

A GUIDE TO THE ROLE OF THE GLUTEN-FREE PRESCRIPTION IN THE MANAGEMENT OF COELIAC DISEASE



Introduction

The British Specialist Nutrition Association (BSNA) has compiled this guide to provide information on the role a gluten-free prescription plays in the management of coeliac disease. Coeliac disease is unique amongst long-term gastrointestinal disorders in that it can be effectively treated by diet alone and does not require long-term drug intervention.¹ Experts agree that when patients adhere to a strict gluten-free diet most will be restored to full health and will be protected against developing long-term health complications.

¹ National Institute of Health & Clinical Excellence (NICE). Clinical Guideline 86. Recognition and assessment of coeliac disease. 2009. www.nice.org.uk

Comment

The role of the gluten-free prescription is not to meet all the daily dietary requirements of coeliacs, but to provide the patient with a guaranteed reasonable supply of essential staple gluten-free foods such as bread and flour from which they can successfully manage their own condition.

Coeliac UK, the national charity working for people with coeliac disease, has stated that gluten-free prescribing focusing on staple foods should be viewed as an essential NHS service available to all patients with diagnosed coeliac disease. The BSNA supports this view in recognising the provision of essential foods on prescription as part of a foundation of support provided by the NHS.

Coeliac Disease – The Facts

- ▶ Coeliac disease is an autoimmune disease triggered by gluten
- ▶ People with untreated coeliac disease may suffer a range of clinical symptoms prompting them to visit their GP on a recurring basis
 - **Adults:** Persistent gastrointestinal symptoms including constipation and diarrhoea (often misdiagnosed as irritable bowel syndrome), anaemia, lethargy, depression and neurological symptoms
 - **Children:** Faltering growth, gastrointestinal symptoms including chronic diarrhoea, abdominal pain, abdominal distension and unexplained anaemia
- ▶ People with coeliac disease cannot eat any foods containing gluten, a protein found in wheat, barley and rye
- ▶ The main health risks linked to untreated and poorly managed coeliac disease are:
 - Deficiencies of essential nutrients
 - Osteoporosis and increased risk of fractures
 - Infertility and adverse outcomes in pregnancy
 - Cancer
- ▶ Treatment for coeliac disease is a strict gluten-free diet
- ▶ Adherence to a strict gluten-free diet alleviates symptoms and reduces long-term health risks

Prevalence Data

“ 1 in 100 people in the UK are affected by coeliac disease ”

... but only

“ 125,000 are estimated to be diagnosed in England and Wales ”

“ Experts estimate more than 1/2 million remain undiagnosed ”

“ 1 in 10 of first degree relatives has a risk of developing coeliac disease ”

This information represents the best evidence currently available and was calculated for the NICE Guideline 86. Recognition and assessment of coeliac disease. 2009. www.nice.org.uk

The NHS does not currently collect data on diagnosed coeliacs in the UK.

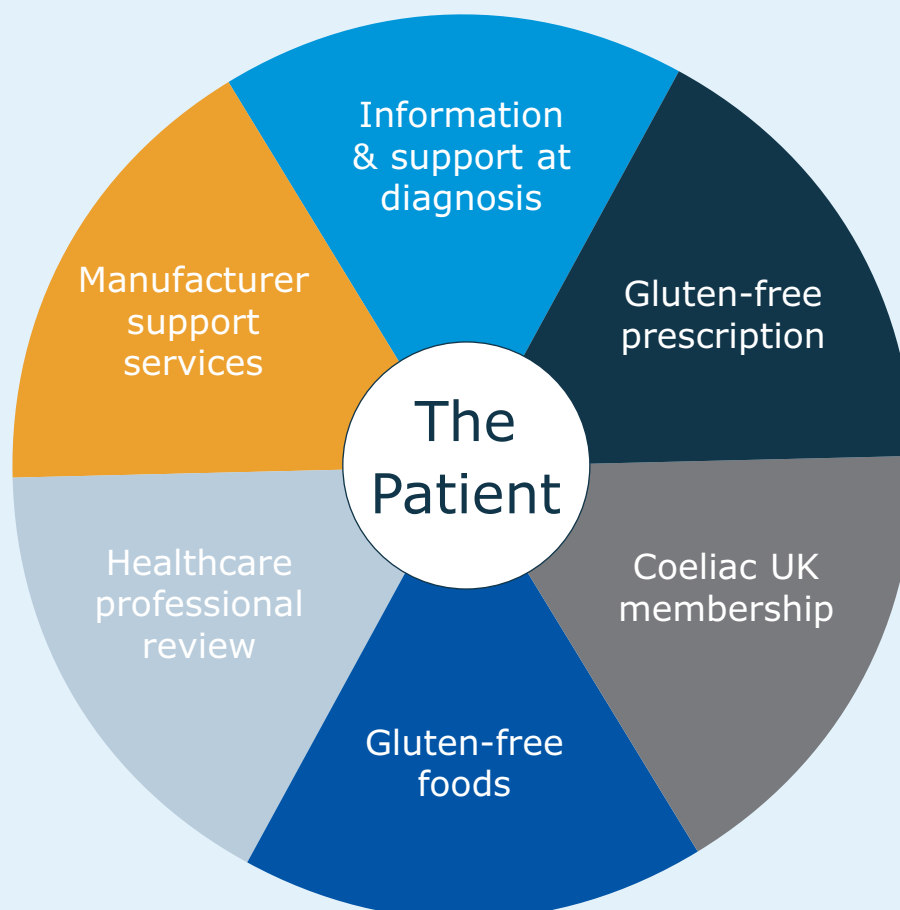
The Gluten-Free Diet

A gluten-free diet is the medically advised treatment for coeliac disease. Choice is not an option as deviation from the diet will have a direct effect on health and morbidity.

Factors Promoting Good Dietary Adherence

The empowered and knowledgeable patient is fundamental to the successful management of coeliac disease. If a gluten-free diet is followed correctly people with coeliac disease are protected from developing serious health risks associated with the untreated condition. It has been demonstrated that when the patient has a clear understanding and knowledge of the condition and takes responsibility for its management they are less likely to lapse from the diet and can lead a full and healthy life.

Foundation of Patient Support



- ▶ Sympathetic healthcare professionals supporting patients through the early stages of diagnosis and management
- ▶ Access to and availability of essential gluten-free foods through a gluten-free prescription, providing 15% of patients energy needs, facilitating good adherence to the diet
- ▶ Coeliac UK providing life-long support, playing a fundamental role in helping people with coeliac disease make the adjustment to a gluten-free diet
- ▶ Access to affordable gluten-free foods from retail outlets making a valuable contribution in supporting adherence to the diet
- ▶ Regular review by a healthcare professional - informing, explaining and reinforcing the value of the diet in protecting against health risks
- ▶ Gluten-free food manufacturers providing education and reinforcing dietary adherence

Nutritional Challenges – The Role of Starchy Foods in a Gluten-Free Diet

For people with coeliac disease a gluten-free diet is non-negotiable. Eating even a small amount of gluten can provoke a severe immune response. To return to good health and prevent future health complications people with coeliac disease must adhere to a strict gluten-free diet for life.* This is no easy task as the diet can prove to be restrictive, nutritionally compromising and potentially difficult to achieve a healthy balance.

*Primary Care Society of Gastroenterology (PCSG). The Management of adults with coeliac disease in primary care. 2006



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The Eatwell Plate illustrates food group proportions reflecting Government recommendations on what constitutes a healthy, balanced diet.

It is not surprising that a gluten-free diet can be nutritionally challenging when one third of the foods we are recommended to eat are starchy foods, many of which contain gluten.

Source: Department of Health in association with the Welsh Government, the Scottish Government and the Food Standards Agency in Northern Ireland.

- ▶ Most everyday starchy foods such as bread, breakfast cereals, biscuits, buns, cakes and pastries contain gluten
- ▶ Only rice, potatoes, maize and pure oats are naturally gluten-free

The Nutritional Contribution of Bread

Bread remains at the heart of the UK diet and forms the foundation of a healthy balanced diet.

- ▶ Bread makes the largest contribution to the cereal and cereal products food group
- ▶ Bread is an important source of fibre, providing 20% of adults total dietary fibre intake
- ▶ Bread is a good source of many essential nutrients including calcium, iron and folate; providing 19%, 15% and 11% respectively of adults total intake

Data from The National Diet & Nutrition Survey: Volume 2 & 3, 2003

The Nutritional Role of Gluten-free Specialist Foods

The prescribing of gluten-free foods is based on providing coeliac patients with 15% of their total energy requirements. This guidance is supported by a UK dietary survey which analysed and reviewed consumption data from food diaries of adults and children with coeliac disease. Specialist gluten-free foods were developed to assist coeliac patients in maintaining dietary balance and nutritional adequacy.

| Nutrient | Prescription Foods | Non-prescription Foods |
|--------------|--------------------|------------------------|
| Energy | 15% | 7% |
| Carbohydrate | 22% | 9% |
| Fibre | 22% | 6% |
| Calcium | 21% | 1% |
| Iron | 16% | 1% |

Kinsey L, Burden ST & Bannerman E. A dietary survey to determine if patients with coeliac disease are meeting current healthy eating guidelines and how their diet compares to that of the British general population. Eur J Clin Nut. 2007;1-10

Nutrition Perspective

- ▶ With the starchy foods group providing a large proportion of essential nutrients, all people with coeliac disease will be nutritionally at risk if they do not obtain these nutrients from alternative gluten-free sources
- ▶ People with coeliac disease who poorly manage their diet may continue to be deficient in calcium, iron, folate and other nutrients
- ▶ A diet that excludes gluten tends to be lower in fibre than a gluten-containing diet, as starchy foods and in particular bread, are a major source of fibre
- ▶ Specialist gluten-free foods were developed to replace those major gluten-containing starchy foods such as bread and flour
- ▶ Analysis of prescription gluten-free foods has shown that they are more likely to be fortified and therefore contribute a major percentage of key nutrients (see previous table)

Prescribing Perspective

To ensure a fair and reasonable distribution, nationally accepted prescribing guidelines set limits on the amount of gluten-free food an individual requires per month. These are classified as units of essential foods based on nutritional recommendations that meet the 15% total energy target.¹

- ▶ Only essential gluten-free foods which contribute to a healthy balanced diet are approved for availability on prescription (FP10)²
- ▶ These essential foods include starchy foods such as bread, flour mixes, pasta, pizza bases, crackers, crispbreads and breakfast cereals
- ▶ It is widely accepted that the diet can then be enhanced and varied with other non-essential luxury foods that can be purchased via supermarkets and other retail outlets

The Coeliac's Perspective

People with coeliac disease have welcomed the wider choice of foods, particularly luxury foods, offered by the supermarkets in their 'free-from' aisles but have some concerns regarding their accessibility, nutritional adequacy and cost.

- ▶ Free-from foods are often free from other ingredients (allergens) coeliacs do not need to avoid. This can compromise on palatability, a fundamental factor shown to influence adherence to the diet
- ▶ Free-from foods cost on average 3 to 4 times more than mainstream gluten-containing foods³

The largest ever survey⁴ of 3,500 coeliacs found that the majority valued the role the gluten-free prescription played in helping them manage their condition

- ▶ 87% were aware of the health risks from not adhering to a gluten-free diet
- ▶ 94% agreed that it was important for them to receive a regular supply of everyday staple gluten-free foods such as bread and flour to help them adhere to the diet
- ▶ 79% rated access to a gluten-free prescription as a key factor affecting their ability to adhere to a gluten-free diet

1 Gluten-free foods: a prescribing guide (BDA, PCSG, Coeliac UK 2004) (Coeliac UK revised its policy on gluten-free prescribing in 2010: www.coeliac.org.uk)

2 British Society of Gastroenterology (BSG). The management of adults with coeliac disease. 2010

3 Coeliac UK Cost Project 2009

4 British Specialist Nutrition Association (BSNA) Survey of 3,500 coeliac patients. October 2010

The Economic Impact of Coeliac Disease

The BSNA has commissioned a thorough data search of information pertaining to coeliac disease and its management. This search highlighted the huge data gap surrounding our understanding of coeliac disease in terms of both its true prevalence and the costs involved with managing its associated complications. The following summary provides some cost indicators where available.

Nutritional Deficiencies

Malabsorption of vital nutrients is a common presenting symptom in coeliac disease as well as a serious complication when the diet is poorly managed.

- ▶ Adherence to a gluten-free diet restores biochemical and nutritional status and protects against many of the complications of coeliac disease¹
- ▶ Analysis of prescription gluten-free foods has shown that they are more likely to be fortified and therefore contribute a major percentage of key nutrients than non-prescription 'free-from' foods²

Osteoporosis

Reduced bone density (osteoporosis and osteopenia) is one of the most serious long-term health risks associated with undiagnosed and poorly managed coeliac disease.

- ▶ The prevalence of osteoporosis amongst the coeliac population has been estimated to be 6% although some studies have indicated that it may be as high as 50%³
- ▶ NHS data⁴ has looked at the cost of treating patients with osteoporosis and related fractures. This data indicates that the cost of treating osteoporosis in the coeliac population may lie somewhere between £2.3 million and £21.3 million per year
- ▶ Clinical studies have demonstrated the role and importance of a gluten-free diet in the normalisation of calcium absorption and improvement in bone mineral density^{5, 6}

Anaemia

Iron deficiency anaemia is a very common presenting symptom in coeliac disease and is effectively corrected by adherence to a gluten-free diet.⁷

- ▶ The prevalence of anaemia amongst the coeliac population has been estimated to be up to 40% upon diagnosis⁴
- ▶ There is no NHS data pertaining to the costs of treating or managing anaemia amongst the coeliac population

Infertility

Unexplained infertility and adverse outcomes in pregnancy has been linked to undiagnosed and poorly managed coeliac disease.⁴

- ▶ Some studies have indicated a higher than average incidence in delayed menopause and low birth weight and pre-term babies associated with coeliac disease^{8, 9}
- ▶ The data search has revealed that around 3% of patients attending fertility clinics are found to have coeliac disease^{9, 10}
- ▶ There is no NHS data indicating how much infertility treatments associated with coeliac disease may cost¹¹

Cancer

Cancer is a serious life-threatening health risk associated with undiagnosed and poorly managed coeliac disease.⁴

- ▶ Currently there is no available data on the cost of treating cancer linked to coeliac disease. However, a long-term study found that people with coeliac disease who did not adhere strictly to a gluten-free diet had a two-fold increase in their overall risk of developing cancer¹²
- ▶ This study concluded that when a gluten-free diet was followed for 3 to 5 years people with coeliac disease have the same risk of developing cancer as the general population.¹²

Hidden Costs of Coeliac Disease

Recently studies have been examining the wider impact of coeliac disease. They have found that a large number of the coeliac population continue to suffer with irritable bowel syndrome symptoms, and a range of mood and wellbeing symptoms which can result in anxiety and depression.¹³

The social and psychological impact of sticking to a life-long gluten-free diet is huge and if managed inappropriately may result in further hidden costs to the NHS including repeated visits to the GP, further investigations and related prescription costs.

New care pathways are being developed that acknowledge the value of providing patients with a foundation of support to help them manage and adhere to a gluten-free diet.

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Prescription Costs

Despite more people being diagnosed with coeliac disease the mean cost of the gluten-free prescription has decreased over the decade. This can be attributed to the widespread adoption of the prescribing guidelines issued in 2004 which has standardised prescribing practices, ensuring patients receive a reasonable quantity of essential foods to help meet their nutritional requirements.

Comparison of treatment costs for coeliac disease for England

| | 2000 | 2010 |
|---|----------------------|----------------------|
| Estimated no of patients | 42,000 ¹ | 120,000 ² |
| Cost of prescription products ³ | £16.9 million | £28.4 million |
| Number of items ⁴ dispensed ³ | 1.4 million | 2 million |
| Average no items/per patient ⁴ | 33 per year | 17 per year |
| Average cost per patient | £402 per year | £237 per year |

1 Based on coeliac UK membership

2 Based on NHS Information Centre: NICE guidelines of diagnosed prevalence 2009

3 NHS Information Centre: prescribing analysis data for England

4 Item = one line on a prescription. An item may equate to one loaf or 6 loaves of bread

Cost Effective Management in the Future

Regular review is part of the foundation of support promoting good adherence to the diet. Traditionally most coeliac patients have been followed up annually within secondary care via a gastroenterology or dietitian led clinic. In 2002 the average follow-up cost was £60 per patient.⁵ New more cost effective care pathways are currently being developed which will place primary care at the centre of ongoing care for coeliac patients. In addition, new prescribing schemes that enforce standardised prescribing practices are delivering further savings of between 20 and 40 per cent per patient, as well as saving on GP time.⁵ As these new care pathways unfold more savings are anticipated.

5. Medicines Management Team: NHS Cumbria (April 2010) Gluten-Free Pilot Scheme

Comment

The BSNA supports the development of new care pathways focused on delivering cost-effective best practice for managing people with coeliac disease. The BSNA believes that the provision of an essential gluten-free prescription not only provides good value, but also fosters good dietary adherence, and, in the long-term will help save the NHS money.

Websites for further reference

www.coeliac.org.uk • www.bsg.org.uk • www.pcs.org.uk • www.bda.uk.com



This executive summary is produced by the British Specialist Nutrition Association (BSNA) which represents manufacturers of specialist nutrition products including gluten-free foods on prescription. For further information please visit: www.bsna.co.uk

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