NHS SUPPORT FOR PATIENTS WITH COELIAC DISEASE

About Coeliac UK

Coeliac UK is the national charity for people with coeliac disease and dermatitis herpetiformis (DH), for nearly 50 years we've been improving the lives of people living without gluten through providing independent and expert information, and campaigning on their behalf for better diagnosis for coeliac disease, better care and better access to gluten free food in and out of the home.

As the only charity in the UK offering comprehensive support for coeliac disease and the gluten free diet, we are a trusted voice, advocate and partner for our community.

Summary of main points

1. Coeliac disease is a serious medical condition where the body's immune system attacks its own tissues when gluten is eaten. Currently, the only medical treatment for coeliac disease is strict adherence to a gluten-free diet for life.
2. Since the late 1960s staple gluten free food has been prescribed to support dietary adherence for the prevention of long term health complications and comorbidities. This rationale is now being challenged by some Clinical Commissioning Group (CCGs) in NHS England. The reason cited is, almost universally, the need for CCGs to make savings to their prescribing budgets.
3. A significant proportion of CCGs in England are now choosing to restrict or to remove this support for patients with coeliac disease. This is leading to significant and unwarranted variation in access to gluten free food across the country and is exacerbating health inequalities, as changes disproportionately impact the most vulnerable. NHS patients across England are now subject to a postcode lottery for NHS support once diagnosed with coeliac disease. NHS patients in Scotland, Wales and Northern Ireland continue to receive full support in the treatment of their condition.
4. CCGs report that the price paid for products by the NHS is higher than that paid in supermarkets, yet there has been no effort to improve procurement processes, including product price negotiations.
5. The annual Net Ingredient Cost (NIC) of gluten-free foods to NHS England was around £25.7m in 2015, or around 0.3% of the total prescribing budget for NHS England of £9.3bn.
6. Failure to treat coeliac disease or to follow a strict gluten free diet can lead to health complications and comorbidities. This means that restricting treatment is likely to be a false economy for the NHS, as it could lead to higher treatment costs and poorer health outcomes in the long term.
7. Recent organisational and structural changes to the NHS in England has meant that innovation or the adoption of alternative forms of support, such as pharmacy-led gluten free prescribing or voucher schemes, has been hindered. Significant efficiency savings could also be made through improved procurement, but these innovations are unlikely to be cost effective at individual CCG level.

Coeliac disease and associated long-term health complications

Coeliac disease is a serious medical condition where the body's immune system attacks its own tissues when gluten is eaten. This causes damage to the lining of the gut and means the body cannot properly absorb nutrients from food. It is not an allergy or simple food intolerance.

Coeliac disease is an autoimmune disease that occurs in people who have the genes that predispose them to the condition. It is more common among people with other autoimmune diseases, such as Type 1 diabetes and autoimmune thyroid disease.

The long term health complications associated with untreated coeliac disease are osteoporosis, ulcerative jejunitis, intestinal malignancy, functional hyposplenism, vitamin D deficiency and iron deficiency. Currently, the only medical treatment for coeliac disease is strict adherence to a gluten free diet for life.

Background to the prescribing of gluten free staple foods

Since the late 1960s gluten free food has been prescribed to support the treatment for patients with coeliac disease. Gluten-free food is prescribed to promote dietary adherence, and thus to prevent long term health complications and comorbidities. NHS support is available to those with coeliac disease in recognition of the highly restrictive nature of the diet, the high price of gluten-free substitute foods, and the very limited choice and availability of many gluten free staple foods.

To assist clinicians and commissioners to support patients with coeliac disease, *National Prescribing Guidelines for the Prescribing of Gluten-free Food* have been produced by Coeliac UK, in consultation with the NHS and other professional healthcare bodies. These Guidelines are endorsed by the Primary Care Society for Gastroenterology (PCSG) and the British Dietetic Association (BDA); they are followed in Scotland, Wales, Northern Ireland and around half of the CCGs in England.[1]

Only gluten free products that are approved by the Advisory Committee on Borderline Substances (ACBS) and appear on Part XV of the Drug Tariff can be prescribed by GP. Products are listed on Part XV of the Drug Tariff following ACBS approval of an application by producers. The ACBS list current includes hundreds of gluten free substitute products, prices are provided by producers at the time of application and subject to annual inflation increases.

In the past, NHS policy has rightly recognised that the costs associated with the treatment of long term health complications are likely to dwarf the costs associated with prescribing gluten free staple foods, dietetic advice and monitoring. However, in some areas in England, local policies are changing to either remove, reduce or restrict this support.

The challenge on price and availability

The rationale for supporting patients with coeliac disease with prescriptions for gluten free food is now being challenged by some Clinical Commissioning Groups (CCGs). Several CCGs have highlighted improvements in access and affordability of staple gluten free foods, but have not properly researched the situation within their area of responsibility, nor presented evidence in support of these claims.

Coeliac UK has asked through Freedom of Information (FOI) requests for details of the evidence used to drive policy change in affected areas. An example of the kind of research being conducted can be found in the FOI response from North East Essex CCG, where

sweeping assumptions seem to have been made devoid of any systematic research, they state:

"We appreciate that there is a large cost-differential between supermarket value brands and GF [gluten-free], but many people within the CCG buy their bread from bakers or do not buy the supermarket value brands and the cost differential is therefore much reduced." [i]

This type of anecdotal evidence, which is being used by CCGs to justify decisions about patient care, is in conflict with peer reviewed research published as recently as September 2015. *A study in the Cost and availability of gluten-free food in the UK: in store and online* by Burden, M., et al., concluded:

"There is good availability of GF [gluten free] food in regular and quality supermarkets as well as online, but it remains significantly more expensive. Budget supermarkets which tend to be frequented by patients from lower socioeconomic classes stocked no GF foods. This poor availably and added cost is likely to impact on adherence in deprived groups." [ii]

NICE recommendations and duties to reduce health inequalities

The National Health Service Act 2006 as amended by the Health and Social Care Act 2012 includes duties on the Secretary of State, the NHS England Board and CCGs to have regard for NICE quality standards. There are also legislative duties requiring CCGs to reduce inequalities with respect to access to patient services and health outcomes.

The first NICE quality standard for coeliac disease was published on 19 October (QS134) and includes a statement on the need to discuss the gluten free diet with a healthcare professional, with specialist knowledge, once diagnosed. This statement from NICE includes guidance on the equality and diversity considerations for healthcare professionals, which recognises the higher cost and limited availability of gluten free food. NICE highlights the difficulties faced by patients on low incomes or with limited mobility, and because there is a genetic component to coeliac disease, NICE also highlights the strain on household budgets where there is more than one person in the family diagnosed. NICE asks healthcare professionals to advise patients on the availability of gluten free food on prescription.

However, the lack of explicit recommendations on the need to provide access to gluten free staple food on prescription has led to CCGs in England to implement local policy change in this area, and a significant proportion are now choosing to restrict or remove all prescribing support for patients with coeliac disease.[iii] This removal of support is leading to significant and unwarranted variation in care across the country, and as noted above, is likely to further exacerbate health inequalities.

NICE Guidance (NG20) was reviewed in 2015, and recommends that all patients with diagnosed coeliac disease are offered an "annual review", which should include measurement of height and weight and a review of symptoms, as well as consideration of the need for specialist dietetic or nutritional advice, or clinical referral. Implementing and establishing the NICE recommendation on annual review within local services will be imperative to enable the monitoring of patient outcomes and assess the impact resulting from local policy change.

The lack of a national prescribing policy from NHS England means considerable uncertainty for those who rely on access to gluten free staples on prescription to manage coeliac disease, and the most vulnerable are most acutely affected. In particular, those on fixed incomes or benefits who receive prescriptions free of charge, and those who are housebound and rely on deliveries from community pharmacies. The result is that NHS patients across England are

now subject to a postcode lottery for NHS care and support, once diagnosed with coeliac disease.

NHS costs and procurement

The annual cost of gluten free food on prescription to NHS England was £25.7m in 2015, this was 0.3% of the total prescribing budget of £9.3bn for 2015. [iv,v] The main argument used for restrictions or service cancellation is the need for efficiency savings. NHS support for patients with coeliac disease is quickly becoming a "Cinderella" service.

CCGs that are restricting or preventing access to gluten-free food on prescription often argue that gluten free food is now available to purchase in large supermarkets, and that patients can do this at a lower cost than the cost to the NHS to buy gluten free staples. For example, in a letter to patients dated 16 June 2015, the North Norfolk CCG stated:

"Today these products are widely available from all supermarkets and are sold to the public at prices that are considerably lower than the NHS is charged when bought for use on prescription."

What is surprising about this statement is that prescription services seem to be now be risk because NHS procurement teams have been unable to secure competitive prices. As stated above, the price the NHS is charged for gluten free food products are advised by producers when applying to the ACBS for product listing on Part XV of the Drug Tariff.

The total UK market value of gluten-free foods in 2015 in England was £247m, making the NHS England annual spend of circa £25.7m on gluten-free food around 10% of the total gluten-free food market. [vi] It would be reasonable to expect that such a significant market share provides sufficient purchasing power to negotiate prices equal to those paid by commercial retailers. Patients should not be suffering the consequences of inefficiencies within procurement systems. Pressing this point, Kevan Jones MP said during the Westminster Hall debate (November 2016):

"I do not know why the NHS cannot negotiate contracts with some commercial companies. Failure in procurement will clearly have an impact." (Hansard Online, Volume 616)

The "patients can buy products at a lower price" position also ignores the additional benefits of appropriate support and monitoring by healthcare professionals, and the fact that this is true of a range of treatment and medicines available on the NHS. The annual cost of gluten free food staples to the NHS is significantly lower than the annual cost of other items prescribed, but available for purchase over the counter at a lower cost than that to the NHS, such as Senna (for occasional constipation) with a total cost of £32.3m and paracetamol at an annual cost of £85.1m and rising.

More importantly, this argument contradicts the principles that guide the NHS, in particular that the NHS: provides a comprehensive service, available to all; that access to NHS services is based on clinical need, not an individual's ability to pay; and that the NHS aspires to put patients at the heart of everything it does.

Gluten free food producers

While some CCGs are not always comparing like for like products when making price assessments, there are circumstances when the NHS does pay a higher price than the retail product equivalent. Coeliac UK has approached the trade association representing gluten free

food producers in the UK, the British Specialist Nutrition Association Ltd. (BSNA) to challenge them on this issue.

BSNA has reported several issues relating to increase costs, including the need to provide a universal service to all pharmacies across the country, ensuring "availability and access to a reasonable supply of staple gluten-free foods". The use of community pharmacies ensures that all patients, regardless of where they live can access staple food when needed, including those who rely on home deliveries.

Is cutting gluten free prescribing a false economy?

The NHS is also guided by the principle of commitment to providing the best value for taxpayers' money and the most effective, fair and *sustainable* use of finite resources. This raises the issue of false economy, where small savings in prescription costs could lead to higher treatment costs associated with poor health outcomes and increased health complications. A hip fracture caused by osteoporosis, the most common complication of untreated coeliac disease, costs on average £27,000 per fracture – the equivalent to 138 years of prescribing gluten free staples for an individual.[vii,viii]

Reducing dietary adherence, risks not only long term health complications, but is also likely to increase absences from work due to continuing ill health amongst patients who aren't able to source or afford gluten-free foods.

This issue was raised by Liz McInnis MP, commenting during the Westminster Hall debate on 1 November, she said:

"Is the Minister aware that the annual cost per diagnosed patient of prescribing gluten-free food is £180 per year? Weight that up against the cost of avoiding infertility, bowel cancer and osteoporosis. What is the obvious conclusion for any NHS professional?" (Hansard Online, Volume 616)

The case for continued gluten free prescribing

Coeliac UK believes that it is important that gluten-free prescribing continues for the following reasons:

1. Treatment and prevention of serious long-term health complications
   Adherence to the gluten free diet is greatly improved through prescriptions for gluten free staples and regular follow-up and support. [ix] Once treated with the gluten free diet for three to five years, the risk of developing the cancers associated with coeliac disease reduces to no greater than that of the general population.[x] The risks associated with osteoporosis are largely dependent on any damage already sustained, or lack of dietary adherence, due to the inability to absorb calcium.

2. Price
   Gluten-free foods can cost around three to four times as much as their gluten containing equivalent[xi]. For example, gram for gram gluten-free bread costs on average 5.1 times that of gluten containing bread and more than 8 times the cost if you compare the cheapest breads. Therefore, the withdrawal of treatment impacts most significantly on those with the low or fixed incomes or those who currently receive prescriptions free of charge.

3. Access

   Gluten-free or "Free From" products tend to only be available in larger supermarkets or health food stores. The former are often out of town, and increasingly supermarkets are opting for convenience sized stores in large cities and urban centres; these stores often cannot justify the shelf space for these low turnover items. Those who rely on community pharmacy deliveries or without access to a car or the internet often have difficulties in sourcing staple foods. It has also been suggested that online ordering is a solution. However, the delivery costs and minimum order restrictions can be prohibitive for some, and because these products lack structure (due to the absence of gluten) they do not always "travel well" through parcel services.

4. Availability

   While many of us are used to the convenience of prepared or take away foods, availability of gluten-free products in these categories are extremely limited. This means that those with coeliac disease often need to make meals at home to take to work or on journeys, and therefore, need to have a range of gluten free staple foods, like bread, available at home.

The financial pressures faced by the NHS are well reported. However, service provision should be driven by clinical need and not adjusted purely on budgetary constraint. The need for NHS England to provide value for money when deciding on appropriate clinical treatment and services is recognised. However, some CCGs are now taking a short term view on health spending. This flies in the face of preventative strategies favoured by NHS England and Public Health England, and has the potential to derail this long-term sustainable spending strategy.

Innovating for efficiencies

Cutting and reducing service provision is not the only way to find efficiencies in the NHS. Service innovation, improved procurement and national collaboration also have the potential to deliver efficiencies, as well as improvements in patient experience.

Some CCGs have attempted to improve or innovate support services for patients with coeliac disease, while also looking for savings. The *NHS Five Year Plan* outlines use of pharmacy services to extend existing primary care resource, but there are significant hurdles in developing sustainable pharmacy-led service models using NHS England organisational and contractual arrangements.

These hurdles appear to have been cleared by NHS Scotland, through the introduction of a national pharmacy-led scheme, which allows for a patient-centred approach which improves the quality of the service while providing for greater control of costs. One of the main benefits delivered by the Gluten Free Food Service (GFFS) in Scotland is the increased capacity in GP surgeries, as community pharmacy is the site of service delivery.

The GFFS evaluation, at the conclusion of the 18-month pilot, reported from the survey of GPs "there was overwhelming support (98% n=442) for the trial GFFS to continue as an ongoing service" and similarly from the survey of community pharmacists "in the opinion of respondents, 92% (n=300), GFFS should continue as an ongoing service". Patients also saw benefits, the evaluation reporting that "the vast majority of respondents liked the service (90% n=1,284) and want it to continue (93% n=1,318)".[xii]

Some CCGs in England are innovating with the aim of reducing costs in all prescribing. NICE published a Quality and Productivity Case Study in 2014 from Walsall CCG, which provides a

practical example of how savings can be made, the CCG implemented a pharmacist-led repeat prescription management service:

"The service was aimed at reducing medicines wastage, minimising possible harm from medicines and improving the quality of repeat prescribing. Cash was saved by ensuring the least expensive, clinically appropriate medicines were prescribed by switching from branded to generic drugs. Practice-based pharmacists worked as an integral part of primary care general practice teams to manage repeat prescriptions.

"*For the financial year 2013/14 the service delivered net savings of £610,270 and demonstrated that for every £1 invested in pharmacist time there was a saving of £3.05*".[xiii]

Capacity in GP surgeries can also be gained through repeat dispensing. Around two thirds of all NHS prescribing in primary care is for patients that require repeat supplies of medicines, food or equipment. Repeat dispensing is available to increase patient choice and convenience, to minimise wastage by reducing the number of products dispense which are not required by the patient and to improve GP capacity by lowering the burden of repeat prescriptions.

For these reasons, since 2005 repeat dispensing has been an Essential Services within the Community Pharmacy Contractual Framework (CPCF). However, according the Pharmaceutical Services Negotiating Committee (PSNC) take up as been very low. The PSNC reports that:

"*Despite the benefits that the service can bring to patients and the NHS, uptake of it has been very low, in part due to lack of engagement by GP practices. In order to increase the benefits being gained by patients and the NHS from this service, it was agreed in September 2014 that from 1 March 2015 there will be a new requirement in the CPCF for pharmacies to give advice to appropriate patients about the benefits of the repeat dispensing service."*

As well as using existing models to drive efficiencies, new schemes are being considered. The Vale of York CCG is trialling a new voucher scheme, or pre-loaded payment card, as a way of helping patients to access gluten free staples from local supermarkets. Coeliac UK supports these innovations, if supported by a positive evaluation of patient outcomes and ongoing monitoring. This scheme is delivering some local benefits, but is likely to need national support from supermarkets and scale to ensure it delivers the savings that warrant set up and administrative costs. This idea was supported by Kevin Foster MP in November 2016, he asked the Parliamentary Under-Secretary of State for Health:

"Will he suggest to CCGS such as Torbay in south Devon that there is a halfway house and that instead of scrapping the prescription of gluten-free products they could provide vouchers that could be taken to a local supermarket?"(Hansard Online, Volume 616)

Other possibilities, not yet being piloted, include web based e-commerce ordering systems, where all products approved for purchase can be loaded on to the site and paid for using a secure wallet (electronic allocation). The patient can then select the retailer, pharmacy or store to arrange a collection.

Such a system could deliver significant savings to the NHS in clinician time and administration for NHS England. However, to be cost effective, such a scheme would need to be developed as a national service, not separate services in 209 CCG areas. All schemes need to be teamed with appropriate local dietary and health support and monitoring or "annual review".

Ministerial commitment to review, Westminster Hall Debate 1 November 2016

As previously referenced, a Westminster Hall debate was held in the House of Commons on 1 November 2016 on this issue, introduced by Keven Jones MP. The Parliamentary Under-Secretary of State for Health, David Mowat MP responded on behalf of the Government.

The Minister felt that there was a consensus of those attending the debate that access to gluten free staple foods should be supported and set out the actions that should be taken. These were to continue to focus on the role that community pharmacy can play, as part of the Murray review, upon the provision of evidence to follow up with CCGs not undertaking public consultation, and to complete a review within six-months of prescribing policies with the view of coming up with a formulary that is more consistent.

Contact information

For further information on this issue please contact Lisa Bainbridge, Head of Campaigns at Coeliac UK on email: lisa.bainbridge@coeliac.org.uk or phone 01494 796 349.

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