

## Prescribing of Gluten Free foods in Greater Nottingham

### 1. Background

Coeliac disease is an autoimmune condition associated with chronic inflammation of the small intestine, which can lead to malabsorption of nutrients, triggered by the protein gluten. If someone with coeliac disease is exposed to gluten (found in wheat, barley and rye) they may experience a range of symptoms and adverse effects. The symptoms from and consequences of not following gluten free (GF) diets may be mild or very severe and can include;

- Abdominal pain, diarrhoea, nausea, bloating, vomiting
- Weight loss in adults or failure to grow at the expected rate in children
- Malnutrition, iron, vitamin B12 and folic acid deficiencies
- Tiredness, headaches
- Skin rash, mouth ulcers, tooth enamel problems
- Osteoporosis, ulcerative jejunitis
- Malignancy (intestinal lymphoma)

The disease affects approximately 1 in 100 people in the UK where women are two to three times more likely to develop coeliac disease than men. There are approximately 850 patients across Greater Nottingham who are prescribed a gluten free product.

People with conditions such as type 1 diabetes, autoimmune thyroid disease, Down's syndrome and Turner syndrome are at a higher risk than the general population of having coeliac disease. First-degree relatives of a person with coeliac disease also have an increased likelihood of having the condition. It can be diagnosed at any age.

Symptoms are controlled by excluding foods that contain gluten from the diet. There are no medicines available to treat the condition and it cannot be cured. People with confirmed coeliac disease must give up eating all sources of gluten for life.

Over twenty to thirty years ago only a small range of GF foods, if any, were available to purchase and they were relatively expensive. To enable people to manage their disease, these foods were made available on prescription. However in recent years the range of GF foods has considerably expanded and become widely available via supermarkets at a more competitive price. However, gluten is not essential for a healthy diet and there are other foods that can provide carbohydrates e.g. potato and rice.

In 2017 the Department of Health (DH) recently conducted a national consultation on the availability of Gluten Free (GF) foods on prescription in primary care.

The options considered were:

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

*Under this option all types of GF foods would continue to be prescribed in primary care at National Health Service (NHS) expense.*

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

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

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

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

The outcome from the national consultation was published on 1<sup>st</sup> February 2018 and the Government decided to restrict gluten-free prescribing to bread and mixes only. The majority of respondents to the consultation preferred this option.

The consultation response stated that:

“It is for CCGs to decide how they commission local services to best meet the needs of their populations”.

This statement signalled that the outcome of the consultation does not affect the statutory authority that a CCG has to determine the availability of gluten-free foods in their local area. Greater Nottingham Clinical Commissioning Partnership decided to undertake a public consultation to support decision making about prescribing of gluten free foods for their population.

## **2. Current position**

### NHS Rushcliffe, Nottingham West and Nottingham North & East CCGs

- May 2016 – Following feedback from a three month consultation and recommendations from clinical, patient cabinets and governing bodies NHS Rushcliffe, Nottingham West and Nottingham North & East made changes to Gluten Free products available on prescription. As of May 2016 all practices within the three CCGs were requested to ensure no more than four units in total of long life bread and/or flour per month were prescribed for patients with a diagnosed condition of coeliac disease or dermatitis herpetiformis. The medicines management teams work with GP practices to monitor adherence to recommendations.

### NHS Nottingham City CCG

- In June 2015 the NHS Nottingham City CCG Executive Management Team decided that the City population needs were different from those in the County and the proposed County options were not in line with these needs, so NHS Nottingham City CCG did not enter in to the consultation about changes to prescribing of gluten free foods alongside NHS Rushcliffe, Nottingham West and Nottingham North & East.
- Clinicians in NHS Nottingham City CCG prescribe staple gluten free products, in line with the Area Prescribing Committee (APC) position statement and currently there is no corporate policy about further restricting quantities or items. The medicines management teams work with GP practices to align quantities with those recommended by Coeliac UK.

### NHS Mansfield & Ashfield and Newark & Sherwood CCGs

- February 2017 – Following a month’s engagement in January 2017 at its meeting on the 16 February 2017, the joint Governing Body for the two CCGs reviewed comments and agreed to stop NHS prescriptions for Gluten Free foods, for all patients, unless there are special circumstances.

Prescription expenditure on GF foods (April to June 2018)

Nottingham City CCG	£26,377
Nottingham North and East CCG	£5,786
Nottingham West CCG	£3,154
Rushcliffe CCG	£3,815

Using this data to calculate a full year effect produces and anticipated expenditure of £156,528 per annum on GF foods.

### **3. Options**

The options in the public consultation were agreed following discussion at Governing Body meetings in each Greater Nottingham CCG:

**Option 1:** Limit prescribing for all patients in Greater Nottingham to four units of long life bread and flour per month.

#### **Benefits**

- This option would ensure that all patients in Greater Nottingham have GF products prescribed in line with the same guidance and will provide equitable provision for patients and clarity for prescribers. It will bring Nottingham City CCG prescribing in line with the other CCGs.
- All patients will be able to access a defined quantity of GF bread and flour to support their adherence to a GF diet
- Prescribing cost efficiencies of approximately £65K could be realised

#### **Risks**

- Patients at risk of developing signs and symptoms of gluten intolerance and subsequently potential serious complication, leading to a pull on primary and secondary care resources should they not be able to afford additional GF products to supplement the prescribed volume. Impact for patients with protected characteristics – please see EQIA (Appendix 1) for more information.
- This option is not in line with the recommendations from the national consultation and could generate considerable public and media interest, which may involve significant resource to manage and may have a detrimental CCG organisational reputational impact.

**Option 2:** All Greater Nottingham CCGs to stop all gluten free prescribing, with the exception of children, who will be able to receive up to four units of long life bread and flour per month

#### **Benefits**

- This option would ensure that all children in Greater Nottingham have GF products prescribed in line with the same guidance and will provide equity for these patients and clarity for prescribers.
- Children will be able to access a defined quantity of GF bread and flour to support their adherence to a GF diet. Information provided through the national consultation stated that the lack of adherence to a GF diet could impact on the growth rate of children, delay puberty and make them susceptible to other auto immune conditions.
- Prescribing cost efficiencies would be realised.

#### **Risks**

- Adult patients at risk of developing signs and symptoms of gluten intolerance and subsequently potential serious complication, leading to a pull on primary and secondary care resources should they not be able to afford GF products.
- This option is not in line with the recommendations from the national consultation and may generate considerable public and media interest, which may involve significant

resource to manage and may have a detrimental CCG organisational reputational impact.

**Option 3:** All Greater Nottingham CCGs to stop all gluten free prescribing

Benefits

- Prescribing cost efficiencies of approximately £156K could be realised

Risks

- Patients at risk of developing signs and symptoms of gluten intolerance and subsequently potential serious complication, leading to a pull on primary and secondary care resources should they not be able to afford GF products.
- This option is not in line with the recommendations from the national consultation and could have a detrimental reputational impact.
- Possible legal challenge - as part of the consultation process across the three south CCGs, legal advice was sought and the recommendation was not to stop all prescribing of GF products on prescription. This was based on patient access and GPs and CCGs responsibility to provide patients with adequate products/medication to prevent harm.
- Impact on patients with certain protected characteristics – please see EQIA (Appendix 1) for more information.

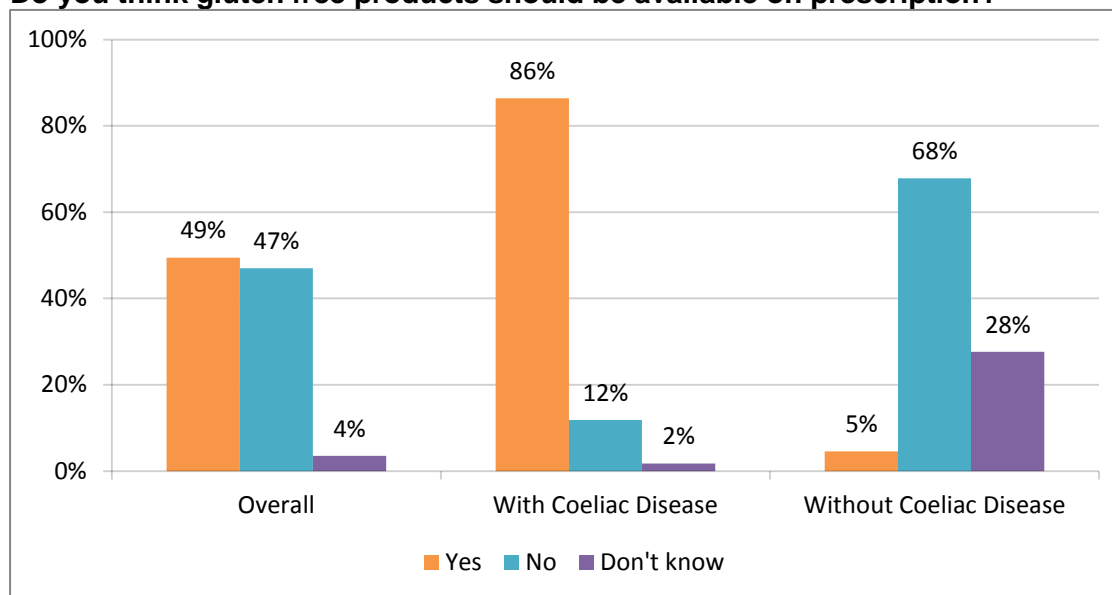
#### **4. Public Consultation**

The results from the public consultation on the options outlined above are given in Appendix 2. There were 462 responses to the consultation. 169 responses were from people who have diagnosed coeliac disease/ dermatitis herpetiformis, or who are caring for or responding on behalf of people who have diagnosed coeliac disease/ dermatitis herpetiformis.

Overall, the outcome of the consultation is that the option to 'limit to 4 units' (option 1 above) is the preferred choice when the responses of people with coeliac disease and those without were combined.

However, 49% of respondents chose this option, and 47% said that GF items should not be available on prescription; this is illustrated below:

## Do you think gluten free products should be available on prescription?



## 5. Recommendation

This scheme was considered at the Clinical Commissioning Executive Group (CCEG) on 19 September 2018. The following were considered in reaching a recommendation for JCC:

- The outcome of the consultation which identified that whilst 86% of respondents with Coeliac Disease supported continued prescribing when all responses are considered the results are marginal (49% in favour and 47% not).
- It was noted that the Mid Nottinghamshire CCGs have already stopped GF prescribing. Greater Nottingham recognise the importance of consistency in care across Nottinghamshire.
- Equity in relation to other conditions e.g. diabetic foods are not provided on prescription.
- The clinical risk for patients with coeliac disease/ dermatitis herpetiformis not following a GF diet was noted.
- It is possible to have a healthy balanced diet without having gluten containing foods or gluten free alternatives.
- Gluten free foods are more widely available and whilst still more expensive have reduced in cost.
- The EQIA was considered in particular the increased impact on people with low incomes was acknowledged.
- The current financial position was noted.

Following consideration of the above factors the recommendation is to stop prescribing of GF products for all patients in Greater Nottingham.

The Joint Commissioning Committee reviewed and approved the recommendation to stop all prescribing of GF products in Greater Nottingham at their meeting on 26th September.

Greater Nottingham will support the implementation with a robust communications plan to ensure that patients who are currently receiving gluten free foods on prescription are notified of the change. The CCGs are liaising with local Dietitians to ensure that nutritional information can be provided to patients. The impact on patients will be monitored as part of the implementation.

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