National Institute for Health and Care Excellence

Myeloma
Scope Consultation Table
10 December 2013 – 21 January 2014

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
18	SH	Association for Palliative Medicine	1	3.1.d	Will the GDG fairly represent the Afro-Caribbean population?	While the incidence of myeloma is higher in the Afro-Caribbean population, the management of their disease is no different from other patient populations. We therefore do not feel that they need to be specified as a sub-group. GDG members are recruited via an open advert and people from all communities and ethnic groups are welcome to apply. Relevant patient groups are also encouraged to register as stakeholders.
19	SH	Association for Palliative Medicine	2	3.1.e	As a significant minority (1%) die in first 3 months, early referral to palliative care is essential	This comment is a recommendation and it is therefore not appropriate to include it in the contextual information of 3.1.
34	SH	Association for Palliative Medicine	3	3.2.d	The list should also include managements for treatment adverse –effects (specifically mucositis and peripheral neuropathy); and psychosocial aspects; family concerns; financial concerns.	We have included psychosocial support (and believe this adequately covers the other points you have raised).
35	SH	Association for Palliative Medicine	4	3.2.e	"supportive and palliative care practitioners" – supportive may need defining in this context as it is not usually recognised as a specific healthcare intervention	This text has been removed as they are part of the core MDT.
44	SH	Association for	5	4.2	Independent hospices should also be included here	The guideline will only apply to

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Palliative Medicine				independent hospices that receive part or all of their funding from the NHS.
55	SH	Association for Palliative Medicine	6	4.3.1.a	The importance of holistic needs assessment should be emphasised	There is a requirement as part of the cancer peer review standards in England to perform holistic needs assessment on all cancer patients. This question will look at specific information and support needs of patients with myeloma.
56	SH	Association for Palliative Medicine	7	4.3.1.k	This list should also include interventional radiology as well as orthopaedic surgery for vertebroplasty and spinal fixation, decompression.	These are interventions that may be encompassed by the management of spinal bone disease and will be discussed by the GDG when they finalise the review questions during their first few meetings.
57	SH	Association for Palliative Medicine	8	4.3.1.o	Follow-up models – should look for evidence for shared care follow-up with haematology and supportive/palliative care	The guideline will explore the evidence base on the best form of follow up in myeloma and make appropriate recommendations based on this evidence.
61	SH	Association for Palliative Medicine	9	4.4	Should specifically include pain and other symptoms, as well as globally mentioning QOL and PROs	This is not intended to be an exhaustive list. The GDG can add to this if they wish.
78	SH	Association for Palliative Medicine	10	4.5.p	Managing bone disease - Must include vertebroplasty / kyphoplasty	This will be discussed by the GDG when they finalise the review questions during their first few meetings.
80	SH	Association for Palliative Medicine	11	4.5.t	Follow-up protocols - Should include shared care with supportive/palliative care	The guideline will examine the evidence base for this question and make appropriate recommendations based on this evidence.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
28	SH	Binding Site Group Ltd	1	3.2 a	Due to 38% of patients being diagnosed in secondary care more emphasis is needed for improved education in primary care to improve detection rates for earlier diagnosis which can improve patient outcomes and potentially cost saving. Clear guidance and sensitive diagnostic protocols need to be available to primary care	Diagnosis of myeloma in primary care and the education of primary care professionals are outside the scope of this guideline and therefore it would not be appropriate to include this information in the background. The Referral for Suspected Cancer guideline (NICE CG27, 2005), is currently being updated. It has already been included in the list of related NICE guidance in the scope (section 5).
30	SH	Binding Site Group Ltd	2	3.2 b	2003 IMWG guidelines have been repeatedly reviewed and we recommend Ludwig et al International myeloma working group recommendations for global myeloma care Leukemia 2013 1-12 that identifies the minimum requirement for global MM management	The guideline will examine the evidence base on the most effective management of myeloma and make appropriate recommendations based on this evidence.
41	SH	Binding Site Group Ltd	3	4.1.1	Smouldering Multiple Myeloma patients need to be considered	Asymptomatic myeloma is covered in 4.1.1b and 4.3.1.h.
50	SH	Binding Site Group Ltd	4	4.3.1	Risk stratification of MGUS needs to be considered in the section using prognostic indicators	Risk stratification forms part of the management of MGUS which has been explicitly excluded from the scope of this guideline (see section 4.3.2).
52	SH	Binding Site Group Ltd	5	4.3.1 b	Need to ensure this is routine diagnostic services that are considered here. Specialist services are discussed in 4.3.1 c. Diagnosis is only mentioned here diagnostic services cover monitoring of disease, relapse and response to treatment as well as risk stratification and providing prognostic information. These scenarios all need to be considered. There is a requirement for specific guidelines on minimum tests required for diagnosis and management of MM (Ludwig et al 2013) In	Section 4.3.1.b addresses the initial diagnosis of myeloma. The use of diagnostic tests to monitor disease response or in follow up will be discussed by the GDG when they finalise the review questions during their first few meetings.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					addition to this technical limitations of some diagnostic tests needs to be considered and what other assays should be requested in these scenarios e.g. co-migration of IgA with serum protein electrophoresis.	
53	SH	Binding Site Group Ltd	6	4.3.1 g	Risk stratification of high risk versus low risk needs to be considered	This will be discussed by the GDG when they finalise the review questions during their first few meetings.
54	SH	Binding Site Group Ltd	7	4.3.1 o	Frequency of monitoring with diagnostic tests, how often, what tests	The guideline will explore the evidence base on the best form of follow up in myeloma and make appropriate recommendations based on this evidence.
63	SH	Binding Site Group Ltd	8	4.4 a	Consider progression free survival also	We have added progression free survival.
65	SH	Binding Site Group Ltd	9	4.4 k	How is the diagnostic, prognostic and predictive accuracy assessed	We have changed this to read diagnostic accuracy. The GDG will assess this using published evidence.
67	SH	Binding Site Group Ltd	10	4.5	How to identify clearly heterogeneity and variable manifestations during treatment	This is covered by section 4.5.d but may also be addressed in specific treatment related topics.
72	SH	Binding Site Group Ltd	11	4.5 b	Also need to include diagnosed myeloma, asymptomatic myeloma and MGUS	Asymptomatic myeloma and MGUS are captured by the term suspected myeloma but we do not feel it needs to be specified in the question. Diagnosed myeloma is not the focus of this question and therefore not relevant to include.
74	SH	Binding Site Group Ltd	12	4.5 c	Monitoring and prognostic assessment needs to be considered for asymptomatic myeloma, MGUS and monitoring of disease. See 4.3.1 b comments.	Monitoring is covered by section 4.5.u and prognostic assessment is covered by section 4.5.d. The

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						management of MGUS is excluded and asymptomatic myeloma is covered by 4.5.j.
76	SH	Binding Site Group Ltd	13	4.5 h	How to risk stratify high risk patients with asymptomatic multiple myeloma	This will be discussed by the GDG when they finalise the review questions during their first few meetings.
79	SH	Binding Site Group Ltd	14	4.5.r	What markers are used to assess this	The guideline will examine the evidence base for this question and make appropriate recommendations based on this evidence.
2	SH	Department of Health	1	General	Thank you for the opportunity to comment on the draft scope for the above clinical guideline. I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.	Thank you
62	SH	Janssen	1	4.4	We suggest the following outcome measures be added to the list of main outcomes; progression free survival, response rates, and relapse free survival	We have added progression free survival as this was felt to be the most relevant of the outcomes listed.
69	SH	Medtronic Ltd	1	4.5 p	**Review question p) :** As an adjunct to review question p, as these questions guide a systematic review of the literature, it may be worth noting that the IPGs 166 & 12 cited for the vertebral augmentation interventions, balloon kyphoplasty and vertebroplasty have been (to some extent) superceded by NICE TAG 279 with more recent	Thank you for this information.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					published data featured within this TA; published 24th April 2013.	
82	SH	Medtronic Ltd	2	4.6	**Economic Aspects:** From NICE TAG 279, cost per QALY established for both balloon kyphoplasty (BKP) and vertebroplasty (VP) were considered to be at the acceptable end of the cost effective threshold; citing BKP <£8,000 ICER per QALY* VP <£7,000 ICER per QALY; albeit in a different patient population of osteoporotic fractures, but some correlation could be drawn. In addition, MSCC CG 75's costing template considered these interventions to be more cost effective than open surgery or longterm non surgical management. This might be worth considering for this draft clinical guideline	Thank you for this information.
5	SH	Myeloma UK	3	3	We are not sure what is meant by 'radical management' and why this needs to be consistent. This should be clarified on Section 3 of the draft scope.	This text has been amended for clarity.
6	SH	Myeloma UK	4	3	We need a guideline that promotes consistency in terms of high quality treatment and care in myeloma, whilst at the same time allowing flexibility for clinicians to treat myeloma patients according to their individual clinical needs, genetics and preferences.	We agree and hope to achieve consistency of care by producing this guideline. While NICE guidelines provide recommendations on the diagnosis and management of certain conditions, they do not replace clinical judgement. Therefore clinicians would still have flexibility according to the patients individual need and preferences.
13	SH	Myeloma UK	11	3.1 - general	The National Cancer Patient Experience Survey found that half of myeloma patients required at least three consultations with their GP before receiving a diagnosis which is the highest	Diagnosis of myeloma in primary care is outside the scope of this guideline and therefore it would not

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					of all cancers (Lyratzopolous et al 2012).	be appropriate to include this information in the background. The Referral for Suspected Cancer guideline (NICE CG27, 2005), is currently being updated. It has already been included in the list of related NICE guidance in the scope (section 5).
14	SH	Myeloma UK	12	3.1 - general	This guidance should only cover follow-up in high-risk MGUS.	The management of MGUS (including follow up) has been excluded from the scope of this guideline (section 4.3.2 a) as it is such a large topic it would require a guideline of its own.
10	SH	Myeloma UK	8	3.1 – general	NICE should consider stratification of the Clinical Guideline into three epidemiological groups: (1) patients eligible for high-dose therapy and stem cell transplant (2) those not eligible for high-dose therapy and stem cell transplant but who are fit (3) those not eligible for high-dose therapy and stem cell transplant who are frail/elderly.	We have amended the paragraph in section 3 (Need for guideline) to reflect the three different groups.
11	SH	Myeloma UK	9	3.1 – general	Perhaps include a statistic of myeloma patients with a comorbidity of AL amyloidosis (15%).	We have not included this statistic because it is rarely a clinical problem and therefore does not warrant being mentioned in this section.
12	SH	Myeloma UK	10	3.1 – general	The estimated 10-year prevalence of myeloma in the UK at the beginning of 2006 was 12,465 people (Maddam et al 2007).	Thank you for this information. This type of information may be covered in the introduction to the guideline.
7	SH	Myeloma UK	5	3.1 b	Does the figure of 4,784 people diagnosed with myeloma apply to England and Wales or the whole of the UK?	We have amended the scope to include 2010 data and clarified that this applies to the UK.
8	SH	Myeloma UK	6	3.1 c	In relation to point C, frail, elderly patients are considered an	We have amended the paragraph in

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					especially complex group of patients to manage (Ludwig et al 2012). In addition to this, although unknown in childhood there are significant numbers of cases in younger adults – 15% of cases affect people under 60 (750 per year) and 2% occur in people aged under 40 (100 cases per year) (Smith et al 2013).	section 3 (Need for guideline) to reflect the different patient groups affected by myeloma.
9	SH	Myeloma UK	7	3.1 g	It is not clear what the scientific evidence is to suggest that people with a close family member with MGUS are 2 - 3 times more likely to develop MGUS than the general population.	We have removed this sentence and replaced it with 'It is therefore important to distinguish between MGUS and myeloma at the time of diagnosis'.
20	SH	Myeloma UK	13	3.2 a	Point A: non-specific clinical presentation of myeloma should include hypercalcaemia (raised calcium levels)	This change has been made.
21	SH	Myeloma UK	14	3.2 a	Point A: patients regularly get diagnosed by being referred to a secondary care department that is not haematology (for example renal unit, orthopaedics) and in a questionnaire based study 31% of patients reported no symptoms prior to or at the time of diagnosis (Howell et all 2013).	Thank you for this information.
22	SH	Myeloma UK	15	3.2 b	Point B: the scoping document should make reference to how the use of genetic profiling is increasing in myeloma and explore what can be done to prepare for the advent of stratified medicine on the NHS	This is already covered by section 3.2b. This would be outside the scope of a NICE clinical guideline.
23	SH	Myeloma UK	16	3.2 c	Point C: novel agents in myeloma aren't typically chemotherapies – they are immunomodulatory drugs (IMiDs) and proteasome inhibitors which are typically prescribed in combination with chemotherapy treatments (alkylating agents) and/or corticosteroids. It is essential that NICE outline the specifics of this and define the specific groups of treatment rather than grouping all myeloma treatments into the chemotherapy 'bracket'	We have clarified that this does not just relate to chemotherapy.
24	SH	Myeloma UK	17	3.2 c	Point C: perhaps mention the role of high-dose therapy and stem cell transplant in the treatment of myeloma.	We have made this change.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
25	SH	Myeloma UK	18	3.2 c	Point C: specific treatments have been approved by NICE in specific disease settings and the pathway of treatment myeloma patients receive is currently largely determined by NICE guidance which has implications for the flexibility clinicians can exercise in treating their patients.	We agree.
26	SH	Myeloma UK	19	3.2 d	Point D: when talking about symptoms and complications – it should be noted that these can be categorised into treatment-related and disease-related complications, although both are equally debilitating for patients.	We have amended the text to read "Symptom-based and supportive management are especially important because of the complex nature of the disease and side effects of its treatment."
36	SH	Myeloma UK	20	4.1.1	A subgroup of AL amyloidosis patients has been identified who, although they may not conform to the strict definition of myeloma, have a similarly poor prognosis to patients whose condition fully conforms to the myeloma criteria. It may be appropriate to discuss management of these patients within this guideline (Kourelis et al 2013).	People with AL amyloidosis have been excluded in section 4.1.2.b. As it is such a large topic it would require a guideline of its own.
39	SH	Myeloma UK	23	4.1.1	The guideline should also cover 'Adults (aged 16 years and over) with newly diagnosed or relapsed myeloma with significant comorbidities (for example, AL amyloidosis and plasmacytoma).	The topics will cover myeloma patients unless otherwise specified. Therefore this patient group will be included.
37	SH	Myeloma UK	21	4.1.1	There are several subgroups which may merit specific consideration: o About 750 patients a year are newly diagnosed with myeloma below the age of 60 years; of these about 100 are aged less than 40 years. The younger members of this cohort face very different issues relating to late effects of treatment and in the case of female patients, the possibility of pregnancy o US experience has shown that the African-American population, which has a higher risk of myeloma, has historically had better outcomes, although recently they	We do not feel it is necessary to specify young people as a sub-group throughout the entire scope. Where there are specific issues relevant to young patients they will be included in the relevant review question. We believe there are very little European data on African-Caribbean groups on which to do analysis.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					have failed to show improvements in survival to the same degree seen in the white population (Waxman etc al 2013). Consideration should be given to separate analysis of trial outcomes in ethnic groups to determine whether the differential outcomes are because of differing pharmacokinetics/pharmacogenetics in this population, differing features of the disease in this population or other factors. There is evidence of variance in the frequency of specific cytogenetic features between African-American and other American patient groups (Weiss et all 2013)	While the incidence of myeloma is higher in the African- Caribbean population, the management of their disease does not differ from the population as a whole. We therefore do not feel that they need to be specified as a sub-group.
					o The oldest myeloma patients, because of general frailty and higher frequency of co-morbidities, present particular issues of complex management. In this group, there may be some patients who are exceptionally fit for their age who should not be denied effective, albeit toxic therapy, and others who, because of their general condition would be served best with palliative care Patients who have AL amyloidosis, whether this is diagnosed before or simultaneously with myeloma, may have enhanced risk of adverse response to standard myeloma therapy and may require additional supportive care	We do not feel it is necessary to specify older myeloma patients as a sub-group throughout the entire scope. Where there are specific issues relevant to frail patients they will be included in the relevant review question. Thank you for this information. The topics will cover myeloma patients unless otherwise specified. Patients with myeloma and AL amyloidoisis as a comorbidity will therefore be covered.
38	SH	Myeloma UK	22	4.1.1	This guideline <u>should</u> cover myeloma patients who have AL amyloidosis and/or plasmacytoma as a comorbidity.	The topics will cover myeloma patients unless otherwise specified. Therefore this patient group will be included.
43	SH	Myeloma UK	25	4.2	We agree that the NICE guidelines should cover all settings in which NHS-funded care is provided. As mentioned previously, thought needs to be given during the scoping exercise as to	The Implementation team at NICE will develop tools to assist in the implementation of this guideline.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					potential avenues for this guideline to be rolled out through the NHS.	
45	SH	Myeloma UK	26	4.3 h	A point needs to be included in this section on the most appropriate treatment and care for myeloma patients with relapsed myeloma (including the second autologous stem cell transplant). There is a point on 'the most effective salvage therapy for relapsed and refractory patients' however this implies very advanced myeloma.	We have clarified that this relates to relapsed and/or refractory myeloma.
46	SH	Myeloma UK	27	4.3.1	It needs to be made clearer what topics they will be covering for MGUS and what they will be covering for myeloma.	The list of topics in section 4.3.1 states which population group the topics apply to. For clarification, we are covering the diagnosis of MGUS but not the management of MGUS.
47	SH	Myeloma UK	28	4.3.1	The guideline could include information about the roles and responsibilities of primary and secondary care, in terms of supportive treatment and care and active monitoring of disease (including relevant tests and when it is important to refer patients who are in remission back to secondary care).	The guideline may make service delivery recommendations if the evidence supports doing so.
48	SH	Myeloma UK	29	4.3.1	The guideline should include o the prevention and management of iatrogenic osteonecrosis of the jaw for myeloma patients o the prevention and management of neuropathy in patients with myeloma o the management of pain in myeloma patients	This issue is not specific to patients with myeloma and therefore we do not think a specific topic is required. We have added a topic on the management of neuropathy to the scope. This excludes the pharmacological management of neuropathic pain since there is already existing NICE guidance in this area. Management of pain is likely to be included within the topics on bone

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						disease and neuropathy (this will exclude pharmacological management). The GDG will finalise what specific issues will be included during their first few meetings.
					o the management of myeloma patients who, because of frailty or comorbidity, are unfit for definitive treatment	This group has been acknowledged in section 3 (Need for guideline) and will be covered by the disease management topics as required.
					o myeloma patients with common comorbities – such as AL amyloidosis	The topics will cover myeloma patients unless otherwise specified. Therefore this patient group will be involved.
					o palliative care as well as end-of-life care	Palliative care will include end of life care where this is myeloma specific. There is a DH end of life care initiative which addresses the more general aspects of care. NICE has also been commissioned to develop a guideline on Care of the dying adult (see section 5.2).
58	SH	Myeloma UK	30	4.4	How is NICE going to measure the outcomes?	These are the outcomes that will be examined in the published literature to help the GDG assess the effectiveness of the interventions considered.
59	SH	Myeloma UK	31	4.4	In terms of the detail covered in this section, it needs to be more specific so it is measurable. For example, with 'morbidity	These are the outcomes that will be examined in the published literature

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					rates' – what does the guideline aim to do with this? What is the rate now and how does NICE aim to improve this?	to help the GDG assess the effectiveness of the interventions considered.
68	SH	Myeloma UK	33	4.5	Other potential questions that could be included: ▪ Can investigations carried out at the diagnosis of myeloma identify suitable markers which can be used to monitor MRD?	This is covered by section 4.5.d.
					▪ Can investigations done at the time of diagnosis identify high-risk MGUS patients who may benefit from early intervention?	Management of MGUS has been excluded from the guideline.
					▪ What are the special needs of patients in geographically isolated areas? (e.g. alternative imaging options locally etc)	This is an implementation issue regarding commissioning of services. It is not specific to patients with myeloma and we do not consider that it needs to be included within scope of this guideline.
					▪ What criteria should be applied to stratify patients as suitable or unsuitable for stem cell transplantation (either allogeneic or autologous)	Transplant issues are covered in 4.5.h, l and m.
					▪ Can MRD monitoring be used to identify which patients are most likely to benefit from consolidation or maintenance therapy?	Consolidation and maintenance therapy are the subject of two NICE technology appraisals that are in development. The guideline will refer to these, in line with NICE process, and therefore will not be investigating this issue.
					▪ What is the most effective treatment for patients	A question has been added on

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					with primary or secondary plasma cell leukaemia?	primary plasma leukaemia. Secondary plasma cell leukaemia is not included within the scope.
					▪ What is the most effective way to prevent iatrogenic osteonecrosis of the jaw in patients treated with bisphosphonates?	This issue is not unique to patients with myeloma and therefore we do not think a topic is required on it.
					▪ What is the optimal strategy for prevention or management of disease-related or iatrogenic neuropathy?	We have added a review question on the management of neuropathy to the scope. This excludes the pharmacological management of neuropathic pain since there is already existing NICE guidance in this area.
					▪ What interventions are the most effective in reducing or controlling pain in patients being treated for myeloma?	Management of pain is likely to be included within the topics on bone disease and neuropathy (this will exclude pharmacological management). The GDG will finalise what specific issues will be covered in the first few meetings
					▪ What interventions are the most effective for high risk MGUS and asymptomatic myeloma?	Management of MGUS is not included in the scope of this guideline. Asymptomatic myeloma is covered by 4.5.j.
					▪ What are the most appropriate interventions for myeloma patients with a comorbidity of AL amyloidosis/plasmacytoma?	The topics will cover myeloma patients unless otherwise specified. Therefore this patient group will be included.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
70	SH	Myeloma UK	34	4.5	There is a need to include specific questions on ▪ MGUS in secondary care ▪ comorbities with myeloma (including AL amyloidosis) ▪ how can the guideline promote flexibility in the treatment of myeloma ▪ roles and responsibilities of follow-up care e.g. during remission	 The management of MGUS has been excluded from the scope of the guideline. The topics will cover myeloma patients unless otherwise specified. Therefore this patient group will be included. We hope the guideline will move us along the path to this goal. This is covered by section 4.5.u.
66	SH	Myeloma UK	32	4.5 a	Amendments to current questions: Question A: should include people who are diagnosed from a young age and older patients who have special needs (e.g. if they have dementia)	This will be discussed by the GDG when they finalise the review questions during their first few meetings.
	SH	Myeloma UK	32	4.5 c	Question C: could include another related question – what is the optimal testing strategy for someone with myeloma in remission (i.e. to test for relapse)?	This is covered by section 4.5.u
	SH	Myeloma UK	32	4.5 g	Question G: should include end of life care as well as palliative care	Palliative care will include end of life care where this is myeloma specific. There is a DH end of life care initiative which addresses the more general aspects of care. NICE has also been commissioned to develop a guideline on Care of the dying adult (see section 5.2).
	SH	Myeloma UK	32	4.5 k	Question K: should include second transplantation	A draft review question on second transplantation has been added to

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
						the scope. This will be discussed by the GDG when they finalise the review questions during their first few meetings.
	SH	Myeloma UK	32	4.5 n	Question N: could include another related question - what is the most effective way of treating bone disease?	This is covered in section 4.5.p and 4.5.q.
81	SH	Myeloma UK	35	4.6	Consider the economic impact of giving patients appropriate end of life and palliative care, rather than over treating with novel agents which have little effect on overall survival and diminish quality of life.	Economic impact of interventions will be considered for all topics.
83	SH	Myeloma UK	36	4.6	Need clarification on how NICE are going to apply health economic issues such as the QALY to the myeloma clinical guideline.	More information can be found here: http://publications.nice.org.uk/the-guidelines-manual-pmg6/assessing-cost-effectiveness
3	SH	Myeloma UK	1	General	Does the myeloma clinical guideline cover both England and Wales? If so, this should be made clear.	NICE guidelines cover both England and Wales but we do not feel it is necessary to explain this in the scope of the guideline.
4	SH	Myeloma UK	2	General	Myeloma UK welcomes the commitment of NICE to develop a clinical guideline on the diagnosis and management of myeloma. As myeloma is a complex relapsing and remitting cancer, it is important that the entire patient pathway is considered rather than continually dividing it into treatment silos with individual health technology guidance.	The text under section 3 (Need for guideline) has been amended to reflect the complex nature of myeloma. We have considered the whole pathway and have identified and focused on those areas where there is known variation in practice or uncertainty. NICE guidelines do not attempt to cover every management decision in the pathway of care.
40	SH	Myeloma UK	24	General	To ensure that the guideline links to the diagnosis of myeloma in primary care, one idea would be to link to ensure that this	The Referral for Suspected Cancer guideline (NICE CG27, 2005), is

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					guideline is tied into haematology referral guidelines - the flow of patients to secondary care should be seamless.	currently being updated. It has already been included in the list of related NICE guidance in the scope (section 5).
84	SH	NHS Direct	1	General	No comments on the content as part of the consultation.	Thank you
49	SH	Onyx Pharmaceuticals International GmbH	1	4.3.1 h	Item H) It is not sufficient to limit this topic to the most effective salvage therapy. Several alternative compounds exist and will be used, depending on the patient's disease progress and condition. Sequencing of salvage therapy is a related topic.	We have clarified that this question relates to the most effective salvage therapies (topic I) however due to existing Technology Appraisals for first, second and third line treatment this topic will only look at relapse after third line treatment. Sequencing of salvage therapy will be discussed by the GDG when they finalise the review questions during their first few meetings but the ability to address sequencing will be limited to post-third line treatment.
33	SH	Royal College of General Practitioners	1	3.2 e	Any multidisciplinary approach to the long term care of MM patients requires GPs to be in integral part	We have revised this section to acknowledge the links to community care through the GP.
51	SH	Royal College of General Practitioners	2	4.3.1 b	Additional item: The guideline should cover the diagnosis of MM in primary care and the role of diagnostic testing	The diagnosis of myeloma in primary care is not within the scope of this guideline. The Referral for Suspected Cancer guideline (NICE CG27, 2005), is currently being updated. It has already been included in the list of related NICE guidance in the scope (section 5).
60	SH	Royal College of General Practitioners	3	4.4	Outcomes should include Emergency Presentation rate, proportion diagnosed as 2 week wait referral. Also consider number of GP consultations prior to referral (available	This is not intended to be an exhaustive list. The GDG can add to this if they wish. Diagnosis of

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					through CPES).	myeloma in primary care is outside the scope of this guideline.
q	SH	Royal College of General Practitioners	4	4.5 b	Additional question: What is the most effective strategy for identifying and testing patients with suspected MM in primary care	Diagnosing myeloma in primary care is not within the scope of the guideline. The Referral for Suspected Cancer guideline is currently being updated. It has already been included in the list of related NICE guidance in the scope.
1	SH	Royal College of Paediatrics and Child Health	1	General	Thank you for inviting the Royal College of Paediatrics and Child Health to comment on the **Multiple Myeloma** draft scope. We have not received any responses for this consultation.	Thank you
15	SH	Royal College of Pathologists and British Society of Haematology	1	3.1 b	specify this is UK number or possibly England	We have amended the scope to include 2010 data and clarified that this applies to the UK.
16	SH	Royal College of Pathologists and British Society of Haematology	2	3.1 e	remove . at start	We have made this change.
17	SH	Royal College of Pathologists and British Society of Haematology	3	3.1 line 1	'the guideline will aim to…'	We have made this change.
29	SH	Royal College of Pathologists and British Society of Haematology	4	3.2 a	include words 'symptoms of' before impaired renal function and anaemia. Also add something about the high frequency of delayed	This change has been made. This change has been made.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
					diagnosis in myeloma patients	
31	SH	Royal College of Pathologists and British Society of Haematology	5	3.2 c	add 'some' before 'variation in the use of….' as we do not believe that it is highly variable	We have made this change.
32	SH	Royal College of Pathologists and British Society of Haematology	6	3.2 e	can remove words 'Haematology Malignancy Diagnostic service' and leave pathologists but add scientists so that those dealing with cytogenetics and flow cytometry are included	We have made amendments to clarify the multidisciplinary approach for the management to myeloma. We have revised this section in order to define the core MDT and the extended MDT for managing patients with myeloma.
42	SH	Royal College of Pathologists and British Society of Haematology	7	4.1.1 a)	although it is reasonable to include those referred with suspected myeloma, I don't think the scope should include management of MGUS (this not very clear at present)	We believe the scope clearly shows the diagnosis of MGUS is included and the management of MGUS is not (as noted in section 4.3.1 c and 4.3.2).
64	SH	Royal College of Pathologists and British Society of Haematology	8	4.4 k	doesn't really make sense. It is not clear what is referred to here. Suggested re-wording 'predictive value of diagnostic prognostic factors'	We have changed this to read 'diagnostic accuracy'.
73	SH	Royal College of Pathologists and British Society of Haematology	9	4.5 b	As written at present, includes a lot of political aspects relating to the delivery of pathology services. We believe the key question should relate to the tests that should be done and the timeframe in which they should be carried out, not the organisation of pathology services - this is already covered in question c) so perhaps b) could be omitted	We agree these two questions are related but there are issues unique to each question. We have changed the order of the questions for clarity.
75	SH	Royal College of Pathologists and British Society of	10	4.5 g	A similar comment for this question – we are not sure that the guideline should be determining service configuration which has many other influences, more, ensuring adequate and	Service delivery issues can be included in NICE guidance where it is appropriate.

ID	Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
		Haematology			timely access to the correct services for all patients	
77	SH	Royal College of Pathologists and British Society of Haematology	11	4.5 l	Would consider re-wording this question. It is not realistic to answer this question for an individual or group of individuals – 'Which patients should be considered for allogeneic transplantation?'	Thank you we have made this change.
27	SH	Royal Pharmaceutical Society	1	3.2 e	The statement on the multidisciplinary team should include a reference to oncology pharmacists who through various activities such as prescribing, checking and authorising prescriptions, reconstitution and advising on administration of chemotherapy drugs as well as advising on symptomatic and supportive treatments play a key role in the safe delivery of chemotherapy drugs and consistent quality care for patients. Pharmacists also support their patients to take their medicines safely and effectively through identifying barriers to medicines adherence and providing them with the necessary information and aids to enable them do so. As the experts on medicines pharmacist also support other healthcare professional within the multidisciplinary team through ensuring that relevant, up to date evidence base information and pharmaceutical expertise is available to them at the point of need.	We have made amendments to clarify the multidisciplinary approach for the management to myeloma. We have revised this section in order to define the core MDT and the extended MDT for managing patients with myeloma. We have specifically listed oncology pharmacists as a member of the extended MDT.

These organisations were approached but did not respond:

Abbott Molecular
Addenbrookes Hospital
Amgen UK
Archimedes Pharma Ltd
Association of Anaesthetists of Great Britain and Ireland
Association of Chartered Physiotherapists in Oncology and Palliative Care

Bristol Myers Squibb Pharmaceuticals Ltd
British Association of Spinal Surgeons
British Dietetic Association
British Medical Association
British Medical Journal
British National Formulary
British Nuclear Cardiology Society
British Nuclear Medicine Society
British Psychological Society
British Red Cross
British Society of Paediatric Gastroenterology Hepatology and Nutrition
BSPGHAN
Care Quality Commission (CQC)
Celgene UK Ltd
Cheshire and Merseyside SCN
counselling for prisoners network
Covidien Ltd.
Croydon Clinical Commissioning Group
Croydon University Hospital
Department of Health, Social Services and Public Safety Northern Ireland
East and North Hertfordshire NHS Trust
East Kent Hospitals University NHS Foundation Trust
Ethical Medicines Industry Group
Faculty of Dental Surgery
Five Boroughs Partnership NHS Trust
Gloucestershire Hospitals NHS Foundation Trust
Health & Social Care Information Centre
Health and Care Professions Council
Healthcare Improvement Scotland
Healthcare Infection Society
Healthwatch East Sussex
Herts Valleys Clinical Commissioning Group
Isabel Hospice
Johnson & Johnson Medical Ltd
Lanes Health

Leukaemia & Lymphoma Research
Leukaemia CARE
Liverpool Community Health
London cancer alliance
Macmillan Cancer Support
Medicines and Healthcare products Regulatory Agency
Milton Keynes Hospital NHS Foundation Trust
Milton Keynes NHS Foundation
Ministry of Defence (MOD)
Napp Pharmaceuticals Ltd
National Association of Primary Care
National Clinical Guideline Centre
National Collaborating Centre for Cancer
National Collaborating Centre for Mental Health
National Collaborating Centre for Women's and Children's Health
National Deaf Children's Society

National Institute for Health Research Health Technology Assessment Programme
National Institute for Health Research
National Patient Safety Agency
NHS Barnsley Clinical Commissioning Group
NHS Connecting for Health
NHS Cumbria Clinical Commissioning Group
NHS Health at Work
NHS Improvement
NHS Plus
NHS Sheffield
NHS South Cheshire CCG
NHS Wakefield CCG
NHS Warwickshire North CCG
North of England Commissioning Support
North West London Hospitals NHS Trust
Nottingham City Council
Novartis Pharmaceuticals
Nutricia Clinical Care

Oxfordshire Clinical Commissioning Group
Pfizer
PHE Alcohol and Drugs, Health & Wellbeing Directorate
Primary Care Pharmacists Association
Primrose Bank Medical Centre
Public Health Wales NHS Trust
Public Health Wales NHS Trust
Queen Elizabeth Hospital King's Lynn NHS Trust
Regional Public Health Agency for Northern Ireland
Robert Jones & Agnes Hunt Orthopaedic & District Hospital NHS Trust
Roche Diagnostics
Roche Products
Royal College of Anaesthetists
Royal College of General Practitioners in Wales
Royal College of Midwives
Royal College of Midwives

Royal College of Obstetricians and Gynaecologists
Royal College of Physicians
Royal College of Psychiatrists
Royal College of Radiologists
Royal College of Surgeons of England
Royal Surrey County Hospital NHS Trust
Scottish Intercollegiate Guidelines Network
Sebia
Serious Hazards of Transfusion
Sheffield Teaching Hospitals NHS Foundation Trust
Smith & Nephew UK Limited
Social Care Institute for Excellence
Society and College of Radiographers
South London & Maudsley NHS Trust
South West Yorkshire Partnership NHS Foundation Trust
Staffordshire and Stoke on Trent Partnership NHS Trust
Stockport Clinical Commissioning Group
Takeda UK Ltd

TB Action Group
The Association for Clinical Biochemistry & Laboratory Medicine
The Institute of Cancer Research
The Patients Association
University College London
University Hospital Birmingham NHS Foundation Trust
University Hospitals Birmingham
Velindre NHS Trust
Welsh Government
Western Sussex Hospitals NHS Trust
Wigan Borough Clinical Commissioning Group
York Hospitals NHS Foundation Trust
Yorkshire and Humber Strategic Clinical Networks