

[REDACTED]

[REDACTED]

Dear [REDACTED]

Somerset CCG (“SCCG”) Proposed Change in Formulary Status - Gluten Free Products (“GFPs”)

Introduction

1. We represent Coeliac UK (“CUK”) and are instructed to write to you in relation to the above.
2. We write in response to your letter dated 10 October 2016 (the “Proposal Letter”) setting out the proposed change in formulary status of GFPs (the “Proposal”) and further to CUK’s response to the Proposal Letter, dated 7 November 2016 (the “CUK Response”).
3. In this letter, we set out the factual background and the issues. We then go on to set out documents and information that are relevant to the issues and that we ask you to provide to us, and, we set out actions that are expected of you.
4. This letter does not purport to be a letter before action. However, it is CUK’s view that the Proposal Letter sets out an unlawful course of action. In light of this, this letter seeks to identify the issues, allow the parties to make informed decisions as to how to proceed, try to settle any dispute without proceedings (or reduce the issues in dispute), and, avoid unnecessary expense and keep down the costs of resolving the dispute.
5. We therefore ask that you substantively respond to this letter within 14 days of its date (i.e. no later than 5 December 2016).

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6. We also reiterate that this letter is further to the CUK Response, and not a substitute or continuation. We would therefore expect you to provide any intended response to the CUK Response separately.
7. Our client hopes that the issues set out in this letter will be resolved by your timely substantive response. However, we reserve our client's right to issue a letter before action and/or issue proceedings in respect of the unlawfulness. Our client undertakes not to do this prior to receipt of your response or the elapse of 14 days, whichever is the earlier. As set out above, this letter is an attempt to resolve a potential dispute in an alternative to legal action. It is therefore without prejudice to any stance taken by CUK should it consider that legal action becomes necessary. CUK may add, retract or modify points made in this letter as is appropriate at the time.

Factual background

8. The Proposal Letter sets out to "*make all gluten-free products non-formulary from 1 December 2016*". The Proposal appears to be an effective instruction to general practitioners ("GPs") who are members of SCCG (which all NHS GPs in the county of Somerset are) not to prescribe GFPs to patients. As such, it is a decision by SCCG to stop its members prescribing GFPs to those suffering from Coeliac disease.
9. The Proposal Letter announced a "*four week period of engagement*" with comments invited until 7 November 2016. Included in the Proposal Letter was an explanation of the Proposal in the form of questions (presumably set by SCCG, although this section is titled "*Proposed Changes to Gluten-Free Prescribing in Somerset - Your Questions Answered*") and answers. We reproduce this section in the Appendix to this letter.
10. As mentioned above, CUK responded to the Proposal Letter by way of the CUK Response. Whilst this letter is separate from the CUK Response, many of the issues set out in this letter were canvassed in the CUK Response.

The issues

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11. In short, our client's central contention is that the Proposal is wrongfully blanket in its application. We set out below the ways in which we suggest that the Proposal is legally flawed.

The National Health Service Act 2006 ("NHS Act 2006") and the NHS Constitution

12. By way of background; the arrangements for the establishment and operation of Clinical Commissioning Groups ("CCGs") are set out in the NHS Act 2006, as amended by the Health and Social Care Act 2012 (in particular). Whilst those arrangements do not explicitly deal with the contents of formularies, the decision to issue the Proposal Letter was done by SCCG in furtherance of its functions.
13. The NHS Act 2006 provides specific duties of CCGs. Those duties include the following: A duty to promote the NHS Constitution (section 14P). A duty to reduce inequalities (section 14T). A duty that each CCG must exercise its functions effectively, efficiently and economically (section 14Q).
14. The NHS constitution provides:

"Nationally approved treatments, drugs and programmes:

You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you.

You have the right to expect local decisions on funding of other drugs and treatments to be made rationally following a proper consideration of the evidence. If the local NHS decides not to fund a drug or treatment you and your doctor feel would be right for you, they will explain that decision to you."

15. Turning to the Proposal and SCCG's reasons; in the answer to Question 6 of the Proposal Letter, you set out three broad reasons for the Proposal.

16. Reasons (a) and (b) provide:

"a) People with coeliac disease can follow a gluten-free diet without needing to have specially formulated gluten-free foods

b) Specially formulated gluten-free foods are now widely available in supermarkets, restaurants and shops. Coeliac patients can find and buy gluten-free foods themselves and no longer need specially prescribed foods. All major supermarkets offer deliveries which is important in a rural area like Somerset."

These two reasons appear to be at odds with each other. Answer 6(a) provides that a gluten-free diet can be followed without GFPs whilst answer 6(b) provides that GFPs are now widely available. Reason 6(b) appears to acknowledge that there is a need for GFPs in Coeliac disease affected diet, and, that there will be an impact and a differential between those that follow a gluten-free diet without using specially formulated GFPs and those that do have specially formulated GFPs.

There is no mention of the consideration of impact and the reasons do not cite an evidence base in support.

17. Answer (c) provides:

"The NHS has a limited prescribing budget and a duty to use its resources wisely. We feel that the money we are currently spending on prescribing gluten-free foods is not the best use of our budget. By implementing the proposal to stop these prescriptions, we estimate that we will save £350,000 per year in prescribing costs across Somerset."

Saving money is, of course, not an absolute duty (in fact, it is not a duty on CCGs at all). Any decision to promote economy (in other words, to use resources wisely) must be informed by evidence that the Proposal is actually economical, that is to say it truly saves the CCG money and is not the simple cutting of costs. As a minimum, a lifecycle costing for the Proposal would be expected. This would include consideration of whether there is a chance of further costs arising for the NHS if the Proposal is implemented. The fact that SCCG accepts that the Proposal will have adverse impacts on a number of groups means that it is duty bound to consider the likelihood and costs of such groups engaging with the mitigation proposed by SCCG (including, for example, the costs of specialist dietitians) and the costs likely to be incurred if those groups do not actually do so or the mitigation otherwise fails (e.g. if CUK is unable to provide the support envisaged by SCCG). If, after the carrying out of that exercise, the evidence supports the Proposal by demonstrating true economy, a further balancing exercise must then be carried out (which ought to be evidenced) that other duties of SCCG are not being unduly compromised.

18. Indeed, answer 7 appears to set out the sole basis for the Proposal:

“Somerset GPs explored the options and implications of gluten-free prescriptions as part of the Somerset Clinical Commissioning Group, which is a membership organisation of all the GP practices in the county. Their decision to propose recommending stopping the prescribing of gluten-free foods was informed by the following factors:

a) Their view was that patients with coeliac disease could continue to safely manage their condition and their diet without prescribed foods.

b) Somerset CCG reviewed how similar actions had already been taken in other parts of the country and had been implemented successfully

c) Somerset CCG believes its proposal to stop the prescribing of gluten-free foods supports its long-term strategy of empowering and activating patients to increase self-care for their long-term conditions.”

This does not appear to constitute a permissible evidence base. Seeking to be economical is not only permissible for a CCG but, in contrast to simply saving money, a duty. However, if an enquiry into the economy of a particular treatment is begun with a conclusion that costs are excessive, it is easy to see that decision making by commissioners whose budgets are being taxed may not be objective. Also, it is not clear what evidence was reviewed. This is particularly so regarding SCCG’s review of similar actions in other parts of the country. Was statistical evidence looked at? Were health outcomes assessed? Were the facts assessed with a view to finding whether inequalities occurred as a result of implementation?

Finally, in relation to other CCGs; in the premises, the fact of other CCGs carrying out policies that are the same as the Proposal does not render those policies or the Proposal in itself lawful. However, to pray the practice of other CCGs in aid, there must be some consideration of whether the cases are significantly similar or different, and, how such practice contrasts with the health outcomes achieved by those CCGs who have not implemented the proposal.

19. Answer 11 asks whether “national prescribing guidance” is being followed by SCCG. The answer cites relevant NICE guidelines.

However, NICE Quality standard QS134 in relation to Coeliac disease provides:

“Equality and diversity considerations

Gluten-free products are more expensive and are usually only available from larger retailers, making access more difficult for people on low incomes or with limited mobility. As coeliac disease can affect more than one member of a family it can also be an additional burden on the family budget. To address this, healthcare professionals should help people who may need support to find suitable gluten-free food products on prescription to enable them to maintain a gluten-free diet.”

20. Answers 13, 14 and 16 makes clear that the Proposal will have no exceptions. In this, it breaches QS134 without any reasoning. For the avoidance of doubt, the listing of alleged mitigation is not reasoning that justifies departure, it is a listing of mitigation of the effects of such departure.
21. This departure from QS134 also represents a breach of the NHS Charter, contrary to the statutory duty to promote the Charter.
22. Further, QS134 represents evidence that a blanket policy (as the Proposal is) will result in outcomes of inequality. We have already stated that these should have been assessed and the assessment transparently evidenced. We should add that the CUK Response refers to evidence that supports the position as set out in QS134.
23. In the light of the NICE evidence, the blanket policy also breaches the statutory duty to reduce inequalities.

The Equality Act 2010 (“EA 2010”)

24. Under section 149 of the EA 2010, CCGs must have due regard to the need to eliminate unlawful discrimination and advance equality of opportunity between people who share a protected characteristic and those who do not (in particular).
25. Under section 29(6) of the EA 2010, CCGs must not, in the exercise of their public functions, do anything that constitutes discrimination.

26. As set out above, no enquiry has been evidenced of what impact (if any) on those with protected characteristics will be. Answer 9 and 16 specifically acknowledge that there will be impacts on people with protected characteristics.

27. Answer 9 provides:

“By proposing to stop prescribing gluten-free foods, there is a risk that some patients, particularly people with learning disabilities, dementia or mental health problems, may have difficulty managing their coeliac condition and may experience health problems as a consequence. It is important that carers for such patients understand the importance of following a gluten-free diet and are supported to do so.”

Answer 16 provides:

“We do recognise that this change may have a disproportionate impact on some vulnerable people, including those with learning disabilities, dementia, a mental health problem or another long-term condition. Resources are available on the Coeliac.org.uk website - <https://www.coeliac.org.uk/home/> - Coeliac UK also offers specific support and advice for parents and families. You can also seek advice from the community dietetics services or your GP practice.

It cannot be “*due regard*” to withdraw a service of the NHS and simply substitute it with aspirations placed on the shoulders of non-NHS parties. There is no evidence of consideration given to whether, for example, carers have adequate training to take on a role that previously a healthcare professional would have carried out, supported by the availability of prescribed GFPs. CUK is a charity, it has no statutory function or remit and no funding to take on wholesale a role previously carried out by healthcare professionals under the auspices of the NHS.

28. Further, a failure to consider impacts on those with other diseases (including learning disabilities) and the elderly may constitute a substantive breach of section 29(6) of the EA 2010.

Issues with the consultation carried out by way of the Proposal Letter

29. Where consultations are carried out by public authorities (such as CCGs) they must be fair. It is established case law that in order to be fair, the Sedley principles apply to consultations. These provide:

- that the consultation must be at a time when proposals are still at a formative stage;
- that the proposer must give sufficient reasons for any proposal to permit of intelligent consideration and response;
- that adequate time is given for consideration and response; and,
- that the product of consultation is conscientiously taken into account when finalising the decision.

30. The Proposal Letter provides:

“Somerset CCG is now undertaking a four week period of engagement to ensure that affected patient groups and organisations have an opportunity to consider the impact of this proposal and to suggest any additional actions to mitigate the potential impact.”

Clearly, this language provides that the Proposal itself is well beyond a formative stage and that the ‘consultation’ is actually an opportunity to propose mitigation of the impact of the Proposal.

31. Further, there has been no analysis or evidence of the impact set out or referred to in the Proposal Letter, as such there are not sufficient reasons that allow intelligent consideration and response.

32. It may be premature to complain at this stage (i.e. before the Proposal has crystallised into a further unlawful decision) that the product of consultation has not been conscientiously taken into account but given the flaws in the Proposal Letter as a consultation document, it is difficult to see how this requirement can be satisfied.

Documents and information that is relevant

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33. We set out below documents and information that is relevant in considering whether SCCG has acted lawfully. We ask that you provide the following.
 34. Please provide the evidence that was used to formulate the Proposal. We would expect to see statistics, reports, minutes of meetings, and, any analysis.
 35. In answer 5, an estimate of approximately 1,000 Coeliac sufferers in Somerset who currently receive prescriptions for GFPs is given. How was this estimate arrived at? Were any of those approximately 1,000 patients specifically and individually engaged with (i.e. not by way of any umbrella organisation)? Were protected characteristics taken into account in relation to consulting with those persons?
 36. Has the Equality Delivery System, EDS2, been implemented by SCCG? If so, what has the impact of that implementation been with regard to the Proposal?
 37. What economic impact assessment was carried out beyond merely assessing the current costs of prescribing GFPs and subtracting that cost from SCCG's budget? Were any potential adverse costs in the future considered?
 38. Please provide details and documentary evidence of how consultation responses were dealt with (beyond their simple classification). Has the Proposal changed or been modified as a result? Has any consultation response, or tranche of responses, provoked further investigation of the evidence? Who was it in SCCG that dealt with consultation response and what authority did they have to initiate or conclude changes to the Proposal?

Actions expected

39. We trust that the above sets out the very serious issues arising from the Proposal. CUK looks forward to a response from you that seeks to address and remedy these issues.
40. Whilst it is not for CUK to be prescriptive about the manner in which SCCG remedies the issues set out in this letter, as a minimum CUK would expect the conclusions of NICE, supported by the further evidence put to SCCG in the CUK Response, to be engaged with. It is our submission that to do so could only rationally lead to the amendment of the Proposal such that it is no longer unlawfully blanket in its approach.

41. We look forward to your response.

Yours faithfully

Bindmans LLP

Appendix

Proposed changes to gluten-free prescribing - your questions answered

From 1 December 2016 it is proposed that the prescribing formulary in Somerset will no longer recommend prescribing of gluten-free foods. Read on to find out more.

1. What exactly is proposed to change?

GPs in Somerset have historically prescribed gluten-free foods to some patients with coeliac disease. Somerset CCG, which is a membership organisation of all GPs in the county, is proposing to change its prescribing position and guidance to GPs. This means gluten-free foods will no longer be recommended on prescription.

2. When is this change proposed to take place?

The new position is proposed to be in place on 1 December 2016 and GP practices would then be recommended to stop prescribing gluten-free foods from that date.

3. Who will be affected by this proposed change?

People who have been diagnosed with coeliac disease and who have been receiving gluten-free foods on prescription will be affected by this change.

4. How common is coeliac disease?

Around 1% of the population is thought to be coeliac, although fewer have actually been tested and formally diagnosed.

5. How many people in Somerset will be affected by this proposed change?

We estimate there are approximately 1,000 people in Somerset currently being prescribed gluten-free foods, it is proposed they will no longer receive these foods on prescription.

6. Why are you proposing this change?

There are three broad reasons for proposing this change:

a) People with coeliac disease can follow a gluten-free diet without needing to have specially formulated gluten-free foods

b) Specially formulated gluten-free foods are now widely available in supermarkets, restaurants and shops. Coeliac patients can find and buy gluten-free foods themselves and no longer need specially prescribed foods. All major supermarkets offer home deliveries which is important in a rural area like Somerset.

c) The NHS has a limited prescribing budget and a duty to use its resources wisely. We feel that the money we are currently spending on prescribing gluten-free foods is not the best use of our budget. By implementing the proposal to stop these prescriptions, we estimate that we will save £350,000 per year in prescribing costs across Somerset.

7. How did you make the decision to propose stopping prescribing gluten-free foods?

Somerset GPs explored the options and implications of gluten-free prescriptions as part of the Somerset Clinical Commissioning Group, which is a membership organisation of all the GP practices in the county. Their decision to propose recommending stopping the prescribing of gluten-free foods was informed by the following factors:

a) Their view was that patients with coeliac disease could continue to safely manage their condition and their diet without prescribed foods.

b) Somerset CCG reviewed how similar actions had already been taken in other parts of the country and had been implemented successfully

c) Somerset CCG believes its proposal to stop the prescribing of gluten-free foods supports its long-term strategy of empowering and activating patients to increase self-care for their long-term conditions.

8. Do you still prescribe foods for any other groups of patients with other conditions?

We are continuing to prescribe foods for a small number of patients with rare metabolic disorders, such as phenylketonuria. This is because following a diet for a rare metabolic disorder without access to prescription products is currently considered much harder than following a gluten-free diet. These products also tend not to be widely available in supermarkets.

9. What are the risks of the proposal to stop the prescribing of gluten-free food?

We understand that there are always risks associated with any change and that we need to minimise the risks. By proposing to stop prescribing gluten-free foods, there is a risk that some patients, particularly people with learning disabilities, dementia or mental health problems, may have difficulty managing their coeliac condition and may experience health

problems as a consequence. It is important that carers for such patients understand the importance of following a gluten-free diet and are supported to do so.

10. Will you be offering extra support and help for people with coeliac disease who it is proposed will no longer receive gluten-free foods on prescription?

We will continue to support, advise and monitor patients diagnosed with coeliac disease through our GP practices, community dietetics services and gastroenterology departments. We will prepare GPs, dieticians and gastroenterologists for this proposed change so that they are particularly alert to any potential risks to vulnerable patients. We encourage patients with coeliac disease who are having difficulty maintaining a gluten-free diet to seek advice and support from Coeliac UK - <https://www.coeliac.org.uk/home/>

11. Is the NHS in Somerset following national prescribing guidance?

We will continue to monitor and advise that coeliac patients are annually reviewed in line with the NICE (National Institute for Clinical Excellence) guidelines, which can be found at <https://www.nice.org.uk/guidance/ng20?unlid=3818974220162201535>

12. If, following the proposal, I no longer get gluten-free foods on prescription, how will I manage my coeliac condition?

Following a gluten-free diet can be achieved without resorting to specially formulated foods on prescription, by avoiding foods which naturally contain gluten. In addition gluten-free foods are widely available in supermarkets and shops, so you can continue to buy and eat appropriate food. You can also seek advice and support from your GP, community pharmacy and dietician. Check out the information and resources on the Coeliac UK website: <https://www.coeliac.org.uk/home/>

13. If I struggle to maintain a gluten-free diet without prescribed foods, what should I do?

If you are having difficulty maintaining a gluten-free diet, please seek advice and support from Coeliac UK, which has a lot of useful resources, information, recipes and contacts on their website: <https://www.coeliac.org.uk/home/>

14. I cannot afford to buy gluten-free foods as I am on a low income. Is it proposed that I will continue to receive gluten-free foods on prescription?

No, it is proposed that this change applies to everyone with coeliac disease. Following a gluten-free diet can be achieved without resorting to specially formulated foods on prescription, by avoiding foods which naturally contain gluten. You can, however, find recipes and tips for managing a gluten-free diet on the Coeliac UK website - <https://www.coeliac.org.uk/home/> - and you can also seek advice from the community dietetics services or your GP practice.

15. Is it proposed that children with coeliac disease will continue to receive gluten-free foods on prescription?

No, this change applies to children as well as adults. Following a gluten-free diet can be achieved without resorting to specially formulated foods on prescription, by avoiding foods which naturally contain gluten. In addition to the resources on their website - <https://www.coeliac.org.uk/home/> - Coeliac UK also offers specific support and advice for parents and families. You can also seek advice from the community dietetics services or your GP practice.

16. My family member has a condition (eg learning disability/long-term condition/ dementia/mental health problem) which will make it difficult for them to maintain a gluten-free diet. Is it proposed that they continue to receive gluten-free foods on prescription?

No, this change applies to everyone with coeliac disease. Following a gluten-free diet can be achieved without resorting to specially formulated foods on prescription, by avoiding foods which naturally contain gluten. We do recognise that this change may have a disproportionate impact on some vulnerable people, including those with learning disabilities, dementia, a mental health problem or another long-term condition. Resources are available on the Coeliac.org.uk website - <https://www.coeliac.org.uk/home/> - Coeliac UK also offers specific support and advice for parents and families. You can also seek advice from the community dietetics services or your GP practice.

17. How will this proposed change affect people who have coeliac-type symptoms but have not been tested or diagnosed?

This proposed change will not directly affect people who have not been diagnosed as the NHS should not be prescribing gluten-free foods for patients without a confirmed diagnosis of coeliac disease. This proposed change will only apply to people who have been diagnosed with coeliac disease and who are already receiving prescriptions for gluten-free foods.

It is proposed that patients who are diagnosed as having coeliac disease in the future will not receive prescriptions for gluten-free foods.