



# Community pharmacy supply of gluten-free foods - a toolkit for commissioners

Developed by



Supported by



# Table of contents

<b>Foreword</b>	3
<b>Executive Summary</b>	4
<b>Community Pharmacy Supply of gluten-free foods</b>	6
A: Background information	6
1. The clinical requirements	6
2. Current provision	6
3. Review by the Department of Health of routes of supply of gluten-free foods	7
4. Alternative routes of supply of gluten-free foods via community pharmacies	7
5. LES for community pharmacy supply of gluten-free foods – the experience	8
B: The case for change	8
1. The case for change from the current FP10 based supply route for gluten-free foods	8
C: Analysis of Costs and Views of Stakeholders in Northamptonshire and Cumbria	10
1. Cost Analysis from PCTs	10
2. Views of Stakeholders on the Pharmacy Supply Scheme	12
D: Potential sources of further cost savings	13
1. Range of foods in ACBS lists	13
2. Avoidance of claims for out of pocket expenses for shipping costs from wholesalers/suppliers	13
Appendix 1 – Possible elements of a gluten-free food supply LES	14
1. Role of service providers	14
2. Role of General Practitioners	14
3. Role of patients	14
4. Role of the PCT / Health Board	14
5. Volunteer patient advisers	15
6. Payment mechanism options	15
Appendix 2: Summary of existing local schemes for supply of gluten-free foods by pharmacies/dispensing doctors	16
1. Northamptonshire PCT Scheme	16
2. Cornwall and Isles of Scilly PCT Scheme	16
3. South West Essex PCT Scheme	17
4. Cumbria PCT Scheme	18
Appendix 3: Summary table of the 2004 Gluten-free foods: a prescribing guide categories for patients with coeliac disease	20
<b>Contact details</b>	21

## Foreword

*I welcome the development of this Toolkit on supply of gluten-free foods by Coeliac UK, working with the PSNC and NPA. It will support commissioners to develop a cost-effective Enhanced service which will increase community pharmacists' clinical role in supporting patients with coeliac disease. An effectively implemented service will aid patients' dietary compliance and improve health outcomes, prevent overprescribing, and improve patient experience. I would encourage its early adoption by commissioning groups in England to take advantage of the potential savings of between 20 and 40% compared to normal GP prescribing, whilst at the same time improving quality of service provided to patients.*

**Jonathan Mason**

**National Clinical Director for Primary Care and Community Pharmacy  
Department of Health**

*The PCSG welcomes the introduction of new approaches to provide a better service to patients, cost savings and efficiencies in terms of clinical time. With the current financial controls within the NHS, it makes sense to consider new ways of managing the supply of gluten-free food on prescription. The new toolkit developed by Coeliac UK in conjunction with the PSNC and the NPA, using community pharmacists to lead on the supply of gluten-free prescriptions provides an ideal solution that fits perfectly within the current climate*

**Jamie Dalrymple**

**Chair of the Primary Care Society for Gastroenterology**

## Executive Summary

1. There are approximately 600,000 people with coeliac disease in the UK, but only 10 – 15% are currently diagnosed (NICE, 2009). However, there is now some evidence that the rate of diagnosis may be increasing. The only treatment currently available is life-long adoption of a gluten-free diet.
2. Non-adherence to the diet may have serious health consequences such as osteoporosis, bowel cancer and infertility.
3. GPs may prescribe gluten-free foods at NHS expense for people with coeliac disease. The Advisory Committee on Borderline Substances (ACBS) publishes a list of gluten-free foods that may be prescribed on FP10 prescriptions in the community. These prescriptions are then dispensed by community pharmacies.
4. The annual ingredient cost in England of ACBS approved gluten-free foods (such as bread, flour mixes and pasta) in 2010 was £28.6 million.
5. Schemes for community pharmacy supply of gluten-free foods have been set up by a number of Primary Care Trusts (PCTs) based on Local Enhanced Service (LES) contracts. The aims of these schemes include reducing the administrative workload of issuing repeat prescriptions for gluten-free foods in general practices and increasing the convenience for people with coeliac disease. These schemes are based on national guidance allocating a number of units to achieve recommended nutritional intake for different groups of the population (such as children, adult males, adult females and pregnant women). Each gluten-free product is assigned a number of units (for example a 400 gram loaf is 1 unit).
6. An alternative option to a LES which can offer many benefits to GP practices and patients is the use of the NHS repeat dispensing service. This allows a GP to prescribe gluten-free food to a person for a period of up to 12 months. The prescriptions can be dispensed by a community pharmacy when required by the person, without the need for the GP practice to issue a new repeat prescription on each occasion. However, the impact on flexibility on prescriptions within the 12 month period needs to be considered.
7. A review of the two most comprehensive LES schemes (where nearly all eligible patients take part) in Northamptonshire and in Cumbria has been undertaken as part of the development of this toolkit.
8. The cost comparison of GP prescribing versus the pharmacy supply schemes in Northamptonshire and Cumbria shows savings of 20% to 40% of costs when gluten-free foods are supplied direct from community pharmacies. If this approach was applied nationally, there is the potential to save between £5 and £11 million per year in England alone.
9. The potential benefits of changing to pharmacy-managed supply of gluten-free foods include:
  - improved dietary compliance and health outcomes, since some patients currently do not

receive prescribed foods, when it is known that access to prescriptions is the single most important factor in helping access to the gluten-free diet

- release of clinical time (saving of 209,000 appointments or over 20,000 hours of GP time according to a 2002 RCGP estimate), which could be used for better management of patients with coeliac disease after diagnosis.
  - prevention of overprescribing by application of the 2011 revised guidelines on appropriate consumption of gluten-free foods
  - better cost control as more people with coeliac disease are diagnosed over the next few years. Currently it is estimated that only 10 – 15% of people with coeliac disease are diagnosed; dissemination of the 2009 NICE guideline combined with improved GP training and awareness of coeliac disease should result in increased diagnosis
  - improvement in patient experience by creating a more flexible service
  - increased patient choice.
8. As part of the development of this toolkit, the views of GP, pharmacy and patient stakeholders in Cumbria and Northamptonshire were canvassed. Rating of the LES schemes by all stakeholders was overwhelmingly positive.
  9. Guidance on the development of a LES is provided which can be used by individual PCTs (and successor organisations) and Health Boards across the UK.
  10. The development of this toolkit was initiated by Coeliac UK. Local third sector involvement in developing and implementing a new approach to the provision of gluten-free foods can be provided by volunteers from the network of Coeliac UK Local Voluntary Support Groups. Volunteers may be able to act as patient advisers during the implementation of the scheme as a social action project.

# Community Pharmacy Supply of gluten-free foods – a toolkit for commissioners

## A: Background information

This toolkit has been developed by the Pharmaceutical Services Negotiating Committee (PSNC), the National Pharmacy Association (NPA) and Coeliac UK (the national charity for people with coeliac disease).

The case for a local scheme is also supported by the English Pharmacy Board of the Royal Pharmaceutical Society and the Dispensing Doctors Association.

### 1. The clinical requirements

- 1.1 There are approximately 600,000 people with coeliac disease (patients with gluten enteropathy or dermatitis herpetiformis) in the UK, but only approximately 10 – 15% are currently diagnosed<sup>1</sup>. However there is now some evidence suggesting that the rate of diagnosis may be increasing<sup>2</sup>. The only treatment currently available for coeliac disease is lifelong adoption of a gluten-free diet. Non adherence to the diet may have serious health consequences such as osteoporosis, bowel cancer and infertility<sup>1</sup>. Difficulties in maintaining the gluten-free diet have been cited as a significant reason for higher anxiety and depression reported among patients with coeliac disease<sup>3</sup>.
- 1.2 Research undertaken by Coeliac UK suggests that access to gluten-free food on prescription is viewed as the most important factor for people with coeliac disease in terms of adherence to a gluten free diet. 86.6% cited it as an important factor in maintaining the gluten-free diet and 47% cited this as the single most important factor.
- 1.3 Cost is a significant barrier for people with coeliac disease in accessing gluten-free foods in supermarkets, with gluten-free foods being several times more expensive than the non-gluten-free equivalents. This is particularly important in view of the fact that the median age at diagnosis (40 – 60 years) means that many patients with coeliac disease are pensioners on low incomes.

### 2. Current provision

- 2.1 Gluten-free foods have been available for GPs to prescribe to patients with coeliac disease since the 1960s. Eligible items are listed in the Drug Tariff by the Advisory Committee on Borderline Substances (ACBS). Prescribable items include bread, flour mixes, pasta and crackers.
- 2.2 The annual ingredient cost in England of the 2010 provision of ACBS approved gluten-free foods was approximately £28.6 million<sup>4</sup>. Since the net ingredient cost for all prescriptions in England was £8.83 billion, gluten-free foods comprise only 0.32% of the total net ingredient cost for all prescribed products.

---

<sup>1</sup> NICE Clinical Guideline 86, NHS National Institute for Health and Clinical Excellence. Recognition and assessment of coeliac disease. May 2009. <http://www.nice.org.uk/nicemedia/live/12166/44356/44356.pdf>. Accessed 20 May 2011

<sup>2</sup> S Sleet, R Jones, C Hunt, K Wang, J Dalrymple, R Stevens, G Thakur. P-098 Diagnosis of coeliac disease: the patient and health-care professional perspective. Poster presented at the 13th International Coeliac Disease Symposium 2009

<sup>3</sup> Hauser W, Janke K, Klump B, Gregor M and Hinz A. Anxiety and depression in adult patients with celiac disease on a gluten-free diet. *World Journal of Gastroenterology*, 16(22):2780-2787

<sup>4</sup> Prescription Cost Analysis England 2010, NHS Information Centre, April 2011

### **3. Review by the Department of Health of routes of supply of gluten-free foods**

3.1 In 2001 the Cabinet Office Regulatory Impact Unit published a report on reducing GP paperwork. It recommended that GPs should no longer need to issue prescriptions for gluten-free foods; instead patients with coeliac disease should be able to obtain supplies from a pharmacy<sup>5</sup>. This proposal was supported by the Royal College of General Practitioners<sup>6</sup>. The Department of Health consulted on this proposal in September 2001. A majority of those who expressed a view were in favour of the proposal, but there were two aspects which gave rise to some concern<sup>7</sup>. These were:

1. the need for more guidance to be provided as to how much food it would be reasonable to supply to people with coeliac disease
2. opposition to the idea that the cost of gluten-free food supplied under the scheme should be met by the Primary Care Trust (PCT) or Health Board in whose area the supplying pharmacy was located. There was a general concern about the lack of financial control, since there would be no-one in a position equivalent to the doctor who had both an interest in and influence over the costs of gluten-free foods which are prescribed.

3.2 In January 2005 the Department of Health issued guidance entitled 'Gluten free foods – local options' which included a survey of some of the existing arrangements which PCTs had made with local pharmacies to supply medicines at NHS expense<sup>8</sup>. It indicated that these schemes could serve as models for supply of gluten-free food. Three such models are given:

1. supply of a range of products through community pharmacies, with identification of eligible patients (e.g. a certificate signed by the patient's GP)
2. as above, but linked to registration to a particular pharmacy which has the advantage that it provides a greater opportunity for cost control over the volume and cost of products provided
3. a voucher scheme that gives good cost control but reportedly requires significant administrative effort.

### **4. Alternative routes of supply of gluten-free foods via community pharmacies**

If a commissioner wishes to improve on the current FP10 based supply route for gluten-free food, there are two options to consider:

1. Use of the national repeat dispensing service to reduce GP workload associated with prescribing gluten-free foods and increase patient convenience<sup>9</sup>. Prescribing should be based on a clear guideline on the amounts of gluten-free foods to be provided linked to the nutritional needs of individual patients. However, the impact on flexibility on prescriptions within the 12 month period needs to be considered.
2. Introduce a LES for supply of gluten-free foods from community pharmacies. Supplies should be based on a clear guideline on the amounts of gluten-free foods to be provided

---

<sup>5</sup> Making a Difference: Reducing General Practitioner (GP) Paperwork. Report from the Cabinet Office Regulatory Impact Unit, 19 March 2001

<sup>6</sup> Chapter 2: Burdens Addressed, Medicines Management and Prescribing, in 'Making a difference: Reducing burdens on general practitioners – second report', June 2002. RCGP Summary Paper 2002 – 2005

<sup>7</sup> Supply of NHS gluten free foods, UK Department of Health Guidance, 12 February 2002

<sup>8</sup> Gluten-free foods – local options, UK Department of Health Guidance, January 2005, [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_4101500](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4101500). Accessed 20 May 2011

<sup>9</sup> [www.psn.org.uk/repeatdispensing](http://www.psn.org.uk/repeatdispensing)

linked to the nutritional needs of individual patients.

A number of approaches to the implementation of a LES have been taken by PCTs, including using vouchers and patient registration to control access to the service. Appendix 1 provides guidance on an approach that could be adopted locally.

It should be noted that the implementation of a LES would have to be undertaken on a voluntary basis, as there is NHS legislation requiring a provider of primary medical services to issue an NHS prescription to an NHS patient requiring treatment. Likewise a provider of pharmaceutical services has a duty to dispense any FP10 presented with reasonable promptness.

## **5. LES for community pharmacy supply of gluten-free foods – the experience**

- 5.1 A number of PCTs have now set up arrangements for pharmacy supply of gluten-free foods. Northamptonshire, Cornwall and the Isles of Scilly, and South West Essex all have established schemes. Cumbria ran a pilot scheme in the Allerdale district which has now been established to the rest of the PCT area. All of the schemes are based on LES contracts with local pharmacies.
- 5.2 Nearly all of the local pharmacy supply schemes use national guidance to provide gluten-free products to patients<sup>10</sup>. The guidance allocates a number of units to achieve recommended nutritional intake for different groups of the population (such as children, adult males, adult females and pregnant women). The units are based on a monthly allowance. Each product is assigned a number of units (for example, a 400 gram loaf is one unit and a 500 gram pack of flour mix is two units). Details are given in Appendix 2.
- 5.3 The two schemes where the switch to pharmacy supply was extended to nearly all patients (Northamptonshire and districts of Cumbria), were evaluated and found to be effective at bringing the benefits of the change to people with coeliac disease.

### *B: The case for change*

#### **1. The case for change from the current FP10 based supply route for gluten-free foods**

- 1.1 Improved dietary compliance and health outcomes:  
Good dietary adherence is aided by the ease with which patients can obtain appropriate amounts of gluten-free products on prescription<sup>11</sup>.
- 1.2 Reduction in the annual cost per patient of supply of gluten-free foods:  
According to the surveys of costs from Northamptonshire and Cumbria, savings of the ingredient cost of gluten-free foods are likely to be between 20% and 40%. On the annual ingredient cost of gluten-free foods in England of £28.6 million this would produce a saving of £5 - £11 million in the

---

<sup>10</sup> Gluten-free foods: a revised prescribing guide 2011. Produced in collaboration with the British Dietetic Association, the Primary Care Society for Gastroenterology and Coeliac UK, 2011. <http://www.coeliac.org.uk/revisedprescribingguideline2011>

<sup>11</sup> The management of adults with coeliac disease in primary care. Primary Care Gastroenterology Society, HF1 Guideline, May 2006



first year.

- 1.3 Release of clinical time:  
The Royal College of General Practitioners estimated in 2002 that if implemented the initiative would have saved 209,000 appointments or over 20,000 hours of GP clinical time<sup>12</sup>. In our survey of clinicians, GPs confirm that the change to pharmacy supply does release their time however, actual time released was not quantified.
- 1.4 Prevention of overprescribing by application of national guidelines:  
Prevention of individual overprescribing or nutritionally unsuitable prescribing for patients such as those identified in the rollout in the Cumbrian PCT pilot scheme.
- 1.5 Better cost control:  
Provide better individual patient cost control as the pharmacy supply schemes are based on a system of units of gluten-free foods linked to the patient's dietary needs rather than patient-led GP FP10 prescribing.
- 1.6 Need for better cost control as more people with coeliac disease are diagnosed:  
Currently only a low number of people with coeliac disease are diagnosed. If the 2009 NICE recommendations in Clinical Guideline 86: 'Coeliac disease: recognition and assessment of coeliac disease' are followed this is likely to lead to more people being diagnosed, with a subsequent risk to GP prescribing costs.
- 1.7 In line with Government policy:  
Pharmacist supply is in line with the recommendations of the 2008 Pharmacy White Paper 'Pharmacy in England: building on strengths – delivering the future' in that it<sup>13</sup>:
  1. would reduce the time-consuming administration of repeat prescriptions in GP surgeries
  2. contribute to the range of clinical services offered by pharmacies, particularly to those with a long term condition
  3. expand patients' access to treatment, making better use of pharmacists' skills.
- 1.8 Improvement in patient experience:  
This will give more rapid access to gluten-free foods (by eliminating the need for GP signature of repeat prescriptions) and more flexibility to allow changes in foods as new gluten-free products are launched or removed from the market. *Equity and Excellence: Liberating the NHS* includes the objective of linking provider income to patient experience and satisfaction<sup>14</sup>. The experience of pharmacy supply of gluten-free foods for people with coeliac disease in all of the PCTs where it was introduced suggests that it is an acceptable service.
- 1.9 The development of this toolkit was initiated by Coeliac UK. Local involvement in the development and implementation of a new approach to the provision of gluten-free foods can be provided

---

<sup>12</sup> Making a Difference: Reducing General Practitioner (GP) Paperwork. Report from the Cabinet Office Regulatory Impact Unit, 19 March 2001

<sup>13</sup> Pharmacy in England: building on strengths – delivering the future, Department of Health, 3 April 2008

<sup>14</sup> Equity and Excellence: Liberating the NHS, Department of Health, 12 July 2010

by volunteers. The Coeliac UK Local Voluntary Support Groups offer a network of volunteers across the UK, who can liaise directly with patients through events, meetings and one-to-one support sessions, to encourage buy in and take up off the scheme.

## *C: Analysis of Costs and Views of Stakeholders in Northamptonshire and Cumbria*

The different local schemes are summarised in the Appendix to this toolkit. An analysis was carried out on the Northamptonshire and Cumbria schemes as these involved nearly all registered patients with coeliac disease. The Northamptonshire scheme was introduced in 2006 and the Allerdale pilot study started in 2009.

The Northamptonshire scheme involves 100 community pharmacies, 16 GP dispensaries and 1012 patients. The Allerdale scheme now involves 19 community pharmacies, 3 GP dispensaries and 260 patients. The Cumbria scheme has now been extended to other areas and involves 917 patients, 49 pharmacies and 14 dispensing doctor practices.

### **1. Cost Analysis from PCTs**

#### 1.1 Northamptonshire Scheme

*Figure 1: Annual costs for supply of gluten-free foods in Northamptonshire*

Parameter	FP10 Prescribing 2005/6	Pharmacy gluten-free supply scheme			
		2006/07	2007/08	2008/09	2009/10
Total cost for all patients with coeliac disease	£296,271	N/A	N/A	£361,187	£427,637
Number of people with coeliac disease diagnosed	639 (estimated) Partial count of 560	711 (estimated)	791 (estimated)	879	1,012
Annual cost/patient	£463.60	-	-	£413.73	£422.56
Cost/patient as % of 2005/06 figures	100%	-	-	89.2%	91.1%
Cost saving over 2005/06 GP prescribing		-	-	10.8%	8.9%

#### Notes

Total costs include ingredients cost of foods, dispensing fees, service and delivery charges

Number of people with coeliac disease estimated for 2005/6, 2006/7 and 2008/9 on the basis of a 10% annual increase in numbers diagnosed – the actual increase in numbers from 2008/9 to 2009/10 was 12%, so the figure used is a conservative estimate.

During the period 2005 to 2010 there was an approximate increase in the Trade Prices for gluten-free bread and rolls of 8.3% (range 3 – 15%), for gluten-free flour mixes of 14% and for gluten-free wheat free pasta of 23% (from the Chemist and Druggist Price Lists for July 2005 - 2010). Thus the pharmacy supply scheme still made substantial savings in Years 3 and 4 even against a background of increasing ingredient costs of gluten-free foods from the suppliers.

## 1.2 Allerdale district of Cumbria Scheme

Figure 2: Cost and number of gluten-free food items in Allerdale

Parameter	FP10 Prescribing April 2008/May 2009	Pharmacy Supply April 2010/March 2011
Total Cost	£84,000	£82,000
Number of patients with coeliac disease diagnosed	200	260
Cost per patient	£420	£315
Cost per patient as % of 2008/9 figure	100%	75%
Percentage cost saving	-	25%
Total number of items dispensed	4939	4045
Items per patient	24.7	15.6
Percentage reduction in number of items from the 2008/9 figure	-	36.8%

### Notes

The total cost of the gluten-free scheme in the October 2009 to March 2010 period included non-recurrent start-up costs of £980 in patient registration fees and £640 for the cost of printing leaflets and posters. It is estimated that dispensing fees and community pharmacy out of pocket expenses accounted for approximately £10,000 in the year 2008/9 (included in the total cost). The 2010/2011 total cost figures include all dispensing and out of pocket expenses.

The Allerdale scheme did not allow supply of cake or biscuits as these were considered unsuitable.

## 1.3 Copeland district of Cumbria Scheme

Figure 3: Cost and number of gluten-free items dispensed in Copeland

Parameter	FP10 Prescribing April 2008/May 2009	Pharmacy Supply April 2010/March 2011
Total cost	£51,000	£37,000
Number of patients with coeliac disease diagnosed	122	147
Cost per patient	£418	£252
Cost per patient as % of 2008/9 figure	100%	60.3%
Percentage cost saving	-	39.7%
Total number of items dispensed	2312	1614
Items per patient	19	11
Percentage reduction in number of items from the 2008/9 figure	-	42%

### Notes

It is estimated that dispensing fees and community pharmacy out of pocket expenses accounted for approximately £5,000 in the year 2008/9 (included in the total cost). The 2010/2011 total cost figures include all dispensing and out of pocket expenses.

As with the Allerdale scheme no supply of cake or biscuits was allowed as these were considered unsuitable.

## 1.4 Annual cost savings

The annual first year savings estimated from both the Northants scheme and the scheme in the two districts of Cumbria is in the range 20% - 40%. There was a reduction in number of gluten-free items provided to patients in Cumbria of between 37% and 42%, which is thought to represent previous overprescribing and prescribing of cakes and biscuits.

## 2. Views of Stakeholders on the Pharmacy Supply Scheme

Views of pharmacists, GPs and patients in Northamptonshire and Cumbria were sought by means of questionnaires. The results for Northamptonshire and Cumbria were pooled for this analysis.

### 2.1 Pharmacists

1. 37 pharmacists completed the survey (a return rate of 30%). The majority have between 1 and 20 patients registered for gluten-free supply. Overall views on the impact of the scheme were positive. The majority felt it decreased time to change items supplied to patients (37%), increased patient knowledge of the range of gluten-free products available (46%), and improved access to pharmacists (56%). 51% felt that patients' overall satisfaction had increased.
2. A majority agreed that it provided an enhancement of service and role (68%). A further 74% felt it improved communication with patients. However, the majority (50%) felt that it had a negative impact on their workload due to having to manage units ordered, payment claims etc.
3. A majority (63%) felt that there was no need for additional training. Those who did want more training focused on the need for a refresher course and the nuances of the scheme.
4. The overall rating of the scheme was positive with 26% rating it as very good, and 66% as good. Almost three quarters (71%) felt that it was an improved service compared to FP10 prescribing.

### 2.2 GPs

1. 28 GPs completed the survey. The majority had between 10 and 30 patients registered for gluten-free foods. Only one GP had patients who had declined to join the scheme.
2. Overall views of the scheme were positive with 53% stating overall satisfaction. The majority felt that the time taken to change gluten-free items supplied to patients had now improved (67%) and that access to pharmacists had improved (50%). The majority agreed that it decreased the workload of GPs and practice staff (64% for each). Nine out of ten felt that it offered an improved service compared to FP10 prescribing.

### 2.3 Patients

1. Cumbria PCT had conducted their own patient survey in Allerdale after 6 months using a questionnaire to 400 patients. 53 had returned the questionnaire. 83% had found collecting their gluten-free products from the pharmacy easier. 60% felt that the community pharmacist had helped them with the choice of products. 83% hoped that the scheme would continue.

2. The pooled Northamptonshire and Cumbria survey for this toolkit was of 310 patients (approximately 30% return rate). 77% collected their prescriptions monthly, and 87% understood the unit system. Only 23% use an NHS prescription charge prepayment certificate, of the remainder 94% are exempt from paying prescription charges.
3. Most patients (52%) felt that the time taken to order gluten-free foods had stayed the same, and 61% felt that the time taken to collect foods had stayed the same. 76% of patients felt that flexibility in regard to changing of products had either stayed the same or improved.
4. 41% of patients rated the scheme as very good, and 32% as good. 19% regarded it as basic, 5% as poor, and 3% as very poor.

It may be that some of this apparent disparity of views between the Cumbria PCT survey and the broader survey relates to the fact that Cumbria is a more rural area where travel is more difficult and thus improvements of access to gluten-free products is rated as more important. Also in Cumbria the Coeliac UK Local Voluntary Support Group was heavily involved in the change and a volunteer patient adviser from the Local Voluntary Support Group advised patients on diet and lifestyle issues during the change-over. In Northamptonshire the scheme has now been running for 3 years; some recently-diagnosed patients may never have experienced GP prescribing. Also for patients where the community pharmacy staff previously collected their repeat prescriptions from the GP surgery, the new scheme may have represented a change that they did not like.

#### *D: Potential sources of further cost savings*

##### **1. Range of foods in ACBS lists**

A reduction in the range of gluten-free foods available on prescription. The ACBS has recently conducted an internal review and will only consider products that are regarded as "dietary staples" in future. "Luxury" products, such as sweet biscuits, cakes and foods with additional products such as fruit, chocolate, nuts, seeds and cheese will not be considered.

##### **2. Avoidance of claims for out of pocket expenses for shipping costs from wholesalers/suppliers**

The supply of gluten-free foods on prescription is dependent on a complex array of local arrangements between pharmacists, wholesalers and producers. In some cases charges, additional to the Drug Tariff price, are being incurred in the supply chain in response to different distribution arrangements. The seemingly uncontrolled charges are undermining the provision of gluten-free prescriptions as the NHS seeks to deal with the tightening budgets. Co-ordinated action on this issue is required nationally but there is the potential with LES to more actively manage and limit such costs. This is demonstrated in Cumbria where a cap is in place on out of pocket expenses that may be incurred by pharmacists.

## **Appendix 1 – Possible elements of a gluten-free food supply LES**

The key elements of the scheme would be:

- for pharmacies (the service provider) to provide a supply service for gluten-free foods to patients with gluten enteropathy or dermatitis herpetiformis (coeliac disease) who are referred by a doctor or dietitian
- the service would be provided only to patients who have a written referral from either an NHS GP or a dietitian contracted to the local PCT/Health Board.

### **1. Role of service providers:**

- provide advice and support to patients on the range and quantities of gluten-free foods available under the scheme, agreeing a standard monthly order according to the locally agreed guidelines
- provide supplies on a monthly basis to patients ensuring that the quantities supplied do not exceed the agreed allowance specified in the locally agreed guideline
- make calendar monthly returns to the PCT/Health Board by the agreed date in order to obtain reimbursement for products supplied
- retain records of supplies to each patient for audit purposes
- refer any patient concerns which cannot easily be dealt with to the GP or dietitian.

### **2. Role of General Practitioners:**

- refer eligible patients to the scheme by means of a standard letter to enable them to register with a particular service provider.

### **3. Role of patients:**

- may select any of the agreed range of gluten-free foods listed in the Drug Tariff up to the agreed monthly number of units
- supply will be limited to monthly periods, except for extra allowances for holiday periods which are judged to be appropriate.

### **4. Role of the PCT / Health Board:**

- provide LES agreements to service providers
- support the scheme at the start with initial training on the organisation of the scheme and management of coeliac disease
- provide literature, record cards etc. to service providers for patients
- inform GPs of the change in supply scheme, provide them with a letter/ form for patients to take to service providers to register for the service
- provide specialist advice and support on request from a dietitian or pharmacist on performance issues or dealing with 'challenging' patients
- monitor costs of the scheme
- carry out selective audits of service providers to ensure compliance with the terms of the LES agreement.

## **5. Volunteer patient advisers:**

Implementation of the scheme would be facilitated for the first few months by having volunteer patient advisers who could advise people with coeliac disease on diet, the unit system and any lifestyle issues. They could be reimbursed for mileage travelled.

## **6. Payment mechanism options:**

The payment mechanism in the LES should be agreed locally between the PCT (or successor body) / Health Board and the Local Pharmaceutical Committee.

Options include:

Remuneration for service providers:

- patient registration fee
- annual fee
- dispensing fee.

Reimbursement for service providers:

- product cost reimbursement
- reimbursement of carriage charges.

## Appendix 2: Summary of existing local schemes for supply of gluten-free foods by pharmacies/dispensing doctors

### 1. Northamptonshire PCT Scheme

The scheme is set up as a Local Enhanced Service contract and is reviewed annually. All pharmacies and GP dispensing practices participate in providing the service to people with coeliac disease.

Written referrals are made to service providers by GPs or dietitians contracted to NHS Northamptonshire.

#### 1.1 Northamptonshire Service providers:

- provide advice and support to patients on the range and quantities of gluten-free foods under the scheme, agreeing a standard monthly order according to the guidelines
- provide supplies on a calendar monthly basis to patients ensuring that the quantities supplied do not exceed the agreed monthly allowance specified in the guideline
- make calendar monthly returns using the Northamptonshire Gluten-free Foods Patient Monthly Order Forms to the PCT by the 15th of each month in order to obtain reimbursement payments for products supplied
- retain records of supplies to each patient for audit purposes
- refer any patient concerns which cannot easily be dealt with to the GP or dietitian
- only those gluten-free foods listed in the ACBS list of Foods for Special Diets in the Drug Tariff may be supplied.

#### 1.2 Northamptonshire PCT:

- supported the scheme at the start with initial training on the organisation of the scheme and management of coeliac disease
- the PCT provides specialist advice and support on request from a dietitian or pharmacist on performance issues or dealing with 'challenging' patients.

#### 1.3 Payment mechanism:

- calendar monthly returns are made by service providers to claim for products supplied (including any carriage charges, except where carriage charges are significantly greater than the cost of products supplied)
- each pharmacy/GP dispensing practice is paid an annual fee to provide the service, which is paid in two instalments in April and October.

### 2. Cornwall and Isles of Scilly PCT Scheme

2.1 The scheme is set up with an operating manual. It allows GP prescribers to issue an order to patients for a monthly number of points worth of gluten-free foods per month for up to a year.

2.2 The scheme is voluntary, the GP practice, the pharmacy or the patient is not compelled to join. If anyone opts out the normal GP prescribing on FP10s continues.



- 2.3 The operating manual cites the Coeliac UK national recommendations for minimum quantities of gluten-free food per month (linked to the nutritional needs of male or female patients of different ages and activity levels).
- 2.4 The maximum length of a prescription is for 12 months. The GP prescriber completes an order card stating the patient's name, the number of points per month and the number of months the prescription is to run. Each time the patient presents the card for dispensing the dispenser changes the card for a new card with one month less on it. Order cards are prestamped by each pharmacy, so that if a patient wants to change the pharmacy they need to bring the unwanted card back to the GP surgery to be exchanged for a new one.
- 2.5 Dispensers are not restricted entirely to ACBS products, but to be permitted in the scheme each product needs to be allocated a points value. There is thus some flexibility and for example mince pies are allowed at Christmas time.
- 2.6 Reimbursement for products is by endorsement of the order card by endorsement of the purchase price. There is no dispensing fee as such, but dispensers receive a patient management fee per patient dispensed per month against the completed card. This fee incorporates any carriage costs for products supplied.
- 2.7 Patients are issued with pads of gluten-free shopping lists which they can forward to dispensers in the same way as repeat prescription requests. Patients are given an information sheet on the scheme.
- 2.8 Dispensers are invited to PCT training events and can start the scheme immediately after completing the training successfully.
- 2.9 If there are any queries the PCT prescribing team can be contacted.

### **3. South West Essex PCT Scheme**

- 3.1 The scheme is set up as a LES and this is detailed in a Specification for supply, monitoring and audit of gluten-free products via pharmacies. The LES is currently operated as a limited voluntary scheme for pharmacies and patients.
- 3.2 Patients are eligible to use this service if they are over 12 years, are not pregnant, are confirmed by their GP as suffering from coeliac disease, have been supplied with gluten-free products for at least 12 months and have the agreement of their GP to use the service.
- 3.3 The service can be provided by any pharmacy in the PCT area with an accredited confidential area and an accredited pharmacist to carry out the service. Only pharmacists with the relevant training can provide the service.
- 3.4 Patients need to give their consent to participate, and their GP needs to complete a declaration and agreement form.

### 3.5 South West Essex service providers will:

- identify suitable patients who meet the eligibility criteria
- obtain the consent of patients
- contact the GP surgery with a letter explaining the service and seeking completion of the declaration and agreement form
- complete the gluten-free Patient Audit form and send a copy to the PCT (the form includes details of when the patient has seen a dietitian, what items were prescribed in the last 12 months, any items not dispensed or at home and not used)
- confirm on PMR that the patient is using this service, create a new PMR if the patient does not already have one
- supply the products listed as previously received, or supply other BNF listed products at the request of the patient
- obtain a patient signature for each supply
- contact the GP if the patient needs additional supplies of products to those originally prescribed or for new products
- contact the GP if there is a major change in the patient's condition
- send a copy of the products supplied to the GP surgery every 3 months
- send a copy of products dispensed with an invoice to the PCT every month.

### 3.6 Payment mechanism:

- providers will be paid a fee for each completed patient audit form returned to the PCT
- providers will be paid for the products supplied by sending a copy of the signed supply log to the PCT. Payment constitutes the manufacturers list price for the product plus a dispensing fee
- a flat-rate annual fee is also paid to each participating pharmacy.

## 4. Cumbria PCT Scheme

This pilot scheme was originally set up as a pilot LES with a contract with service providers in the Allerdale district. This scheme was deemed a success and is now being rolled out in the rest of the PCT area. All pharmacies and dispensing doctor practices participate in providing the service to people with coeliac disease.

### 4.1 Cumbria service providers:

- provide advice and support to patients on the range and quantities of gluten-free foods under the scheme, agreeing a standard monthly order according to the guidelines
- provide supplies on a four weekly basis to patients ensuring that the quantities supplied do not exceed the agreed allowance specified in the guideline
- make calendar monthly returns using the Gluten-free Foods Patient Monthly Order Forms to the PCT by the 1st of each month in order to obtain reimbursement payments for products supplied
- retain records of supplies to each patient for audit purposes
- refer any patient concerns which cannot easily be dealt with to the GP or dietitian
- only selected gluten-free foods listed in the ACBS list of Foods for Special Diets in the Drug Tariff may be supplied (cake and some other high sugar content items are excluded as being

nutritionally undesirable)

#### 4.2 Cumbria PCT:

- support the scheme at the start with initial training on the organisation of the scheme and management of coeliac disease
- the PCT provides specialist advice and support on request from a dietitian or coeliac disease Support Worker.

#### 4.3 Payment mechanism:

- a fee for each new patient registration
- products are reimbursed at Drug Tariff prices including any handling charges with a dispensing fee.

### Appendix 3: Summary table of the Gluten-free foods: a revised prescribing guide 2011 categories for patients with coeliac disease<sup>10</sup>

Age group and Sex	Recommended no. units per month
1 – 3 years	10
4 - 6 years	11
7 – 10 years	13
11 – 14 years	15
15 – 18 years	18
Male 19-59 years	18
Male 60-74 years	16
Male 75+ years	14
Female 19-74 years	14
Female 75+ years	12
High Physical Activity Level	Add 4 units
3rd Trimester Pregnancy	Add 1 unit
Breastfeeding	Add 4 Units

Prescribable food item	No. of units
400g bread	1
400g rolls/baguettes	1
500g bread mix/flour mix/pastry mix	2
200g sweet/savoury biscuits/crackers	1
250g pasta	1
2x 110g-180g pizza bases	1

<sup>10</sup> Gluten-free foods: a revised prescribing guide 2011. Produced in collaboration with the British Dietetic Association, the Primary Care Society for Gastroenterology and Coeliac UK, 2011. <http://www.coeliac.org.uk/revisedprescribingguideline2011>

## Contact details

### Coeliac UK

3rd Floor Apollo Centre, Desborough Road,  
High Wycombe, Bucks HP11 2QW  
Main number: 01494 437 278  
Helpline: 0845 305 2060  
[www.coeliac.org.uk](http://www.coeliac.org.uk)



### Pharmaceutical Services Negotiating Committee

59 Buckingham Street, Aylesbury HP20 2PJ  
Main number: 01296 432 823

[www.psn.org.uk](http://www.psn.org.uk)



### National Pharmacy Association

Mallinson House, 38-42 St. Peter's Street, St. Albans AL1 3NP  
Main number: 01727 858 687

[www.npa.co.uk](http://www.npa.co.uk)

