National Institute for Health and Clinical Excellence

Coeliac disease

Scope Consultation Table

14 March – 15 April 2013

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Alliance Healthcare	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	yes	Thank you for your comment.
SH	Alliance Healthcare	2	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	I believe there is an opportunity whereby the pharmacist can support an individual and their carers with regard to the management of Ceoliac disease. Particularly with regard to the adherence to a gluten free diet. It is the pharmacist that will be able to discuss regularly what is available to the patient. The management of the adherence can be in partnership with a dietitian however it is the pharmacist that is more accessible both in distance and with availability to the patient.	Thank you for your comment. Section 4.5.4 of the scope includes review questions around the information education and support people with coeliac disease need to improve adherence to a gluten-free diet. Section 4.5.2 will also cover different strategies on how people with coeliac

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						disease should be monitored and followed-up. However, the implementation of the monitoring and follow-up strategies and who should be delivering them will depend on local service configuration, and hence this is outside the scope of this guideline.
SH	Alliance Healthcare	3	4.3 Management	*Are there any other non-serological tests we need to include (e.g. breath tests, point-of-care tests) in section 4.3.1a?*	We should consider whether diagnostic testing can be undertaken in a focused way within pharmacy. Sufferers will often be visiting their pharmacy on a regular basis for medication either prescribed or OTC for other gastro complaints and be presenting with symptoms. The pharmacist is in a position where they could undertake rapid tests in their consultation room to provide an indicator as to whether a patient is potentially coeliac	Thank you for your comment. The guideline will address the most appropriate test for coeliac disease. If evidence suggests the test should be undertaken in specific settings, this will be considered by the GDG.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Alliance Healthcare	4	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	Yes	Thank you for your comment.
SH	Alliance Healthcare	5	4.5 Review questions	*Are there any additional review questions that should be covered by the guideline?*	No	Thank you for your comment.
SH	Alliance Healthcare	6	Any other comments	*Please insert the section number that your comment relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.*	General The pharmacist can provide a support and a service to a patient that can be more immediate than other healthcare practitioners. We believe that the pharmacist can play a part in both identifying sufferers and steering them towards their GP as well as being a partner with the management and education of treatment of the condition particularly with regard to adherence to a gluten free diet.	Thank you for your comment. Section 4.5.2 will cover different strategies on how people with coeliac disease should be monitored and followed-up. However, the implementation of the monitoring and follow-up strategies and who should be delivering them will depend on local service

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						configuration, and hence this is outside the scope of this guideline.
SH	Association of children's diabetes clinicians	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	Yes. We are keen that the guidelines group review the evidence on 1. Need to screen children with Type 1 diabetes for celiac disease 2. When to screen ? at diagnosis or subsequently 3. Frequency of screening 4. Benefits to screening	Thank you for your comment. Consideration of active case finding in those at high risk because of co-existing conditions (which includes diabetes) is covered within section 4.5.1. Population based screening is not within the scope as population screening considerations fall within the remit of the National Screening Committee.
SH	Association of children's diabetes clinicians	2	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h)*	The benefits of screening asymptomatic children with diabetes needs review. Majority of Paediatric diabetologists screen at diagnosis and annually. We will be interested in the evidence for and against this practise. Who should be referred for biopsy? What do you do with children who are biopsy negative with positive serological tests. What about children who are	Thank you for your comments. The question of whether active case finding should be

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				appropriate and correct?	biopsy positive but asymptomatic and see no benefit on gluten free diet? What is the risk of long term complications if compliance is poor? I think efficacy of a gluten free diet needs to be covered	implemented in people with co-existing conditions that are associated with an increased risk of coeliac disease is addressed in review question 4.5.1.b). Diagnosis and management is covered within 4.3.1. Particular recommendations for subgroups will be addressed if indicated by the evidence reviews. Reviewing the efficacy of a gluten free diet was considered by stakeholders at the Stakeholder workshop to be less of a priority than the other areas covered.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Association of children's diabetes clinicians	3	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	Seem ok	Thank you for your comment.
SH	Association of children's diabetes clinicians	4	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	yes	Thank you for your comment.
SH	British Specialist Nutrition Association	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	It is important for the draft scope to consider patient populations with a strong family history of coeliac disease and how healthcare professionals can establish whether such a history exists. It should also consider how those with no obvious symptoms or associated conditions can best be reached in the clinical setting (see section 4.3 a) to help boost diagnosis rates.	Thank you for your comment. Groups that will be covered include people considered to be at high risk of coeliac disease which will take into account those with a first-degree family history of the disease. Population screening considerations would fall within the remit of the National Screening Committee. As

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						population screening will not be covered, testing people with no associated symptoms or conditions will not be addressed.
SH	British Specialist Nutrition Association	2	4.1 Population	*Are there any specific subgroups that are managed differently?*	Some patient sub-groups may access clinically led services delivered by pharmacists or specialist dietitians. Such groups can include hard to reach individuals who are better reached in the community setting.	Thank you for your comment. Specific subgroups in whom the investigation and management of coeliac disease is known to be different is covered by the guideline (section 4.1.1.d).
SH	British Specialist Nutrition Association	3	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	4.3.1 a) the scope should also consider blood tests for transglutaminase antibodies and their potential role in improving diagnosis rates. Recent case studies have illustrated the utility of such tests in diagnosing more patients. See for example: http://tinyurl.com/cmscygs	Thank you for your comments. These tests will be covered in review questions 4.5.1.c) & d).

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					4.3.1 The scope should include an assessment of the benefits associated with clinically led service delivery in a range of settings, including the acute setting and community pharmacy. 4.3.1 d) the scope should consider what information primary care professionals have at their disposal regarding clinical pathways and referrals to clinical and/or community based services. 4.3.1 g) The scope should consider the role played by patient groups in providing prescribing guidance for healthcare professionals. Coeliac UK has published such guidance which is available on its website, here: http://tinyurl.com/d2nxy88	Section 4.5.1 will cover assessment and testing of coeliac disease. However, the settings for carrying out the assessment and testing are outside the scope of this guideline. The delivery of the service will depend on local service configuration The guideline will cover general principles of care but will not address locally specific professional information needs. NICE will produce an Information for the Public leaflet which will include a section on 'sources of advice and support'
SH	British Specialist Nutrition	4	4.4 Main	*Are the outcomes in*	The scope could also consider contact with community based services, including dietitians and pharmacists as outcome	Thank you for your comment. Section

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Association		outcomes	*section 4.4.appropriate and correct?*	measures, given that current patient access to specialists remains poor (as recognised in the scope).	4.4.c) highlights that contact with healthcare professionals (which includes dietitians and pharmacists) will be considered as an outcome measure**.**
SH	British Specialist Nutrition Association	5	4.5 Review questions	*Are there any additional review questions that should be covered by the guideline?*	The scope should assess the diagnosis and management of coeliac disease from a clinical perspective only, given that clinically led management leads to better patient adherence to treatment and, ultimately, better outcomes. Clinically led services can be delivered through a variety of routes including the acute care setting, community pharmacy and primary care practices. Community based specialist dietitians also offer patients clinically led support in accessible settings, however access is patchy and specialists are often required to cover more than one clinical area of expertise. 4.5.1 The scope does not currently consider what role community based services play in clinically led diagnosis and in commissioning services for patients with suspected or confirmed coeliac disease. In Scotland, for example, NHS Tayside has pioneered a scheme which facilitates much	Thank you for your comments. Contact with healthcare professionals is an identified outcome that will be explored (section 4.4.c). The management of people with coeliac disease is covered in section 4.5.2, This includes different strategies on how people with coeliac disease should be monitored and followed-up.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					greater patient engagement with community pharmacy, reducing pressure on GPs. The suitability of such schemes on a wider basis in England should be included in the scope.	However, the implementation of the monitoring and follow-up strategies and who should be delivering them will depend on local service configuration, and hence outside the scope of this guideline.
					4.5.1 The scope should consider the long term cost savings for the NHS that could be achieved through earlier clinically led diagnosis and management of coeliac disease. Given the financial pressures facing the health service, a cost effectiveness analysis must include a look at the long term projection associated with failing to prevent chronic conditions.	Economic aspects of recommendations will be considered, as highlighted in section 4.6.
					4.5.1 The scope should also consider whether there is sufficient awareness of the condition and/or associated conditions amongst primary care healthcare professionals and how to refer those presenting with symptoms or appropriate family history.	Levels of awareness are outside the scope of the guideline, though recognition, assessment and diagnosis is covered within section 4.3.1.
					4.5.2 The scope should look at the role of community	Information, education and

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					pharmacy in providing information and support (post diagnosis by a clinical specialist) as well as services supported by patient groups, such as Coeliac UK.	support will be covered under section 4.5.4. However, it is outside the scope to address who should be providing such information and education.
					4.5.2 The scope could look at whether barriers to access exist for clinically led primary care services, including pharmacy based support for the management of coeliac disease in rural areas.	Contact with different healthcare professionals is covered as one of the main outcomes to be assessed across the evidence base4 (in section 4.4).
					4.5.2 The scope should consider what inequalities in outcomes between different social groups exist and what societal factors affect adherence to recommended treatment.	Information, education and support is covered in 4.3.1.h) & i). Specific recommendations around subgroups will be identified if supported by

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					4.5.2 The scope should consider what variations exist in the clinically led management of coeliac disease and, in particular, what variations exist between the policies adopted by newly formed Clinical Commissioning Groups. 4.5.2 The scope should question how commissioning can be improved and how alternative models of commissioning could benefit patients.	evidence and GDG discussion. Models of commissioning are outside the scope of the guideline.
SH	Coeliac UK	1	General		No comment	Thank you for your comment.
SH	Diabetes UK	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	Yes, we welcome the inclusion of people with type 1 diabetes.	Thank you for your comment.
SH	Diabetes UK	2	4.1 Population	*Are there any specific subgroups that are managed differently?*	In CG86 it was stated that 'good quality, longitudinal cohort studies are needed to determine whether adherence to a gluten-free diet improves diabetes-related outcomes in adults and children with newly-diagnosed type 1 diabetes and coeliac disease.' The finding of these studies should be considered in determining whether the scope should be extended to include	Thank you for your comment. The issue about what dietary advice should be given will be addressed by review question 4.5.2.g). If

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					specific dietary advice for people with type 1diabetes.	on searching the evidence it is highlighted that people with type 1 diabetes need different advice this will be discussed by the GDG who will decide if specific recommendations should be made.
SH	Diabetes UK	3	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	Yes, in general terms these issues are appropriate and correct. Specifically, we recommend that the guidelines for conducting serological testing for coeliac disease in people with type 1 diabetes be clarified. We would suggest that guidelines should specify a timeframe for repeat serological testing at regular intervals. The current guidance recommendation that serological testing should be 'offered' is too vague and may mean that people with type 1 diabetes and coeliac disease could be missed.	Thank you for your comment. Guidance on serological testing will be addressed by review questions 4.5.1. c) & d). If on searching the evidence it is highlighted that people with type 1 diabetes require a different approach this will be discussed by the GDG who will decide if specific recommendations should be made.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						If the evidence enables the GDG to specify a timeframe for testing then recommendations will be made.
SH	Diabetes UK	4	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	*4.4 c) Access to healthcare professionals* Need to ensure appropriate levels of access are always available. For example, it has been reported that people have had difficulty accessing dietetic input due to limited resources.	Thank you for your comment. The term contact, rather than access was chosen as a desired outcome, recognising that this is a potential marker of both access/availability of services and also ongoing attendance /recognition of benefit.
SH	Diabetes UK	5	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	In response to 4.5.1 b), active case finding should definitely be implemented, given the high prevalence of people with coeliac disease and type 1diabetes, the low diagnostic rate and the fact that many people are asymptomatic. We would suggest that clear guidelines (in the form of a flow diagram) be	Thank you for your comment. This question will address whether case finding should be

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					implemented to ensure people with type 1 diabetes are screened for coeliac disease at regular and appropriate intervals. Specific guidelines are required for these tests as opposed to current guidance, stating that the tests should be 'offered'.	implemented, looking at the evidence available, recognising both risks and benefits.
SH	Diabetes UK	6	Any other comments	*Please insert the section number that your comment relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.*	*4.3.2 (f): Management of co-existing conditions that are associated with coeliac disease* It has been stated by a member of our Council of Healthcare Professionals that people with type 1 diabetes and coeliac disease can have difficulty managing their blood glucose control because some gluten free foods are low in fibre. Given also that the majority of people with type 1 diabetes carbohydrate count, and gluten containing foods are predominantly rich sources of carbohydrate, we would suggest that the scope be extended to look specifically at dietary management in type 1diabetes.	Thank you for your comment. There is the potential to look at the subgroup of the population with diabetes in a number of areas within the guideline and may be covered in sections 4.3.1.h) & i) and 4.5.2.g).
SH	Expert Patients Programme Community Interest Company	1	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	Within the outcomes there needs to be provision for an integrated approach to self-management skills. Where the patient is activated to self-manage effectively and work in partnership with the clinician. Where the clinician is skilled to work with the patient to encourage and support active self-management. With both working within patient-centred services that encourage and support active self-management. Through this, holistic approach people living with long-term health conditions (Coeliac Disease) become central to their care, which effectively 'puts patients in the heart of the NHS'.	Thank you for your comment. Supporting self management will be addressed in sections 4.3.1.h) & i) and review question 4.5.4.o)
SH	Expert Patients	2	Any other	*Please insert*	General Comment: The provision for an integrated approach	Thank you for your

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	Programme Community Interest Company		comments	*the section number that your comment relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.*	to self-management skills. Where the patient is activated to self-manage effectively and work in partnership with the clinician. Where the clinician is skilled to work with the patient to encourage and support active self-management. With both working within patient-centred services that encourage and support active self-management. Through this, holistic approach people living with long-term health conditions (Coeliac Disease) become central to their care, which effectively 'puts patients in the heart of the NHS'. This approach not only supports self-management and listens to the patient's needs, as well as improving relationships, but it has the potential to significantly increase cost efficiency. If a patient is activated, met by positive and supportive clinicians and offered pathways, services and tools which are designed in response to patient's needs, the potential for lasting change is great.	comment. The guideline will have a specific focus on information education and support for people with coeliac disease and their family members or carers.
SH	Medicines and Healthcare Products Regulatory Agency	1	General		No Comment	Thank you for your comment.
SH	NCC-WCH (on behalf of GDG for Diabetes in Children and Young People)	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	Yes 4.1.1c includes children and young people with type 1 diabetes and high risk of coeliac disease.	Thank you for your comment.
SH	NCC-WCH (on behalf of GDG	2	4.3	*Are the key issues to be*	No. 4.3.1.a implies that it is only important to diagnose coeliac disease in people "with presenting symptoms and signs"	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
	for Diabetes in Children and Young People)		Management	*covered in section 4.3.1(a-h) appropriate and correct?*	suggestive of coeliac disease whereas many children and young people with diabetes have few, if any symptoms.	The question around whether or not active case finding should be implemented in people with co-existing conditions at high risk of coeliac disease is covered in 4.5.1.b). Section 4.5.1 makes it clear that the guideline will address the recognition, assessment and diagnosis of people with co-existing conditions who are at high risk of developing coeliac disease.
SH	NCC-WCH (on behalf of GDG for Diabetes in Children and Young People)	3	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	Yes, although the additional burden of a gluten-free diet on children and young people with diabetes should be considered, especially if they are asymptomatic and detected on screening. (4.4.g & h)	Thank you for your comment. Health related quality of life is included as an outcome measure and will address this burden to some extent. Considerations of the

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						"risks" of case finding will also be addressed within 4.5.1.
SH	NCC-WCH (on behalf of GDG for Diabetes in Children and Young People)	4	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	Yes. In particular 4.5.1.b regarding case-finding in high risk groups.	Thank you for your comment.
SH	NCC-WCH (on behalf of GDG for Diabetes in Children and Young People)	5	Any other comments	*Please insert the section number that your comment relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.*	It is very important that current guidance regarding screening for coeliac disease in Type 1 diabetes is reconsidered. The current guidance of a single test at diagnosis is at variance from that initially included in the NICE 2004 Diabetes in Children and Young People guidance; from the National Diabetes Audit schedule; from the Best Practice Tariff for Diabetes and from the clinical experience of paediatric diabetologists in that coeliac disease (including symptomatic disease) can develop after diagnosis where there has been previously negative serology. A screening approach reliant on HLA testing in the first instance as proposed by BSPGHAN 2013 would be expensive and unhelpful in type 1 diabetes where the associated HLA status is common to both coeliac disease and type 1 diabetes. However a tissue transglutaminase antibody (TTG) screen at diagnosis and then at intervals of 3-5years, as has been proposed in the original Type 1 guidance and BSPGHAN would detect later-onset disease. This would be important for detection of unrecognised symptomatic patients and also, if it could be shown in the scope that there was	Thank you for your comment. Case finding in people with co-existing conditions at an increased risk of coeliac disease is covered within the guideline (section 4.5.1.b).

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					clinical benefit, in detecting asymptomatic individuals (4.5.1.e).	
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	yes	Thank you for your comment.
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	2	4.1 Population	*Are there any specific subgroups that are managed differently?*	Only possibly in terms of screening: we note and appreciate comments 4.1.1.c and 4.5.1b and would like to stress the importance to the type 1 diabetes guideline of understanding the evidence of need for, cost effectiveness of and optimum frequency of screening adults with type 1 diabetes for coeliac disease. 4.1.1.c We would like to suggest adding explicit mention of "autoimmune diseases including type 1 diabetes" to this statement	People with autoimmune conditions (including diabetes and other conditions) are highlighted within section 3.1 d). The list of conditions in 4.1.1.c) has been updated to make this more explicit. Inclusion of this group in 4.5.1.b) is implicit.
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	3	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	4.3.1 – there is a high index of suspicion in people with other autoimmune conditions like type 1 diabetes and we would like to see this explicitly mentioned in 4.3.1.(a) 4.3.1 (a), 4.3.1.(d) and 4.3.1.(.h). Coeliac disease is often considered by clinicians as a contributor to poor glycaemic control, perhaps particularly with hypoglycaemia or at least	Thank you for your comment. The question around whether or not active case finding should be implemented in people with co-

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					wide glycaemic variability, in people with type 1 diabetes. We would be very interested in evidence relating to the presence of markers of coeliac disease in people with unstable type 1 diabetes who do not have gastrointestinal symptoms. If there is evidence of benefit for regular screening of all adults with type 1 diabetes for coeliac disease, this is less of an issue but if not, the detection rate in those with unstable glycaemic control would be of great interest to us. Likewise, we would also welcome a review of the evidence for screening for coeliac disease in people with type 1 diabetes and neuropathy with no gastro-intestinal symptoms. (4.3.1.a)	existing conditions at high risk of coeliac disease is covered in 4.5.1.b). Section 4.5.1 makes it clear that the guideline will address the recognition, assessment and diagnosis of people with co-existing conditions who are at high risk of developing coeliac disease.
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	5	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	We would be interested in evidence relating to improved diabetes control in adults with type 1 diabetes associated with the diagnosis and treatment of coincident coeliac disease In other words, in patients with both conditions, we would regard reduced glycated haemoglobin and/or less hypoglycaemia as important outcomes for the treatment of the coeliac disease.	Thank you for your comment. Consideration of the impact of coeliac disease management on diabetes outcomes is likely to be part of 4.5.1.b), when investigating whether active case finding should be implemented.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	6	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	4.5.1.b As per comment above we would welcome specific mention of autoimmune diseases such as type 1 diabetes.	Thank you for your comment. People with autoimmune conditions (including diabetes and other conditions) are highlighted within section 3.1.d) The list of conditions in 4.1.1.c) has been updated to make this more explicit. Inclusion of this group in 4.5.1.b) is implicit.
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	7	4.5 Review questions	*Are there any additional review questions that should be covered by the guideline?*	'Is there evidence of correlation between non-adherence in one condition and non-adherence in the other?'	Thank you for your comment. This is outside the scope of the guideline.
SH	NICE (clinical guideline committee, Type 1 diabetes in adults)	8	Any other comments	*Please insert the section number that your comment relates to (e.g*	General: Our comments are intended to highlight the importance of clear guidance on the need for, and frequency of, screening in our constituency. Your scope explicitly recognises the link to	Thank you for your comments.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				3.1.1), or state 'general' if your comment is in relation to the whole document.	adults (and indeed children) with type 1 diabetes and our comments are intended merely to indicate the areas of most concern to us. Our experience of current practice indicates that services for adults with type 1 diabetes do not have consistent protocols for screening for coeliac disease and reiterating the current recommendations, modified by any new evidence, will be valuable.	
SH	Primary Care Society for Gastroenterology	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	Yes	Thank you for your comment.
SH	Primary Care Society for Gastroenterology	2	4.1 Population	*Are there any specific subgroups that are managed differently?*	No	Thank you for your comment.
SH	Primary Care Society for Gastroenterology	3	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	4.3.1.a Diagnostic criteria in children – the need for endoscopy if tTG serology positive and HLA DQ2 and DQ8 present 4.3.1.b Indications for endoscopic referral in children (as above)	Thank you for your comments. Recognition, assessment and diagnosis will provide different recommendations for

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						subgroups (including children) if the need for this is suggested by the evidence and GDG discussion.
					4.3.1.d Should hyposplenism and flu and pneumococcal immunisation be considered?	Participants at the stakeholder workshop felt that immunisation was not an area of significant controversy and did not need to be specifically mentioned. Hyposplenism is covered in this section (4.3.1.e).
					4.3.1.d Where should monitoring and follow-up take place – primary or secondary care? What are the measures that should be used in monitoring the follow-up of people with coeliac disease? What is the role of QoL measures in follow-up?	Follow up strategies is addressed in 4.3.1.e) but the level to which these areas can be detailed will be dependent on the availability and strength of evidence available

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					4.3.1.e Commonest cause of non-responsive and refractory coeliac disease is non-adherence to a gluten-free diet or trace contamination in the diet with gluten, will this be considered as the likely causes? 4.3.1.g Prescribing gluten-free products	The list of conditions in 4.3.1.f) is illustrative of potential causes of non-responsive and refractory disease. 4.3.1.i) will address information, education and support to improve adherence to a gluten-free diet. Section 4.3.1.h) does not address prescribing of gluten-free products although information, education and support to improve adherence to a gluten-free diet is within the scope (section 4.3.1.i).
SH	Primary Care Society for Gastroenterology	4	4.3 Management	*Are there any other non-serological tests we need to include (e.g. breath tests,*	No	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				point-of-care tests) in section 4.3.1a?		
SH	Primary Care Society for Gastroenterology	5	4.4 Main outcomes	*Are the outcomes in section 4.4.appropriate and correct?*	4.4.f Is serological response an adequate measure for response to treatment?	Thank you for your comment. This outcome was added in response to feedback at the scoping workshop.
SH	Primary Care Society for Gastroenterology	6	4.5 Review questions	*Are the review questions in section 4.5 appropriate and correct?*	We feel that there should be an indication of the follow-up strategies specific for community care as many of these people will be followed-up in the community after the diagnosis has been made.	Section 4.5.2 will also cover different strategies on how people with coeliac disease should be monitored and followed-up. However, the implementation of the monitoring and follow-up strategies and who should be delivering them will depend on local service configuration, and hence outside the scope of this guideline.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Primary Care Society for Gastroenterology	7	4.5 Review questions	*Are there any additional review questions that should be covered by the guideline?*	Review of people with coeliac disease must include follow-up by an appropriately trained dietitian who ideally should be based in the community	Thank you for your comment. Section 4.5.2 will cover different strategies on how people with coeliac disease should be monitored and followed-up. However, the implementation of the monitoring and follow-up strategies and who should be delivering them will depend on local service configuration, and hence outside the scope of this guideline.
SH	Primary Care Society for Gastroenterology	8	Any other comments	*Please insert the section number that your comment*	General – advice on how to improve adherence to a gluten-free diet is an important aspect of the care of people with coeliac disease	Thank you for your comment. Information, education and

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.		support to improve adherence to a gluten free diet is within the scope (section 4.3.1.i).
SH	RCGP	1	4.3.2		In section 4.3.2 Clinical issues that will not be covered the draft scope includes: *d) The role of nutritional supplements in the dietary management of people with coeliac disease.* Coeliac disease may result in significant deficiency of a variety of micronutrients such as zinc and other metals important in enzyme activity. General practitioners are often asked about multivitamin and mineral supplements. I suggest that the draft scope should specifically consider micronutrient deficiency incidence, symptoms, diagnosis, treatment and monitoring under 4.3.1	Thank you for your comment. Section.4.3.1.e) covers how people with coeliac disease should be monitored, particularly those at risk of developing complications. Complications will include nutritional deficiencies. Dietary management advice is covered in section 4.5.2.g).
SH	RCN	1	4.1 Population	*Are there any specific subgroups that are managed differently?*	Support for those who have learning difficulties	Thank you for your comment. Specific subgroups in whom the

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						investigation and management of coeliac disease is known to be different will be covered by the guideline. If on searching the evidence it is highlighted that people with learning difficulties are a subgroup that need to be managed differently, this will be discussed by the GDG who will decide if specific recommendations should be made. Please note that the Patient experience guideline (CG138) will support this guideline.
SH	RCN	2	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h)*	Seems appropriate	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				appropriate and correct?		
SH	RCN	3	4.3 Management	*Are there any other non-serological tests we need to include (e.g. breath tests, point-of-care tests) in section 4.3.1a?*	1) Idea for inclusion: How should the risk of osteoporosis be managed for example; frequency of Vitamin D and pathology blood tests, DEXA scans - the BSG guidance on this is now quite dated. 2) Idea for inclusion: the role of oral budesonide in refractory coeliac disease for example; dose and duration for first line management as opposed to oral prednisolone which has a greater side effect profile. 3) Will there be mention of recommended support for those people who have learning difficulties, especially regarding diagnosis and onward management of their coeliac disease?	Thank you for your comments. 1) Monitoring the risk of osteoporosis is covered in section 4.3.1.e), though the ongoing management of osteoporosis is outside the scope of this guideline. 2) The role of corticosteroids in the management of refractory coeliac disease will be addressed (4.3.1.g) **3)** Specific subgroups in whom the investigation and management of coeliac disease is known to be different will be covered by the guideline. If on searching the

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						evidence it is highlighted that people with learning difficulties are a subgroup that need to be managed differently, this will be discussed by the GDG who will decide if specific recommendations should be made. Please note that the Patient experience guideline (CG138) will support this guideline.
SH	RCOG	1	4.1 Population	*Is the population to be covered in section 4.1.1 appropriate and correct?*	We would like to see pregnant women identified as a specific target group	Thank you for suggesting pregnant women as a potential subgroup. We will pay particular attention to all potential subgroups during the evidence reviews, and if supported by

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						robust evidence, the GDG will make specific considerations for recommendations where appropriate.
SH	Royal College of Paediatrics and Child Health	1	General		No Comment	Thank you for your comment.
SH	Royal Liverpool University Hospital	1	4.3 Management	*Are the key issues to be covered in section 4.3.1(a-h) appropriate and correct?*	4.3.1.b. Is it appropriate to include a comment regarding the length of time and quantity of gluten that should be consumed before endoscopic biopsy?	Thank you for your comment. The guideline will cover indications for referral for biopsy but not the procedure itself. Section 4.5.4 addresses the information needed before serological testing to ensure that test results are as accurate as possible.
SH	Royal Liverpool University Hospital	2	Any other comments	*Please insert the section number that your comment*	4.3.2.d Should the role of calcium supplements in the dietary management of coeliac disease be included? Particularly in the light of recent research suggesting increased cardiovascular mortality (Byberg et al .British Medical Journal	Thank you for your comment. Complications will include nutritional

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole document.	13 February 2013). General. Recent research from Bristol presented at the Coeliac UK research conference last month showed that there was increased diagnosis of coeliac disease from higher socio economic groups should this be addressed in the guidelines?	deficiencies. Dietary management advice is covered in section 4.5.2.g). Section 4.3.1.e) covers how people with coeliac disease should be monitored, particularly those at risk of developing complications. We acknowledge that this subgroup is potentially a high risk group and will be addressed in section 4.5.1 b).
SH	Society and College of Radiographers	1	Any other comments	*Please insert the section number that your comment relates to (e.g 3.1.1), or state 'general' if your comment is in relation to the whole*	The SCoR is pleased that fragility fracture and osteoporosis is discussed in the document. Often younger patients with coeliac disease are unaware of the long term effects on their bone health and some lifestyle adjustments may prevent fracture s in later life.	Thank you for your comment.

Type	Stakeholder	Order No	Section No	Notes	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
				document.		
SH	UK National Screening Committee	1	General		The UK National Screening Committee does not have any comments to make on the draft scope. The Committee is in the process of reviewing the evidence relating to population screening and will share this with the NICE GDG in due course.	Thank you for your comment.

.