



Department
of Health &
Social Care

Title: The Availability of Gluten-Free Food on Prescription in Primary Care IA No: 14002 RPC Reference No: N/A Lead department or agency: Department of Health & Social Care Other departments or agencies: N/A	Impact Assessment (IA)			
	Date: 22/01/2018			
	Stage: Economic & Domestic Affairs Secretariat (EDS) clearance			
	Source of intervention: Domestic			
	Type of measure: Secondary legislation			
Contact for enquiries: Carol Walker				

Summary: Intervention and Options	RPC Opinion: Not Applicable
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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
£717m/ £165m	N/A	N/A	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, formulated and naturally GF foods are available in supermarkets and other food retail outlets. Restricting GF 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 aim of prescribing GF foods was to encourage patients to adhere to a GF diet, when availability of formulated GF foods was limited. This helped prevent more complex health problems from developing. As formulated GF foods (and naturally GF foods including meat, fish, vegetables, fruit, rice and most dairy products) are now available to purchase in supermarkets and other 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 responsibilities 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 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;

Option 3 – Restrict prescribing of GF foods: To only allow the prescribing of certain GF foods (e.g. bread and mixes) in primary care. **This is the Minister’s preferred option.**

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



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What is the CO₂ equivalent change in greenhouse gas emissions?
(Million tonnes CO₂ 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:

Date:
e:

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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



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NHS spending on GF foods (and associated primary care appointments and dispensing costs) is assumed to decrease by 4% per year 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 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 683	High: 888	Best Estimate: 717
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		18	184	
Description and scale of key monetised costs by 'main affected groups'					
<p>Patients must now purchase GF-formulated foods in place of prescriptions, at a Present Value cost of £ 145.6 m. The NHS loses revenue from prescription charges worth £10.4m. When reinvested into the NHS this would have generated 693 QALYs, which discounted at 1.5% and monetised at £60k each represents a Present Value cost to the NHS of £ 38.5 m forgone health.</p>					
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		0	Optional	Optional	
High			Optional	Optional	
Best Estimate	0		90	902	
Description and scale of key monetised benefits by 'main affected groups'					
<p>The NHS saves approximately £ 240.8 m; comprising £ 173.1 m from reduced Net Ingredient Cost (NIC) spend; £ 17.1 m from reduced dispensing fees; and £ 50.6 m from fewer primary care appointments to attain prescriptions. When reinvested in the NHS, this is expected to generate 16,055 QALYs, which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £ 892.8 m. Patients avoid prescription charges with a Present Value of £ 8.7 m.</p>					
Other key non-monetised benefits by 'main affected groups'					
<p>Additional savings where pharmacies faced costs over and above NIC (for example, increased delivery costs when handling fresh food) to dispense GF foods.</p>					
Key assumptions/sensitivities/risks Discount rate (%)				NHS 1.5 Other 3.5	
<p>There is no effect on adherence to GF diets for patients diagnosed with gluten sensitivity enteropathies.</p> <p>Where an effect on adherence is considered (in sensitivity analysis as low estimate) the assumed cost effectiveness of GF food is £15k/QALY. Savings to the NHS are reinvested at the margin.</p>					



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 mixes

FULL ECONOMIC ASSESSMENT

Price Base Year 2017	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: 163	High: 204	Best Estimate: 165
COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)		Total Cost (Present Value)
Low	Optional				Optional
High	Optional				Optional
Best Estimate	0		5		51
Description and scale of key monetised costs by 'main affected groups'					
Patients must now purchase GF foods in place of some prescriptions, at a Present Value cost of £ 26.6 m. The NHS loses revenue from prescription charges worth £6.5m. When reinvested into the NHS this would generate 436 QALYs, which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £ 24.2 m.					
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	0		22		216
Description and scale of key monetised benefits by 'main affected groups'					
The NHS saves approximately £ 56.7 m; comprising £ 31.6 m from reduced Net Ingredient Cost (NIC) spend, £ 6.3 m from reduced dispensing fees; and £ 18.8 m from fewer primary care appointments to attain prescriptions. When reinvested in the NHS, this is expected to generate 3,781 QALYs, which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £ 210.2 m. Patients avoid prescription charges worth a Present Value of £ 5.5 m.					
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 as low estimate) the assumed cost effectiveness of GF food is £15k/QALY. Savings to the NHS are reinvested at the margin. Bread and mixes prescribing does not grow in a 'compensatory' fashion.					
THIS IS THE MINISTER'S PREFERRED OPTION					



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)

Revisions to this Impact Assessment (IA)

1. This IA has been updated following the DH consultation '*The Availability of Gluten Free Food on Prescription in Primary Care.*' The IA invited additional views on four specific assumptions:
 - i. The effect on adherence to a gluten-free (GF) diet if changes were made to prescribing policy i.e. Options 2 & 3
 - ii. The availability of GF foods in supermarkets and other food outlets and the impact this had on adherence to a GF diet
 - iii. The costs patients are faced with if changes were made to prescribing policy i.e. Options 2 & 3
 - iv. The cost-effectiveness of GF foods
2. Of the 7,941 responses the consultation received, 20 related directly to the IA. These mainly fell in to 3 categories:
 - i. National guidance on some aspect of coeliac disease (CD) i.e. NICE quality standard on CD, guidelines from the British Society of Gastroenterology on diagnosis and management of CD
 - ii. Studies specially designed to look at a particular aspect of GF foods i.e. availability and cost in food outlets, levels of patient adherence to a GF diet
 - iii. Surveys of patients with CD as carried out by either GF food manufacturer associations or by patient representative organisations
3. This IA has been revised and updated to allow for this new evidence with references provided as footnotes.
4. In a further change, option 3 has been amended from bread and flour to bread and mixes. This change was made on the back of evidence received from South Hertfordshire Coeliac Patient Group. South Herts highlighted the misconception that coeliac patients routinely used GF flour. According to them, GF baking could only be done by using a mixture of different GF flours with an added gum (e.g. Xanthan gum) to replace the gluten. Coeliac patients obtained proprietary mixes which could be used as such, with, for example, the addition of only eggs or milk. Based on this argument and no contradictory evidence from other sources, DH has opted to revise option 3 accordingly.

Background

5. Coeliac disease (CD) is a serious medical condition where the body's immune system attacks its own tissue when gluten is eaten¹. Currently, the only medical treatment for CD is strict adherence to a GF diet for life. Gluten is not necessary for a healthy diet and patients can safely exclude it from their diet and still eat healthily without purchasing formulated foods. Naturally GF foods include meat, fish, vegetables, fruit, rice and most dairy products.
6. Formulated GF foods are those foods that are specially produced and processed by manufacturers to be gluten-free. Staple GF foods are available on prescription to patients diagnosed with gluten

¹ Coeliac UK 'NHS support for patients with coeliac disease' (Westminster Hall Debate 1st November 2016)



sensitivity enteropathies, including CD, and have been since the late 1960s when the availability of GF foods was limited.

7. Today, GF foods are available in supermarkets and other food outlets where patients can purchase items in-store or online. In spite of this advancement however, availability is not consistent throughout the sector. Evidence submitted as part of the consultation showed that availability could be poor in budget supermarkets and corner shops with some of these outlets having no GF foods to offer.² Additionally, whilst some branded GF products are available in supermarkets, others are only available on the NHS.
8. In practise, patients consume some combination of naturally GF foods and formulated GF foods. A survey from the British Specialist Nutrition Association (BSNA) of almost 4,000 CD patients showed that 97% of respondents ate GF bread at least once a week with 76.6% consuming bread daily.³

Net Ingredient Cost & Items Dispensed

9. Monetary costs associated with the Net Ingredient Cost (NIC) of GF prescriptions in 2016 were £22.4 million. Data showed that this spend mainly related to the prescribing of staple foods such as bread, mixes 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 2016 was 1,476, 501.
10. 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 GF foods as part of a lifestyle choice.

CCG prescribing of GF foods

11. GF prescribing is an area where CCGs have already been working to deliver efficiencies. A good number of CCGs have restricted GF prescribing to some degree, either restricting to certain products or ending prescribing all together. We have spoken to several CCGs to understand what impact their changes have had on patient adherence to a GF diet but the work is still at an early stage and such data is not available.

Adherence rates

² Burden M, Mooney P, Blanshard RJ, White WL, Cambray-Deakin DR, Sanders DS, Cost and availability of gluten-free food in the UK: in store and online (2015)

³ BSNA Survey (unpublished)



12. Reported levels of strict adherence to the GF diet in adults with coeliac disease varied between 36% and 96%.^{4 5} The level varied depending on the study method used to determine dietary adherence and was associated with a variety of demographic, psychosocial and clinical factors.⁶ According to the National Institute for Care and Health Excellence (NICE), the adherence rate in children is 84%.⁷ Evidence submitted on adherence is explored in detail in paragraphs 36 to 43.

NHS Constitution

13. The NHS Constitution⁸ 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

14. The main societal benefit of spending in the NHS is the provision of health gains to patients. Despite inconsistencies in the provision in some supermarkets and other food outlets, availability of GF foods is such that patients can access a range of products 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

15. The consultation document detailed the consideration of equalities, health inequalities and the impact on vulnerable groups. An Equalities Analysis will be published alongside the Government response to the consultation.
16. 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 obtain formulated GF foods at food retail outlets, including supermarkets

Policy objective

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

Description of Options Considered

18. **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.

⁴ Kempainen TK, Kroger H, Janatuinen E, et al: Bone recovery after a gluten-free diet: a 5 year follow up study (199)

⁵ Hogberg L, Grodzinsky E, Stenhammer L; Better dietary compliance in patients with coeliac disease diagnosed in early childhood

⁶ Ford, Howard & Oyeboode (2012); Psychosocial Aspects of Coeliac Disease: A cross-sectional survey of a UK population

⁷ NICE guideline [NG20] Coeliac disease: recognition, assessment and management (2015)

⁸ <http://www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Pages/Overview.aspx>



19. **Option 2 - To end the prescribing of all GF foods** for patients. This option will prevent products from being prescribed in primary care, and will require the updating of the above regulations.
20. **Option 3 - To supply only basic provisions** to all patients with gluten sensitive enteropathies, e.g. bread and mixes. This option will prevent non staple GF foods from being prescribed in primary care and will require the above regulations to be updated. **This is the Minister's preferred option.**

Option 1: Make no Changes (the Counterfactual)

21. The Net Ingredient Cost (NIC) of GF foods prescribed by the NHS in 2017 is estimated at £21,520,678⁹. The NIC is the basic price of a drug; that is, the price listed in the British National Formulary. For the purpose of this IA, this is taken to reflect the cost to the NHS of reimbursing pharmacies for providing these items to patients.
22. In addition to the 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 item¹⁰. We estimate that 1,417,441 prescription items of GF food will be dispensed in 2017¹¹, costing a total of £2,126,161 (that is, 1,417,441 x £1.50).
23. 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 £6,291,775 . This is derived as below:
- a. We estimate 1,417,441 prescription items in 2017
 - b. The average number of prescription items per script is 2.03¹²
 - c. Thus, the number of prescriptions is estimated at 698,827 (That is, a/b)
 - d. 23% of prescriptions are acute¹³. It is assumed each of these is associated with a consultation. Thus it is estimated there are 160,730 consultations associated with acute prescriptions (that is, 23% of 698,827 [c]).
 - e. 77% of prescriptions are repeat prescriptions¹⁴. We assume each repeat prescription is filled three times before a further consultation is required. Thus it is estimated there are 179,366 consultations associated with repeat prescriptions (that is, 77% of 698,827 /3 [c]).
 - f. The total number of consultations associated with GF prescriptions is thus 340,096 (that is, [d] + [e]).
 - g. Some consultations will be for the management of diagnosed conditions needing other healthcare interventions, such as regular screening. It is assumed to be equally likely that a 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 170,048 consultations arranged primarily to gain a prescription for GF food. (That is, g/2.)

⁹ Prescription Cost Analysis data 2016, adjusted.

¹⁰ 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.

¹¹ Prescription Cost Analysis data 2016, adjusted.

¹² BSA data

¹³ Petty, D.R., Zermansky, A.G., and Alldred, D.P. (2015). *The scale of repeat prescribing – time for an update.*

¹⁴ Ibid



h. The cost of these appointments is estimated at £6,291,775 . (That is, 170,048 [g] x £37¹⁵)

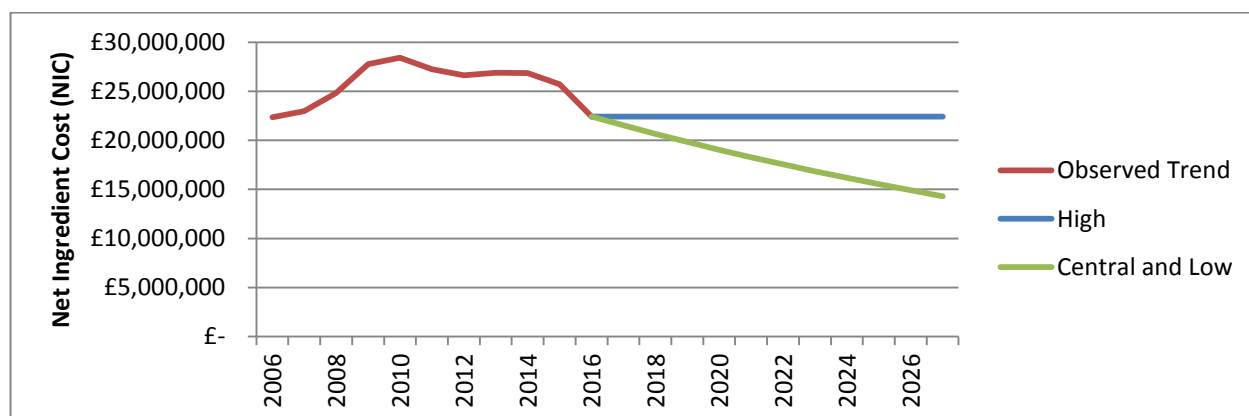
24. Only 10.6% of prescription items attract a prescription charge payable by the patient¹⁶. This charge is currently £8.60¹⁷. Thus, the cost to patients of prescription charges in 2017 is estimated at £1,292,139 . (That is, 10.6% of 1,417,441 prescription items, x £8.60).

25. 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.

Forecast

26. The costs associated with current prescribing practice estimated above are per year. For the purposes of this IA, it is necessary to forecast how these will change over time. Chart 1, below, shows how the NIC of GF foods has grown in the past 10 years. For the first four years, the NIC rose steadily (2006 to 2010) and then experienced a small decline in the latter 6 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. For a central estimate, it is assumed that the costs associated with prescribing GF foods continue to fall by 4% per year, as per the recent trend. An assumption of flat spend informs the 'high' scenario analysis.

Chart 1: Trend and forecast Net Ingredient Cost (NIC), 2006 - 2027



Overview of Costs and Benefits

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

Benefits

- A saving to the NHS from reduced NIC spending;

¹⁵ £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)

¹⁶ HSCIC, Prescriptions Dispensed in the Community, 2006-2016.

¹⁷ <http://www.nhs.uk/NHSEngland/Healthcosts/Pages/Prescriptioncosts.aspx>



- 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
28. Cost savings to the NHS are assumed to be reinvested at the margin, where they achieve a cost effectiveness of £15k per QALY¹⁸ (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.
29. The preferred option is Option 3. Although Option 3 has an NPV that is lower than that of Option 2, both are driven by assumptions regarding the cost-effectiveness of GF foods, and of potential changes to diet adherence. This is set out in the sensitivity analysis. Option 3 provides greater certainty of a positive NPV across a range of scenarios.

Patient Choices and Adherence

30. 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*
31. 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.
32. 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*
33. Under Option 3, patients are able to obtain bread and mixes through prescription. Options are thus:
- Adhere through purchasing naturally GF food
 - Adhere through purchasing formulated GF food
 - Adhere through obtaining formulated GF bread and mixes through prescription
 - *Not adhere*

¹⁸ The Quality Adjusted Life Year (QALY) is a standard unit used to measure health gains that combines both quantity (mortality) and quality (morbidity) effects.



34. 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 3, this presents a cost to the NHS.

Health Effects: The link between GF food prescriptions and adherence

35. In our consultation, we invited evidence that demonstrated a clear link between the availability of GF foods through prescription and increased adherence to GF diets among patients with gluten sensitivity enteropathies. The evidence received conveyed the complex issues at play and the difficulty in isolating adherence solely to the availability of GF foods on prescription or any other single cause.
36. Reported levels of strict adherence to the GF diet in adults with coeliac disease varied between 36% and 96%^{19 20}. The level varied depending on the study method used to determine dietary adherence and was associated with a variety of demographic, psychosocial and clinical factors.²¹
37. A 2013 study by Hall, Rubin and Charnock, '*Intentional and inadvertent non-adherence in adult coeliac disease*' provided an analysis of the reasons why patients adhered to a GF diet. There were four main themes:
- i. To feel better
 - ii. To avoid symptoms
 - iii. To maintain future health
 - iv. To avoid potential complications
38. The study found that, when asked what would make it easier to stick to a GF diet, the most frequently cited responses related to better quality choice, cost and availability of GF food, followed by improved awareness and understanding, clearer and universal product labelling and clearer information when eating out.
39. The study concluded that strict adherence to the GF diet required a range of knowledge, skills and complex behaviours in order to avoid all sources of gluten. It was therefore important to also acknowledge and continue those efforts to facilitate dietary self-management in CD which extended beyond the individual and the health care setting. These included continued improvements in food labelling, the increasing provision of GF foods within supermarkets and increased awareness within the catering and food manufacturing industry.
40. Other studies were consistent with Hall, Rubin and Charnock and highlighted the challenge faced by patients in adhering to a strict GF diet. It required knowledge, skills and modified behaviours to undertake substantial changes to dietary habits, including managing social situations.²²
41. In cases where adherence was low, studies reported that this could be due to frequent occasional lapses which were influenced by a number of factors such as age at diagnosis, knowledge of disease and psychological factors.^{23 24} Food labelling could also cause some confusion.

¹⁹ Kempainen TK, Kroger H, Janatuinen E, et al: Bone recovery after a gluten-free diet: a 5 year follow up study (199)

²⁰ Hogberg L, Grodzinsky E, Stenhammer L; Better dietary compliance in patients with coeliac disease diagnosed in early childhood

²¹ Ford, Howard & Oyeboode (2012); Psychosocial Aspects of Coeliac Disease: A cross-sectional survey of a UK population

²² Silvester, J.A.; Weiten, D; Graff, L.A; Walker, J.R; Duerksen, D.R; Is it gluten-free? Relationship between self-reported gluten-free diet adherence and knowledge of gluten content of foods (2016)

²³ Kurppa K, Lauronen O, Colin P, et al: Factors associated with dietary adherence in coeliac disease: a nationwide study

²⁴ Van Hees, NJ, Van der Does, W, Giltay EJ. Coeliac disease, diet adherence and depressive symptoms



42. 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 scenario and sensitivity analyses.

Health Effects: The link between adherence and health effects

43. Non-adherence to GF diets among patients with gluten sensitivity enteropathies can cause serious health problems. According to NICE, those who are not following a strict GF diet are at a higher risk of long term complications, including osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency²⁵. Other guidance, that of the British Society of Gastroenterology, identifies CD patients as being at increased risk of osteoporosis and bone fracture.²⁶
44. These complications present a cost to the patient (forgone health), and to the NHS (as treatment costs).
45. 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 £15,000 per QALY (that is, the midpoint of the range in which NICE tend to recommend a treatment)²⁷. 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

46. The central estimate assumes there is no effect on patient's propensity to consume GF formulated foods, and so no consequent impact on adherence or 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).
47. In the absence of robust evidence on the cost effectiveness of GF foods, we assume that NHS spending on GF formulated foods has a cost effectiveness of £15,000 per QALY. That is, it has a cost effectiveness approximately equivalent productivity at the margin of NHS spend. Note that GF formulated food does not have a therapeutic benefit in itself, and so the cost effectiveness of such products implicitly reflects the value of GF formulated food in aiding patient adherence.
48. 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 food²⁸. If consumers were to purchase less (that is, if there were an effect on their propensity to consume GF formulated food), 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).
49. For example, if Option 2 were to cause a 1% drop in adherence in 2018, this would mean private consumers spent £206,599 less than the NHS spent previously (that is, 1% of £ 20.7 m). Given the assumption that spending on GF food has a cost effectiveness of £15,000 per QALY, £206,599 would previously have 'bought' 13.8 QALYs (that is, 206,599 /15,000). Thus, the health impact of a 1% effect on adherence at an assumed cost effectiveness of £15,000 per QALY would be a loss of 13.8 QALYs per year.

²⁵ National Institute for Health and Care Excellence NG20 (2015) Coeliac disease: recognition, assessment and management 2015

²⁶ Ciclitira P, Dewar DH, McLaughlin SD, et al. The management of adults with coeliac disease (British Society of Gastroenterology, 2010)

²⁷ <https://www.nice.org.uk/news/blog/carrying-nice-over-the-threshold>

²⁸ 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



50. QALYs are valued at £60,000 each. Thus, in this worked example, the monetised cost of a 1% change in adherence is £ 826,394 per year (that is, 13.8 x £60,000).
51. 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 effects for those patients that are only able to adhere to a GF diet through obtaining formulated GF foods by prescription.

The Relative Prices and Availability of Formulated GF foods

52. This IA assumes that the money previously spent by the NHS is now spent by private consumers, who face the same price. However, such costs may be overestimated. Although there is evidence to show that a good number of patients consume formulated GF foods (paragraph 8, reference 3 refers) patients may choose to adhere to a GF diet more through purchasing naturally GF foods, at a significantly lower price.
53. 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) ²⁹	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) ³⁰
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

54. Evidence from the CCGs suggests that the NHS pays much more than the consumer for the same gluten-free products. Upon further investigation, there is little transparency on how NHS costs are comprised. In discussion with CCGs, the general consensus was that costs are shared between the manufacturers, a dispensing fee, a pharmacy fee and a delivery charge. Again, this may mean that the costs to consumers are overestimated.

²⁹ Data taken from respective CCG websites

³⁰ Data taken from www.sainsburys.co.uk



55. GF foods are available in supermarkets and other food outlets where patients can purchase items in-store or online. Although availability is inconsistent (paragraph 7, reference 2 refers) we assume that it still encourages consumers to adhere to a GF diet.

Retail demand

56. We do not anticipate a drop in demand for GF foods from retail outlets as a result of any policy changes. The sales value of GF foods in the UK rose from £166.2 million in 2010 to £324.2 million in 2015, representing an increase of 95%.³¹
57. In the case of any restriction to the prescribing of GF foods, we would expect patients to replace items previously accessible through the NHS with their own purchases from supermarkets, and from pharmacies where the retail provision of GF foods proves economical for a given pharmacy. Evidence shows that patients adhere to a GF diet to feel better and avoid potential complications and the challenge they face in this is having the knowledge, skills and modified behaviours to avoid all sources of gluten. Supermarket provision of GF foods is important in facilitating the self-management of CD outside any health care setting.
58. We expect that any increase in demand for privately-purchased GF products would be met by retailers in the same way that changes in demand for other food and retail items are met by changes in supply, such that shortages are avoided.
59. Furthermore, in our central estimate, we assume that any change in policy will not have an effect on the total amount of GF food consumed, and in turn on adherence to a GF diet. We are not aware of evidence that isolates the effect of the availability of GF foods on prescription to adherence to a GF diet. The issue of adherence is explored in detail in paragraphs 36 to 43.

Option 2: End prescribing of GF foods

60. Option 2 would end the prescribing of GF foods in primary care. Prescribing regulations would be amended accordingly.

Option 2 Benefits

61. 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 £ 173.1 m over the appraisal period.
62. Similarly, savings to the NHS from reduced dispensing fees are estimated at £ 17.1 m.
63. Savings to the NHS from fewer primary care consultations primarily to attain a prescription for GF foods is estimated at £ 50.6 m.
64. Total savings to the NHS are thus estimated at £ 240.8 m. (That is, the sum of savings from NIC, dispensing costs, and primary care consultations.)
65. It is assumed that these cost savings are reinvested into the NHS, at the margin, where they generate an additional health gain of 16,055 QALYs, which discounted at 1.5% and monetised at £60k each give a Present Value to the NHS of £ 892.8 m.

³¹ <https://www.statista.com/statistics/646593/gluten-free-food-sales-united-kingdom-uk/>



66. 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 with a Present Value of £ 8.7 m. The derivation of this is explained in Option 1.
67. Total benefits (that is, benefits to the NHS and benefits to patients) are estimated to have a Present Value of £ 901.6 m .
68. 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.
69. The estimated benefits of option 2 are presented in Table 2, below:

Table 2: Option 2 Benefits

Year	1	2	3	4	5	6	7	8	9	10
Prescription charges avoided by patients, £	1,240,454	1,190,835	1,143,202	1,097,474	1,053,575	1,011,432	970,975	932,136	894,850	859,056
NPV of private savings (3.5% discount rate), £	8,744,167									
Net Ingredient Cost, £	20,659,851	19,833,457	19,040,119	18,278,514	17,547,373	16,845,478	16,171,659	15,524,793	14,903,801	14,307,649
Dispensing fees, £	2,041,115	1,959,470	1,881,092	1,805,848	1,733,614	1,664,269	1,597,699	1,533,791	1,472,439	1,413,542
Primary care appointments, £	6,040,104	5,798,500	5,566,560	5,343,898	5,130,142	4,924,936	4,727,939	4,538,821	4,357,268	4,182,977
Total, £	28,741,070	27,591,427	26,487,770	25,428,259	24,411,129	23,434,684	22,497,297	21,597,405	20,733,508	19,904,168
QALYs generated	1,916	1,839	1,766	1,695	1,627	1,562	1,500	1,440	1,382	1,327
QALYs, monetised, £	114,964,280	110,365,709	105,951,081	101,713,038	97,644,516	93,738,735	89,989,186	86,389,619	82,934,034	79,616,673
NPV of NHS savings (1.5% discount rate), £	892,824,105									
Total NPV of Benefits, £	901,568,271									

Option 2 Costs

70. Patients must now purchase GF foods in place of prescriptions, at a Present Value cost of £145.6 m³².
71. It is assumed that, given the availability of GF foods in supermarkets and other food retail outlets, this policy has no impact on patients' propensity or ability to consume GF formulated food and so impact on adherence, health, or associated costs. This assumption is tested in scenario analyses below.
72. The NHS loses revenue from prescription charges worth £ 10.4 m. 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 692.9 QALYs (that is, £ 10.4 m divided by £15,000³³), which discounted at 1.5% and monetised at £60k each give a Present Value (cost) to the NHS of £ 38.5 m.
73. The estimated costs of option 2 are presented in Table 3, below:

Table 3: Option 2 Costs

³² It is assumed that 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.

³³ Where £15,000 is the estimated 'marginal cost' to the NHS of producing a QALY



Year	1	2	3	4	5	6	7	8	9	10
Additional spending by consumers, £	20,659,851	19,833,457	19,040,119	18,278,514	17,547,373	16,845,478	16,171,659	15,524,793	14,903,801	14,307,649
NPV of private costs (3.5% discount rate), £	145,634,770									
Loss of prescription charge revenue, £	1,240,454	1,190,835	1,143,202	1,097,474	1,053,575	1,011,432	970,975	932,136	894,850	859,056
QALYs forgone	83	79	76	73	70	67	65	62	60	57
QALYs forgone, monetised, £	4,961,814	4,763,342	4,572,808	4,389,896	4,214,300	4,045,728	3,883,899	3,728,543	3,579,401	3,436,225
NPV of NHS costs (1.5% discount rate), £	38,533,947									
Total NPV of Costs £	184,168,718									

Option 2 Net Effect

74. The Net Present Value (NPV) of Option 2 is thus estimated at £ 184.2 m (that is, the Present Value of benefits minus the Present Value of costs).

'High' and 'Low' Scenario Analysis

75. 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 scenario analysis below.

76. High. 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 trend in spending in Option 1. The central estimate is based on GF spending by 4% per year, in line with recent years: if counterfactual spending were in fact observed to be flat, the NPV of Option 2 would rise by £ 205.8 m, to £ 888 m. The estimate given flat spend is presented as the 'high' estimate for Option 2.

77. Low. To determine a 'low' estimate, two model inputs are varied:

- a. Adherence. The central estimate assumes there is no detrimental effect on adherence. The low estimate considers a reduction in patients' propensity to consume GF formulated food of 10% (that is, 1 in 10 patients that previously accessed GF formulated food do not go on to purchase their own GF food).

As described in 'Modelling Health Effects' above, this is assumed to have a detrimental effect on patient health equivalent to the reduction in total (NHS plus individuals') spend on GF formulated food, divided by the cost-effectiveness of that spend (assumed to be £15,000/QALY).

- b. Prescription charge revenue. Although the central estimate assumes that the 10.6% of prescriptions that attract a charge do so at the single item fee rate of £8.60, this is a simplifying assumption and in practice many will be dispensed against a Prescription Prepayment Certificates (PPC). These certificates reduce the effective fee per prescription item paid by patients, and correspondingly the revenue per prescription item received by the NHS.

To model the true reduction in revenue, it would be necessary to understand any effect on the number of PPCs bought by patients – and to do this it would be necessary to understand for each patient that has a GF formulated food item dispensed against a PPC, the number of GF and non-GF items dispensed against that PPC. Instead, the 'Low' estimate considers a 50% smaller reduction in revenue than the central estimate.

78. Reflecting these two variables, the NPV of Option 2 would fall by £ 34.7 m, to £ 683 m. This is presented as the 'Low' estimate of Option 2.



Additional Sensitivity Analysis

79. The Net Present Value of this option is sensitive to assumptions on the propensity of patients to continue to consumer GF formulated foods, and the cost-effectiveness of such items. Table 4 (below) further explores the implications of these assumptions, considering the NPV of various combinations.

Table 4: Option 2 Sensitivity Analysis, showing NPV (£m) implied by varied assumptions

		Assumed Cost-Effectiveness of GF Formulated foods, £/QALY									
		5,000	10,000	15,000	20,000	25,000	30,000	35,000	40,000	45,000	50,000
Effect on Propensity to purchase GF formulated food, %reduction	10%	539	636	668	684	693	700	704	708	711	713
	20%	361	554	618	650	670	682	692	698	704	708
	30%	183	472	569	617	646	665	679	689	697	703
	40%	5	391	519	583	622	647	666	679	690	699
	50%	- 173	309	469	550	598	630	653	670	683	694
	60%	- 351	227	420	516	574	612	640	660	676	689
	70%	- 528	145	370	482	550	595	627	651	670	685
	80%	- 706	64	320	449	526	577	614	641	663	680
	90%	- 884	- 18	271	415	502	560	601	632	656	675
	100%	- 1,062	- 100	221	382	478	542	588	622	649	670

80. For Option 2 to have a negative NPV (that is, for the costs to outweigh the benefits), it would be necessary either for: GF formulated foods to have a cost-effectiveness of £10,000 per QALY, and for 9 out of 10 patients that previously obtained those items by prescription to opt not to purchase their own; or, for GF formulated foods to have a cost-effectiveness of £5,000 per QALY, and for half of patients that currently receive a prescription for GF food to opt not to purchase such items.



Option 3: Restrict Prescribing of GF foods

81. Option 3 would restrict prescribing to basic provisions only to all patients with gluten sensitive enteropathies (e.g. bread and mixes) and would prevent non-staple GF foods from being prescribed in primary care. Prescribing regulations would be amended accordingly.
82. Option 3 ends a subset of the prescribing of Option 2, with costs and benefits estimated in the same way, and reduced accordingly.
- NIC savings reduced in line: as bread and mixes account for £ 17.6 m of GF food NIC in 2017, the maximum NIC saving from ending prescribing of non-bread and non-mix GF foods would be £ 3.9 m in 2017 (that is, £ 21.5 m – £ 17.6 m), and is assumed to fall 4% per year.
 - Savings from reduced dispensing fees and primary care consultations are calculated in the same way as in Option 2 and again reduced accordingly. That is, we estimate a reduction of 504,676 prescription items in 2018 (an estimated 856,068 prescription items of bread and mixes will continue to be prescribed under Option 3).
83. Where non-bread and non-mix formulated GF foods are no longer available through prescription, it is feasible that patients may request (or GPs may offer) additional bread and mixes 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 also be feasible that bread and mix prescriptions fall, as fewer patients think it worthwhile to visit a GP to obtain a prescription that only offers formulated GF bread and mixes.
84. Option 3 offers an additional route to adherence to a GF diet relative to Option 2, as formulated GF bread and mixes are still prescribed; thus, any effect on adherence is likely to be lessened in Option 3. 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 the propensity of patients to consumer GF formulated food or on adherence, the relative effect is only relevant where such an effect is considered in sensitivity analysis, below.

Option 3 Benefits

85. The Net Ingredient Cost (NIC) saving is estimated at £ 31.6 m.
86. Savings to the NHS from reduced dispensing fees are estimated at £ 6.3 m. The derivation of this is explained in Option 1 above.
87. Savings to the NHS from fewer primary care consultations primarily to obtain a prescription for GF formulated food is estimated at £ 18.8 m. The derivation of this is explained in Option 1.
88. Total savings to the NHS are thus estimated at £ 56.7 m. (That is, the sum of savings from NIC, dispensing costs, and primary care consultations.)
89. It is assumed that these cost savings are reinvested into the NHS, at the margin, where they generate an additional health gain of 3,781 QALYs over the appraisal period. Discounted at 1.5% and monetised at £60k per QALY, this gives a Present Value to the NHS of £ 210.2 m.
90. 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 with a total Present Value of £5.5m. The derivation of this is explained in Option 1 above.
91. Total benefits (that is, benefits to the NHS and benefits to patients) are estimated to have a Present Value of £ 215.7 m.



92. 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 a conservative estimate.

93. The estimated benefits of Option 3 are presented in Table 5, below:

Table 5: Option 3 Benefits

Year	1	2	3	4	5	6	7	8	9	10
Prescription charges avoided by patients, £	780,391	749,176	719,209	690,440	662,823	636,310	610,857	586,423	562,966	540,448
NPV of private savings (3.5% discount rate), £	5,501,110									
Net Ingredient Cost, £	3,770,906	3,620,070	3,475,267	3,336,256	3,202,806	3,074,694	2,951,706	2,833,638	2,720,292	2,611,481
Dispensing fees, £	757,013	726,733	697,663	669,757	642,967	617,248	592,558	568,856	546,102	524,257
Primary care appointments, £	2,240,167	2,150,561	2,064,538	1,981,957	1,902,678	1,826,571	1,753,508	1,683,368	1,616,033	1,551,392
Total, £	6,768,087	6,497,363	6,237,469	5,987,970	5,748,451	5,518,513	5,297,773	5,085,862	4,882,427	4,687,130
QALYs generated	451	433	416	399	383	368	353	339	325	312
QALYs, monetised, £	27,072,347	25,989,453	24,949,875	23,951,880	22,993,805	22,074,053	21,191,091	20,343,447	19,529,709	18,748,521
NPV of NHS savings (1.5% discount rate), £	210,246,557									
Total NPV of Benefits, £	215,747,667									

Option 3 Costs

94. Patients must now purchase GF foods in place of prescriptions, at a Present Value (cost) of £ 26.6 m.

95. It is assumed that, given the wide availability of GF formulated 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 scenario analyses below.

96. The NHS loses revenue from prescription charges worth £ 6.5 m over the appraisal period. 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 436 QALYs (that is, £ 6.5 m divided by £15,000³⁴), which discounted at 1.5% and monetised at £60k each give a Present Value (cost) to the NHS of £ 24.2 m.

97. The estimated costs of option 3 are presented in Table 6, below.

Table 6: Option 3 Costs

Year	1	2	3	4	5	6	7	8	9	10
Additional spending by consumers, £	3,770,906	3,620,070	3,475,267	3,336,256	3,202,806	3,074,694	2,951,706	2,833,638	2,720,292	2,611,481
NPV of private costs (3.5% discount rate), £	26,581,753									
Loss of prescription charge revenue, £	780,391	749,176	719,209	690,440	662,823	636,310	610,857	586,423	562,966	540,448
QALYs forgone	52	50	48	46	44	42	41	39	38	36
QALYs forgone, monetised, £	3,121,566	2,996,703	2,876,835	2,761,761	2,651,291	2,545,239	2,443,430	2,345,693	2,251,865	2,161,790
NPV of NHS costs (1.5% discount rate), £	24,242,391									
Total NPV of Costs £	50,824,143									

Option 3 Net Effect

³⁴ Where £15,000 is the estimated 'marginal cost' to the NHS of producing a QALY



98. The Net Present Value (NPV) of Option 3 is thus estimated at £ 165 m (that is, the Present Value of benefits minus the Present Value of costs).

'High' and 'Low' Scenario Analysis

99. High. 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 trend in spending in Option 1. The central estimate is based on GF spending by 4% per year, in line with recent years: if counterfactual spending were in fact observed to be flat, the NPV of Option 3 would rise by £ 39 m, to £ 204 m; the estimate given flat spend is presented as the 'High' estimate for Option 2.

100. Low. To determine a 'low' estimate, three model inputs are varied:

- a. Adherence. The central estimate assumes there is no detrimental effect on adherence. The low estimate considers a reduction in patients' propensity to consume GF formulated food of 5% (that is, 1 in 20 patients that previously accessed GF formulated food do not go on to purchase their own GF food). This is half the effect considered in Option 2, to reflect Option 3 offering an additional route to adherence to a GF diet relative to Option 2

As described in 'Modelling Health Effects' above, this is assumed to have a detrimental effect on patient health equivalent to the reduction in total (NHS plus individuals') spend on GF formulated food, divided by the cost-effectiveness of that spend (assumed to be £15,000/QALY).

- b. Prescription charge revenue. Although the central estimate assumes that the 10.6% of prescriptions that attract a charge do so at the single item fee rate of £8.60, this is a simplifying assumption and in practice many will be dispensed against a Prescription Prepayment Certificates (PPC). These certificates reduce the effective fee per prescription item paid by patients, and correspondingly the revenue per prescription item received by the NHS.

To model the true reduction in revenue, it would be necessary to understand any effect on the number of PPCs bought by patients – and to do this it would be necessary to understand for each patient that has a GF formulated food item dispensed against a PPC, the number of GF and non-GF items dispensed against that PPC. Instead, the 'Low' estimate considers a 50% smaller reduction in revenue than the central estimate.

- c. 'Compensatory Prescribing'³⁵ leads to a 20% increase in bread and flour prescriptions (and associated NIC, primary care, and dispensing fees costs) in year one and a 10% rise in year two (relative to Option 1). This effect disappears in year 3, as CCGs introduce mitigations.

101. Reflecting these three variables, the NPV of Option 3 would fall by £ 2 m, to £ 163 m. This is presented as the 'Low' estimate of Option 2.

Additional Sensitivity Analysis

102. The Net Present Value of this option is sensitive to assumptions on the propensity of patients to continue to consumer GF formulated foods, and the cost-effectiveness of such items. Table 7 (below) further explores the implications of these assumptions, considering the NPV of various combinations.

³⁵ An initial growth in prescriptions of bread and mixes that prescribers and patients may view as compensation for no longer being able to obtain non-bread and non-mix GF foods through prescription. This phenomenon is described at paragraph 77.



Table 7: Option 3 Sensitivity Analysis, showing NPV (£m) implied by varied assumptions

		Assumed Cost-Effectiveness of GF Formulated foods, £/QALY									
		5,000	10,000	15,000	20,000	25,000	30,000	35,000	40,000	45,000	50,000
Effect on Propensity to purchase GF formulated food, %reduction	10%	149	157	160	162	163	163	164	164	164	164
	20%	132	150	156	159	161	162	163	163	164	164
	30%	116	143	151	156	158	160	161	162	163	164
	40%	100	135	147	153	156	159	160	161	162	163
	50%	84	128	142	150	154	157	159	161	162	163
	60%	67	120	138	147	152	155	158	160	161	162
	70%	51	113	133	143	150	154	157	159	161	162
	80%	35	105	129	140	147	152	155	158	160	161
	90%	19	98	124	137	145	151	154	157	159	161
	100%	2	90	120	134	143	149	153	156	159	161

103. No combination of these assumptions result in a negative NPV.