NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Coeliac disease

Date of Quality Standards Advisory Committee post-consultation meeting:
20 July 2016

2 Introduction

The draft quality standard for coeliac disease was made available on the NICE website for a 4-week public consultation period between 25 February and 24 March 2016. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 16 organisations, which included service providers, national organisations, professional bodies, patient groups and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendices 1 and 2.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. If the systems and structures were available, do you think it would be possible to collect the data for the proposed quality measures?

3. Do you have an example from practice of implementing the NICE guideline that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources required to deliver them? Please describe any resource requirements that you think would be necessary for any statement. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

5. For draft quality statement 2: Is it reasonable to suggest that an endoscopic intestinal biopsy should be carried out within 6 weeks of referral to ensure that people have a time limit for continuing with a gluten containing diet?

6. For draft quality statement 4: Are people with coeliac disease currently being informed about the gluten-free foods available on prescription? Please explain your answer.

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Stakeholders welcomed the quality standard and there was broad support for the areas identified for quality improvement.
- It was suggested that although systematic data collection is not currently in place it would be possible to collect the data identified for the quality measures.
- There was confirmation of variation in practice in the long-term management of coeliac disease.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

People at increased risk or with symptoms of coeliac disease are offered a serological test for coeliac disease.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- There was a suggestion that more emphasis is needed on testing people with symptoms of irritable bowel syndrome as there is variation in practice.
- Stakeholders questioned why some groups who are at risk are not included in the statement such as those with: balance problems and ataxia; dermatitis herpetiformis; dental enamel effects; osteoporosis; unexplained raised liver enzymes and unexplained liver disease.
- It was suggested that the statement should emphasise the need for re-testing, particularly for those with type 1 diabetes.
- The difficulty of measuring whether those with common symptoms such as constipation are tested was acknowledged.
- A stakeholder suggested amending the outcome to ‘rate of suspected diagnosis of coeliac disease’.
- It was suggested that an equality and diversity consideration should be added to address the variation in diagnosis rates in socioeconomically deprived areas.

5.2 Draft statement 2

People with a positive serological test for coeliac disease are referred to a specialist for further investigation and advised to continue with a gluten-containing diet until diagnosis is confirmed.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- A stakeholder indicated that it should be clearer which serological testing should be available. Currently there is variability in the availability of EMA testing which is required for cases where results are less clear cut.
- It was suggested that it needs to be clearer on which specialist a child should be referred to.

Consultation question 5

Stakeholders made the following comments in relation to consultation question 5: *Is it reasonable to suggest that an endoscopic intestinal biopsy should be carried out within 6 weeks of referral to ensure that people have a time limit for continuing with a gluten containing diet?*

- Some stakeholders indicated that it is reasonable to expect an endoscopic intestinal biopsy to be carried out within 6 weeks.
- Others suggested, however, that while 6 weeks is acceptable for some people, those with severe symptoms should be given priority, and a biopsy should be carried out within 2 weeks.
- There was some concern that a 6 week timescale may be a challenge for some paediatric gastroenterology services to meet.
- It was suggested that an endoscopy should be classed as urgent and should be made available through the choose and book system so that patients can choose the shortest waiting time if they wish.

5.3 Draft statement 3

People diagnosed with coeliac disease are given advice about a gluten free diet by a healthcare professional with specialist knowledge of coeliac disease.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- A stakeholder indicated that it is incorrect to state that a gluten-free diet is the only treatment for coeliac disease in the rationale as there are other treatments.
- It was suggested that although a gluten-free diet diet usually helps with managing the condition it is not a treatment.
- There was a suggestion that 'information on which types of food are naturally gluten-free' should be added to the definition of 'Advice about a gluten-free diet'.
- It was suggested that an equality and diversity consideration should be added to ensure healthcare professionals take the increased cost and variable availability of gluten-free foods into consideration when giving advice to people on low or fixed incomes and/or with poor mobility or limited transport options.

5.4 Draft statement 4

People diagnosed with coeliac disease are informed about the gluten free foods available on prescription.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4:

- There was a concern that the statement as it stands will not address the variability in access to gluten-free food on prescription.
- It was felt that the rationale should acknowledge that although gluten free foods are still more expensive there is now a smaller price difference for some products such as pasta, flour and biscuits.
- It was suggested that it is important to acknowledge that there are local prescribing formularies for gluten free foods.
- It was suggested that the descriptors should emphasise the potential for pharmacy led supply of gluten-free food and the role of community pharmacists in providing information about gluten-free foods available on prescription.
- There was a suggestion that the definition for gluten-free foods available on prescription should be more precise.
- It was mentioned that the equality and diversity statement needs to be clearer that additional support is focused on advice on gluten free foods that people need on prescription to maintain a healthy diet.

Consultation question 6

Stakeholders made the following comments in relation to consultation question 6: *Are people with coeliac disease currently being informed about the gluten-free foods available on prescription?*

- A stakeholder indicated that every person with coeliac disease will be advised on the availability of gluten-free foods on prescription at their initial dietetic consultation; however, in some areas availability has been reduced or removed.
- Information about gluten-free foods available on prescription is provided nationally by Coeliac UK but information about local prescribing policies may be limited.

5.5 Draft statement 5

People with coeliac disease are offered an annual review.

Consultation comments

Stakeholders made the following comments in relation to draft statement 5:

- Stakeholders indicated that it needs to be clearer that more regular reviews may be required following diagnosis but that an ‘at least’ annual review is appropriate once a gluten-free diet is established.
- There was a suggestion that the definition of an annual review does not need to include the measurement of height in adults.
- There was a concern that once a person with coeliac disease is discharged to their GP there are currently inadequate resources to ensure an annual review is carried out.
- It was suggested that the descriptors should emphasise the potential role of community pharmacists in supporting reviews.
- Consideration should be given to measuring both those offered a review and those who attend as some people persistently default on appointments.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Detection of asymptomatic patients
- Vitamin D testing and supplementation
- Screening people with coeliac disease for neurological signs and symptoms

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	Royal College of Paediatrics and Child Health	General	It is appropriate that the clinical guideline does NOT advocate specific monitoring of bone health, as that would be a research tool and is not a required element of clinical care in this condition. We agree with the approach taken.
2	Royal College of Paediatrics and Child Health	General	The guideline offers no advice on when to start gluten free diet (GFD). For those symptomatic, and likely have coeliac based on serology, they should start GFD as soon as tests completed and before answers received. Perhaps prescribed gluten-free items can only follow once diagnosis confirmed by the tests. This allows managing symptoms as soon as possible for patient's benefit
3	Royal College of GPs	General	The RCGP feels that the document is a sensible approach to testing for coeliac disease, diagnosis means significant changes to lifestyle and it would be helpful to have an appendix considering the sensitivity/specificity of antibody tests and of intestinal biopsy. There is a concern of over diagnosis without testing and this needs to be managed-gluten free has become "fashionable" and a whole gamut of pathologies linked to it. Strict criteria for diagnosis and management are important, some coeliacs seem to manage small amounts of gluten without consequence, others are highly sensitive- i.e the population of coeliacs is not uniform while there is some evidence that there can be recovery over time and resumption of gluten consumption.
4	HQT Diagnostics	General	General Practitioners should test and supplement Vitamin D 25(OH)D to between 100-150 nmol/L for all Coeliac patients and review blood tests after 3 months There is good evidence that increased levels of Vitamin D help Coeliac patients High levels of Vitamin D reduce many gut problems, including Inflammation Evidence: http://www.vitamindwiki.com/Overview+Gut+and+vitamin+D http://greenvits.eu/collections/vitamin-d
5	British Society of Gastroenterology	General	The Draft QS is well written and addresses most important issues clearly and correctly.

---

[1] PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments[1]
6	British Society of Gastroenterology	General	There is a problem with the detection of asymptomatic patients as these are not identified by any of the pathways discussed unless they fall into the very short list of those considered “at risk” because of intercurrent illness or family history. This may have an impact on the value of the quality measures for detection rates.
7	Royal College of Physicians	General	We would like to formally endorse the response submitted by the British Society of Gastroenterology.
8	NHS England	General	I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
9	Royal College of Nursing	General	There are no further comments to make on this document on behalf of the Royal College of Nursing.
10	British Specialist Nutrition Association (BSNA)	Questions for consultation – Question 1	Yes. BSNA is fully supportive of the draft quality standard for coeliac disease and believes it reflects the key areas for quality improvement
11	Coeliac UK	Questions for consultation – Question 1	The quality standard largely reflects the key areas for quality improvement in coeliac disease.
12	Coeliac UK	Questions for consultation – Question 2	Systematic data collection is not currently in place. However, coeliac disease specific primary care audit tools are available for use locally for the collection of data for the proposed quality measures. Nationally, the Health and Social Care Information Centre collect prescribing data which can be used to monitor trends relating to gluten-free food provided on prescription. A validated coeliac disease specific PROM is also available to measure the impact of interventions [1]. [1] Available from iOutcomes, Oxford, UK. Contact Dr David Churchman David.Churchman@innovation.ox.ac.uk
13	British Specialist Nutrition Association (BSNA)	Questions for consultation – Question 4	Statements 3,4,5 require provision for the ongoing long-term management of coeliac disease. At present, provision of management practices following diagnosis, including access to annual reviews varies greatly across England. BSNA strongly believes that gluten-free prescribing is an important support mechanism for patients with coeliac disease to aid adherence to a strict lifelong gluten-free diet and to help prevent long-term health complications. Adherence to the gluten-free diet is greatly improved through prescriptions for staple gluten-free foods and regular follow-up and support. BSNA is, therefore, supportive of Coeliac UK’s call for England to adopt a national pharmacy-led scheme following the success of the new national pharmacy-led Gluten-Free Food Service in Scotland.[1] This national scheme successfully incorporates the provision of gluten-free foods on prescription and an annual health check in a pharmacy setting into a management pathway, which is in line with the NHS Five Year Forward View.[2] BSNA is aware that the establishment of such a scheme in England is hindered by the current local commissioning framework in England, and that a number of barriers would need to be overcome before such a scheme can be considered. BSNA would welcome and support any initiative which addresses these barriers. [1] Review of the Gluten-Free Food Additional Pharmaceutical Service. Friday 18th September 2015. ISBN:

ID	Stakeholder	Statement number	Comments[1]
			9781785446108 http://www.gov.scot/Resource/0048/00485151.pdf (accessed 24 March 2016). [2] NHS England Five Year Forward View, October 2014. https://www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf (accessed 24 March 2016).
14	Coeliac UK	Questions for consultation – Question 4	One potential area for cost efficiencies is through the use of alternatives to FP10 prescribing for the supply of gluten-free food. An example of a pharmacy-led scheme is the Gluten-free Food Service which has been developed by the Scottish Government for adults and children across Scotland. This centralised NHS service is available through community pharmacies, and following the trial period has been adopted as a permanent service within NHS Scotland from 1 October 2015. The final report revealed a high level of satisfaction from all stakeholders including healthcare professionals and patients and led to savings in GP time.
15	Coeliac UK	Questions for consultation – Question 4	The offer of annual review for patients diagnosed with coeliac disease both empowers patients to self-manage but also allows medical oversight to monitor for associated conditions and complications. Commissioners should consider resource requirements and how these requirements will be met locally.
16	Coeliac UK	Statement 1	Rationale - The proactive approach to serological testing should also highlight recommendation 1.3.4 from the NICE guidance for coeliac disease (NG20) [2] which states that healthcare professional should have a low threshold for re-testing people for coeliac disease. [2] National Institute for Health and Clinical Excellence (2015) Coeliac disease: recognition, assessment and management 2015
17	Coeliac UK	Statement 1	Equality and diversity considerations - Diagnosis rates in the UK vary regionally and by socioeconomic area, with a higher incidence of coeliac disease among patients registered at general practices located in less socioeconomically deprived areas [3]. Commissioners and healthcare professionals should take this variation in diagnosis rates into account when developing local arrangements to identify people with increased risk or symptoms of coeliac disease. [3] West, J., et al., Incidence and prevalence of celiac disease and dermatitis herpetiformis in the UK over two decades: population-based study. Am J Gastroenterol, 2014. 109(5): p. 757-68.
18	British Association of Dermatologists	Statement 1	Patients with unexplained itch or a rash suspicious of dermatitis herpetiformis should undergo serological screening
19	Royal College of Paediatrics and Child Health	Statement 1	Symptoms listed are not exclusive, and should include : • idiopathic short stature • Constipation • Dental enamel defects • Osteoporosis / pathological fractures • Delayed menarche

ID	Stakeholder	Statement number	Comments[1]
			• Autoimmune liver disease/ Unexplained liver disease • Unexplained raised transaminases without known liver disease • Dermatitis herpetiformis • Also consider: JCA, epilepsy, with associated intracranial calcification, unexplained neurological problems (palsies, neuropathies, migraine). • Recurrent aphthous stomatitis https://www.coeliac.org.uk/document-library/122-bspghan/
20	British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Statement 1	Some paediatric indications, such as constipation, are extremely common. Unlike type 1 diabetes, it will be difficult to get accurate denominator data. It is likely that screening in diabetes will be more complete, as this will take place in secondary care. The majority of missed cases are likely never considered for referral because of the relative infrequency of classic coeliac disease and the variable manifestations of non-classic disease.
21	Diabetes UK	Statement 1	This section of Statement 1 states that, “A serological test should be offered to people with Type 1 diabetes, at diagnosis”. This should be altered to read instead that, “A serological test should be offered to people with Type 1 diabetes, both at diagnosis and at regular intervals after diagnosis”. People with Type 1 diabetes should be required to undergo serological screening for coeliac disease at regular and appropriate intervals. This quality statement should, moreover, specify a timeframe for repeat serological testing at regular intervals in addition to at the point of diagnosis of Type 1 diabetes. This is because some people with Type 1 diabetes find that it is only after starting to administer insulin that the symptoms of coeliac disease become noticeable. Some people with Type 1 diabetes have a ‘silent’ form of coeliac disease, which means no symptoms are apparent and it is only diagnosed by screening. The low diagnostic rate and the fact that many people are asymptomatic, combined with the higher rates of coeliac disease amongst people with Type 1 diabetes makes regular serological testing extremely important for them.
22	Thermo Fisher Scientific	Statement 1	We noticed that the outcome measures defined in Quality Statements 1 and 2 is identical (“Rate of diagnosis of coeliac disease”) – please see pages 9 and 13. As: a. Quality Statement 1 recommends serological testing for people at increased risk of developing coeliac disease, or with symptoms indicative of this condition, and b. Quality Statement 2 suggests referring people with positive serological results to a specialist for further investigations and diagnosis confirmation,

ID	Stakeholder	Statement number	Comments[1]
			we are convinced that different definitions should be associated to the outcome measures of the two Quality Statements, in order to avoid confusion. Therefore, we suggest changing the definition of the outcome associated to the Quality Statement 1 as follows: “Rate of suspected diagnosis of coeliac disease”.
23	British Society of Gastroenterology	Statement 1	Although the aim to seek serological testing in all patients presenting with irritable bowel syndrome is stated it may be felt that this is not given sufficient prominence. In adult practice most new diagnoses of CD will be made in patients presenting with anaemia or non-specific/IBS symptoms. At present many patients with IBS-like symptoms do not get tested for CD serology. The guidance given is correct but may not be “loud” enough to change practice.
24	Alder Hey Children’s NHS Foundation Trust	Statement 1	The Consultation Document omits significant advances made in recognising that gluten hypersensitivity, autoimmune pathology and toxicity results in CNS damage which involves the cerebellum and the brainstem + the Neurovestibular pathways. In order that Quality of Service is improved for patients in the UK (I suggest) that patients with coeliac disease are screened for neurological symptoms and signs and patients with ataxia and balance problems are screened for Coeliac Disease In the NHS Trust I was employed in before ie:- Sheffield NHS Teaching Hospital NHS Trust ... The Consultant Neurologist Prof Marios Hadjivassiliou and I was often dealing with patients with balance difficulties and ataxia as a result of Gluten (and Coeliac disease).
25	Royal College of Paediatrics and Child Health	Statement 2	Guideline recommends referral to a ‘specialist’. For children specialist needs to be defined. Is this someone who can endoscopic biopsies or does it include general paediatrician?
26	British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Statement 2	Positive serological test - The availability of EMA testing (and DGP) is patchy across the country. The unavailability of EMA testing means that the BSPGHAN serology based testing is potentially compromised, and a second TTG is relied on. More specific guidance from NICE on the testing that should be available would be helpful in improving diagnostic capability for less clear cut cases.
27	British Society of Gastroenterology	Statement 2 – Question 5	Timely investigation is appropriate. A delay of up to 6 weeks for endoscopic confirmation is reasonable as the condition is not immediately life-threatening. Longer periods of delay are no longer accepted for most specified GI conditions however and this seems a very reasonable and achievable target.
28	Coeliac UK	Statement 2 – Question 5	Securing a diagnosis of coeliac disease can take many years and on average it takes 13 years for patients to secure a diagnosis [4]. This delay results in continuing symptoms and an increased risk of complications. A delay in referral

ID	Stakeholder	Statement number	Comments[1]
			for endoscopy may result in some patients commencing the gluten-free diet in an attempt to alleviate symptoms. It is therefore vitally important that referral times for endoscopic intestinal biopsy, or diagnosis by a paediatric gastroenterologist for children, are carried out within a maximum of 6 weeks from referral. While a maximum of 6 weeks for referral for endoscopy or diagnosis by a paediatric gastroenterologist may be acceptable for most patients, prioritisation of referral to 2 weeks for individuals presenting with severe symptoms is recommended. [4] Gray AM & Papanicolas IN (2010) Impact of symptoms on quality of life before and after diagnosis of coeliac disease: results from a UK population survey. BMC Health Serv Res 10: 105. doi:10.1186/1472-6963-10-105
29	Royal College of Paediatrics and Child Health	Statement 2 – Question 5	Q5 asks if 6 weeks reasonable for timescale from referral to intestinal biopsy, given that gluten in diet should continue till then. For children, especially those younger or more symptomatic, parents would be reluctant to wait this long if told serology suggests Coeliac very likely. Medically also a small child who is symptomatic and has weight loss shouldn't have to wait 6 weeks. We feel that such cases should have the biopsy within 2 weeks.
30	Royal College of GPs	Statement 2 – Question 5	The endoscopic intestinal biopsy should be carried out within 6 weeks of referral to ensure that people have a time limit for continuing with a gluten-containing diet as some may try this gluten free. Endoscopies of this type should be treated/classed as urgent and available through choose and book so patients can choose the shortest waiting time and/ or the most convenient hospital. Many will go switch to a gluten-free diet the day after their endoscopy was done, as they will not see the point of waiting for the results of the biopsies to come back. The result should be sent directly back to them within 4 weeks.
31	British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Statement 2 – Question 5	Obtaining a biopsy within 6 weeks is going to present some challenges for paediatric gastroenterology in parts of the country. It might be helpful to differentiate between persons with classic coeliac disease manifesting with substantial symptoms and those with less clear symptomatology (eg positive serology in newly diagnosed diabetic).
32	Coeliac UK	Statement 3	Equality and diversity considerations - Quality statement 3 recommended that healthcare professionals provide information about gluten-free substitutes. Healthcare professionals should be aware of the increased cost and variable availability of these foods. Gluten-free substitute foods are not readily available to purchase in budget supermarkets and corner shops [5, 6], where these foods are available to buy, they are 3-4 times more expensive than their gluten containing equivalents [5, 6]. Healthcare professionals should therefore consider this when advising patients on low or fixed incomes and those with poor mobility and limited transport options. [5] Singh, J. & Whelan, K. (2011). Limited availability and higher cost of gluten-free foods. Journal of Human Nutrition

ID	Stakeholder	Statement number	Comments[1]
			and Dietetics, 24, 479-486. [6] Burden, M., et al., Cost and availability of gluten-free food in the UK: in store and online. Postgrad Med J, 2015. 91(1081): p. 622-6.
33	British Society of Gastroenterology	Statement 3	Gluten free diet is the usual treatment but it is incorrect to say it is “the only” treatment for CD as some patients with resistant/intractable disease may need additional immunomodulatory therapy. This is very rare and applies only to specialist practice but the statements should be factually correct
34	Department of Health	Statement 3	Rationale (p16). “A gluten free diet is the only treatment for coeliac disease”. I think this would read better as “A gluten free diet is the only way to manage coeliac disease”, as changing the diet is not a treatment but aids the management of the condition, following a GF diet will not treat coeliac disease. Definition (p18). Suggest that a new bullet point to appear first on the list: “information on which types of food are naturally gluten-free” I think this gives a stronger message that patients do not have to eat replacement GF foods to maintain a healthy diet.
35	Coeliac UK	Statement 4	Having a statement requiring provision of information alone about the gluten-free foods available on prescription is not enough to address the inequality in provision of gluten-free food on prescription across England. There is variation in the amount and type of gluten-free food available on prescription depending on the policy implemented by the local clinical commissioning group (CCG) in England. Currently, 30% of CCGs have restricted or completely removed access to Advisory Committee on Borderline Substances (ACBS) approved products on prescription (as mentioned in the consultation documentation under Definition of Terms on page 20). The quality standard should address this potential for variation in provision by having a mandate for a minimum level of support which should be provided by all CCGs.
36	Coeliac UK	Statement 4	Quality measures/ structure - Consideration should also be given to a centralised scheme for the provision of gluten-free food which would reduce cost inefficiencies resulting from local administration/procurement and would provide a national standard of care for patients with coeliac disease.
37	Coeliac UK	Statement 4	What the quality statement means for commissioners - If gluten-free prescribing continues to be agreed at local level, commissioners should consider options to FP10 prescribing such as pharmacy led supply of gluten-free food when local policies for prescribing gluten-free food are reviewed.
38	Coeliac UK	Statement 4	Definitions of terms used in this quality statement - Gluten-free foods approved for prescription can be found in the British National Formulary within the section Foods for special diets in Appendix 2: Borderline substances of the British National Formulary and the British National Formulary for children.
39	Royal Pharmaceutical Society	Statement 4	Pharmacist and pharmacy teams are suitably trained on the availability of gluten-free foods available on prescriptions. Pharmacist are able to identify patients with coeliac disease and often provide consultations to inform patients or carers’ of gluten-free foods available on prescription according to the patients’ individual needs.
40	Royal College of GPs	Statement 4	A number of general practices are losing funding for medicine managers. These individuals received additional training and support to advise/improve prescribing and conduct audits for cost saving. Also a number of practices

ID	Stakeholder	Statement number	Comments[1]
			have relatively poor support from medicine optimisation pharmacists. The RCGP feels that the standard could be more specific to nominate community pharmacists to provide information about gluten free products on prescription. There may not be the resource or expertise within general practice to provide this.
41	British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Statement 4	The impact of the recent guidelines has been the withdrawal of gluten free prescription foods by some CCG's, as it was not specifically mandated. The cost of supermarket gluten free foods provides significant economic challenge for less well-off families (over a year, loss of gluten free prescription would have a similar financial impact on a family to the global removal of NHS dentistry, and likely similar long term impact on health equality). It is really important that the commitment to gluten free prescription is mandated by NICE.
42	British Society of Gastroenterology	Statement 4	There is quite a lot of attention given to specified gluten free foods that are expensive and may (or may not) be obtained on prescription. This is reasonable but misses the opportunity to balance this "problem" with the fact that a nutritionally complete, gastronomically satisfying diet can be composed quite easily from naturally gluten free items. This need not be expensive and should be accessible even to those with few financial resources given the right dietetic support
43	Department of Health	Statement 4	General comments on "Rationale" (p19) - Whilst some GF equivalents are still more expensive many now have a smaller price difference, for example pasta, flour and biscuits. - Many CCGs already publish local formularies for what types and quantities of GF foods can be prescribed to patients. Many have made recent changes following consultations. General comments on "Equality and diversity considerations" (p21) - Suggest that the sentence "…offer additional support…" is changed to "….offer additional appropriate support…" it is important that patients receive advice on which products they need on prescription to maintain a healthy diet.
44	British Specialist Nutrition Association (BSNA)	Statement 4 – Question 6	Adherence to the gluten-free diet is greatly improved through prescriptions for staple gluten-free foods and regular follow-up and support.[1] Every patient with coeliac disease will be advised on the availability of gluten-free foods on prescription during their initial dietetic consultation. However, in a minority of clinical commissioning group (CCG) areas, the provision of gluten-free foods on prescription has been reduced, or even removed, thereby removing a key support mechanism for this patient group. The impact of such changes in policy has been examined and the cost to patients calculated as being approximately £36 per month. [2] This would suggest the potential for a health inequality amongst those patients who fall within a lower socio-economic group and those who have limited mobility or are elderly, as they may struggle to access retail gluten-free products available in supermarkets. In addition, it appears there is no proposal to monitor the impact of policy changes to gluten-free prescriptions and the potential health inequality created. [1] Hall et al., (2013) Intentional and inadvertent non-adherence in adult coeliac disease: a cross-sectional survey, Appetite Vol 68; 56-62

ID	Stakeholder	Statement number	Comments[1]
			[2] Kurien M et al. (2016) Does restriction of gluten-free prescription foods affect people with coeliac disease? Poster session presented at: Coeliac UK Research Conference, 9-10 March 2016; London, UK.
45	Coeliac UK	Statement 4 – Question 6	Coeliac UK provides information about national prescribing guidelines, the Advisory Committee on Borderline Substances (ACBS) list of approved foods and local gluten-free prescribing policies using a range of communication channels, both hard copy and electronic via direct mailings, our website and Helpline. Information provided at local CCG regarding prescribing policies at CCG level can be limited.
46	Coeliac UK	Statement 5	Rationale - Quality statement 5 should clarify that the offering of annual review should be initiated once patients are established on the gluten-free diet and that more regular review may be required immediately after diagnosis.
47	Royal Pharmaceutical Society	Statement 5	Pharmacists are well placed to support Quality Statement 5: ‘patients with coeliac Disease are offered annual reviews. Pharmacists routinely review medication with patients to ensure that they get the best use from their medicines, and are appropriate for managing their conditions. Patients are provided with information on the importance of reviewing therapy and will be made aware of the need for referral to their GP.
48	Royal College of Paediatrics and Child Health	Statement 5	This recommends ‘annual review’. The guideline should make clear that for new diagnoses the patient should be reviewed sooner to gauge symptomatic response and to re-educate on diet. There then should be ‘at least’ annual review.
49	Royal College of Paediatrics and Child Health	Statement 5	The data collected will be those who attended for annual review. Some patients default, or persistently default, offered appointments. Will such non-attendance be seen as failings by the specialist service? Perhaps both sets of data should be collected – those offered appointments at least yearly, and those that did attend.
50	British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)	Statement 5	There is probably little benefit in measuring height annually in adult patients.
51	British Society of Gastroenterology	Statement 5	Annual review is desirable and we agree that this should be offered. This will probably be the biggest hurdle to implementation however as it has become policy in very many centres for patients with newly diagnosed CD to get initial dietetic support in the form of one or a small number of consultation(s) and then to be discharged permanently to their GPs. GPs are not well placed to conduct the review suggested and would require extra resources to perform this adequately (better access to dieticians for example). Hospital clinics are able to provide what is needed but are under huge pressure to stop seeing fundamentally well patients.

Registered stakeholders who submitted comments at consultation

- Alder Hey Children’s NHS Foundation Trust
- British Association of Dermatologists
- British Society of Gastroenterology
- British Society of Paediatric Gastroenterology, Hepatology and Nutrition (BSPGHAN)
- British Specialist Nutrition Association (BSNA)
- Coeliac UK
- Department of Health
- Diabetes UK
- HQT Diagnostics
- NHS England
- Royal College of GPs
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal Pharmaceutical Society
- Royal College of Physicians
- Thermo Fisher Scientific