Title: The Availability of Gluten Free Food on Prescription in Primary Care **IA No:** TBC **RPC Reference No:** N/A **Lead department or agency:** Department of Health **Other departments or agencies:** **N/A**	**Impact Assessment (IA)** **Date:** 06/09/2016 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Secondary legislation **Contact for enquiries:** Carol Walker

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One-In, Three-Out**	**Business Impact Target Status**
£1,206m	£m	£m	Not in scope	Non qualifying provision

What is the problem under consideration? Why is government intervention necessary?

Gluten-free (GF) foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, including coeliac disease. However, a wide range of formulated and naturally gluten-free foods are available in supermarkets and other food retail outlets. Restricting gluten-free prescribing would deliver savings that could be re-invested more effectively in other areas. Any such restrictions would be a matter of amending national prescribing legislation: the NHS does not have the statutory authority to do this.

What are the policy objectives and the intended effects?

The original policy of prescribing gluten-free foods was to encourage patients to adhere to a gluten-free diet, when availability of formulated GF foods was limited. This helped prevent more complex health problems from developing. As formulated GF foods (and naturally gluten-free foods including meat, fish, vegetables, fruit, rice and most dairy products) are now widely available to purchase in supermarkets and other retail outlets, the policy objective is to make cost savings through restricting the prescribing of GF foods, whilst maintaining adherence among patients and so avoiding detrimental health effects.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

There is no alternative to regulation. The NHS cannot tell a GP what to prescribe. Prescribing rights are explicitly laid down in legislation as part of General Medical Services regulations and only the Government can amend them.

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

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

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

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 2021

Does implementation go beyond minimum EU requirements?		N/A		
Are any of these organisations in scope?	**Micro** Yes/No	**Small** Yes/No	**Medium** Yes/No	**Large** Yes/No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY: ....

Summary: Analysis & Evidence

Policy Option 1

Description: Make no changes

FULL ECONOMIC ASSESSMENT

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised costs by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

Other key non-monetised costs by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate				

Description and scale of key monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

Other key non-monetised benefits by 'main affected groups'

This is the baseline against which other options are assessed and is by definition 0.

Key assumptions/sensitivities/risks — **Discount rate (%)** NHS 1.5 Other 3.5

NHS spending on GF foods (and associated primary care appointments and dispensing costs) is assumed to remain constant in real terms over the appraisal period. This assumption is tested in sensitivity analyses.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Summary: Analysis & Evidence

Policy Option 2

Description: End Prescribing of GF Foods

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 958	**High:** 1,509	**Best Estimate:** 1,206

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low		0	Optional	**Optional**
High			Optional	**Optional**
Best Estimate	0		• 27	**275**

Description and scale of key monetised costs by 'main affected groups'

Patients must now purchase GF foods in place of prescriptions, at a cost of £25.5m p.a., with a Present Value of £225.5m. The NHS loses revenue from prescription charges worth £1.4m p.a. When reinvested into the NHS this would generate 95 QALYs p.a., which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £53m.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional	2	Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		148	**1,481**

Description and scale of key monetised benefits by 'main affected groups'

The NHS saves approximately £39m p.a.; comprising £25.5m from reduced Net Ingredient Cost (NIC) spend, £11m from fewer primary care appointments to write prescriptions, and £2.5m from reduced dispensing fees. When reinvested in the NHS, this is expected to generate 2,614 QALYs p.a., which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £1,468m. Patients avoid prescription charges of £1.4m p.a., giving a Present Value of £12.2m.

Other key non-monetised benefits by 'main affected groups'

Additional savings where pharmacies faced costs over and above NIC (for example, increased delivery costs when handling fresh food) to dispense GF foods.

Key assumptions/sensitivities/risks — **Discount rate (%)** NHS 1.5 Other 3.5

There is no effect on adherence to GF diets for patients diagnosed with gluten sensitivity enteropathies.

Where an effect on adherence is considered (in sensitivity analysis and low estimate) the assumed cost effectiveness of GF food is £25k/QALY. Savings to the NHS are reinvested at the margin.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Summary: Analysis & Evidence

Policy Option 3

Description: Limit prescribing of GF foods to bread and flour

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 372	High: 600	Best Estimate: 479

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional	2		**Optional**
High	Optional			**Optional**
Best Estimate	0		• 10	**104**

Description and scale of key monetised costs by 'main affected groups'

Patients must now purchase GF foods in place of some prescriptions, at a cost of £8.9m p.a., with a Present Value of £76.6m. The NHS loses revenue from prescription charges worth £0.7m p.a. When reinvested into the NHS this would generate 49 QALYs p.a., which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £27.5m.

Other key non-monetised costs by 'main affected groups'

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate			58	**583**

Description and scale of key monetised benefits by 'main affected groups'

The NHS saves approximately £15m p.a.; comprising £8.9m from reduced Net Ingredient Cost (NIC) spend, £5.3m from fewer primary care appointments to write prescriptions, and £1.2m from reduced dispensing fees. When reinvested in the NHS, this is expected to generate 1,027 QALYs p.a., which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £577m.

Patients avoid prescription charges of £1.4m p.a., giving a Present Value of £12.2m.

Other key non-monetised benefits by 'main affected groups'

Additional savings where pharmacies faced costs over and above NIC (for example, increased delivery costs when handling fresh food) to dispense GF foods.

Key assumptions/sensitivities/risks — **Discount rate (%)** NHS 1.5 Other 3.5

There is no effect on adherence to GF diets for patients diagnosed with gluten sensitivity enteropathies.

Where an effect on adherence is considered (in sensitivity analysis and low estimate) the assumed cost effectiveness of GF food is £25k/QALY. Savings to the NHS are reinvested at the margin.

Bread and flour prescribing does not grow in a 'compensatory' fashion (testing in sensitivity analysis).

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	**Benefits:**	**Net:**	

Evidence Base (for summary sheets)

Introduction

1. Gluten-free (GF) foods are available on prescription to patients diagnosed with gluten sensitivity enteropathies, including coeliac disease, and have been since the late 1960s when the availability of GF foods was limited. Formulated GF foods are now readily available in a range of supermarkets and other food outlets. Formulated GF foods are those foods that are specially produced and processed by manufacturers to be gluten free.

2. Gluten is not necessary for a healthy diet and patients 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 as these do not contain gluten.

3. Monetary costs associated with the Net Ingredient Cost (NIC) of gluten-free prescriptions in 2015 were **£25.7 million**. This has increased over the last 10 years by **25%**. Data from 2015 shows that this spend mainly related to the prescribing of staple foods such as bread, flour and pasta but also to non-staple items including biscuits, cakes and pastries which were all prescribed at NHS expense. Meanwhile, the number of GF food prescription items dispensed in 2015 was **1,678,200**. This is an increase of **9.5%** over the last 10 years.

4. The listing in the Drug Tariff advises that GF foods should only be prescribed for those patients with established gluten-sensitive enteropathies. This is the case in the majority of NHS Clinical Commissioning Groups (CCGs). However we understand from conversations with CCGs that there are cases where a GP will prescribe to patients without a formal diagnosis and to those patients who wish to include gluten-free foods as part of a lifestyle choice.

5. Gluten-free prescribing is an area where CCGs have already been working to deliver efficiencies. 121 out of **209** CCGs have restricted prescribing in some way. Of these, **45** have restricted to bread and flour, or bread, flour and pasta whilst **18** have ended prescribing of all GF foods. We have gathered much evidence from the CCGs to help determine the impact of our proposed national changes.

6. Figures on patient adherence rates, based on a model from 2005 and quoted by the National Institute for Health and Care Excellence (NICE) are; adult adherence rates of **65.7%,** and **84%** in children. This difference could be due to diet choices for children being made by a parent or carer who are more aware of the implications of ill health for that child should a GF diet not be followed.

7. The NHS Constitution[1] sets down principles, values, rights and pledges that apply to both patients and NHS employees. Principle 6 states that treatments should make best use value for taxpayers money, and principle 7 states that it should be accountable to everyone it serves.

Problem under Consideration & Rationale for Intervention

8. The main societal benefit of spending in the NHS is the provision of health gains to patients. Gluten-free foods are now more readily available and patients can access a varied range of products from supermarkets without a prescription. More health gains would be generated if prescribing expenditure was reduced, and the funds used elsewhere in the NHS.

Equalities and Health Inequalities

9. The consultation document details the consideration of equalities, health inequalities and the impact on vulnerable groups. An Equalities Analysis will be published alongside our response to this consultation.

10. For the purposes of this IA, it is important to identify any potential for worsening access to healthcare, which may affect some groups of individuals disproportionately. The policy proposals largely mitigate this risk as follows:

    - Patients will have access to naturally GF foods
    - Patients can easily obtain formulated GF foods at a range of food retail outlets, including supermarkets

[1] http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx

Policy Objective

11. To reduce the costs of gluten-free prescribing on the NHS which will release savings that can be used to provide health gains to patients elsewhere in the NHS. This to be done whilst maintaining patient adherence to a gluten-free diet so that detrimental health outcomes do not occur.

Description of Options Considered

12. **Option 1 –** Make no changes – Not to make any legislative changes to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 - Schedule 1 – continue with the current policy which allows GF foods to be prescribed in primary care. This option will allow the continued prescribing of GF foods in primary care and there will be no changes to patient access to secondary care for the management of coeliac disease, or treatment to related health conditions.

13. **Option 2** - To end the prescribing of all gluten-free foods for patients. This option will prevent GF foods from being prescribed in primary care, and will require the updating the above regulations.

14. **Option 3** - To supply only basic provisions to all patients with gluten-sensitive enteropathies, e.g. bread and flour. This option will prevent non staple GF foods from being prescribed in primary care and will require the above regulations to be updated.

Option 1: Make no Changes (the Counterfactual)

15. The Net Ingredient Cost (NIC) of GF foods currently prescribed by the NHS is £25,727,200[2]. The NIC is the basic price of a drug; that is, the price listed in the British National Formulary. For the purpose of the Impact Assessment, this is taken to reflect the cost to the NHS of reimbursing pharmacies for providing these items to patients.

16. In additional to reimbursement of the cost of purchasing medicines, pharmacies are reimbursed for services they provide. Dispensing prescription items to patients attracts a per item fee estimated at £1.50 per item[3]. There were 1,678,200 prescription items of GF food dispensed in 2015[4], costing a total of £2,517,300 (that is, 1,678,200 x £1.50).

17. A consultation with a GP in primary care is required to gain a prescription. A prescription may result from an initial diagnosis, from routine (planned) management, or from a consultation arranged primarily to gain a prescription. The cost to the NHS of the primary care consultations primarily to gain a prescription for GF foods is estimated at £10,969,770. This is derived as below:

    a. There are 1,678,200 prescription items
    b. There average number of prescription items per script is 2.03[5]
    c. Thus, the number of prescriptions is estimated at 827,387 (That is, a/b)
    d. 23% of prescriptions are acute[6]. It is assumed each of these required a consultation. Thus it is estimated there are 190,299 acute prescriptions (that is, 23% of 827,387 [c]).
    e. 77% of prescriptions are repeat prescriptions[7]. We assume each repeat prescription is filled three times before a further consultation is required. Thus it is estimated there are 212,363 repeat prescriptions (that is, 77% of 827,387 [c]).
    f. Repeat prescriptions are likely to be for management of diagnosed conditions needing other healthcare interventions, such as regular screening. It is assumed to be equally likely that a repeat prescription comes from a consultation arranged primarily to gain a prescription or from a consultation also including other management. Thus, it is estimated that there are 106,181 consultations arranged primarily to gain a prescription for GF food. (That is, e/2.)
    g. The total number of primary care consultations arranged primarily to gain a prescription for GF food is estimated at 296,480. (That is, d+f.)
    h. The cost of these appointments is estimated at £10,969,770. (That is, 296,480 [g] x £37[8]

[2] Electronic Prescription Analysis and CosT (e-PACT) data 2015

[3] This comprises: a Professional Fee of £0.90 per item; a (variable) Practice Payment of approx. £0.54 per item; and other smaller payments including for Electronic Transmission of Prescriptions.

[4] Electronic Prescription Analysis and CosT (e-PACT) data 2015

[5] BSA data

[6] Petty, D.R., Zermansky, A.G., and Alldred, D.P. (2015). *The scale of repeat prescribing – time for an update*.

[7] Ibid

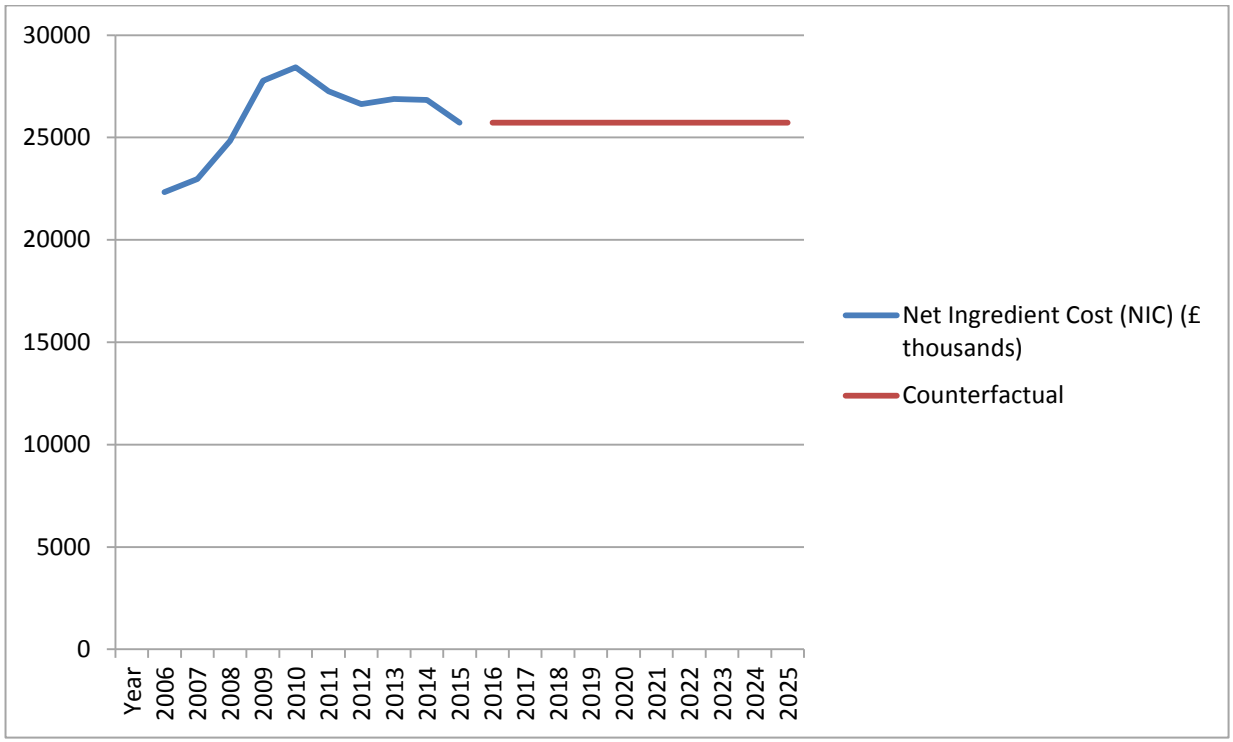
18. Only 10.1% of prescription items attract a prescription charge payable by the patient[9]. This charge is currently £8.40[10]. Thus, the cost to patients of prescription charges is estimated at £1,423,785. (That is, 10.1% of 1,678,200 prescription items, x £8.40.)

19. It is assumed that the NIC (and associated primary care and dispensing costs) fully captures the cost to the NHS of prescribing GF foods. However, anecdotal evidence suggests that pharmacies may face additional costs, including substantial delivery costs, to dispense GF foods. These potential savings are not monetised and so savings are considered a conservative estimate. We invite any further evidence on this to be submitted during the consultation.

Forecast

20. The costs associated with current prescribing practice estimated above are per year. For the purposes of this Impact Assessment, it is necessary to forecast how these will change over time. In the past 10 years, the NIC of gluten-free foods has grown by 25%. For the first five years, the NIC rose steadily and then experienced a small decline in the latter 5 years. It is assumed the rise reflects the increase in prices and increasing number of cases of patients diagnosed with gluten-sensitive enteropathies and that the decline occurred as CCGs restricted gluten-free prescribing in some way. It is assumed that the costs associated with prescribing GF foods would remain constant in real terms, as illustrated in Chart 1 below.

Chart 1: Observed Trend and Forecast Costs of GF Prescribing in Primary Care



Overview of Costs and Benefits

21. Options 2 and 3 restrict the prescribing of GF foods to different degree. The same impacts are thus identified for each, but the scale of these impacts differs between the two options. The following impacts are identified:

[8] £37 is the estimated cost of a GP appointment (PSSRU, Unit Costs of Health and Social Care 2015, Per patient contact lasting 11.7 minutes, Including direct care staff costs, Without Qualification costs)

[9] HSCIC, Prescriptions Dispensed in the Community, 2004-2014.

[10] http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Prescriptioncosts.aspx

Benefits

- A saving to the NHS from reduced NIC spending;
- A saving to the NHS from requiring fewer primary care consultations to offer prescriptions for GF foods;
- A saving to the NHS from reduced dispensing fees associated with prescriptions for GF foods; *and*
- A saving to patients who no longer pay prescription charges

Costs

- The cost to patients of buying their own GF foods;
- The loss of revenue to the NHS from prescription charges; *and*
- The potential for adverse health outcomes if patients diagnosed with gluten sensitivity enteropathies, including coeliac disease, become non-adherent to a GF diet

22. Cost savings to the NHS are assumed to be reinvested at the margin, where they achieve a cost effectiveness of £15k per QALY[11] (that is, every £15,000 invested at the margin generated an additional QALY). These QALYs are discounted at a rate of 1.5%, and monetised at a value of £60,000 each.

Patient Choices and Adherence

23. Patients diagnosed with gluten sensitivity enteropathies, including coeliac disease, face a choice of whether to adhere to a GF diet. Where they are adherent, they face a reduced risk of complications. A patient presently faces the following choice:

    - Adhere through purchasing naturally GF food
    - Adhere through purchasing formulated GF food
    - Adhere through obtaining formulated GF food through prescription
    - *Not adhere*

24. In practice, patients that adhere to a GF diet will do so through some combination of naturally GF food and formulated GF food both purchased privately and obtained through prescription. That is, through a combination of the three routes to adherence.

25. Under Option 2, patients are no longer able to obtain formulated GF food through prescription. Thus, if they choose to adhere to a GF diet, they must do so by purchasing naturally GF food or by purchasing formulated GF food. Effectively, patients have one fewer route to adherence. Options are thus:

    - Adhere through purchasing naturally GF food
    - Adhere through purchasing formulated GF food
    - *Not adhere*

26. Under Option 3, patients are able to obtain bread and flour through prescription. Options are thus:

    - Adhere through purchasing naturally GF food
    - Adhere through purchasing formulated GF food
    - Adhere through obtaining formulated GF bread and flour through prescription
    - *Not adhere*

27. Where patients elect to become non-adherent, there are cost implications for themselves and for the NHS. It does not matter whether patients who elect to adhere to a GF diet do so through purchasing naturally or formulated GF foods; where they do so through obtaining GF foods through prescription, as is possible under Options 2 and 3, this presents a cost to the NHS.

Health Effects: The link between GF food prescriptions and adherence

28. Gluten is not necessary for a healthy diet and patients 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 as these do not contain gluten.

29. Formulated and naturally GF foods are readily available in a range of supermarkets and other food outlets.

[11] The Quality Adjusted Life Year (QALY) is a standard unit used to measure health gains that combines both quantity (mortality) and quality (morbidity) effects.

30. 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[12] and that options for the standardised evaluation of adherence remain unsatisfactory[13]. We invite any further evidence on this to be submitted during the consultation.

31. In order to assess the likely impact of this policy, it is assumed that there is no effect on adherence. This assumption is tested in sensitivity analyses.

Health Effects: The link between adherence and health effects

32. Non-adherence to GF diets among patients with gluten sensitivity enteropathies can cause serious health problems. According to the National Institute for Health and Care Excellence (NICE), those who are not following 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[14].These complications present a cost to the patient (forgone health), and to the NHS (as treatment costs).

33. We are not aware of robust evidence leading to consensus on the clinical or cost effectiveness of GF formulated foods. Thus, this Impact Assessment has assumed a cost effectiveness of spending on GF formulated food (through prescriptions) at £25,000 per QALY (that is, the midpoint of the range in which NICE tend to recommend a treatment)[15]. This value is used in sensitivity analyses that consider the link between prescribing and adherence. The assumption itself is tested in sensitivity analyses.

Modelling Health Effects

34. The central estimate assumes there are no effect on adherence, and so no consequent impact on health. Nonetheless, it is important to consider how to estimate the effect on health were there any effect on adherence (as is considered in sensitivity analysis, and presented in the 'low' estimate of NPV).

35. In the absence of robust evidence on the cost effectiveness of GF foods, we assume that NHS GF spending has a cost effectiveness of £25,000 per QALY. That is, it has a cost effectiveness approximately equivalent to the mid-point of the range in which NICE recommend treatments for use by the NHS. We invite any further evidence on this to be submitted during the consultation.

36. In options 2 and 3, spending on GF foods by the NHS is replaced by spending by private consumers, who purchase the same amount of formulated and naturally GF food[16]. If consumers were to purchase less (that is, if there were an effect on adherence), the health effect would equal the difference in spending divided by the assumed cost effectiveness of GF food (that is, health forgone through reduced spending would equal the health previously 'bought' through that spending).

37. For example, if Option 2 caused a 1% drop in adherence, this would mean private consumers spent £257,272 less than the NHS spent previously (that is, 1% of £25.7m). Given the assumption that spending on GF food has a cost effectiveness of £25,000 per QALY, £257,272 would previously have 'bought' 10.3 QALYs (that is, 257,272/25,000). Thus, the health impact of a 1% effect on adherence at an assumed cost effectiveness of £25,000 per QALY would be a loss of 10.3 QALYs per year.

38. QALYs are valued at £60,000 each. Thus, in this worked example, the monetised cost of a 1% change in adherence is £617,453 per year (that is, 10.3 x £60,000).

39. Gluten is not necessary for a healthy diet and patients can safely exclude it from their diet and still eat healthily without purchasing formulated GF foods. Patients can safely eat meat, fish, vegetables, fruit, rice and most dairy products as these do not contain gluten. This modelling approach thus considers the health

[12] 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

[13] 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

[14] National Institute for Health and Care Excellence NG20 (2015) Coeliac disease: recognition, assessment and management 2015

[15] https://www.nice.org.uk/news/blog/carrying-nice-over-the-threshold

[16] We are assuming that the consumer re-prioritises spending their income to gluten-free foods to ensure they maintain the same QALYs they had previously, with no off-set

effects on those patients that are only able to adhere to a gluten-free diet through obtaining formulated GF foods.

The Relative Prices and Availability of Formulated GF foods

40. This Impact Assessment assumes that the money previously spent by the NHS is now spent by private consumers, who face the same price. However, consumers may also choose to adhere to a GF diet through purchasing naturally GF foods, at a significantly lower price. Thus, the costs faced by private consumers are likely to be overestimated. We invite any further evidence on this to be submitted during the consultation.

41. Evidence suggests the NHS faces higher prices for formulated GF foods than patients, for example through increased delivery costs when handling fresh food (that is, pharmacies are less well-equipped to handle fresh foods than a supermarket is). Table 1, below, based on evidence from Clinical Commissioning Groups, illustrates this difference.

Table 1: Relative pricing of GF foods

Gluten-free (GF) product	Clinical Commissioning Group (CCG)[17]	CCG estimate of cost of GF product on prescription to the NHS	CCG estimate of cost of GF product in supermarket	Supermarket own-brand price of gluten-containing equivalent(s)[18]
3 bags of gluten-free pasta (500g)	Herefordshire	£20.97	£5.04	£3.60
1 bag of gluten-free pasta (500g)	West Hampshire	Between £2.72 and £11.25	Between £1.35 and £2	£1.20
1 bag of gluten-free pasta (500g)	Telford	Between £3.60 and £6.60	Between £1.50 and £1.99	£1.20

42. Evidence from the CCGs clearly shows that the NHS pays much more than the consumer for the same gluten-free products. Upon further investigation, there is not a lot of transparency on how the NHS costs are made up. In discussion with CCGs, the general consensus is that costs are shared between the manufacturers, a dispensing fee, a pharmacy fee and a delivery charge.

43. Again, this may mean that the costs to consumers are overestimated. We invite any further evidence on this to be submitted during the consultation.

44. GF foods are widely available for consumers to purchase from supermarkets, health food shops and other food outlets. In addition to these being available in-store, GF products in the major supermarket chains are available on-line and consumers can have their shopping delivered to their home. We assume that such availability of GF products encourages consumers to maintain a gluten-free diet.

Option 2: End prescribing of GF foods

45. Option 2 would end the prescribing of gluten-free foods in primary care. Prescribing regulations would be amended accordingly.

Option 2 Benefits

46. The Net Ingredient Cost (NIC) saving from ending the prescribing of GF foods in primary care must equal the amount that would otherwise have been spent ('the counterfactual' as determined in Option 1), and is thus estimated at £25,727,200[19].

[17] Data taken from respective CCG websites

[18] Data taken from www.sainsburys.co.uk

[19] Electronic Prescription Analysis and CosT (e-PACT) data 2015

47. Similarly, savings to the NHS from reduced dispensing fees are estimated at £2,517,300 p.a. The derivation of this is explained in Option 1.
48. Savings to the NHS from fewer primary care consultations primarily to gain a prescription for GF foods is estimated at £10,969,770. The derivation of this is explained in Option 1.

49. Total savings to the NHS are thus estimated at £39,214,270 p.a. (That is, the sum of savings from NIC, dispensing costs, and primary care consultations.)

50. It is assumed that these cost savings are reinvested into the NHS, at the margin, where they generate an additional health gain of 2,614 QALYs p.a., which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £1,468m.

51. Those patients that previously paid a prescription charge will no longer do so. This saving is considered a benefit to those patients. Patients avoid prescription charges of £1.4m p.a., giving a Present Value of £12.2m. The derivation of this is explained in Option 1.

52. Total benefits (that is, benefits to the NHS and benefits to patients) are estimated to have a Present Value of £1,480m.

53. Note that it is assumed that NIC and associated primary care and dispensing costs (as described above) fully capture the cost to the NHS of prescribing GF foods. However, anecdotal evidence suggests that pharmacies may face additional costs, including substantial delivery costs, to dispense GF foods. These potential savings are not monetised and so savings are considered a conservative estimate. We invite any further evidence on this to be submitted during the consultation.

54. The estimated benefits of option 2 are presented in Table 2, below:

Table 2: Option 2 Benefits

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Benefits to NHS										
Reduction in NHS GF Foods NIC Spend	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200
Reduction in Dispensing fees	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300	£ 2,517,300
Reduction in Primary Care Spend (through reduction in appointments to gain prescriptions)	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770	£ 10,969,770
Total Benefits to NHS, £	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270	£ 39,214,270
QALYs gained through reinvesting saving at NHS margin	2,614	2,614	2,614	2,614	2,614	2,614	2,614	2,614	2,614	2,614
Value of QALYS gained, £	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082	£ 156,857,082
NPV of Benefits to NHS (1.5% discount rate), £	£1,468,263,429									
Benefits to Patients										
Avoided Prescription Charges	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785
NPV of Benefits to Patients (3.5% discount rate), £	£12,255,494									
Total NPV of Benefits, £	£1,480,518,923									

Option 2 Costs

55. Patients must now purchase GF foods in place of prescriptions, at a cost of £25.5m per year[20], with a Present Value (cost) of £225.5m.

56. It is assumed that, given the wide availability of GF foods in supermarkets and other food retail outlets, this policy has no impact on adherence, and so impact on health, or associated costs. This assumption is tested in sensitivity analyses below, and we invite any further evidence to be submitted during the consultation.

57. The NHS loses revenue from prescription charges worth £1.4m per year. As with benefits accruing to the NHS, the health gains (in this case the health gains forgone) are calculated and expressed in QALYs, with an assumption that the revenue would previously have been invested at the margin. Lost revenue is thus

[20] It is assumed that, where no effect on adherence effect is observed, patients face the same cost for a given item as the NHS. However, limited evidence from CCGs comparing the prices that the NHS pays with the price available to patients in major supermarkets suggests that patients may, in fact, face much lower costs, and so this cost to patients may be overestimated. We invite any further evidence on this to be submitted during the consultation.

equivalent to a loss of 95 QALYs per year. (That is, £1.4m divided by £15,000[21]), which discounted at 1.5% and monetised at £60k each give a Present Value (cost) to the NHS of £53m.

58. The estimated costs of option 2 are presented in Table 3, below:

Table 3: Option 2 Costs

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Costs to the NHS										
Loss of prescription charge revenue	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785	£ 1,423,785
QALYs forgone at NHS margin	94.9	94.9	94.9	94.9	94.9	94.9	94.9	94.9	94.9	94.9
Value of QALYS forgone £	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140	£ 5,695,140
NPV of Costs to NHS (1.5% discount rate), £	£1,468,263,429									
Costs to Patients										
Additional spending by consumers	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200	£ 25,727,200
NPV of Costs to Patients (3.5% discount rate), £	£221,451,672									
Total NPV of Costs, £	£274,761,124									

Option 2 Net Effect

59. The Net Present Value (NPV) of Option 2 is thus estimated at £1,206m (that is, the Present Value of benefits minus the Present Value of costs).

Sensitivity Analysis

60. A number of assumptions are made in quantifying the impact above, and it is necessary to consider how varying these assumptions might affect the estimated NPV. This is done through sensitivity analysis below.

61. As benefits (cost savings) are implied by the reduction in spend against the counterfactual (that is, what would have happened anyway), estimated benefits are sensitive to the assumed growth in spending in Option 1. The central estimate is based on there being no growth in GF spending: if counterfactual spending were in fact observed to be rising by 5% per year, the NPV of Option 2 would rise by £304m, to £1,509m; if counterfactual spending were observed to be falling by 5% per year, the the NPV of Option 2 would fall by £233m, to £972m. The estimate given rising spend is presented as the 'high' estimate for Option 2.

62. Costs are estimated by modelling a number of interdependent variables, making it difficult to isolate and explore the impact of varying any one. For example, the cost effectiveness of GF spend only becomes relevant where an effect on adherence is assumed. Thus, to present a 'low' estimate, the following assumptions are made:

    - GF spend was falling by 5% per year (as opposed to being constant in the central estimate);
    - there is a detrimental effect on adherence of 5% (that is, 5% of patients that were previously adherent through NHS GF spending become non-adherent, as opposed to the policy having no effect on adherence); *and*
    - the cost effectiveness of GF spend is estimated at £25,000 per QALY

63. Under these assumptions, the NPV of Option 2 would fall by £248m, to £958m. This is presented as the 'low' estimate of Option 2.

64. We invite views on appropriate sensitivity analyses to be submitted during the consultation.

Option 3: Restrict Prescribing of GF foods

65. Option 3 would restrict prescribing to basic provisions only to all patients with gluten-sensitive enteropathies (E.g. Bread and flour) and would prevent non-staple gluten-free foods from being prescribed in primary care. Prescribing regulations would be amended accordingly.

66. Option 3 ends a subset of the prescribing of Option 2, with costs and benefits estimated in the same way, and reduced accordingly.

[21] Where £15,000 is the estimated 'marginal cost' to the NHS of producing a QALY

- NIC savings reduced in line: as bread and flour account for £16,827,200 of GF food NIC, the maximum NIC saving from ending prescribing of non-bread and non-flour GF foods is £8,900,000 (that is, £25,727,200 - £16,827,200).
- Savings from reduced dispensing fees and Primary Care Consultations are calculated in the same way as in Option 1, but for a reduction of 809,800[22] prescription items per year rather than 1,678,200 (there are 868,400 prescription items of bread and flour, and these will continue to be prescribed under Option 3).

67. Where non-bread and non-flour formulated GF foods are no longer available through prescription, it is feasible that patients may request (or GPs may offer) additional bread and flour prescriptions by way of what we term 'compensatory prescribing'. The central estimate assumes that this phenomenon is effectively mitigated by GPs and CCGs. This assumption is tested in sensitivity analysis, and informs the 'low' estimate. Note that it might equally be feasible that bread and flour prescriptions fall, as fewer patients think it worthwhile to obtain a prescription that only offers formulated GF bread and flour. We invite views on compensatory prescribing to be submitted during the consultation.

68. Option 3 offers an additional route to adherence to a GF diet, relative to Option 2, as formulated GF bread and flour are still prescribed; thus, any effect on adherence is likely to be lessened in Option 2. This 'relative adherence effect' is assumed to be 50% (that is, the detrimental effect on adherence of Option 3 is half that of Option 2), but as the central estimate assumes no effect on adherence, the relative effect is only relevant where an adherence effect is considered in sensitivity analysis, below.

Option 3 Benefits

69. The Net Ingredient Cost (NIC) saving is estimated at £8,900,000 per year.

70. Similarly, savings to the NHS from reduced dispensing fees are estimated at £1,214,700 per year. The derivation of this is explained in Option 1 and above.

71. Savings to the NHS from fewer primary care consultations primarily to gain a prescription for GF foods is estimated at £5,293,362. The derivation of this is explained in Option 1 and above.

72. Total savings to the NHS are thus estimated at £15,408,062 per year. (That is, the sum of savings from NIC, dispensing costs, and primary care consultations.)

73. It is assumed that these cost savings are reinvested into the NHS, at the margin, where they generate an additional health gain of 1,027 QALYs per year, which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £577m.

74. Those patients that previously paid a prescription charge will no longer do so. This saving is considered a benefit to those patients. Patients avoid prescription charges of £736,751 per year, giving a Present Value of £6.3m. The derivation of this is explained in Option 1 and above.

75. Total benefits (that is, benefits to the NHS and benefits to patients) are estimated to have a Present Value of £583m.

76. As with Option 2, it is assumed that NIC and associated primary care and dispensing costs (as described above) fully capture the cost to the NHS of prescribing GF foods. However, anecdotal evidence suggests that pharmacies may face additional costs, including substantial delivery costs, to dispense GF foods. These potential savings are not monetised and so savings are considered a conservative estimate. We invite any further evidence on this to be submitted during the consultation.

77. The estimated benefits of option 3 are presented in Table 4, below:

[22] Electronic Prescription Analysis and CosT (e-PACT) data 2015

Table 4: Option 3 Benefits

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Benefits to NHS										
Reduction in NHS GF Foods NIC Spend	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000	£ 8,900,000
Reduction in Dispensing fees	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700	£ 1,214,700
Reduction in Primary Care Spend (through reduction in appointments to gain prescriptions)	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362	£ 5,293,362
Total Benefits to NHS, £	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062	£ 15,408,062
QALYs gained through reinvesting saving at NHS margin	1,027	1,027	1,027	1,027	1,027	1,027	1,027	1,027	1,027	1,027
Value of QALYS gained, £	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248	£ 61,632,248
NPV of Benefits to NHS (1.5% discount rate), £	£576,909,724									
Benefits to Patients										
Avoided Prescription Charges	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751
NPV of Benefits to Patients (3.5% discount rate), £	£6,341,718									
Total NPV of Benefits, £	£583,251,442									

Option 3 Costs

78. Patients must now purchase GF foods in place of prescriptions, at a cost of £8.9m per year[23], with a Present Value (cost) of £76.6m.

79. It is assumed that, given the wide availability of GF foods in supermarkets and other food retail outlets, this policy has no impact on adherence, and so impact on health, or associated costs. This assumption is tested in sensitivity analyses below, and we invite any further evidence to be submitted during the consultation.

80. The NHS loses revenue from prescription charges worth £736,751 per year. As with benefits accruing to the NHS, the health gains (in this case the health gains forgone) are calculated and expressed in QALYs, with an assumption that the revenue would previously have been invested at the margin. Lost revenue is thus equivalent to a loss of 49 QALYs p.a. (that is, £736,751 divided by £15,000[24]), which discounted at 1.5% and monetised at £60k each give a Present Value (cost) to the NHS of £28m.

81. The estimated costs of option 3 are presented in Table 5, below:

Table 5: Option 3 Costs

Year	2017	2018	2019	2020	2021	2022	2023	2024	2025	2026
Costs to the NHS	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	£ 736,751	736750.56
Loss of prescription charge revenue										
QALYs forgone at NHS margin	49.1	49.1	49.1	49.1	49.1	49.1	49.1	49.1	49.1	49.1
Value of QALYS forgone £	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002	£ 2,947,002
NPV of Costs to NHS (1.5% discount rate), £	£27,585,466									
Costs to Patients										
Additional spending by consumers										
NPV of Costs to Patients (3.5% discount rate), £	£76,608,410									
Total NPV of Costs, £	£104,193,875									

[23] It is assumed that, where no effect on adherence effect is observed, patients face the same cost for a given item as the NHS. However, limited evidence from CCGs comparing the prices that the NHS pays with the price available to patients in major supermarkets suggests that patients may, in fact, face much lower costs, and so this cost to patients may be overestimated. We invite any further evidence on this to be submitted during the consultation.

[24] Where £15,000 is the estimated 'marginal cost' to the NHS of producing a QALY

Option 3 Net Effect

82. The Net Present Value (NPV) of Option 3 is thus estimated at £479m (that is, the Present Value of benefits minus the Present Value of costs).

Sensitivity Analysis

83. As benefits (cost savings) are implied by the reduction in spend against the counterfactual (that is, what would have happened anyway), estimated benefits are sensitive to the assumed growth in spending in Option 1. The central estimate is based on there being no growth in GF spending: if counterfactual spending were in fact observed to be rising by 5% per year, the NPV of Option 3 would rise by £121m, to £600m; if counterfactual spending were observed to be falling by 5% per year, the NPV of Option 2 would fall by £93m, to £386m. The estimate given rising spend is presented as the 'high' estimate for Option 3.

84. Costs are estimated by modelling a number of interdependent variables, making it difficult to isolate and explore the impact of varying any one. For example, the cost effectiveness of GF spend only becomes relevant where an effect on adherence is assumed. Thus, to present a 'low' estimate, the following assumptions are made:

    - GF spend was falling by 5% per year (as opposed to being constant in the central estimate);
    - there is a detrimental effect on adherence of 5% (that is, 5% of patients that were previously adherent through NHS GF spending become non-adherent, as opposed to the policy having no effect on adherence); *and*
    - the cost effectiveness of GF spend is estimated at £25,000 per QALY
    - 'Compensatory Prescribing[25]' leads to a 10% increase in bread and flour prescriptions (and associated NIC, primary care, and dispensing fees costs) in year one and a 5% rise in year two. This effect disappears in year 3, as CCGs introduce mitigations.
    - The 'relative adherence effect[26]' of Option 3 to Option to is 50%. That is, where Option 2 considers a 5% adherence effect, Option 3 considers a 2.5% effect.

85. Under these assumptions, the NPV of Option 3 would fall by £107m, to £372m. This is presented as the 'low' estimate of Option 3.

86. We invite views on appropriate sensitivity analyses to be submitted during the consultation.

[25] An initial growth in prescriptions of bread and flour that prescribers and patients may view as compensation for no longer being able to obtain non-bread and non-flour GF foods through prescription. This phenomenon is described at paragraph 67.

[26] Option 3 offers an additional route to adherence relative to Option 2, as formulated GF bread and flour are still prescribed; thus, any effect on adherence is likely to be lessened in Option 2.