist, and GPs are not permitted to prescribe products from this list at NHS expense.
1.2. In certain conditions some food and toilet preparations have characteristics of drugs; these are known as "borderline substances" and these include GF foods. Individual GF food products are submitted by manufacturers for consideration by the Advisory Committee on Borderline Substances (ACBS). The committee recommends products for inclusion on the Drug Tariff based on product type and cost effectiveness, indicating their suitability to be prescribed in primary care.
1.3. GF foods are prescribed for 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. Gluten is found in foods that contain wheat, barley and rye (such as bread, pasta, cakes and some breakfast cereals). Screening for coeliac disease involves a two-stage process; a blood test to help identify people who may have coeliac disease and a biopsy to confirm the diagnosis. For patients who may have dermatitis herpetiformis (an itchy rash caused by gluten intolerance) a skin biopsy may be taken to confirm it.
1.4. Staple GF foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, and have been 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. Quantities of units are used to calculate the patient's GF dietary needs, and are based upon patient age and circumstances.
1.5. The national charity - Coeliac UK - provides advice and guidance to patients with coeliac disease on following a GF diet, and has a range of resources to support them. They provide recommendations on the units of GF foods that patients should be prescribed based on their gender, age and whether they are pregnant or breastfeeding. Clinical Commissioning Groups (CCGs) often use these guidelines to inform local prescribing formularies.
1.6. A range of options have been set out in this consultation document including ending the prescribing of all GF foods by amending the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) Regulations 2004. These are:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.
- Option 2: To add all GF foods to Schedule 1 of the above regulations to end the prescribing of GF foods in primary care.
- Option 3: To only allow the prescribing of certain GF foods (e.g. certain types of bread and flour) in primary care.
1.7. The Department of Health would welcome the views of interested parties as part of this formal consultation process. Replies to specific questions are sought through this consultation, these are highlighted in bold throughout this document and are summarised in Chapter 5.


## 2. Patient Health and Gluten Free Prescribing

## Patient Health

2.1. Staple GF foods, e.g. bread, flour, pasta, oats etc., are available on prescription to patients diagnosed with gluten sensitivity enteropathies. A limited number of non-staple foods are also available, including crackers, biscuits, and pizza bases. Eligible patients include those with coeliac disease and dermatitis herpetiformis. Prescriptions for these foods can be written by GPs and some CCGs issue local prescribing guidance based on the eligible foods listed in the Drug Tariff which are approved by the ACBS. Most CCG guidelines limit the amount of GF foods that can be prescribed per patient, which varies depending on a patient's age, gender and circumstances.
2.2. Following a lifelong GF diet is the only effective management of gluten sensitive enteropathies. How strict the diet needs to be depends on the severity of the patient's condition, most patients can tolerate trace amounts of gluten (e.g. gluten that may be present due to cross-contamination in the food preparation process). Patients with refractory coeliac disease continue to experience symptoms even when following a completely GF diet.
2.3. Failure to follow a GF diet can result in complications including osteoporosis and iron deficiency anaemia. Malnutrition can also occur in patients with severe cases of coeliac disease when a GF diet is not followed.
2.4. Unlike other foodstuffs, gluten containing products are not necessary for a healthy diet and patients with gluten sensitivity can safely exclude it from their diet and still eat healthily without purchasing special foods. Patients can safely eat meat, fish, vegetables, fruit, rice and most dairy products, and there are a wide variety of products now on the market e.g. rice cakes, crackers etc. to allow patients to complement their GF diets safely and obtain all their nutritional requirements.

## Gluten Free Prescribing

2.5. GF foods were made available on prescription in the late 1960 s when the availability of such foods on general sale was extremely limited. GF foods are now readily available in large supermarkets and therefore the ability of patients to obtain these foods without a prescription has greatly increased. However, some GF foods, in particular bread, are still more expensive than non-GF foods and there are fewer budget brands available.
2.6. Research into the prescribing position in England, as at March 2016, has shown that out of 209 CCGs in England, 112 have adopted policies to restrict the provision of GF foods. This includes 18 CCGs that have stopped the prescribing of all GF foods, and a further 12 that are considering or consulting on changes to GF prescribing. Of the CCGs that have made restrictions to the type of GF available, most have restricted to either bread and flour, or bread, flour and pasta.
2.7. GF foods are within the category of "Other Food for Special Diets", which appears at number 10 in the Top 20 drugs prescribed (table A2) ${ }^{2}$ which had the greatest Net

[^1]Ingredient Cost (NIC) $)^{3}$ in 2015, as published in the Prescriptions Dispensed in the Community: England 2005-2015 report. The amount totalled £99.7m, of which GF foods accounted for $£ 26.8 \mathrm{~m}$.
2.8. There are many different GF product types available on prescription, for example, the Drug Tariff (March 2016) lists 80 different bread products, consisting of bread types such as brown sliced loaf, white sliced loaf, flatbreads, wraps and part baked loaves. CCG research has found that this large range can be confusing for prescribers, especially for those who are not specialist nutritionists. Prescribers have limited time to spend in patient consultations and to comprehensively browse the large variety of products. Prescribing may therefore be largely led by the patient's personal choice and marketing by manufacturers. If Options 1 or 3 are implemented following this consultation, we will consider whether the range of products available should be limited to make prescribing easier and more cost effective.
2.9. Patients with coeliac disease have been able to obtain GF foods on prescription for many years, and may have become accustomed to receiving GF foods on prescription to supplement their food shopping. Some patients may put pressure on their GPs to prescribe non-staple products, or larger quantities, especially if they are exempt from prescription charges, to feed other family members to avoid cross contamination or separate meal preparation. Guidance is available to support professionals in making decisions on quantities to prescribe depending upon the age, gender or circumstances of the patient.
2.10. Following diagnosis GPs or dietitians will want to be confident that their patient is excluding gluten from their diet, prescriptions for GF food may assist the patient in gaining confidence in adjusting and maintaining a GF diet.
2.11. GPs may also feel a professional responsibility to provide GF foods on prescription to their patients, as they do for patients requiring special diets. Some health conditions that depend on certain foods on prescription, have greater health impacts if special diets are not adhered to, for example, low protein foods for patients with Phenylketonuria. Prescribers may also have a perception that some patients may not be able to afford to purchase GF products, and therefore not adhere to a GF diet.
2.12. If a patient with established gluten sensitivity does not visit their GP or dietitian on a regular basis, there is a risk that long term health conditions will not be picked up and treated accordingly. NICE guidance recommends annual medical appointments ${ }^{4}$ to review the patient's health, adherence and access to a GF diet. Coeliac patients are also advised to have an annual review, and many coeliac patients who do not access GF food on prescription still attend a health review with their GP or dietitian.
2.13. Some people choose to follow a GF diet as a lifestyle choice, believing that GF foods are healthier than gluten containing equivalents. Whilst the majority of GPs would not offer prescriptions for these patients without a coeliac disease diagnosis, research has found that some GPs will prescribe GF food to their patient if they request it. Lack of

[^2]gluten in a food product does not necessarily make it a healthier option, this is a common misconception as GF foods often contain more fat and sugar. ${ }^{5}$

[^3]
## 3. Evaluation and Patient Impact

3.1. Many of the local CCG changes have taken place in recent months or years, so the impact and evaluation on patient health has not yet been fully realised or only limited datasets are available upon which to conduct a comprehensive evaluation. However, Oxfordshire CCG, which restricted prescribing to bread and flour only in October 2012, ran patient and GP practice surveys over the following year to review the change. It found that $47 \%$ of patients reported no change to their diet, $38 \%$ reported their diet becoming unhealthier, and 7\% reported their diet becoming healthier. In answer to the question, 'Has your health suffered as a result of the change in policy?' $59 \%$ of patients answered 'no' and $25 \%$ answered 'yes' (the remainder answered 'don't know' or gave no response). In answer to the question 'Since the more restrictive policy was introduced in October 2012, is your perception that you've seen your patients with coeliac disease more frequently?' $75.6 \%$ of GPs answered 'no change' and the rest answered 'don't know'. In answer to the question, 'Have you referred more patients with coeliac disease to the dietetics service for advice and support?' $85 \%$ of GPs answered 'no change' and the rest answered 'don’t know'. Spend reduced by $£ 9,000$ per month, giving the CCG $£ 100,000$ annual savings. Feedback from GPs highlighted difficulty calculating how much food each patient was entitled to, following this, the CCG further restricted the policy to 8 units per patient per month regardless of sex or age.
3.2. Four main areas have been identified that could impact a patient's ability to follow a GF diet if any changes were made to prescribing legislation. These are:
3.2.1. Availability - GF foods are now more widely available to purchase from supermarkets, health food shops, and online retailers. They are also available in some budget and local convenience stores, although ranges in smaller retailers are limited. Staple GF foods are available on prescription in England, although some CCGs have made recent changes to their local prescribing formularies (see paragraph 2.6). Patients can safely exclude from their diets foods that would normally contain gluten.
3.2.2. Affordability - Research has shown that GF foods can be more expensive than their equivalents. This is especially the case for bread, and could impact upon adherence to a GF diet. However, a direct comparison between bread products is not accurate as GF bread may be more nutritionally complete meaning a patient would require a lower quantity. A comparison undertaken on product prices between GF food staples and non-GF products is shown in Figure 1.
3.2.3. Access to dietary advice - It is important that coeliac patients receive advice on maintaining a healthy diet and avoiding gluten containing foods. Many CCGs provide patient access to a dietitian, who can provide advice on ensuring their dietary needs are met, and what foods they can eat. Gluten is not necessary for a healthy diet and patients can safely exclude it and still eat healthily without special foods as many foods are naturally GF such as meat, fish, vegetables, fruit, eggs, lentils and rice.
3.2.4. Adherence - It is important that those diagnosed with established gluten sensitive enteropathies adhere to a lifelong GF diet to avoid health complications. The National Institute for Health and Care Excellence (NICE) provides guidance to clinicians on the diagnosis and management of coeliac disease. Figures on patient adherence rates, based on a model from 2005 and quoted by NICE are: adult adherence rates of $65.7 \%$, and $84 \%$ in children. The Department is not aware of any evidence that demonstrates a clear link between the availability of GF foods through
prescription and increased adherence to GF diets among patients with gluten sensitivity enteropathies. Systematic reviews of this issue show that the existing evidence for factors associated with adherence to a GF diet is of variable quality ${ }^{6}$ and that options for the standardised evaluation of adherence remain unsatisfactory ${ }^{7}$. We invite any further evidence on this to be submitted during the consultation.
3.3. The above narrative on patient impact is analysed and costed in the associated impact assessment in particular paragraphs 30, 56 and 79. The impact assessment is available as a separate document.

Figure 1 - Table of cost comparisons

| Product | NHS Indicative Price ${ }^{8}$ (Price per 100 g ) | GF product price per packet (price per 100g) | Branded non-GF equivalent price per packet (price per 100g) |
| :---: | :---: | :---: | :---: |
| White bread* | £3.69 (92p) | £1.94 (43p) | £1.00 (12.5p) |
| Pasta | £6.73 (£1.34) | £1.57 (45p) | £1.22 (22.9p) |
| Cornflakes | £3.48 (93p) | £1.72 (48p) | £1.75 (35p) |
| Plain flour | £3.10 (62p) | £1.62 (17p) | £1.44 (14.4p) |
| Oats | £2.78 (56p) | £2.30 (49p) | £1.04 (20.9p) |
| Biscuits | £3.46 (£1.73) | $\begin{aligned} & £ 2.08 \\ & (£ 1.37) \end{aligned}$ | £1.36 (45.3p) |
| Total price (one of each item) | £23.24 | £10.47 | £7.81 |

The items selected for NHS indicative pricing represent the most frequently prescribed item in each category from NHS Digital's Prescription Cost Analysis Report (England) 2015.
Price averages of Asda, Tesco \& Morrisons as published on mysupermarket.com on 19/01/2017
*Non-GF version may not be directly equivalent to GF version as many GF prescription products have additional characteristics, e.g. fortified, organic, dairy free; and may have a higher nutritional content per gram.

[^4]
## NHS Costs

3.4. The cost of GF food (Net Ingredient Cost (NIC)) in 2015 was $£ 25.7$ million. This figure includes $£ 16.8$ million on GF bread and GF grains/flour. CCG local action may continue to reduce this spend, but an increase from the current 250,000 patients to the figures estimated by NICE of $700,000-890,000^{9}$, would offset potential savings already made. Coeliac UK estimates that only $24 \%$ of people with coeliac disease currently have a diagnosis, meaning nearly half a million people may have the disease but are undiagnosed.
3.5. The availability of GF foods on prescription now varies across England as different CCGs adopt individual strategies for providing GF foods; some have limited types of GF foods available to patients, whilst others have completely ended GF food prescribing.
3.6. The GF foods listed on the Drug Tariff are provided on prescription at a price that provides the NHS with value for money. However, CCGs have identified out of pocket expenses that occur for some products, for example, fresh bread delivery charges, which are "Out of Pocket Expenses" (OOPE), these can significantly add to the price of providing that product for the patient, as NHS spend is shown as the Net Ingredient Cost (NIC) only.
3.7. The costs of handling GF food stocks adds to the costs of providing these foods from community pharmacies via pharmaceutical wholesalers who are not equipped to accommodate these products, especially when handling those with short expiry dates. In October 2016, 1179 product items whose NIC cost $£ 17,503$ attracted out of pocket expenses totalling $£ 33,912$.
3.8. If changes are made so that only certain GF food types are prescribed, for example, bread and flour, then patients would be able to obtain these items on prescription. As GF bread remains more expensive to buy than the gluten containing equivalent, this would assist the patient in obtaining some of their basic requirements. They could use flour to make a variety of GF items to assist in a varied diet.
3.9. There may be costs to the NHS associated with ceasing to prescribe GF foods if stopping prescribing leads to lower adherence GF diets. If adherence decreases there could be costs associated with treating increased numbers of complications relating to gluten sensitive enteropathies. However, we are not aware of any evidence that proves a link between the availability of GF foods on prescription and adherence to a GF diet. Therefore, it is difficult to predict the likelihood of these costs arising.
3.10. The Prescription Cost Analysis for England (2015) provided statistics on GF items that were prescribed in primary care. Figure 2 shows the breakdown of GF food type by NIC and items.

[^5]Figure 2 - Types of GF Food Prescribed in 2015 Cost and Items

| Type | Net Ingredient Cost (NIC) ${ }^{10}$ | Items <br> dispensed ${ }^{11}$ |
| :--- | :--- | :--- |
| Biscuits | $£ 1,086,400$ | 174,300 |
| Bread | $£ 16,710,900$ | 844,900 |
| Cakes/Pastries | $£ 300$ | 100 |
| Cereals | $£ 912,700$ | 160,800 |
| Cooking Aids | $£ 1000$ | 200 |
| Grains/Flours | $£ 132,100$ | 23,500 |
| Mixes (flour/bread) | $£ 4,328,900$ | 221,300 |
| Pasta | $£ 2,554,900$ | 262,100 |
| TOTALS | $£ 25,727,200$ | $1,678,200$ |

## Patient Options

3.11. If changes to the prescribing of GF foods were made at a national level, then patients would have several options for maintaining a GF diet. These are explored below and fully evaluated in the impact assessment.
3.11.1. Patients can follow a GF diet by consuming foods that are naturally GF, these include: meat, fish, eggs, fruit, vegetables, rice and most dairy products. Patients are able to obtain all their nutritional needs from these foods and do not need to seek GF equivalents.
3.11.2. Patients can purchase GF equivalents, such as bread, pasta, cereal and biscuits. These foods are not necessary for a healthy diet and can safely be excluded without any health impacts. These foods are now more widely available for patients who wish to buy them.
3.11.3. All patients can access dietary advice from their GP, community dietitian or pharmacist. Some CCGs are already using a dietitian led service to advise coeliac patients on maintaining a GF diet. It is also important that the patient attends a review appointment with their clinician at the recommended intervals to ensure any health complications arising from coeliac disease can be identified and treated. This is the case regardless of whether GF food is being prescribed.

[^6]3.11.4. A coeliac patient can choose not to adhere to a GF diet, this is a risk for all patients regardless of access to GF food on prescription. Adherence rates are shown to be $65.7 \%$ in adults, the Department is not aware of any research that demonstrates a clear link between the provision of GF foods on prescription and increased adherence.

## QUESTION ONE

Do you think GF foods should be available on prescription in primary care? Yes or no and why.

## QUESTION TWO

Do you think GF prescribing should be restricted to certain foods? Yes or no.
If yes, which foods should remain on prescription and why?

## QUESTION THREE (See paragraph 2.8)

Do you think the range of bread products available on NHS prescription should be limited? Yes or no.
If yes, please explain your answer.

## 4. Legislative Context

4.1. Any changes made to the prescribing of GF foods on prescription in primary care would need to comply with the National Health Service Act 2006.

The National Health Service Act 2006-Section 1A
4.2. The Secretary of State for Health has an obligation under the above Act to provide continuous improvement in the quality of service in connection with the prevention of illness. In freeing up resources from this area, the NHS could have additional funds to spend elsewhere including on medicines and on services for patients with gluten sensitive enteropathies.

## Legislative Updates

4.3. If any changes were to be made to the prescribing of GF foods, amendments to various pieces of legislation would be necessary.

Schedule 1 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004
4.4. In 1985, the Government issued a list of preparations which would no longer be prescribed on NHS prescriptions which became known as the "blacklist". To compile the list, the Government looked at several therapeutic groups then assessed the products in these groups on the grounds that, on expert advice, they had no clinical or therapeutic advantage over other, cheaper, drugs in seventeen therapeutic categories.
4.5. The blacklist is formally laid down in statute in Schedule 1 of the "National Health Services (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. General Practitioners are not able to prescribe medicines which are listed in Schedule 1. If pharmacists issue products that are listed then they will not receive reimbursement for those items. Hospital clinicians are not affected by these statutory restrictions.
4.6. The Department has not amended the criteria or added to the blacklist since the 2004 Regulations were enacted, therefore the blacklist is a historic list. However, it remains relevant in current NHS primary care settings.

## EU Transparency Directive

4.7. Depending on the outcome of this consultation, the Department may need to notify the European Commission of an amendment to the EU Transparency Directive (89/105/EC) which sets out the criteria used to regulate medicine pricing and inclusion in NHS reimbursement arrangements. It is not anticipated however that the EU requirements would in themselves lead to any timetabling delays.

Equalities and Health Inequalities
4.8. The Government is committed to equal treatment and equality of opportunity. The Public Sector Equality Duty (PSED), also known as the "General duty", is a key lever for ensuring that public bodies take into account equality when conducting their day-to-day work in shaping policy and delivering services. Under Section 149, public bodies are required to consider the need to eliminate unlawful discrimination, advance equality of
opportunity and foster good relations when making policy decisions and delivering services.
4.9. In developing the proposals contained in this consultation, the Department has taken into account the PSED as set out in the Equality Act 2010, and the Secretary of State's duties under the NHS Act 2006, including the duty to have regard to the need to reduce inequalities relating to the health service.
4.10. The Department has developed its proposals so as not to have an unjustifiable adverse impact on any protected groups, and would welcome your views on how to ensure this is done as effectively as possible. An Equalities Analysis will be published alongside the Government response to this consultation.

## 5. Consultation Proposals and Questions

5.1. The Department is consulting on whether or not to make any changes to the prescribing of GF foods at NHS expense in primary care. The options for consideration are as follows:

- Option 1: Make no changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004

Under this option GF foods would continue to be prescribed in primary care at NHS expense as now.

- Option 2: To add all GF foods to Schedule 1 of the above regulations, or to amend the above regulations, to end the prescribing of GF foods in primary care.

Under this option GF foods would no longer be available on prescription in primary care.

- Option 3: To only allow the prescribing of certain GF foods (e.g. bread and flour) in primary care.

Under this option only certain GF foods would be available on prescription in primary care.

## QUESTION ONE

Do you think GF foods should be available on prescription in primary care? Yes or no and why.

## QUESTION TWO

Do you think GF prescribing should be restricted to certain foods? Yes or no.
If yes, which foods should remain on prescription and why?

## QUESTION THREE

Do you think the range of bread products available on NHS prescription should be limited? Yes or no.

If yes, please explain your answer.

## 6. How to Respond to the Consultation

## Responding to the consultation

The Department welcomes responses to all of the questions above. Please submit your responses to the questions by 12pm on Thursday 22nd June 2017.

The preferred method of receiving your response is via the on-line consultation questionnaire, which can be found on CitizenSpace:
https://consultations.dh.gov.uk/homeopathic/nhs-prescribing-of-gluten-free-foods
Please use this to record your responses. Alternatively, you may wish to complete the response form and e-mail it to us at:

## GFprescribing@dh.gsi.gov.uk

If you do not have internet or e-mail access, then please write to:
Prescribing Policy and Legislation Team
Department of Health
Room 2E14
Quarry House
Quarry Hill
Leeds
LS2 7UE

A paper copy of this consultation document, and the corresponding response form, is available on request, using the e-mail address. If you have any questions about the content of this consultation then please send them to: GFprescribing@dh.gsi.gov.uk

If you wish to do so, you can request that your name and/or organisation be kept confidential and excluded from the published summary of responses.

Please note that we may use your details to contact you about your responses or to send you information about our future work. We do not intend to send responses to each individual respondent. However, we will analyse responses carefully and give clear feedback on how we have developed the implementation plan as a result.

## Comments on the consultation process

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
2E26 Quarry House
Leeds
LS2 7UE
e-mail: consultations.co-ordinator@dh.gsi.gov.uk
Please do not send consultation responses to this address.

## Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter.

Any information received, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information you have provided we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding by the Department.

The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

## Next Steps

The Department will collate and consider all responses to this consultation and will make a recommendation to the Minister for Health, who will make a decision on whether or not to make any changes to the prescribing of GF foods in primary care. The outcome will usually be published within three months of the consultation closing date.


[^0]:    ${ }^{1}$ Prescription Cost Analysis England 2015, spend on GF foods.

[^1]:    ${ }^{2}$ http://digital.nhs.uk/catalogue/PUB20664/pres-disp-com-eng-2005-15-rep.pdf

[^2]:    ${ }^{3}$ Net Ingredient Cost (NIC) is the basic cost of a drug; it does not take into account discounts, dispensing costs, fees or prescription charges income.
    ${ }^{4}$ NICE NG20: https://www.nice.org.uk/guidance/ng20/chapter/key-priorities-for-implementation

[^3]:    ${ }^{5} \mathrm{http}: / /$ www.foodnavigator.com/Market-Trends/How-nutritious-are-gluten-free-foods

[^4]:    ${ }^{6}$ Haines ML, Anderson RP, Gibson PR. Systematic review: The evidence base for long-term management of coeliac disease. Aliment Pharmacol Ther 2008;28(9):1042-66. http://www.ncbi.nlm.nih.gov/pubmed/18671779
    ${ }^{7}$ Leffler DA, Edwards George JB, Dennis, M, et al. A prospective comparative study of five measures of gluten-free diet adherence in adults with coeliac disease. Aliment Pharmacol Ther 2007; 26: 1227-35.
    http://www.ncbi.nlm.nih.gov/pubmed/17944737
    ${ }^{8}$ The NHS Indicative price is the listed price of the product and does not include dispensing fees or delivery charges.

[^5]:    ${ }^{9}$ NICE Shared Learning Resource: https://www.nice.org.uk/sharedlearning/service-evaluation-for-group-clinics-for-new-patients-with-newly-diagnosed-coeliac-disease

[^6]:    ${ }^{10}$ The Net Ingredient Cost (NIC) is the basic cost of the product; it does not take into account discounts, dispensing costs, fees, or prescription charges income.
    ${ }^{11}$ The Items Dispensed may equate to more than one product, for example, $2 \times 400 \mathrm{~g}$ brown loaf listed on a prescription form would be counted for prescribing purposes as one item.

