

**Chronic heart failure
Consultation on draft scope
Stakeholder comments table**

20 January 2016 – 17 February 2016

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
Association for Palliative Medicine of Great Britain and Ireland	General	General	We welcome the inclusion of palliative care in this document and the recognition of the role it can offer to patients with chronic heart failure, many of whom have complex needs.	Thank you for your comment.
Association for Palliative Medicine of Great Britain and Ireland	3-4	82-83	We welcome the inclusion of how to refer patients to palliative care	Thank you for your comment.
Association for Palliative Medicine of Great Britain and Ireland	7	193-204	We welcome the inclusion of these questions and consider them to be pertinent in the needs of patients with chronic heart failure.	Thank you for your comment.
Association of British Healthcare Industry (ABHI)	5	120 - 121	<p>We are very disappointed to see that the draft scope proposes to remove information on referrals for implantable cardiac defibrillators from the Chronic Heart Failure guidelines. We feel that the removal of this part of the guidelines contradicts the setting which the draft scope identifies for the guidelines (line 38/39) – “Primary and secondary NHS-commissioned care including referral to tertiary care.”</p> <p>Referral to tertiary care would include referrals for consideration of an implantable cardiac defibrillator device. We are concerned that these plans could limit awareness amongst secondary physicians of the important role that implantable cardiac devices can play in the management of patients with chronic heart failure. We strongly oppose this proposal and would like to see referrals for these life-saving devices included in the updated guidelines.</p> <p>The current Technology Appraisal guidance on implantable cardioverter defibrillators & cardiac resynchronisation therapy for arrhythmias & heart failure from NICE clearly identifies (cost-effective) mortality benefits from the use of these devices in defined patient groups, helping to support the delivery of the NHS Outcomes Framework 2015/16. However, despite long standing device-</p>	<p>Information on Implantable Cardioverter Defibrillators in the published guideline is out of date. There is other NICE guidance that now covers this and the guideline will cross refer to this: NICE TA314: Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.</p>

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			specific guidance there is a continuing low implant rates for these devices in the UK versus other European countries identified in the NICOR audit for cardiac rhythm devices (https://nicor5.nicor.org.uk/_802571400070B77E.nsf?OpenDatabase). This means that patients do not have access to the same quality of care across the country and suggests that more awareness needs to be raised earlier in the patient pathway to ensure all eligible patients are able to access the most appropriate treatment. We believe the removal of references to these devices in the clinical guidelines aimed at healthcare professionals in primary and secondary could undermine efforts to improve access to this treatment. We would recommend that, similar to the existing CG108 clinical guidelines, the updated guidelines should include a clear reference to the TA314 guidance.	
BACPR	General	General	I am writing on behalf of BACPR to say we whole-heartedly support the content of the scoping document and we are delighted to see that rehab is going to be focused upon and that we are very keen to be involved in promoting the importance of rehabilitation for patients with heart failure. With Kind Regards	Thank you for your comment.
Boston Scientific	5	120 - 121	We are very disappointed to see that the draft scope proposes to remove guidelines for referrals for implantable cardiac defibrillators from the Chronic Heart Failure guidelines. We feel that the removal of this part of the guidelines contradicts the setting which the draft scope identifies for the guidelines (line 38/39) – “Primary and secondary NHS-commissioned care including referral to tertiary care.” Under current practice, referrals to tertiary care include referrals for consideration of an implantable cardiac defibrillator device. We are concerned that a lack of guidelines here could risk inappropriate referrals for this treatment.	Thank you for your comment. Information on Implantable Cardioverter Defibrillators in the published guideline is out of date. There is other NICE guidance that now covers this and the guideline will cross refer to this: current guidance given in NICE TA314: Implantable

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			<p>We strongly oppose this proposal and would like to see guidelines for referrals for this treatment option remain included in the updated guidelines.</p> <p>Referrals from secondary care are a critical part of the chronic heart failure patient pathway in ensuring patients receive the most appropriate treatment for their condition. Despite clear guidance from NICE as to which patients an implantable cardiac defibrillator device would be the most appropriate treatment for, market data continues to highlight a wide variation in implant rates across the UK. This implies that patients do not have access to the same quality of care across the country and suggests that more awareness needs to be raised earlier in the patient pathway to ensure all patients have equitable access to the most appropriate treatment for them. By retaining guidelines for appropriate referral for treatments involving devices, referral pathways could be strengthened and implementation of appropriate NICE treatment recommendations could be supported.</p> <p>We would recommend that, similar to the existing CG108 clinical guidelines, the updated guidelines should include a clear reference to the current Technology Appraisal guidance on implantable cardioverter defibrillators & cardiac resynchronisation therapy for arrhythmias & heart failure (TA314) and additionally should include a copy of the summary table identifying eligible patients for devices.</p>	cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.
Boston Scientific	General	General	We welcome the update to these clinical guidelines as an important step in ensuring healthcare professionals have access to the most up to date recommendations for care of chronic heart failure patients.	Thank you for your comment.
British	2	33,3	The draft scope indicates that patients with heart failure and other conditions	Thank you for your comment. This is

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Cardiovascular Society		4,35	(chemotherapy, HIV, pregnancy) will be excluded from the guidance. These groups will benefit from HF treatment. Although there are additional issues regarding these patients, the role of conventional therapy should be discussed	a specialist area and therefore cannot be covered adequately by this guideline.
British Cardiovascular Society	General	General	Consideration should be given to identifying patients suitable for heart transplantation and who should be referred for consideration of advanced therapies	Thank you for your comment. This guidance can be found in NICE CG187: Acute heart failure .
British Cardiovascular Society	2	42	An update on the roles of ivabradine and Entresto should be added to the published guideline, in the same way that MRA use is being considered	Thank you for your comment. NICE TA267: Ivabradine for treating chronic heart failure will be incorporated into this guideline and the scope has been amended to make this clearer.
British Cardiovascular Society	5	120	ICDs and CRT play an important role in the management of HF patients and their role should not be removed from the published guidelines. Clearly the NICE guideline on device therapy will be linked into the pathway.	Thank you for your comment, Information on Implantable Cardioverter Defibrillators in the published guideline is out of date. There is other NICE guidance that now covers this and the guideline will cross refer to this: NICE TA314: Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.

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British Nuclear Cardiology Society & British Nuclear Medicine Society	6	145	Radionuclide ventriculography (RNV) and myocardial perfusion scintigraphy (MPS) should be included in the diagnostic accuracy question involving echocardiography and cardiac MRI.	Thank you for your comment. It is acknowledged that there are many ways to measure ejection fraction including scintigraphy. The review question is focused on the techniques that are considered most relevant to definitive diagnosis.
British Nuclear Cardiology Society & British Nuclear Medicine Society	6	175	This section should include the following question: "What is the clinical and cost-effectiveness of MPS or RNV in the monitoring of chronic heart failure compared with standard care?"	Thank you for your comment. It is acknowledged that there are many ways to measure ejection fraction including scintigraphy. The review question is focused on the techniques that are considered most relevant to definitive diagnosis..
British Nuclear Cardiology Society & British Nuclear Medicine Society	6	169	Cardiac adrenergic activity can now be measured using mIBG scintigraphy. This test could be used to improve prognostication in HFREF patients (J Am Coll Cardiol. 2010;55(20):2212-2221).	Thank you for your comment. The guideline will review the use of routine diagnostics available or potentially available across the NHS.

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Society				
British Nuclear Cardiology Society & British Nuclear Medicine Society	3	58	The draft scope includes an update on referral for coronary revascularisation. It is not mentioned whether this will also include recommendations on non-invasive testing for myocardial ischaemia -or guidance on how to access this information. We feel this should be considered because demonstration of myocardial ischaemia is relevant to the decision-making process regarding intervention.	Thank you for your comment. This is covered in NICE CG95: Chest pain of recent onset (recommendation 1.36 'non-invasive procedures for myocardial ischaemia')
British Nuclear Cardiology Society & British Nuclear Medicine Society	6	163	In addition to the detection of ischaemia, we feel that recommendation/guidance on the assessment of myocardial viability should be provided because there is consensus that people with heart failure and coronary disease who has dysfunctional but viable myocardium may be more likely to benefit from revascularisation. Nuclear techniques (myocardial perfusion scintigraphy (MPS) and positron emission tomography (PET)) are sensitive at detecting viable myocardium in this population. This has been highlighted in practice guidelines (European Society of Cardiology guidelines. European Heart Journal. 2012; 33:1787-1847)	Thank you for your comment. This is covered in NICE CG95: Chest pain of recent onset (recommendation 1.36 'non-invasive procedures for myocardial ischaemia')
British Nuclear Cardiology Society & British Nuclear Medicine Society	6	163	In relation to comment No. 1, we feel that the question on whether there is a role for coronary revascularisation cannot be answered without formulating another important question: How does flow-limiting coronary lesions and myocardial ischaemia affect the management and prognosis of people with chronic heart failure?	Thank you for your comment. We will review the evidence around coronary revascularisation and make recommendations accordingly.

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British Nuclear Cardiology Society & British Nuclear Medicine Society	3	78	Elderly patients have more HFPEF. A significant proportion is due to transthyretin (TTR) amyloidosis. This can now be easily identified with a simple DPD nuclear medicine test. The role of identification and therapy in HFPEF should be expanded. (See European Heart Journal (2015) 36, 2585–2594 and Eur Heart J Cardiovasc Imaging 2014;15:1289 – 1298.)	Thank you for your comment. The following question has been added to the scope to address this issue; ' <i>What is the role of secondary imaging investigations in diagnosing suspected amyloidosis?</i> '
British Society for Heart Failure			Remote monitoring and telephone clinics need to be addressed too	Thank you for your comment. These areas will be considered when determining the review protocol for the following question ' <i>What is the efficacy and safety of distance monitoring (including telemonitoring) compared with outpatient monitoring in people with chronic heart failure?</i> '.
British Society for Heart Failure			We feel that NICE should include specific and detailed guidance on new drugs that have been evaluated since the last update eg Ivabradine & Valsartan-Sacubitril (both of which have been through the TA process)	Thank you for your comment. NICE TA267: Ivabradine for treating chronic heart failure will be incorporated into this guideline (subject to a NICE technology appraisal review process) and the scope has been amended to make this clearer. The NICE TA Heart failure - sacubitril valsartan [ID822] will also be incorporated into this guideline,

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				subject to a NICE technology appraisal review process.
British Society for Heart Failure			We would like NICE to include guidance on the transition between acute heart failure and chronic heart failure with specific reference to the national heart failure audit	Thank you for your comment. We will coordinate this guidance with NICE CG187: Acute heart failure .to provide a transition between both guidelines.
British Society for Heart Failure			We welcome the guidance addressing adequate follow up and monitoring in heart failure patients. Appropriate time intervals for follow up (after up titration of therapies) needs to be discussed	Thank you for your comment. The frequency of monitoring will be discussed when assessing the evidence for this area and when developing recommendations.
British Society for Heart Failure			We commend NICE on the document and that the scope is timely given the advances in CHF treatment over the past 6 years since the last update	Thank you for your comment.
British Society for Heart Failure			We welcome specific guidance on certain areas eg palliative care, elderly care	Thank you for your comment.
British Society for Heart Failure			We hope that BSH Board members will be applying to join the committee for this guideline	Thank you. Recruitment to the guideline committee is an open application process. Applications from are all suitable candidates are welcomed.
Cardiomyopathy UK	5	117	The draft scope states that the management of depression and anxiety will be removed from the published guideline. We are concerned about this omission as	Thank you for your comment. We agree that this is an important issue.

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			this is a significant factor in the patients recovery and experience in living with a heart failure condition. This has bearing on the patient's compliance with therapy and general well-being. The exclusion appears at odds with the documents recognition of the importance of cardiac rehabilitation.	While the existing section will be removed from the guidance, it will be replaced by a cross-referral to NICE CG91: Depression in adults with chronic physical health problem .
Cardiomyopathy UK	7	185	We support the inclusion of the question regarding what are the specific needs to be considered when communicating a diagnosis and consequent prognosis, to people with chronic heart failure, their families and carers? However, we feel that in addressing this issue the role of the patient groups should be more formally recognised in order to increase the availability of services to patients. We feel this also provides an opportunity to ensure a more consistent level of quality of the information provided to patients.	An 'Information for the public' document will be produced and published alongside the completed guideline. This will contain information on stakeholders and relevant organisations
Cardiomyopathy UK	2	35	The draft scope currently excludes people who have heart failure due to pregnancy. We feel this group should be included because peripartum cardiomyopathy is an often missed diagnosis and the needs of woman affected by this condition should be recognised.	Thank you for your comment. This is a specialist area therefore cannot be adequately covered by this guideline. Furthermore, peripartum cardiomyopathy is an acute condition whereas this guideline covers chronic heart failure.
Cardiomyopathy UK	7	191	In addressing the question of how should the transition between secondary and primary care be managed in people with chronic heart failure be managed, we feel that this should include the services available from patient groups.	Thank you for your comment. We will consider services available from patient groups when developing the protocol for this review question.
Department of Health	General	General	Dear NICE	Thank you for your comment.

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			<p>Thank you for the opportunity to comment on the draft scope for the above clinical guideline.</p> <p>I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation.</p> <p>Many thanks and best wishes</p>	
Marie Curie	7	194	We welcome a closer consideration of the criteria that should be used to refer people with chronic heart failure to palliative care, and encourage that these discussions include considerations about when decisions around supportive and palliative care should be revisited following changes in an individual's condition.	Thank you for your comment. CG108 includes regular reassessment of patients with heart failure, which would encompass decisions around supportive and palliative care when indicated. Furthermore, as part of the multidisciplinary approach to care, health care professionals in palliative care are approached when assessing patients.
Marie Curie	3	67	We welcome the inclusion of supportive and palliative care in the guideline scope.	Thank you for your comment.
Marie Curie	3	82	We welcome that palliative care will be included in the update to be published by NICE.	Thank you for your comment.
Marie Curie	3	83	We welcome the inclusion of referral to palliative care in the future update.	Thank you for your comment.
Medtronic Limited	5	120 - 121	It is very disappointing to note that the draft scope proposes to remove information on referrals for implantable cardiac defibrillators from the Chronic	Thank you for your comment.

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			<p>Heart Failure guidelines. During the scoping workshop it was discussed this should remain in scope, however this is not in the summary report of the scoping meeting. Removing this part of the guidelines conflicts with the setting of the draft scope for the guidelines (line 38/39) – “Primary and secondary NHS-commissioned care including referral to tertiary care.”</p> <p>Referral to tertiary care would include patient referrals for assessment for an implantable cardiac device. Removing this reference will limit awareness amongst referring physicians of the important role that implantable cardiac devices can play in the management of patients with chronic heart failure and of NICE TA 314. We recommend this is re- instated within the guidelines. The technology appraisal has shown these devices to be cost effective and to improve mortality. Adoption of the policy and the technology is very varies across the NHS as is demonstrated in the NICOR audit for cardiac rhythm devices :https://nicor5.nicor.org.uk/_802571400070B77E.nsf?OpenDatabase</p>	<p>Information on Implantable Cardioverter Defibrillators in the published guideline is out of date. There is other NICE guidance that now covers this and the guideline will cross refer to this: NICE TA314: Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.</p>
NDPCHS			<p>I registered our group (NDPCHS) just yesterday to provide feedback on this so it is unlikely I will be able to do so through the normal channels. Nevertheless I thought it would be important to at least let you know some comments we would like to make regarding the current documents in case you could make them available to the relevant people.</p> <p>Comments:</p> <ul style="list-style-type: none"> Educational element is not mentioned. Our current work as well as other Systematic Reviews (evaluating the role of BNP in monitoring) point towards education as an important component in the management of CHF. Monitoring of weight is not mentioned. This might be by design but there has been suggestions of using weight as an alternative for management. 	<p>Thank you for your comment. Education is considered under the area ‘information and support’ of the scope. There is also likely to be educational elements to rehabilitation packages.</p> <p>Due to the complexity of chronic heart failure, weight cannot be considered as an independent treatment option. However, weight is considered under the area ‘fluid balance’, and weight</p>

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			<ul style="list-style-type: none"> Mentions tele-monitoring but not structured telephone support. These have been classed as two distinct types for remote monitoring in Pandor 2013. It might be important to make this distinction. Mentions monitoring in general, but not specifically frequency of? Our work suggests that advice on frequency might be required. Qualitative work as part of our NIHR funded Programme points towards patients equating shorter intervals to increase in severity. Even pointing towards a lack of evidence for the selection of the frequency would be useful to set a Research agenda. 	<p>loss is likely to be a result of rehabilitation packages.</p> <p>Furthermore, for the management of obese patients NICE CG189: Obesity should be consulted.</p> <p>Structured telephone support will be covered as a form of tele-monitoring.</p> <p>The frequency of monitoring will be discussed when reviewing the evidence around this area during the development of the guideline.</p>
NHS England	General	General	<p>Dear NICE</p> <p>Thank you for the opportunity to comment on the above clinical guideline, I wish to confirm that NHS England has no substantive comments to make regarding this consultation.</p> <p>Kind Regards</p>	<p>Thank you for your comment.</p>
NICE Medicines and prescribing programme	General	General	<p>Section 1.3 (p 2) states that initiation and sequencing of pharmacological therapies will be updated, and section 1.5 (p 6) states that key questions include</p> <ul style="list-style-type: none"> In people with CHF who have received one pharmacological treatment, what is the next most clinically and cost effective option? How will the use of pharmacological interventions for people with CHF be different in people who also have CKD? 	<p>Thank you for your comment. Section 1.3 lists areas which will and will not be included within this scope (please see the bold headings for distinction). As stated, beta-blockers will be included whereas</p>

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			<ul style="list-style-type: none"> • What is the comparative clinical and cost effectiveness of mineralocorticoid receptor antagonists and angiotensin II receptor antagonists (ARBs) in people with symptomatic chronic heart failure who are having treatment with: <ul style="list-style-type: none"> o a beta-blocker and an ACE Inhibitor or o a beta-blocker alone because of intolerance to ACE inhibitors? <p>But section 1.3 (p 4) states that pharmacological therapies will not be updated. This is very confusing and seems to make little sense. For the avoidance of doubt, we would support the planned updates related to medicines described in section 1.3 and 1.5</p>	Isosorbide/hydralazine, angiotensin-converting enzyme (ACE) inhibitors, angiotensin-II receptor antagonists (ARBs), diuretics, beta-blockers in the absence of secondary atrial fibrillation, calcium-channel blockers, digoxin and amiodarone will not be included within this scope. The key questions have been formulated around this.
NICE Medicines and prescribing programme	General	General	Section 1.3 (p 2) states that initiation and sequencing of pharmacological therapies will be updated, so the guideline should include TA 267 (ivabradine for treating chronic heart failure) and the TA on sacubitril/valsartan is expected in May (ID822). It is not sufficient to include them only in the NICE Pathway, they must be in the guideline otherwise it will be incomplete (cf the SGLT-2 inhibitors TAs and NG28)	Thank you for your comment. Both ivabradine and sacubitril/valsartan will be included in the following review question (subject to a NICE technology appraisal review process) '2.1 In people with CHF who have received one pharmacological treatment, what is the next most clinically and cost effective option?'. For other areas of guidance on these drugs, we will cross-refer to NICE TA267 Ivabradine for treating chronic heart failure and NICE TA Heart failure - sacubitril valsartan [ID822] .
NICE Medicines	4	114 and	It is proposed that use of statins and aspirin will be removed from the guideline. I cannot find a reference to statins in the published CG108. I suggest that a cross	Thank you for your comment. Cross-referral will be made to NICE CG181

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and prescribing programme		115	reference is made to CG181 and CG172, similar to recommendation 1.5.2 in NG28	Lipids and Cardiovascular disease risk assessment and NICE CG172: Myocardial infarction
NICE Medicines and prescribing programme	8	219-223	Reference should also be made to NG5: medicines optimisation	Thank you for your comment. This guidance has been added to the scope.
Novartis Pharmaceuticals Ltd	2	44	This should include the impact on this of use of sacubitril/valsartan on biomarkers (specifically natriuretic peptides) as sacubitril/valsartan affects BNP and NTproBNP levels	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	5	138-140	This should include the impact on this of use of sacubitril/valsartan on BNP/ NTproBNP as sacubitril/valsartan affects BNP and NTproBNP levels	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	3	54	This should include the impact on this of use of sacubitril/valsartan on biomarkers (specifically natriuretic peptides) as sacubitril/valsartan affects BNP and NTproBNP levels	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals	3	79	Sacubitril/valsartan should be added to pharmacological therapies not in the published guideline that will be included in the update because this drug is now	Thank you for your comment. The NICE TA Heart failure - sacubitril

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cals Ltd			available in England and Wales	valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	2	48	Sacubitril/valsartan should be added to key areas that should be covered with regards to managing chronic heart failure because this drug is now available in England and Wales	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	6	170-171	This needs to be considered with impact of sacubitril/valsartan use on the markers.	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	9	238	The draft scope should include reference to sacubitril/valsartan TA/ACD as this pharmacological therapy is now available in England and Wales.	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	10	266-267	This guidance should review the deaths prevented and clinical and cost-effectiveness of ACEi and ARBs as well as sacubitril/valsartan as this pharmacological therapy is now available in England and Wales.	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals	6	148-149	This does not reflect the licensed use of sacubitril valsartan as a first line therapy (not treatment failure on their first therapy). Suggest to be rephrased "In people	Thank you for your comment. The NICE TA Heart failure - sacubitril

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			Please insert each new comment in a new row	Please respond to each comment
cals Ltd			with CHF, what is the most clinically and cost effective option"	valsartan [ID822] .will be incorporated into this guideline, subject to a NICE technology appraisal review process.
Novartis Pharmaceuticals Ltd	6	157-161	This section might be redundant depending on rephrasing of line 138-149	Thank you for your comment.
Novartis Pharmaceuticals Ltd	7	208	Should include both CV and all-cause mortality	Thank you for your comment. This will be considered when developing the review protocols.
Novartis Pharmaceuticals Ltd	4	100	We want to ensure that the recommendation for HF patients to be reviewed every 6 months (from CG108) is maintained in the revised guideline. Rationale: HF is a progressive condition and it is vital that patients are treated with the right medication at the correct dose and HF patients therefore require regular review. HF patients are not receiving regular reviews, market research shows that only 20% of patients are being reviewed on an annual basis. CG108 recommendation on monitoring can be found in section 1.4.1.1- 1.4.1.3	Thank you for your comment. The frequency of monitoring will be discussed when assessing the evidence for this area and when developing recommendations.
Quality Standards, NICE	General	General	The updated quality standard for chronic heart failure will publish 18/02/16. It will be revisited to check for any necessary amendments as the updated guideline approaches publication.	Thank you for your comment.
RCGP	General	General	With heart failure there is a tendency to rush to a 'pharmacentric' approach. Central obesity itself is a potent cause of dyspnoea so diet and weight loss is a chance for patients to have some control, to improve their health and feel less impotent. To this end please include comment on lifestyle modification- and not as an afterthought. It is a great chance to involve patients in their care.	Thank you for your comment. This guideline has considered non-pharmacological options i.e. rehabilitation and fluid-balance. Guidance for lifestyle modification for patients with obesity can be found in

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			Over the past year I have had four patients who are delighted and proud to find that with weight loss they breathe better and need less medication. All four have lost over two stone in weight –the oldest is 83.	NICE CG189: Obesity.
RCGP	General	General	It would be worth it to change wording in order to encourage a 'patient-centred approach' and with it an awareness of balancing risks of multiple medication please. This was well done in the recent NICE diabetes guidelines. See below: 'When caring for older adults with type 2 diabetes, particular consideration should be given to their broader health and social care needs. Older people are more likely to have co existing conditions and to be on a greater number of medicines. Their ability to benefit from risk reduction interventions in the longer term may also be reduced. Treatment and care should take into account individual needs and preferences. Patients should have the opportunity to make informed decisions about their care and treatment, in partnership with their healthcare professionals.'	Thank you for your comment. This will be considered when developing the guideline.
REACH-HF research team and British Assoc of Cardiovascular Prevention and Rehabilitation	6	165-8	We are delighted to see the revision of the cardiac rehabilitation to "3.1 What is the clinical and cost-effectiveness of home-based rehabilitation (that includes an exercise element) for people with chronic heart failure?" This is certainly the key policy question. As I discussed at scoping meeting in London, as the lead for the Cochrane cardiac rehab portfolio of reviews, I would be pleased to offer update of the current Cochrane review – 'Exercise-based rehabilitation interventions for heart failure' with a specific focus on the latest evidence on the clinical and cost-effectiveness of home-based rehab interventions for heart failure.	Thank you for your comment.

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			http://openheart.bmj.com/content/2/1/e000163.full I would pleased this to discuss the offer and timing of our update Cochrane review to maximise utility with the Guideline Panel.	
Resuscitation Council (UK)	7	194	The wording here seems to imply that there may be a 'one-size-fits-all' answer to this question, when in fact what is needed is good individualised clinical care based on shared decision-making. The wording 'refer people with chronic heart failure to palliative care' implies that palliative care is somehow distinct from other aspects of clinical care and that other professionals (e.g. cardiologists, general physicians, geriatricians, general practitioners, heart failure nurses, cardiac physiologists) are not involved in its delivery. Delivery of good-quality care in advanced heart failure, including relevant palliative care, requires an integrated approach by all specialties and professionals involved working together to meet the specific needs of each individual. The optimal timing of involvement of palliative care specialists in that integrated approach will vary from person to person and be identified by clinicians talking to their patients and using good clinical skills.	We agree that decisions should take into account the needs of the individual involving the MDT where applicable. This principle is outlined in Making decisions using NICE guidelines. http://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/nice-guidelines/making-decisions-using-nice-guidelines
Resuscitation Council (UK)	7 8	201 233	The draft scope makes no mention of the 2015 NICE-accredited guidance: 'Cardiovascular implanted electronic devices in people towards the end of life, during cardiopulmonary resuscitation and after death' from the Resuscitation Council (UK), British Cardiovascular Society and National Council for Palliative Care: https://www.resus.org.uk/defibrillators/cardiovascular-implanted-electronic-devices/ We hope that this guidance will be considered by the Guideline Development Group for the Chronic Heart Failure guidance and by NICE for inclusion in the pathway.	Thank you for your comment and for highlighting this publication. However we are only able to refer to other NICE guidance within the scope and the guideline mentioned within the scope.

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Resuscitation Council (UK)	7	192	Duplicate wording: 'be managed' X2	Thank you for your comment: this edit has been made.
Roche Diagnostics Ltd	2	44	The draft scope advises that the role of circulating biomarkers (including natriuretic peptides) in diagnosing heart failure will be updated. We feel that their role in diagnosing acute decompensated heart failure should also be included as there is evidence that clarity may be needed in light of newer treatment options: Mair J, Lindahl B, Giannitsis E, et al. Will sacubitril-valsartan diminish the clinical utility of B-type natriuretic peptide testing in acute cardiac care? European Heart Journal: Acute Cardiovascular Care, 2016. Available from: DOI: 10.1177/2048872615626355	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] will be incorporated into this guideline, subject to a NICE technology appraisal review process. Please note that the remit is to update the chronic heart failure guideline and not the acute heart failure guideline.
Roche Diagnostics Ltd	2	31	The draft scope proposes to exclude diagnostic screening for heart failure in asymptomatic patients. As there is accumulating evidence on the growing numbers of undiagnosed and mis-diagnosed heart failure (HF) sufferers, the role of testing circulating biomarkers in picking up this group of patients should not be omitted	Thank you for your comment. This scope is limited to people with symptomatic heart failure. Screening for asymptomatic patients would fall under the remit of Public Health England's National Screening Committee.
Roche Diagnostics Ltd	5	138-140	Roche Diagnostics will be happy to provide evidence to support the evaluation of diagnostic accuracy of NT proBNP vs. BNP, if requested. We would also request clarity on whether the comparison will be made in patients receiving pharmacological treatment with angiotensin receptor/neprilysin inhibitor (ARNI) drugs.	Thank you for your comment. The guidance will review the optimal choice of biomarker for diagnosis and monitoring for all agents in the model of care for chronic heart failure.
Roche Diagnostics	4	108-109	We ask for clarity on why the goals of treatment have been removed as we feel these are important measures with which to reference success of treatment or	Thank you for your comment. Goals of treatment were discussed in the

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Ltd			effectiveness of monitoring.	previous guideline (CG108) but no recommendations made. Advice on this will be drawn out of other areas of management and care within this scope and covered in individual recommendations. r
Roche Diagnostics Ltd	5	141-142	Roche Diagnostics will be happy to provide more recent evidence to support the evaluation of diagnostics thresholds for NT-proBNP in people with HF and chronic kidney disease.	Thank you for your comment
Roche Diagnostics Ltd	6	170-171	Roche Diagnostics will be happy to provide more recent evidence on the clinical and cost-effectiveness of NT-proBNP-guided care vs. standard of care, if requested	Thank you for your comment
Royal College of Nursing	General		Dear Sir or Madam, This is just to inform you that the feedback I have received from nurses working in this area of health suggests that there are no comments to submit on behalf of the Royal College of Nursing to inform on the consultation of the draft scope of Chronic heart failure in adults: diagnosis and management. Thank you for the opportunity to participate. We look forward to participating at the next stage. Please acknowledge receipt.	Thank you for your comment.
Royal College of Physicians			We would like to endorse the comments of the British Society	Thank you for your comment.
Royal College of	5	117	Management of co-existent or resultant depression and anxiety remains of relevance in clinical guidelines, especially in the context of recognising and	Thank you for your comment. While the existing section will be removed

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Physicians of Edinburgh			Please insert each new comment in a new row managing dyspnoea resulting from anxiety. We would therefore recommend continuing to include this in the guideline.	Please respond to each comment from the guidance, it will be replaced by a cross-referral to NICE CG91: Depression in adults with chronic physical health problem
Royal College of Physicians of Edinburgh	3	51-52	Clinicians have differing views regarding the effect on uptake of rehabilitation by the need to attend centres where rehabilitation programmes are delivered (in addition to the level of provision of these centres and the inability of certain groups of patients with chronic heart failure to access these programmes). It may be helpful if the scope did not restrict the review to home based rehabilitation. This might be done with a minimal alteration to these two lines which could state: "Rehabilitation, including home-based rehabilitation packages that include an exercise element."	Thank you for your comment. The importance of a supervised rehabilitation programme designed for people with HF has been acknowledged in CG108, and the guidance will remain. The focus of the update will be on home-based rehabilitation due to the emergence of new evidence and the need for home rehabilitation options for patients who are unable to access rehabilitation centres.
Royal College of Physicians of Edinburgh	4	General	The absence of an assessment of the new heart failure treatment Entresto (sacubitril/valsartan) is surprising as it is generally considered the most promising heart failure drug to be licensed in over 10 years.	Thank you for your comment. The NICE TA Heart failure - sacubitril valsartan [ID822] .will be incorporated into this guideline , subject to a NICE technology appraisal review process.
Royal College of Physicians of Edinburgh	2	43	There are no proposals to update diagnosis of heart failure based on symptoms and signs (see also p4, line 89). It would be helpful if the updated guidance includes information on sensitivity and specificity of heart failure symptoms to aid clinical triggers for investigations.	Thank you for your comment. Signs and symptoms was considered in CG108 by referral to the health technology assessment (Mant, 2009).

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Royal College of Physicians of Edinburgh	3	62	Will the guidance outline which members of the multidisciplinary team should be involved in care of all patients with CHF? Current UK practice incorporates a range of individuals who have developed skills locally – inclusion of a geriatrician clinical lead would be recommended in recognition of the range of co-morbidities which many patients with CHF present with in addition to CHF itself.	Thank you for your comment. This has been covered by CG108 and does not need updating.
Royal College of Physicians of Edinburgh	7	177	We would recommend that fluid restriction and salt restriction are treated as two separate processes within guidance rather than under a single heading.	Thank you for your comment. These have been listed under the same heading as they are clinically assessed together. During the review, evidence on these will be assessed separately.
Royal College of Physicians of Edinburgh	2	49	The College would recommend that optimising fluid balance should be the first step in managing Chronic Heart Failure (CHF), in advance of initiation of pharmacological therapies.	Thank you for your comment. This will be considered when reviewing the evidence for these areas.
Royal College of Physicians of Edinburgh	8	210	We suggest that re-admission to hospital is considered under two categories: – readmission attributable to progression / destabilisation of CHF and - readmission attributable to complications from the treatment of CHF – e.g. AKI, falls, syncope, bradycardia.	Thank you for your comment. This will be considered when developing the review protocols.
Royal College of Physicians of Edinburgh	6	154	We recommend inclusion of information on both dose adjustment, and monitoring, and cautions in patients with coexistent CKD and CHF.	Thank you for your comment. Pharmacological interventions for people with CKD and CHF will be considered in this guideline.
Royal	Gener	Gene	The draft scope is wide ranging and provides comprehensive guidance on the	Thank you for your comment.

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College of Physicians of Edinburgh	al	ral	management of patients with left heart failure due to left ventricular dysfunction. It will address some areas where previous guidelines were vague eg indications for revascularisation of coronary artery disease in patients with impaired left ventricular systolic function. There are a few specific areas which require comment as below.	
Royal College of Physicians of Edinburgh	4	General	An assessment of the role of aldosterone antagonists seems reasonable.	Thank you for your comment.
Royal College of Physicians of Edinburgh	6	155-156	The College supports the inclusion of "What is the clinical and cost effectiveness of beta-blockers in people with chronic heart failure and secondary atrial fibrillation?" as mentioned above in the text.	Thank you for your comment.
Royal College of Surgeons			Dear Sir/Madam, Thank you for your e-mail. Unfortunately, we are unable to assist with this request. Kind Regards,	Thank you for your comment.
Royal Devon and Exeter NHS Foundation Trust	6	143	For the answer to this question to be clinically useful, it will be important not just to consider the accuracy of determining heart failure with reduced or preserved ejection fraction but to determine other values of the test. This could include assessment of the aetiology of heart failure, accuracy of reassessment over time or the incremental clinical value of each test.	Thank you for your comment. This will be addressed when reviewing the question 'What should the diagnostic thresholds for BNP's in people with heart failure and chronic

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				<i>kidney disease be?</i> The role of biomarker guided management of heart failure will also be reviewed.
Royal Devon and Exeter NHS Foundation Trust	2	33	It is a shame not to include people having chemotherapy. Heart failure related to chemotherapy is an increasing problem and is often diagnosed too late. A question around the monitoring or screening for this group would be an excellent driver for an increase in quality of care.	Thank you for your comment. This is a specialist area and therefore cannot be covered adequately by this guideline.
Royal Devon and Exeter NHS Foundation Trust	7	191	This section should also examine the transition from primary to secondary care. Questions could be developed around the appropriate timing of referral, the adequacy of primary care to manage decompensations and the infrastructure needed to manage the increasing complexity of heart failure.	Thank you for your comment. This will be covered within this guideline when it reviews optimal models of care.
Royal Devon and Exeter NHS Foundation Trust	2	38	This suggests that tertiary care institutions are exempt from this guideline which would not seem appropriate.	Thank you for your comment. This guideline will only cover primary and secondary care settings. Tertiary care institutes are part of secondary care but also have more specialist roles.
Servier Laboratories Ltd	6	169	The draft scope does not mention heart rate. In April 2012 the National Heart Failure Audit dataset was revised to include a series of new fields, one of which was heart rate. Heart rate is now established as a predictor of outcomes in patients with heart	Thank you for your comment. Ivabradine will be included in the following review question '2.1 In people with CHF who have received one pharmacological treatment, what

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			<p>failure due to LVSD. Beta blocker trials show that for every 5 bpm reduction in heart rate achieved, there was an 18% reduction in all cause-mortality. (McAlister. Ann Intern Med 2009;150:784-794)</p> <p>Also, the placebo arm of SHIFT showed a clear link between baseline heart rate and outcomes. Patients with the highest heart rates (≥ 87 beats per minute, $n=682$, 286 events) were at more than two fold higher risk for primary composite endpoint (cardiovascular death or hospital admission for worsening heart failure) than were patients with the lowest heart rates (70 to <72 bpm, $n=461$, 92 events; hazard ratio [HR] 2.34, 95% CI 1.84–2.98, $p<0.001$). Risk of primary composite endpoint events increased by 3% with every beat increase from baseline heart rate and 16% for every 5-bpm increase. (Bohm. The Lancet 2010; 376: 886–94)</p> <p>Therefore, heart rate is an important risk factor that should be considered within the new guidelines, potentially within the section 'Key issues and questions' under 'Monitoring heart failure'. A relevant question would be 'What is the clinical and cost effectiveness of monitoring heart rate in people with chronic heart failure?'</p>	<p><i>is the next most clinically and cost effective option?'. For other areas of guidance on these drugs, NICE TA267: Ivabradine for treating chronic heart failure will be incorporated into this guideline and the scope has been amended to make this clearer...</i></p>
Servier Laboratories Ltd	3	79	<p>The section on 'Areas not in the published guideline that will be included in the update' does not include ivabradine under 'Pharmacological therapies'. It does however include 'beta blockers'.</p> <p>TA267 recommended ivabradine for patients consistent with the indication, in heart failure due to LVSD, under advice from a specialist in the following:</p>	<p>Thank you for your comment. NICE TA267: Ivabradine for treating chronic heart failure will be incorporated into this guideline and the scope has been amended to make this clearer.</p>

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			<p>Please insert each new comment in a new row</p> <p>1. Patients (in sinus rhythm) who are contraindicated to beta-blockers or are intolerant to these agents and have a resting HR ≥ 75bpm</p> <p>2. Patients (in sinus rhythm) on beta-blockers at maximally tolerated doses whose resting heart rate remains ≥ 75bpm</p> <p>It should therefore be listed for inclusion in the guideline update.</p>	Please respond to each comment
St Jude Medical	3	56	We believe that this section of the guideline should further consider the role of the CardioMEMS Heart Failure Monitoring System in the remote management of patients. This device offers opportunities to remotely manage patients with both reduced and preserved ejection fractions, to improve outcomes and reduce hospitalisation. This technology has been initially reviewed under IPG 463, however more data are now available that the guideline may wish to consider.	Thank you for your comment. Information on monitoring can be found in NICE TA314: Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.
St Jude Medical	5	121	It is proposed that referral for implantable defibrillator will be removed from the guideline, although there is a note to the effect that TA 314 (implantable defibrillators and cardiac resynchronisation therapy) will be included in the NICE Pathway. We would not expect TA 314 to be reviewed in the context of this guideline, but a more overt reference to it as being embedded within the guideline would be useful and ensure that these two NICE outputs are 'joined up'.	Thank you for your comment. Information on Implantable Cardioverter Defibrillators in the published guideline is out of date. There is other NICE guidance that now covers this and the guideline will cross refer to this: NICE TA314: Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure.
St Jude Medical	3	72	We believe that inclusion of referral for Ventricular Assist Devices would be a helpful addition to the guideline, particularly as they are already in use within the NHS and have been reviewed under IPGs 177 and 516.	Thank you for your comment. This guidance can be found in NICE CG187: Acute heart failure.

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Stanningley Pharma Ltd	3	73-74	Might it be better to say the management of iron deficiency in chronic heart failure? The management of chronic heart failure may not be any different what is important is the identification and correction of iron deficiency.	Thank you for your comment. We feel this has been adequately addressed in the scope.
Stanningley Pharma Ltd	6	150-152	Though the inclusion of this question as a key issue/question is to be welcomed it would benefit from greater clarity. Is the question related to anaemia or iron deficiency or both? This is important as evidence to support the benefits of managing iron deficiency in patients with or without anaemia is far stronger than that for the use of ESA therapy in any form. In Renal medicine where ESA therapy is most widely used increasing evidence suggests that high ESA doses are potentially detrimental and are associated with both increased stroke risk and all cause mortality. In terms of iron management the evidence to support the use of IV iron therapy to improve iron status regardless of change in Hb is growing. The question remains as to whether similar outcomes come be achieved in some patients by using oral iron therapy. This of course would potentially be a far less expensive option and may explain why such studies have yet to be carried out. Interestingly the editorial published at the time of the publication of the pivotal FAIR-HF trial in 2009 raised this very question. One point that may be wise to include here would be the issues of how to define and identify iron deficiency. The scope and final version of the updated Nice CKD anaemia guidelines may be helpful in this respect. http://www.nice.org.uk/guidance/ng8	Thank you for your comment. This question will only be reviewing treatment of iron deficiency in chronic heart failure. All forms of iron therapy will be considered when developing this evidence review. Other NICE guidelines address the topic of anaemia in a variety of contexts e.g. chronic kidney disease (NG8).
The Pumping Marvellous Foundation	5	117	Why take this out? Big QOL indicator	Thank you for your comment. While the existing section will be removed from the guidance, it will be replaced by a cross-referral to NICE CG91: Depression in adults with chronic

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				physical health problem
The Pumping Marvellous Foundation	3	71	As this is blank shouldn't we be including how the conversation around HF and their condition is discussed by their doctor at consultation	Thank you for your comment. The sensitivity around discussing heart failure is important, but difficult to formulate into an evidence review. Therefore this cannot be included within the guideline scope. Guidance on interaction with patients is covered in the NICE CG138: Patient experience in adult NHS services .
The Pumping Marvellous Foundation	2	31-35	By excluding these patient groups can you demonstrate where they are covered and in which guidelines	Thank you for your comment. Unfortunately, we are unable to provide this information. The rationale for their exclusion was not because they are necessarily covered by other guidelines but because their treatment would require specialist care which cannot be covered adequately by the NICE guideline.
The Pumping Marvellous Foundation	5	116 & 122	Why take this out – Valvular disease causes a significant impact on HF	Thank you for your comment. Although this section of the previous guidance will be removed, it will be

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				<p>replaced by a cross-referral to NICE IPG504: Transcatheter valve-in-valve implantation for aortic bioprosthetic valve dysfunction</p> <p>Other relevant NICE guidance includes: NICE CG187: Acute heart failure</p> <p>NICE IPG309: Percutaneous mitral valve leaflet repair for mitral regurgitation</p> <p>NICE IPG421: Transcatheter aortic valve implantation for aortic stenosis</p>
The Pumping Marvellous Foundation	4	108-109	Why are we removing this line. There are two big QOL indicators and significant cost implication indicator	Thank you for your comment. Goals of treatment were discussed in the previous guideline (CG108) but no recommendations made. We have removed this from the scope to avoid confusion, as advice on this will be drawn out of other areas of management and care within this scope and covered in individual recommendations..
The Pumping	3	62	Which multi-disciplinary team are you referring to	Thank you for your comment. We are

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Marvellous Foundation				referring to the heart failure multi-disciplinary team. The scope has been amended to state this.
Vifor Pharma UK Limited	3	79	Following up on Line 74, we would suggest to include as an additional pharmacological therapy – Iron supplementation in patients diagnosed with iron deficiency	Thank you for your comment. This will be considered when reviewing the following question ' <i>What is the clinical and cost-effectiveness of pharmacological interventions (erythropoietin and intravenous iron) in people with chronic heart failure and iron deficiency?</i> '.
Vifor Pharma UK Limited	6	150	We would like to inform that ferric carboxymaltose is the only treatment for iron deficiency which demonstrated early, sustained improvements in symptoms, quality of life, physical performance and a reduction in hospitalisations in systolic chronic heart failure. The key reference is Anker SD, et al. ESC Congress 2015, P2796, Sunday August 30th, London UK.	Thank you for your comment. This will be considered when reviewing the following question ' <i>What is the clinical and cost-effectiveness of pharmacological interventions (erythropoietin and intravenous iron) in people with chronic heart failure and iron deficiency?</i> '.
Vifor Pharma UK Limited	6	150	We would like to inform that ferric carboxymaltose has proven to be cost effective vs placebo in chronic heart failure iron deficiency patients with and without anaemia in the UK setting. (Gutzwiller FS et al, Eur J Heart Fail 2012, 14:782-790)	Thank you for your comment. This will be considered when reviewing the following question ' <i>What is the clinical and cost-effectiveness of pharmacological interventions (erythropoietin and intravenous iron)</i> '.

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 recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

Chronic heart failure

Consultation on draft scope Stakeholder comments table

20 January 2016 – 17 February 2016

Comments forms with attachments such as research articles, letters or leaflets cannot be accepted.

Stakeholder	Page no.	Line no.	Comments Please insert each new comment in a new row	Developer's response Please respond to each comment
				<i>in people with chronic heart failure and iron deficiency?.</i>
Vifor Pharma UK Limited	6	150	We would like to inform that the European Society of Cardiology (ESC) will be updating their Guidelines for the diagnosis and treatment of acute and chronic heart failure to be published in May 2016 and they will include the evidence of CONFIRM-HF (reference: Ponikowski P, et al. Eur Heart J 2015;36:657-668.) and a meta-analysis of individualized patient data from four clinical trials using ferric carboxymaltose (Anker SD, et al. ESC Congress 2015, P2796, Sunday August 30th, London UK.)	Thank you for your comment.
Vifor Pharma UK Limited	6	151	When considering a possible benefit of erythropoietin for managing CHF, the results of the RED-HF trial should be considered: (Treatment of Anaemia with Darbepoetin Alfa in Systolic Heart Failure; N Engl J Med 2013; 368:1210-1219; DOI: 10.1056/NEJMoa1214865). The authors of this publication concluded "treatment with darbepoetin alfa did not improve clinical outcomes in patients with systolic heart failure and mild-to-moderate anaemia."	Thank you for your comment. A number of iron therapies will be reviewed, and all relevant published clinical evidence will be considered.
Vifor Pharma UK Limited	7 and 8	205 / General	We believe it is relevant to consider as main outcomes (in addition to those listed) symptoms, patient reported outcomes, clinical outcomes e.g. New York Heart Association (NYHA) Functional classification, exercise capacity and cost effectiveness	Thank you for your comment. This will be considered when developing the review protocols.

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