Title: Availability of gluten-free food on prescription in primary care **IA No:** 14002	Impact Assessment (IA)
RPC Reference No: N/A	**Date:** 30/10/2018
Lead department or agency: Department of Health & Social Care	**Stage: Final**
Other departments or agencies: N/A	**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**
£20m	N/A	N/A	Not applicable	Non-qualifying provision

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

Gluten free (GF) foods can be prescribed to patients diagnosed with gluten sensitivity enteropathies, including coeliac disease. Formulated and naturally GF foods are available in supermarkets and other food retail outlets. Restricting GF food prescribing in primary care would deliver savings that could be reinvested more effectively in other NHS services.

What are the policy objectives and the intended effects?

The original policy of prescribing GF foods was designed to encourage patients to adhere to a GF diet, at a time when the availability of GF foods was limited. A GF diet for life is the only effective treatment for coeliac disease. Since then, formulated and naturally GF foods have become more widely available to buy in supermarkets and other outlets. The current policy objectives are: to make cost savings through restricting prescribing of GF foods; reduce geographical variation in prescribing; and support adherence to a GF diet among patients with coeliac disease.

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

Since the Government initially consulted on changes to national prescribing policy, many Clinical Commissioning Groups (CCGs) have introduced local policies to restrict or end GF food prescribing. Nevertheless, regulatory changes are still needed to support local policies that may otherwise be at risk of challenge, and to reduce wide variation in local prescribing policies. Changing national prescribing policy would require amendments to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004. Two options are evaluated:
1) end prescribing of GF foods in primary care; and
2) restrict prescribing in primary care to GF breads and mixes, which is the Government'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?		Yes / No / 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: ..... Date: .....

Summary: Analysis & Evidence

Policy Option 1

Description: NO AMENDMENTS TO REGULATIONS (I.E. BUSINESS AS USUAL)

FULL ECONOMIC ASSESSMENT

Price Base Year http	PV Base Year	Time Period 10 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'

Option 1 is the "business as usual" baseline against which other options are assessed, and the costs are zero by definition. No amendments would be made to regulations governing prescribing of GF foods in primary care.

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

As above.

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'

As above.

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

As above.

Key assumptions/sensitivities/risks **Discount rate**

It is assumed that prescribing volumes and costs would continue in line with downward trends in prescribing over the last two years. In areas where CCGs have already withdrawn GF food prescribing, it is assumed that spending would remain at zero. In other CCG areas, it is assumed that spending would continue fall by 10% per year. These assumptions are altered 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 GLUTEN-FREE FOODS IN PRIMARY CARE

FULL ECONOMIC ASSESSMENT

Price Base Year http	PV Base Year	Time Period 10 Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £151m**

COSTS (£m)	Total Transition	Average Annual	Total Cost
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	No transitional costs	£6.7m	**£67m**

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

Patients would have to purchase formulated GF foods privately to replace prescribed GF foods at a cost of £57 million over the 10-year appraisal period – valued at £49 million when discounted at 3.5% per year. The NHS would forego prescription charge revenue of approximately £5 million (undiscounted), which would have generated monetised health benefits worth £18 million (1.5% annual discount rate) if reinvested in NHS services.

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

DHSC has consulted extensively on the proposed policy changes, including actively informing of CCGs about the likely timing and extent of any changes to prescribing policy. Familiarisation costs are likely to be small and are not monetised in this IA.

There is insufficient evidence to quantify impacts and adherence of ceoliac patients on lower incomes, but the possibility of disproportionate impacts on these groups is one of the reasons for preferring Option 3.

BENEFITS (£m)	Total Transition	Average Annual	Total Benefit
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	No transitional benefits	£21.9m	**£219m**

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

The NHS would save £57 million in reduced spending on GF foods (undiscounted). When reinvested in NHS services, this would be expected to generate health benefits equivalent to 3,800 QALYs with a monetised discounted value of £214 million. Patients would save approximately £5 million in prescription charges, with a discounted value of £4 million.

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

Pharmacies could achieve savings from reduced costs of handling and dispensing GF foods, although these would be likely to be small. These savings would not be passed onto the NHS and are not monetised.

Key assumptions/sensitivities/risks **Discount rate** NHS 1.5

It is assumed that patients would purchase GF foods privately, and that restricting GF food prescribing would not have an overall impact on adherence on a GF diet for patients diagnosed with gluten sensitivity enteropathies. Alternative scenarios are considered in a sensitivity analysis.

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: RESTRICT PRESCRIBING TO GLUTEN-FREE BREAD AND MIXES

FULL ECONOMIC ASSESSMENT

Price Base Year http	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: £20m**

COSTS (£m)	Total Transition	Average Annual	Total Cost
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	No transitional costs	£1.3m	**£13m**

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

Patients could still be prescribed GF breads and mixes, but would have to purchase other formulated GF foods privately at a cost of £8 million over the 10-year appraisal period – valued at £7 million when discounted at 3.5% per year. The NHS would forego prescription charges revenue of £1.5 million (undiscounted), which would have generated monetised health benefits worth £5.5 million (1.5% annual discount rate) if reinvested in NHS services.

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

DHSC has consulted extensively on the proposed policy changes, including actively informing of CCGs about the likely timing and extent of any changes to prescribing policy. Familiarisation costs are likely to be small and are not monetised in this IA.

BENEFITS (£m)	Total Transition	Average Annual	Total Benefit
Low	Optional	Optional	**Optional**
High	Optional	Optional	**Optional**
Best Estimate	No transitional benefits	£3.3m	**£33m**

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

The NHS would save £8 million in reduced spending on GF foods (undiscounted). When reinvested in NHS services, this would be expected to generate 600 QALYs with a monetised discounted value of £32 million. Patients would save £1.5 million in prescription charges, with a discounted value of £1.3 million.

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

Key assumptions/sensitivities/risks **Discount rate** 1.5%

It is assumed that restricting GF food prescribing to breads and mixes would not have an impact on adherence on a GF diet for patients diagnosed with gluten sensitivity enteropathies. Alternative scenarios are considered in a 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)

Problem under consideration

1. Gluten-free (GF) foods can be prescribed to patients diagnosed with gluten sensitivity enteropathies, including coeliac disease (CD), and have been available on the NHS since the late 1960s when the availability of GF foods was limited. Today, GF foods are more widely available in supermarkets and other food outlets where patients can purchase items in-store or online.
2. Despite inconsistencies in provision across supermarkets and other food outlets, a range of GF products can be purchased without a prescription. In turn, savings to the NHS from reducing GF food prescribing could be reinvested in other NHS services.
3. The policy question is: would ending or restricting GF food prescribing in primary care through amending national regulations achieve savings that would provide greater health benefits if reinvested in other NHS services? The policy aim is to achieve this whilst supporting patient adherence to a GF diet, so that adverse health outcomes linked to non-adherence are avoided.

Revision to this Impact Assessment

4. This IA has been updated to incorporate new information showing that three-quarters of Clinical Commissioning Groups (CCGs) in England have introduced local guidance recommending that GPs withdraw or restrict prescribing of GF foods.[1]
5. Consequently, the volume and cost of GF food prescribing was lower in 2017 and the first half of 2018 than was originally forecast in the previous version of this IA. Future trends in GF food prescribing and spend have been re-forecast to reflect this new information.
6. Future trends in prescribing are uncertain since they depend on the interaction of local and national policy. For example, some CCGs that have already ended all GF food prescribing could review or reverse their local policies when proposed national regulations to restrict GF food prescribing to bread and mixes comes in force at the end of the year. The national charity, Coeliac UK, has an active campaign to challenge the variation in CCGs' local policies.[2] To reflect this uncertainty, different scenarios are used to provide alternative estimates of the impact of amending national regulations.
7. Estimates of the future impact on GF food prescribing of a change in national policy, presented in this IA, do not reflect the full impact of national activity in this policy area up to now. The Department began contacting CCGs in 2015 to understand what approaches they had to managing the costs of prescribing GF food. We followed this up in 2017 with a public consultation on proposed changes to national arrangements and in February 2018 we announced our intention to restrict GF food prescribing to bread and mixes. CCGs had anticipated a degree of change in the national position and this prompted them to scrutinise their own local position. This has resulted in a reduction of 39% in the Net Ingredient Cost (NIC)[3] of GF foods to the NHS between 2015 and 2017. This is illustrated in Table 1.

Table 1

YEAR	NET INGREDIENT COST OF GLUTEN-FREE ITEMS (£)	% DECREASE FROM PREVIOUS YEAR	% DECREASE FROM 2015
2015	25,727,200		
2016	22,417,373	-13%	-13%
2017	15,727,030	-30%	-39%

[1] https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

[2] https://www.coeliac.org.uk/campaigns-and-research/campaigning-on-health/campaign-to-protect-prescription-services-in-england/

[3] NIC is the is the basic cost of a drug prescribed in primary care excluding VAT. https://digital.nhs.uk/news-and-events/latest-news/prescription-cost-analysis-report-published. See further details in paragraph 25.

Previous revisions to this Impact Assessment

8. This IA was previously updated following the original DHSC consultation "The Availability of Gluten Free Food on Prescription in Primary Care." The IA invited evidence on four specific assumptions:
   i. The effect of changes to national prescribing policy on adherence to a GF diet.
   ii. The availability of GF foods in supermarkets and other food outlets and the impact this has on adherence to a GF diet.
   iii. The costs patients are faced with if changes were made to national prescribing policy.
   iv. The cost-effectiveness of a GF diet.
9. Out of 7,941 responses to the consultation, 20 specifically commented on these topics in the IA. Evidence was cited from three types of sources:
   i. National guidance on management of coeliac disease (CD) e.g. NICE quality standard;
   ii. Studies on the availability and cost of GF foods in food outlets, and factors influencing patient adherence to a GF diet; and
   iii. Surveys of patients with CD carried out by GF food manufacturer associations and patient representative organisations.
10. The IA was revised to include this evidence.
11. In a further change, option 3 was amended to restrict prescribing from GF bread and flour to bread and mixes. This change was made in response to 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 with the addition of only eggs or milk. Based on this argument and no contradictory evidence from other sources, DHSC revised option 3 accordingly.

Policy objective

12. To reduce GF food prescribing in primary care to release savings that would be reinvested to provide health benefits to patients elsewhere in the NHS. This is to be done whilst maintaining patient adherence to a GF diet to avoid detrimental health outcomes.

Options considered

13. Changes to national prescribing policy in primary care would require amendments to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004.[4]
14. None of the options considered would make any change patient access to secondary care for the management of coeliac disease, or to the treatment of related health conditions.

Option 1: Make no changes to regulations ("business as usual" option)

15. Not to make any changes to regulations. This option would continue with the current national policy which allows GF foods to be prescribed in primary care.

Option 2: End prescribing of all GF foods

16. This option would prevent all GF products from being prescribed in primary care, and would require the amendment of the above regulations.

Option 3: Restrict prescribing of GF foods to breads and mixes

[4] http://www.legislation.gov.uk/uksi/2004/291/contents/made

17. To restrict prescribing to GF breads and mixes for patients with gluten sensitive enteropathies. This option would end prescribing of other GF foods in primary care and would require the above regulations to be amended. **This is the Government's preferred option**.

Equalities and Health Inequalities

18. The consultation document detailed the consideration of equalities, health inequalities and the impact on vulnerable groups. An Equalities Analysis has previously been published and is available on GOV.UK alongside the previous Impact Assessment (January 2018) and the Government response to the consultation.

19. 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 preferred option to restrict prescribing to GF breads & mixes, rather then end all GF food prescribing, is to mitigate the risk of patients from low income families being worse off. Like other patients with CD, those in low income families can still consume foods that are naturally gluten-free such as meat, fish, rice, fruit and vegetables. Alongside this, the proposed regulations will allow for the provision of GF bread and mixes on NHS Prescription.

Evidence used to inform estimates of costs and benefits

Background

20. Coeliac disease (CD) is a serious medical condition where the body's immune system attacks its own tissue when gluten is eaten.[5] 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. Naturally GF foods include meat, fish, vegetables, fruit, rice and most dairy products.

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

22. Today, formulated GF foods are available in supermarkets and other food outlets where patients can purchase items in-store or online. 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 formulated GF foods to offer.[6] Additionally, whilst some branded GF products are available in supermarkets, others are only available via prescription on the NHS.

23. In practice, patients consume a 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.[7]

NHS prescribing of GF foods and associated costs

24. In 2017, there were just over a million prescriptions of GF food in primary care dispensed to 67,365 patients in England, but prescribing fell throughout 2017 and 2018. Fewer than 400,000 items were dispensed in the first half of 2018.[8] A prescription for GF food is typically of 6-8 units e.g. 6-8 loaves of bread.

25. The Net Ingredient Cost (NIC) of these prescriptions was just under £16 million in 2017, falling to £6 million in the first half of 2018. Basic prices of GF foods prescribed on the NHS are the list prices published by the manufacturer, wholesaler or supplier for a single dispensing unit of approved GF

[5] https://bestpractice.bmj.com/topics/en-gb/636

[6] 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 Postgrad Med J. 2015; 91: 622-6.

[7] BSNA Survey – see BSNA response to DHSC consultation at https://bsna.co.uk/uploads/banners/DH-Consultation-BSNA-Supplementary-Information-Final.pdf

[8] NHS prescribing data come from NHS Business Services Authority (BSA) Prescription Services via the online application which gives users access to ePACT2 data. https://www.nhsbsa.nhs.uk/epact2

products, as with other borderline substances not listed under Part VIII of the Drug Tariff.[9] NIC does not cover dispensing fees (paragraph 43) or prescription charges paid by patients (paragraph 31).

26. Prescribing of breads and mixes accounted for over half (57%) of items prescribed and three-quarters (76%) of NIC spend. Other prescribing covered staple items such as pasta but also non-staple items including biscuits, cakes and pastries.

Geographical variation in GF food prescribing

27. CCGs have some powers over prescribers in primary care. Legislation prevents them from telling a prescriber what products to prescribe, but they hold the budget for primary care prescribing and have management functions that flow from this. CCG guidance to local GPs supports them to meet local health needs within their budgets. This can vary, as illustrated in the different approaches CCGs have taken to GF food prescribing (see Figure 1).

28. The national charity, Coeliac UK, contacted all 207 CCGs and collected information on their prescribing policies.[10] Two-fifths of CCGs had restricted prescribing to specified GF foods, or to certain patient groups. A further two-fifths had ended routine prescribing of GF foods. Figure 1 shows the differences in prescribing trends across these groups of CCGs.

Figure 1 Trends in GF food prescribing across CCGs with different local policies, mean quarterly number of prescription items per CCG

Data sources: Coeliac UK survey, NHS BSA prescribing data (ePACT2)

Characteristics of people who are prescribed GF foods

29. There is a distinction between three groups of people: people who have coeliac disease that may be undiagnosed; people who have diagnosed coeliac disease; and people who are prescribed GF foods.

30. There is evidence that rates of diagnosed coeliac disease are higher among children living in more affluent areas,[11] but there is less evidence that people prescribed GF foods are from more affluent areas.

31. Prescription exemptions data provided by the NHS BSA show that 80% of GF prescription items are exempt from any charge on grounds of a patient's age, a medical exemption or receipt of income-based

[9] Products falling under Part XV of the Tariff are approved by the Advisory Committee on Borderline Substances (ACBS) https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/455113/Pricing_of_ACBS_products_-_August_2015.pdf

[10] https://www.coeliac.org.uk/gluten-free-diet-and-lifestyle/prescriptions/prescription-policies/

[11] Zingone F, West J, Cooks CJ, et al. Socioeconomic variation in the incidence of childhood coeliac disease in the UK. *Arch Dis Child* 2015; 0:1-8. https://adc.bmj.com/content/archdischild/early/2015/01/07/archdischild-2014-307105.full.pdf

benefits, which is lower than the overall rate of exemptions from prescription charges overall. This reflects the slightly younger age profile of people with coeliac disease compared to NHS patients as a whole.

32. Given the poor availability and high cost of GF foods in some areas and budget supermarkets (paragraph 22), the impacts of withdrawing prescribing of GF foods could have a disproportionate impact on people on lower incomes.

Relative prices of GF foods

33. Evidence provided by CCGs who responded to the consultation suggests that the NHS could pay more than the consumer for the same GF products. For example, one CCG reported that three 500g bags of GF pasta cost the local NHS £20 on prescription, compared to £5 in a supermarket. Others reported similar price differentials. CCGs also reported a lack of transparency on how NHS costs are comprised for GF foods. In the analysis in this IA, given the variability in availability and cost of GF foods, it is assumed that individuals would pay the same amount as the NHS, but this is likely to overstate the private costs to individuals of purchasing GF foods.

34. The cost that the NHS pays for GF foods is not linked to the prescription charge paid by patients. Out of a fifth of people who pay for their prescriptions, the vast majority use a pre-payment certificate (PPC). Just 1% of people pay the single charge of £8.80 per item. The annual cost of a PPC is £104 and this covers the cost of all prescriptions. The mean annual number of GF items per patient is 15, where an item is equal to 6-8 units. Based on this, a patient who pays for their prescription would typically pay £1 or less per unit e.g. 1 bag of 500g pasta.

Health effects: The link between GF food prescribing and adherence to a GF diet

35. In our 2017 public consultation to propose changes to the availability of GF foods on prescription, we invited evidence on the link between prescribing GF foods and adherence to a GF diet among patients with gluten sensitivity enteropathies.

36. Generally, reported rates of adherence to a GF diet in adults with coeliac disease varied from 36% to 96%.[12,13] This variation occurred according to the study method used to determine dietary adherence, and was associated with demographic, psychosocial and clinical factors.[14]

37. The strongest evidence for a link between prescribing and adherence appeared in the 2017 study '*Adherence to gluten free diet is associated with receiving gluten free foods on prescription and understanding of food labelling.'*[15] This reported that a significantly higher proportion of patients adhered to a GF diet when receiving GF foods on prescription. The study concluded that adherence could not be isolated to one single factor and recommended that patients become members of Coeliac UK to support them in managing their condition and that they consult dietitians to better understand food labelling. Additionally, the study concluded that further work was needed to understand the impact on adherence when restricting GF foods on prescription.

38. Other evidence submitted as part of the consultation explained the difficulty in isolating adherence solely to the availability of GF foods on prescription. A 2013 study by Hall, Rubin and Charnock[16] analysed 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.

39. The study concluded that adherence to the GF diet required a range of knowledge, skills and complex behaviours to avoid all sources of gluten. A range of public health policies were identified as being

[12] Kemppainen TK, Kroger H, Janatuinen E, et al. Bone recovery after a gluten-free diet: a 5 year follow up study. *Bone* 1999; 25: 355-60.

[13] Hogberg L, Grodzinsky E, Stenhammer L. Better dietary compliance in patients with coeliac disease diagnosed in early childhood. *Scand J Gastroenterol*. 2003; 38:751-4.

[14] Ford S, Howard R, Oyebode J. Psychosocial Aspects of Coeliac Disease: A cross-sectional survey of a UK population. *Br J Health Psychol*. 2012; 17: 743-57.

[15] Muhammed H, Reeves S, Ishaq S, et al. Adherence to a gluten free diet is associated with receiving gluten free foods on prescription and understanding food labelling. *Nutrients* 2017; 9:205. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5537820/

[16] Hall NJ, Rubin GP, Charnock A. Intentional and inadvertent non-adherence in adult coeliac disease. A cross-sectional survey. *Appetite*. 2013 Sep; 68:56-62.

important to facilitate dietary self-management in CD, which extended beyond the individual and the health-care setting. These included: improvements in food labelling; increasing provision of GF foods within supermarkets; and improving awareness within the catering and food manufacturing industry.

40. Further studies similarly highlighted the challenge faced by patients in adhering to a GF diet. GF products tended to be more expensive than their gluten-containing equivalents.[17] Adherence also required knowledge, skills and modified behaviours to undertake substantial changes to dietary habits, including managing social situations.

41. In cases where adherence was low, studies reported that this was often due to frequent occasional lapses influenced by factors such as age at diagnosis, knowledge of disease and psychological factors. As already explained, food labelling could also cause some confusion.

42. The main analysis in this IA assumes that there is no impact, but this assumption is tested in a sensitivity analysis.

Health effects: The link between adherence to a GF diet and health outcomes

43. Adherence to a GF diet for life is currently the only effective treatment for coeliac disease. Improvement of symptoms such as diarrhoea, constipation and bloating typically occurs within days or weeks of removing gluten from a diet. Following a strict GF diet also reduces the risk of long term complications linked to coeliac disease (CD), ranging from Vitamin D and iron deficiency through to osteoporosis, development of intestinal ulcers, intestinal malignancy and defective immune responses to infectious diseases.[18,19] Guidance produced by the British Society of Gastroenterology identifies CD patients as being at increased risk of osteoporosis and bone fracture. These complications have negative health consequences for the individual and can result in higher NHS treatment costs.

44. We are not aware of robust evidence on the clinical or cost-effectiveness a strict GF diet for treating coeliac disease. For the purposes of the sensitivity analysis, it is assumed that its cost-effectiveness is equal to other NHS care, i.e. £15,000 per QALY (see paragraph 45), but this was also altered in sensitivity analyses.

The Costs and Benefits of Each Option

Overview of Costs and Benefits

45. Option 2 ends the prescribing of all GF foods in primary care. Option 3 restricts it to GF breads & mixes. The same impacts are identified for each option, but the scale of these impacts differs between them. The following impacts are quantified and monetised:

Benefits

- A saving to the NHS from reduced NIC spending; and
- A saving to patients who no longer pay prescription charges,

Costs

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

46. It is assumed that everyone who pays for their GF prescriptions purchases an annual PPC and that the annual PPC cost remains frozen at £104.00, as it has been over the last ten years. Each PPC is assumed to cover 15 items per year: the mean annual number of GF prescription items per person. And it is assumed that people would no longer purchase a PPC if they were no longer prescribed GF foods.

47. It is assumed that individuals would pay the same for GF foods as the NHS pays for these foods. Based on evidence described in paragraph 33, this is likely to be the maximum cost that patients would pay.

17 Lee AR, Ng DL, Zivin J, Green PH. Economic burden of a gluten-free diet *J Hum Nutr Diet* 2007; 20: 423-430.

18 NICE guideline NG20. Coeliac disease: recognition, assessment and management https://www.nice.org.uk/guidance/ng20.

19 Lebwohl B, Sanders DS, Green PHR. Coeliac disease. *The Lancet* 2018; 301: 70-81. https://www.sciencedirect.com/science/article/pii/S0140673617317968

48. There would be no savings to the NHS from reduced dispensing costs associated with the reduction in dispensing. This is because contractors providing NHS pharmaceutical services receive a fixed amount in total (£2.6 billion in 2017/18) agreed under the Community Pharmacy Contractual Framework (CPCF). The single activity fee is adjusted in-year to deliver this amount.[20]

49. Evidence submitted by the British Specialist Nutrition Association suggested that people would infrequently have a GP appointment to have their prescription repeated or changed, and, even then, would typically see their GP for an additional health condition alongside getting a prescription.[21] NICE guidance also recommends that coeliac patients are managed in primary care, and offered an annual review. Considering this, we have revised the assumption that the reduction in GF food prescribing would release GP time. Instead, it is assumed that the reduction in prescribing would have no impact on GP activity.

50. The DHSC has consulted extensively on the proposed policy changes, including actively informing of CCGs about the likely timing and extent of any changes to prescribing policy. Any further familiarisation costs are likely to be small and are not monetised in this IA.

51. Cost savings to the NHS are assumed to be reinvested in other NHS services, where additional spending is valued at £15,000 per QALY.[22] These QALYs are discounted at a rate of 1.5% per year, and the social value of these QALYs is monetised using a value of £60,000 per QALY, based on standard DHSC valuation methods.[23]

Assumed trends in spending on GF food prescribing

52. The baseline NIC spend in 2018 is estimated to be £10.5 million (extrapolating from the first two quarters). Of this £8.9 million is on breads & mixes, and £1.6 million is on other GF foods. Forecasts of NIC spend on GF food prescribing from 2019 to 2028 have been updated to incorporate new information on local CCG prescribing trends (see Figure 1).

53. Under option 1 (no change to regulations, "business as usual"), it is assumed that the volume and NIC cost of prescribing would fall by 10% per year in CCGs that have not already withdrawn GF food prescribing. These "counterfactual" trends are based on observed prescribing trends over the last two years in CCGs that have not introduced formal policies to restrict prescribing (see Figure 1). This downward trend could be due to changes in GP's prescribing behaviours or patient demand for prescribed GF foods. In CCGs that have already withdrawn GF food prescribing, it is assumed that spending remains at zero (Table 3). This assumption is based on intelligence that many CCGs have consulted locally on their policies and do not intend to reintroduce GF food prescribing regardless of any changes to regulations. Alternative assumptions are considered under "Assumptions, sensitivities and risks".

54. Under option 2 (end GF food prescribing), it is assumed that GF food prescribing would immediately end in 2019 and then remain at zero. Under Option 3 (restrict GF food prescribing), it is assumed that volume & NIC costs of prescribing of breads & mixes would fall by 10% per year, and that all other GF food prescribing would be withdrawn immediately and then remain at zero. Again, as described in paragraph 48, the assumption that prescribing of GF breads & mixes would continue to fall under option 3, even though it is permitted, is based on observed trends in CCGs that have not formally restricted prescribing.

Table 2 Assumed future trends in spending on GF food prescribing across different CCGs under different policy options

	Annual percentage change in NIC		
Local CCG policy, product type	**Option 1 – "business as usual"**	**Option 2 – end GF food prescribing**	**Option 3 – restrict GF food prescribing**

[20] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/561495/Community_pharmacy_package_A.pdf

[21] https://bsna.co.uk/uploads/banners/DH-Consultation-BSNA-Supplementary-Information-Final.pdf

[22] The QALY is a standard unit used to measure health gains that combines impacts on longevity and health-related quality-of-life. The DHSC estimate of the cost at which an additional QALY is gained or lost in the NHS is £15,000. This figure is based on a published estimate of the cost per QALY at the margin in the NHS, https://www.york.ac.uk/che/research/teehta/thresholds/.

[23] https://www.gov.uk/government/publications/quantifying-health-impacts-of-government-policy.

Local GF food prescribing not withdrawn*			
Breads & mixes	↓ 10% p.a.	↓ 100% year 1.	↓ 10% p.a.
Other GF foods	↓ 10% p.a.	↓ 100% year 1.	↓ 100% year 1
Local GF food prescribing withdrawn*			
Breads & mixes	Flat at zero*	Flat at zero*	Flat at zero*
Other GF foods	Flat at zero*	Flat at zero*	Flat at zero*

*It is assumed that spending falls to zero in CCGs that have already withdrawn GF food prescribing and then remains flat.

Option 2: End prescribing of GF foods

55. Option 2 would amend national regulations to end prescribing of all GF foods in primary care. The annual financial saving to the NHS would be **£5.3 million per year**, based solely on reductions in NIC spending and loss of prescription charges revenue. This is equal to the annual financial cost of GF purchasing that is transferred to patients who would have been prescribed GF foods.

56. The net monetised and discounted health benefits over 10 years are valued at approximately **£151 million.** The costs and benefits are described and summarised in Table 3. The annual profile of costs and benefits is included in tables in Annex A.

Option 2 Benefits

57. The estimated NIC saving to the NHS from ending prescribing of GF foods in primary care is **£57 million** over the ten-year appraisal period (undiscounted total). It is assumed that these savings are reinvested into other NHS services, where they generate health gains (3,800 QALYs). When monetised at a rate of £60,000 per QALY, and discounted at a rate of 1.5% per year, these savings are valued at **£214 million**.

58. For patients, there would be savings to those who previously paid for their prescriptions (using a pre-payment certificate) total **£5 million** over the appraisal period, with a discounted value of **£4 million** (discount rate of 3.5% per year).

Option 2 Costs

59. For patients, the estimated financial costs of purchasing their GF foods privately over the appraisal period are **£57 million**, and these are discounted at a rate of 3.5% per year to give a total of **£49 million.**

60. For the NHS, there would be a loss of prescription charge revenue worth **£5 million** over the appraisal period. The foregone health gains associated with this reduction in revenue equate to 300 QALYs and **£18 million** in monetised health benefits.

Option 3: Restrict prescribing of GF foods

61. Option 3 would amend national regulations to restrict prescribing of all GF foods in primary care to breads and mixes, ending prescribing of all other GF foods. The annual financial saving to the NHS would be **£0.7 million per year**, based solely on reductions in NIC spending and loss of prescription charges revenue. These are equal to the annual financial costs of the policy that would be transferred to patients who would have been prescribed GF foods.

62. The monetised and discounted net health benefits over 10 years are valued at **£20 million.**

Option 3 Benefits

63. The NIC savings from restricting prescribing of GF foods in primary care to breads & mixes amount to **£8 million** over the ten-year appraisal period (undiscounted total). Monetised health benefits resulting from these savings are valued at **£32 million** (discounted at a rate of 1.5% per year).

64. Savings to patients who previously paid for their prescriptions (using a pre-payment certificate) are **£1.5 million** over the appraisal period, with a discounted value of **£1.3 million** (discount rate of 3.5% per year).

Option 3 Costs

65. The estimated financial costs to patients over the appraisal period are **£8.4 million**, and these are discounted at a rate of 3.5% per year to give a total of **£7.2 million.**

66. The NHS would lose prescription charges revenue worth **£1.5 million** over the appraisal period, associated with **£5.5 million** in monetised health benefits.

Table 3 Estimated costs and benefits of each policy option relative to option 1 (no change to regulations, "business as usual" option) over 10-year appraisal period

£ millions, QALYs

Costs and benefits of policy	Option 2 - end GF food prescribing	Option 3 - restrict GF food prescribing
Net benefits of policy (net present value)	**£151.4**	**£20.1**
Benefits (net present value of discounted monetised health benefits from NHS savings and financial savings to patients)	£218.5	£32.8
NHS: financial savings from reduced NIC spending, providing:	£57.4	£8.4
- health benefits to NHS patients (QALYs)	3,800	600
- discounted monetised health benefits	£214.4	£31.5
Patients prescribed GF foods: financial savings in prescription charges :	£4.8	£1.5
- discounted financial savings	£4.1	£1.3
Costs (net present value of discounted financial costs to patients and foregone monetised health benefits from reduced prescription charge revenue)	£67.2	£12.7
Patients prescribed GF foods: financial costs of private GF food purchasing :	£57.4	£8.4
- discounted financial costs	£49.1	£7.2
NHS: financial costs from reduced prescription charge revenue , providing:	£4.8	£1.5
- health benefits to NHS patients (QALYs)	300	100
- discounted monetised health benefits	£18.0	£5.5

Figures are not discounted unless stated. Financial savings to the NHS are assumed to produce health benefits at a rate of £15,000 per Quality Adjusted Life Year (QALY). In turn, QALYs are assumed to have a societal value of £60,000 per QALY. Monetised health benefits are discounted at a public health discount rate of 1.5% per year. Financial costs to patients are discounted at a private discount rate of 3.5% per year.

67. Option 3 is the Government's preferred option, despite the fact that it is anticipated to save the NHS less money and generate fewer health benefits than option 2. Following public consultation, the reason for preferring this option is that it mitigates the health risks to patients with coeliac disease.

Assumptions, sensitivities and risks

68. The estimated net benefits of either restricting or ending GF food prescribing through national policy are much lower now than when the policy was originally proposed. This is because many CCGs have restricted or ended GF food prescribing locally, many anticipating changes to national policy (see paragraphs 7 and 27-28).

69. The risks of CCGs policies being effectively challenged if national policy is not now changed have not been quantified in this IA.

70. The estimated costs and benefits are sensitive to assumed trends in GF food prescribing under the different policy options. These trends are uncertain since they depend on the interaction of local and national prescribing policy.

71. For example, we have assumed that spending on GF foods in CCGs that have withdrawn it would remain flat even if national regulations were not now amended. If instead spending in these CCGs reverted to previous levels, rising by 10% per year under option 1 ("business as usual" option), the estimated net monetised health benefits of option 2 increase by a fifth to **£184 million,** and the those of option 3 would more than double to **£52 million** (Table 3 below).

72. Two further assumptions were altered in sensitivity analysis: the impact of GF food prescribing on adherence to a GF diet; and the impact of adherence to a GF diet on health outcomes, measured as the cost-effectiveness of a GF diet. In these analyses, the financial costs to patients of buying GF foods were reduced, but new health costs were introduced. For example, if people spent 10% less on GF foods when they were not prescribed, this 10% translated into foregone QALYs which were monetised at a rate of £60,000 per QALY as which health benefits produced by the NHS.

73. The estimated net benefits of the policy were not very sensitive to a range of realistic assumptions about the effects of restricting GF food prescribing on adherence. For example, if private spending on GF foods reduced by 10% and this was linked to a rise in non-adherence with negative health effects, the overall net monetised health benefits of option 2 and option 3 would fall to **£129 million** and **£17 million** respectively (Table 4 below). This assumed that the cost-effectiveness of adherence to a GF diet was the same as that of NHS care (£15,000 per QALY).

74. We also carried out a "switching values" analysis to test which combinations of impacts resulted in a cost-neutral policy for option 2. We found that private spending on GF foods linked to non-adherence would need to fall by 70% for the costs of the policy to equal the benefits, assuming that the cost-effectiveness of adherence was £15,000 per QALY. If adherence to a GF diet was very cost-effective, e.g. £5,000 per QALY, adherence would need to fall by 20% for the policy to be cost-neutral.

Table 4 Impact of alternative assumptions on estimated policy impacts

£ millions

Alternative assumption	**Option 2 - end GF food prescribing**	**Option 3 - restrict GF food prescribing**
Main estimate	£151.4	£20.1
(a) Assume prescribing would increase (revert) by 10% p.a. in CCGs that have withdrawn GF food prescribing *if* no change to national policy	£183.5	£52.2
(b) Assume prescribing would remain flat in CCGs that have not withdrawn GF food prescribing *if* no change to national policy	£256.2	£124.9
(c) Assume both (a) and (b) would occur	£288.3	£157.0
(d) Assume private GF spending would reduce by 5% if prescribing ended or restricted with a corresponding rise in non-adherence to a GF diet	£140.2	£18.4
(e) Assume private GF spending would reduce by 10% if prescribing ended or restricted with a corresponding rise in non-adherence to a GF diet	£129.0	£16.7

Annex – Additional Tables

Table A1 Benefits from restricting or ending GF food prescribing compared to option 1 ("business as usual" option)

£ millions, QALYs

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Option 2 - end GF food prescribing										
NHS: reduced NIC spending on GF foods:	£8.8	£7.9	£7.1	£6.4	£5.8	£5.2	£4.7	£4.2	£3.8	£3.4
- health benefits generated (no. of QALYs)	590	530	480	430	390	350	310	280	250	230
- monetised value of health benefits	£35.3	£31.7	£28.6	£25.7	£23.1	£20.8	£18.7	£16.9	£15.2	£13.7
Patients: savings in prescription charges	£0.7	£0.7	£0.6	£0.5	£0.5	£0.4	£0.4	£0.4	£0.3	£0.3
Option 3 - restrict prescribing to GF breads & mixes										
NHS: reduced NIC spending on GF foods:	£1.3	£1.2	£1.0	£0.9	£0.8	£0.8	£0.7	£0.6	£0.6	£0.5
- health benefits generated (no. of QALYs)	90	80	70	60	60	50	50	40	40	30
- monetised value of health benefits	£5.2	£4.7	£4.2	£3.8	£3.4	£3.1	£2.8	£2.5	£2.2	£2.0
Patients: savings in prescription charges	£0.2	£0.2	£0.2	£0.2	£0.1	£0.1	£0.1	£0.1	£0.1	£0.1

Table A2 Costs of restricting or ending GF food prescribing compared to option 1 ("business as usual" option)

£ millions, QALYs

	2019	2020	2021	2022	2023	2024	2025	2026	2027	2028
Option 2 - end GF food prescribing										
Patients: cost of buying GF foods privately	£8.8	£7.9	£7.1	£6.4	£5.8	£5.2	£4.7	£4.2	£3.8	£3.4
NHS: reduced prescription charge revenue:	£0.7	£0.7	£0.6	£0.5	£0.5	£0.4	£0.4	£0.4	£0.3	£0.3
- health benefits foregone (no. of QALYs)	50	40	40	40	30	30	30	20	20	20
- monetised value of health benefits	£3.0	£2.7	£2.4	£2.2	£2.0	£1.8	£1.6	£1.4	£1.3	£1.2
Option 3 - restrict prescribing to GF breads & mixes										
Patients: cost of buying GF foods privately	£1.3	£1.2	£1.0	£0.9	£0.8	£0.8	£0.7	£0.6	£0.6	£0.5
NHS: reduced prescription charge revenue:	£0.2	£0.2	£0.2	£0.2	£0.1	£0.1	£0.1	£0.1	£0.1	£0.1
- health benefits foregone (no. of QALYs)	10	10	10	10	10	10	10	10	10	10
- monetised value of health benefits	£0.9	£0.8	£0.7	£0.7	£0.6	£0.5	£0.5	£0.4	£0.4	£0.3