

Suspension of Gluten Free NHS Prescribing for Adults

Governing Body meeting

2 November 2017

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Purpose of Paper	
<p>To provide Governing Body with the results of the formal consultation on the proposal to suspend the availability of gluten free substitute products on NHS prescription to adults in Sheffield and to recommend that the proposal is approved.</p> <p>Could members please note that due to the size of the appendices, these have been circulated separately and are also available on the CCG's website.</p>	
Key Issues	
<p>NHS Sheffield Clinical Commissioning Group (SCCG) has a responsibility to review the services it commissions to ensure that they provide the best outcomes for the public and patients in Sheffield and that it is using NHS funds appropriately. SCCG has a duty to meet its statutory financial obligations.</p> <p>The availability of gluten free alternative foods on prescription for people with coeliac disease has been in operation since the 1960s and reflects the limited availability of gluten free foods at that time. SCCG currently spends £340,000 per annum on gluten free foods. Prescribing for adults is limited to 8 units per month but the estimated cost of adult prescriptions is £100,000 per annum. SCCG is considering options to cease NHS prescription of gluten free substitute foods for adults in Sheffield.</p> <p>Following approval from Governing Body in September 2017 SCCG has undertaken a formal consultation on the proposal and has considered the responses.</p> <p>SCCG proposes to recommend that GPs do not prescribe gluten free foods to adults (aged 18 or above) except where there is a real risk a vulnerable adult is or will become undernourished without the provision of gluten free substitute foods on NHS prescription. Prescriptions for children remain unaffected.</p> <p>SCCG will monitor implementation and availability of foods and make further recommendations to Governing Body in twelve months' time.</p>	
Is your report for Approval / Consideration / Noting	
Approval	

Recommendations / Action Required by Governing Body

The Governing Body is asked to approve the following recommendations:

1. The CCG will ask GP practices to stop prescribing gluten free products on NHS Prescription for adults (aged 18 or above).
2. Where a GP prescriber is sufficiently convinced that there is a genuine risk that a patient with a diagnosis of coeliac disease is, or will become undernourished, then the GP may prescribe 'NHS Drug Tariff listed' gluten free products for that individual alone. It is anticipated that this exceptionality will be very rare.
3. The CCG recommends that coeliac patients continue to follow a gluten free diet, with advice available through various patient support organisations, like Coeliac UK, on how to achieve an appropriate diet through natural and manufactured gluten free foods. This lifestyle management should help to reduce the risk of long-term complications associated with poor nutrition.
4. The CCG will undertake monitoring of the impact of the recommendations and a full review will be presented to Governing Body in 12 months for decision on future arrangements.

Governing Body Assurance Framework

Which of the CCG's objectives does this paper support?
To ensure there is a sustainable, affordable healthcare system in Sheffield.

Are there any Resource Implications (including Financial, Staffing etc)?

As discussed in section 6, management and clinical time to completed the implementation of the project.

Have you carried out an Equality Impact Assessment and is it attached?

Please attach if completed. Please explain if not, why not
Yes, attached

Have you involved patients, carers and the public in the preparation of the report?

Yes, consultation has been undertaken as described in the report and appendices.

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1. Introduction

NHS Sheffield Clinical Commissioning Group (SCCG) has a responsibility to review the services it commissions to ensure that they provide the best outcomes for the public and patients in Sheffield and that it is using NHS funds appropriately. SCCG has a duty to meet its statutory financial obligations.

In September 2017 Governing Body received a report setting out a number of options to improve the financial position in 2017/18. These included an option to suspend gluten free prescribing for adults in Sheffield. These options were only considered after a full review of other opportunities to deliver additional financial savings was exhausted. Consideration of these options reflects difficult decisions about the prioritisation of available resources within the local health system.

Governing Body approved a recommendation to move to public consultation on this proposal on gluten free prescribing and to receive final recommendations following the end of the consultation. The consultation has now ended and this paper presents the final recommendations on the proposal to Governing Body.

2. Proposal to Cease Provision of Gluten Free Products for Adults on NHS Prescription

Coeliac disease is an autoimmune disease caused by a reaction to gluten. Adherence to a gluten free diet remains the effective means of managing coeliac disease.

Many common foods are naturally gluten free, such as fresh fruit and vegetables, including potatoes, meat, chicken, fish, cheese, eggs, rice and lentils. But gluten is found in wheat, barley and rye, therefore products like flour, bread, pasta, biscuits and cakes typically contain gluten unless they have been manufactured to be gluten free. Eating manufactured gluten-free foods is not necessary for a healthy diet.

It is important to note that a number of people without a diagnosis of coeliac disease may choose to follow a gluten free diet. Availability of gluten free items on NHS prescription is only allowed for individuals with a clinical diagnosis of coeliac disease (established gluten sensitive enteropathy, with or without coexisting established wheat sensitivity).

Gluten free alternatives to a range of common foodstuffs (bread, pasta *etc.*) have been available on prescription to patients diagnosed with gluten sensitivity enteropathies since the late 1960s when the availability of gluten free foods was otherwise limited.

In 2016/17 SCCG spent over £340k on the prescribing of gluten free products. Prescribing for adults is limited to 8 units per month but the estimated cost of adult prescriptions is £100,000 per annum. These food products are now widely available, with greatly improved choice and quality from retail outlets in all areas in the CCG plus the greater majority of supermarkets. Their price to the consumer has greatly reduced compared to the significantly higher price the NHS pays for similar products on prescription.

Following consideration of the options and formal consultation, the recommendation made to the Governing Body is that GPs do not prescribe gluten free products for adults on NHS prescription. Prescribing GPs will be able to apply discretion in exceptional but rare circumstances where they are sufficiently convinced that there is a genuine risk that a vulnerable individual is, or will become, undernourished if they do not prescribe gluten free products for that individual alone. The CCG recommends that coeliac patients continue to follow a gluten free diet.

3. Consultation Process

The CCG has a legal duty to involve people in decisions about commissioning plans and service changes, especially those who may be affected by any proposed change. The CCG therefore conducted a formal public consultation to ensure that any decision to change was informed by a wide range of perspectives.

The consultation into proposed changes to prescribing guidelines for adults opened on September 8, 2017 to seek people's views and help inform the decision made by the Governing Body.

It was an opportunity for people to feedback their thoughts on the proposals, raise any concerns about the potential impact they might have and also put forward any suggestions. The consultation ran until Friday October 20 and a total of 376 responses were received.

4. Key Findings from the Consultation

There was a mixed response about the proposals. The majority of respondents believed that Gluten Free foods should continue to be prescribed, although this should possibly be limited to a certain amount of units of only bread and flour per month. A significant number of respondents were in favour of the proposals as they felt that food should not be prescribed by the NHS or funds would be better used elsewhere.

Full details of the consultation are presented in a report '*Prescribing of Gluten Free food for adults in Sheffield Consultation Report*' at appendix 1 to this report. A number of key themes were identified in the feedback to the consultation:

4.1 Availability and Cost of Gluten Free Products

People are significantly concerned about the effect these proposals may have on people with lower incomes, who are less likely to be able to adapt to a restricted diet due to limited finances, time and working conditions. It was also highlighted that there is an increasing use of food banks and that gluten free products cannot be guaranteed from this support. They believe that these changes will lead to either a lack of adherence to a gluten free diet or malnutrition in these individuals.

Respondents raised concerns about the widespread availability of gluten free alternative foods and the cost of these foods when self-purchased. Some were concerned that current availability may reduce in the future.

- There has been an increased availability in gluten free products in shops, although these can still be limited in local shops and rural areas.
- Gluten free products in shops are much more expensive than gluten containing alternatives.
- People are significantly concerned about the effect on people with lower incomes and that these changes will lead to a lower adherence of a gluten free diet.

4.2. Health consequences and costs to the NHS of People Not Following a Gluten Free Diet

Respondents raised concerns about the risk to health of people with coeliac disease failing to adhere to a gluten free diet and the costs this may place on the NHS in the longer term.

- There are serious potential health consequences for a person with Coeliac disease who does not adhere to a gluten free diet. These include malnutrition, anaemia, vitamin D and iron deficiency, stomach and bowel cancers, osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism and neurological gluten ataxia.
- Future cost to NHS, especially in light of limited savings announced.
- Coeliac disease is a serious, lifelong autoimmune condition that is not a result of lifestyle choices.
- A gluten free diet is the only treatment available to someone with Coeliac disease. The NHS does not spend anything on medication for people with Coeliac disease.

4.3 Equity for People with Coeliac Disease

A number of respondents considered the changes to be unfair and discriminatory. Many highlighted that other long term conditions, including those as a result of lifestyle choices, still receive medication through prescription. Other responses highlighted that other dietary related conditions did not receive prescribed foods.

4.4 Changes to Diet

Respondents highlighted that a gluten free diet does not require manufactured gluten free products and there are many alternatives, such as naturally gluten free foods. Some people believe there is an over reliance on gluten free products when there are better, healthier alternatives.

4.5 Alternative Supply Routes and Funding Mechanisms

Several respondents cited changes or pilots taking place elsewhere which established different supply routes for gluten free products such as the Rotherham and Vale of York approaches.

4.6 Supporting People with Coeliac Disease to Better Manage Their Condition

Respondents to the consultation were asked what could be done to better support people with coeliac disease to manage their condition; a number of suggestions were received:

- dietary advice and information including recipes
- regular reviews and monitoring
- voucher scheme
- access to a dietician
- shopping guide with a list of naturally gluten free products and
- monitor availability of gluten free products in shops, concern that availability is associated with fad diets and will decrease if demand drops.
- support groups and cookery classes
- consistent care for all people with Coeliac disease

5. Considerations Resulting from Consultation Responses

SCCG has carefully considered the proposals made in the light of the responses to the consultation received and considers that these concerns are addressed as far as is reasonable by the recommendations made in this paper.

5.1 Availability and Cost of Gluten Free Products

SCCG is assured, on the basis of local review, that there is wide availability of gluten free products across Sheffield, all national supermarkets and several discount supermarket chains now offer gluten free product ranges. SCCG notes that in some particular areas however, coverage may be poorer. Gluten free substitute products do cost more than own-brand gluten containing however, this cost differential is lower than previously reported and is substantially less than the cost of supplying products on prescription to the NHS.

SCCG believes that gluten free substitute ranges are general affordable however, it recognises that this may be harder for people on low incomes. The CCG recognises and is concerned about the nutritional status of vulnerable individuals. While purchasing food is determined by choice and necessity for the majority of the population, this is not as applicable to vulnerable individuals, where food products are typically chosen for them. Children are excluded from this recommendation and exceptionality has been included in the recommendations to protect vulnerable adult individuals at risk with GPs prescribing according to their clinical judgement.

SCCG will continue to review the cost and availability of gluten free products and will include findings in the report to Governing Body in 12 months.

5.2 Health consequences and costs to the NHS of People Not Following a Gluten Free Diet

Those diagnosed with established gluten sensitive enteropathies should adhere to a lifelong gluten free diet to avoid health complications. The National Institute for Health and Care Excellence (NICE) provides guidance to clinicians on the diagnosis and management of coeliac disease. Figures on patient adherence rates, based on a model from 2005 and quoted by NICE are: adult adherence rates of 65.7%, and 84% in children. No evidence has been identified that demonstrates a clear link between the

availability of gluten free foods through prescription and increased adherence to gluten free diets among patients with gluten sensitivity enteropathies. Systematic reviews of this issue show that the existing evidence for factors associated with adherence to a gluten free diet is of variable quality and that options for the standardised evaluation of adherence remain unsatisfactory.

SCCG proposes as part of monitoring the impact of ceasing prescribing gluten free products for adults to monitor any impact to the health of patients. This will be done by using a cohort of GPs in the city to monitor rates of adherence and impact on health status, this will be reflected in the review and reported to Governing Body in 12 months.

5.3 Equity for People with Coeliac Disease

As discussed above, SCCG has a responsibility to review the services it commissions to ensure that they provide the best outcomes for the public and patients in Sheffield and that it is using NHS funds appropriately. The CCG must make difficult decisions in order to deliver these responsibilities. Equality and quality impact assessments have been completed and are attached at appendix 2 and 3 to this paper.

GPs will always retain the clinical discretion to prescribe gluten free products adults where they believe that there is genuine risk that a patient with a diagnosis of coeliac disease is, or will become, undernourished,

5.4 Alternative Supply Routes and Funding Mechanisms

A number of respondents asked SCCG to consider alternative routes to provision of gluten free products such as the Contractual arrangements in place in Rotherham or the voucher scheme pilot operated by Vale of York CCG.

Alternative supply or funding mechanisms have been considered by SCCG. The availability of gluten free substitute foods on prescription for adults in Sheffield is already limited to 8 units per month or bread, pasta and flour. While the alternative supply options may reduce cost of provision somewhat they generate their own transaction costs in maintaining a voucher scheme and in funding provision of products directly or through another provider. However, the difficult decision SCCG is considering is driven by an urgent requirement to make further financial savings and therefore cessation of provision is the only option considered for recommendation.

5.5 Supporting People with Coeliac Disease to Better Manage Their Condition

SCCG notes the comments by respondents about improving availability of advice and information for people with coeliac disease. access to dietetic advice is in place across the City and as a result of recommendations SCCG will take a number of steps to ensure that people with coeliac disease and those newly diagnosed have access to a range of advice and support:

- Ensure patients are able to access suitable dietetic advice as required
- Develop a page on the CCG website containing useful information, clinically reviewed advice and guidance, contacts and links
- Provide advice and guidance to GPs to support the change in prescribing recommendations including how to access dietetic advice, to work with

gastroenterologists to develop a coeliac disease pathway and guidelines for GPs and secondary care clinicians to follow

- Develop a patient support leaflet to provide information on the importance of maintain a gluten free diet, advice and guidance
- Explore opportunities to work with local voluntary sector organisations to offer further support and guidance

6. Next Steps

Subject to Governing Body approval the next steps to implementation will be as follows:

- Share recommendation with Area Prescribing Group for information
- Confirm recommendation at Prescribing Forum
- Prepare GP and patient information leaflets
- Implement communications plan for patients and public
- Develop web page and information sources
- Implement GP communications plan commencing with locality managers
- Implement the suspension with effect from 1 December 2017.

7. Action for Governing Body / Recommendations

The Governing Body is asked to approve the following recommendations:

5. The CCG will ask GP practices to stop prescribing gluten free products on NHS Prescription for adults (aged 18 or above) with a diagnosis of coeliac disease.
6. Where a GP prescriber is sufficiently convinced that there is a genuine risk that an adult patient with a diagnosis of coeliac disease is, or will become, undernourished, then the GP may prescribe 'NHS Drug Tariff listed' gluten free products for that individual alone. It is anticipated that this exceptionality will be very rare.
7. The CCG recommends that people diagnosed with coeliac disease continue to follow a gluten free diet, with advice available through various patient support organisations, such as Coeliac UK, on how to achieve an appropriate diet through natural and manufactured gluten free foods. This lifestyle management should help to reduce the risk of long-term complications associated with poor nutrition.
8. SCCG will undertake monitoring of the impact of the recommendations and a full review will be presented to Governing Body in twelve months for decision on future arrangements.

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On behalf of: Brian Hughes, Director of Commissioning and Performance

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