National Institute for Health and Care Excellence

SingleTechnology Appraisal (STA)

Ledipasvir-sofosbuvir for treating chronic hepatitis C

Response to consultee and commentator comments on the draft remit and draft scope (pre-referral)

Comment 1: the draft remit

Section	Consultees	Comments	Action
Appropriateness	Gilead Sciences	Hepatitis C Virus (HCV) is an area of high unmet need, with an estimated 160,000 people currently infected in England. Whilst HCV is a curable disease and there are treatments available that offer this possibility, significant safety/tolerability issues combined with variable success rates mean that only a small proportion of diagnosed patients are successfully treated each year. The burden of HCV is growing rapidly as patients infected with the disease in the 1980s and 1990s begin to develop serious complications. Health Protection England have estimated that whilst in the year 2000 there were 4,310 people with HCV related cirrhosis by 2010 this number had more than doubled to 9,670, and if left untreated this number is projected to reach 15,840 by 2020. These data demonstrate how there is a growing public health need and burden to the NHS regarding HCV. Sofosbuvir/ledipasvir fixed dose combination (SOF/LDV FDC) offers a step-change in efficacy, safety and tolerability for the treatment of patients, making successful HCV cure a realistic probability for a higher proportion of patients within a broader population. It should be noted that the EMA has adopted an accelerated regulatory process for SOF/LDV FDC, a designation only granted to those medicines of major public health interest. Gilead fully supports timely referral to and review by NICE. The best opportunity for cure with any patient is to treat as early as possible as increased fibrosis/cirrhosis	Comments noted. No changes required.

Section	Consultees	Comments	Action
		correlates to poorer treatment outcomes. For patients diagnosed with advanced liver disease (it is estimated that 10,000 patients have HCV-related cirrhosis), there is an urgent need to treat to prevent further disease progression. In particular, patients awaiting liver transplant may have limited treatment options to clear the HCV and for the vast majority, failure to cure their HCV prior to transplant will result in infection of their new liver and, as a result, the patient could develop rapid fibrosis progression in the graft. Given the urgency of treating life-threatening liver disease, Gilead wishes to ensure that the timing of NICE guidance aligns as closely as possible with the anticipated accelerated regulatory review timelines for SOF/LDV FDC. We therefore strongly support an STA submission during 2014 in order to support this alignment.	
	Merck, Sharp and Dohme	MSD agree it is appropriate to refer to NICE for appraisal	Comments noted. No changes required.
	Royal College of Nursing	The remit and draft scope of this proposed appraisal is welcomed. It seems appropriate to be fast tracked	Comments noted. No changes required.
	Terence Higgins Trust	No comment	Comments noted. No changes required.
	United Kingdom Clinical Pharmacy Association (UKCPA) - Gastroenterology /Hepatology Committee	This technology appraisal is appropriate for review by NICE	Comments noted. No changes required.

Section	Consultees	Comments	Action
Wording	Gilead Sciences	The following information is provided as commercial-in-confidence: [redacted]	Comment noted. Following the scoping workshop the remit has been updated as follows: "To appraise the clinical and cost effectiveness of ledipasvir-sofosbuvir within its licensed indication for treating chronic hepatitis C."
	Merck, Sharp and Dohme	Wording is appropriate	Comment noted. The remit has been updated as follows: "To appraise the clinical and cost effectiveness of ledipasvir-sofosbuvir within its licensed indication for treating chronic hepatitis C."

Section	Consultees	Comments	Action
	Royal College of Nursing	Not aware of any evidence to present to reflect cost effiveness in this draft scope	Comment noted. No changes required.
	Terence Higgins Trust	No comment	Comment noted. No changes required.
	UKCPA	No specific issues with wording as it currently stands.	Comment noted. No changes required.
Timing Issues	Gilead Sciences	SOF/LDV FDC is a medicine that offers a step-change in an area of high unmet and urgent need. The recent NHS Outcomes Framework has set a priority to reduce mortality due to liver disease in the under-75s. HCV is a significant driver for liver-related deaths (at least 296 in 2011) and a key driver for morbidity, with HCV-related cirrhosis and hepatocellular carcinoma (HCC) being life-threatening end stages of HCV disease. A substantial proportion of liver transplants performed in the UK are required as a result of advanced HCV infection. With around 10,000 UK patients living with HCV-related cirrhosis or HCC there is a significant group of patients whose health would be further compromised by any delay to treatment, due to an increased risk of progression to end stage liver disease, decompensation and/or death. The implications of disease progression for the patient is a reduction in quality of life combined with an increase in associated healthcare costs to the NHS. SOF/LDV FDC represents a breakthrough treatment for HCV, offering: • Superior clinical efficacy vs. NICE-recommended SoC (even amongst cirrhotic patients who are typically the most difficult to treat) • The first complete all-oral non-IFN-based treatment regimen	Comment noted. NICE aims to provide guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted.

Section	Consultees	Comments	Action
		• The following information is provided as commercial-in-confidence: Data demonstrating high efficacy in reducing graft re-infection pre- and post-liver transplant, which is an area of great unmet need • A side effect profile similar to placebo and superior to the current SoC • Shorter treatment duration (8-12 weeks with SOF/LDV, compared with up to 48 weeks with current SoC) The implications are as follows: • Significantly greater proportion of HCV patients can achieve a cure (93%-99% demonstrated in recent clinical trials) • Decreased treatment-emergent side effects and discontinuations compared to NICE-approved SoC, which leads to decreased healthcare costs associated with managing the potentially severe side effects • Improved QoL for patients as demonstrated by a reduced treatment side effect profile and decreased duration of treatment • As this is an infectious disease with the potential for cure, the result of improving cure rates together with increasing numbers of patients eligible for treatment, there is the potential to positively impact on the overall epidemiology and long-term burden of HCV to the NHS. All of this means that there is an urgent need for timely patient access to SOF/LDV FDC, re-iterating the need for timely NICE review and guidance. Given the urgent need for those patients with life-threatening liver disease, Gilead wishes to ensure that the timing of NICE guidance aligns with the anticipated accelerated regulatory review timelines for SOF/LDV FDC. We therefore strongly support an STA submission in 2014 to support this alignment.	
	Merck, Sharp and Dohme	No comment	Comment noted. No changes required.

Section	Consultees	Comments	Action
	Royal College of Nursing	The ability to remove interferons and their related adverse effects for patient patient Groups proposed makes this appropriate to fast track	Comment noted. NICE aims to provide guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted.
	Terence Higgins Trust	Current treatments are effective 60% of the time. The improved efficacy of this treatment, in addition to the innovation in administration of the treatment, mean that it should be a priority to ensure the most effective treatment is available on the NHS and that NHS resources are used effectively.	Comment noted. NICE aims to provide guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted.
	UKCPA	Due to the rapidly evolving HCV treatment climate there is an urgency to get this appraisal completed and finalised by end of year.	Comment noted. NICE aims to provide guidance to the NHS within 6 months from the date when the marketing authorisation for a technology is granted.
Additional comments on	Gilead Sciences	None	No changes required

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

Section	Consultees	Comments	Action
the draft remit	Merck, Sharp and Dohme	None	No changes required
	Royal College of Nursing	None	No changes required
	Terence Higgins Trust	None	No changes required
	UKCPA	None	No changes required

Comment 2: the draft scope

Section	Consultees	Comments	Action
Background information	Gilead Sciences	Gilead wishes to note that HCV is a disease which may take up to 40 years to develop into cirrhotic disease, rather than the description which states that this is an average time for progression.	Comment noted. The background section of the scope has been amended accordingly.
	Merck, Sharp and Dohme	One very minor comment. In the last paragraph of page 1 we believe the text should be amended to: "NICE guidance on hepatitis C (technology appraisals 75 and 106) recommend combination therapy with ribavirin and either peginterferon alfa-2a or peginterferon alfa-2b…."	Comment noted. The background section of the scope has been amended accordingly.
	Royal College of Nursing	Seems appropriate	Comment noted. No changes required.
	Terence Higgins Trust	No comment	No changes required.
	UKCPA	Standard background information –no issues with current content.	Comment noted. No changes required.
The technology/ intervention	Gilead Sciences	Gilead suggests that the description of the technology has in part been taken from the simeprevir documentation. The following wording describes SOF/LDV FDC: "SOF is a uridine nucleotide analogue that inhibits HCV polymerase and LDV is a HCV NS5a inhibitor, with NS5a being essential for post-replication assembly. SOF/LDV FDC is administered orally as a single tablet." We also suggest adding the following wording to the last sentence: "…who have or have not received previous treatment, including the protease inhibitors telaprevir or boceprevir."	Comment noted. The technology section of the scope has been amended to state that: "….ledipasvir is a macrocyclic antiviral agent and *an inhibitor of the HCV NS5a protein*."
	Merck, Sharp and Dohme	No comment	No changes required.

Section	Consultees	Comments	Action
	Royal College of Nursing	Seems appropriate	Comment noted. No changes required.
	Terence Higgins Trust	No comment	No changes required.
	UKCPA	Yes the technology content is accurate	Comment noted. No changes required.
Population	Gilead Sciences	The following information is provided as commercial-in-confidence: [redacted]	Comment noted. Following the scoping workshop consultees were in agreement that the population has been amended in the scope as follows: Adults with chronic hepatitis C • who have not had treatment for chronic hepatitis C before (treatment-naive) • who have had treatment for chronic hepatitis C before (treatment-experienced)

Section	Consultees	Comments	Action
	Merck, Sharp and Dohme	If the phase III trials demonstrate that sofosbuvir-ledipasvir achieved different SVR rates for genotype 1a and 1b, it would be appropriate to sub-group the genotype 1 chronic hepatitis C patients by type G1a and G1b.	Comment noted. Following the scoping workshop consultees were in agreement that the scope be update to note that i f evidence allows the following subgroups will be considered: • Genotype • Co-infection with HIV • People with and without cirrhosis • People who have received treatment pre- and post-liver transplantation • Response to previous treatment (non-response, partial response, relapsed) • People who are intolerant to or ineligible for interferon treatment
	Royal College of Nursing	Seems appropriate	Comment noted. No changes required.
	Terence Higgins Trust	If the numbers are sufficient we would recommend a sub group looking at HIV co-infections.	Comment noted. Attendees at the scoping workshop agreed that people with HIV co-infection should be included as a subgroup, if evidence allows. The 'Other considerations' section of the scope has been updated accordingly.

Section	Consultees	Comments	Action
	UKCPA	Population appropriate but as outlined in other considerations a broader subgroup should ideally be considered	Comment noted. Following the scoping workshop consultees were in agreement that the population has been amended in the scope as follows: Adults with chronic hepatitis C • who have not had treatment for chronic hepatitis C before (treatment-naive) • who have had treatment for chronic hepatitis C before (treatment-experienced)
Comparators	Gilead Sciences	Gilead agrees that the two protease inhibitors, telaprevir or boceprevir, in combination with PEG/RBV would be appropriate comparators for GT1. In addition, for GT1 patients the option of SOF/PEG/RBV or SOF/RBV as standard of care should also be considered, together with 'no treatment'. For a significant proportion of patients there are no alternative treatment options (i.e. those who are unsuitable for interferon – such as those who are medically ineligible or those who are interferon-intolerant). For such patients the alternative is a 'no treatment' or placebo comparator. The following information is provided as commercial-in-confidence: [redacted]	Comment noted. Attendees at the scoping workshop agreed that sofosbuvir in combination with ribavirin, with or without peginterferon alfa (subject to ongoing NICE appraisal ID 654) should be considered a comparator subject to NICE appraisal. The following comparators have also been included for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal: • Simeprevir in combination

Section	Consultees	Comments	Action
			with peginterferon alfa and ribavirin (for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal [ID668]) • Simpeprevir in combination with sofosbuvir with or without ribavirin for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal [ID668]) • Best supportive care (watchful waiting) (genotypes 1-6) (when interferon based regimens are inappropriate because of contraindications or intolerance)

Section	Consultees	Comments	Action
	Merck, Sharp and Dohme	The three comparators in the draft scope are appropriate for this appraisal. We would like to bring to NICE's attention the timing of this scope consultation and scoping workshop with the first appraisal meeting for sofosbuvir. The scoping workshop for sofosbuvir-ledipasvir is May 6th, with the first appraisal meeting for sofosbuvir on May 15th. If at the first appraisal meeting the FAD is developed, then there will be published NICE guidance on sofosbuvir approximately 10 weeks post the first appraisal meeting. As sofosbuvir has a marketing authorisation for the UK, and likely NICE guidance prior to referral of sofosbuvir-ledipasvir from the DoH, sofosbuvir could be considered a comparator for sofosbuvir-ledipasvir in genotype 1 patients. MSD believe this should be discussed at the scoping workshop with NICE, clinical experts, consultees and commentators.	Comment noted. Attendees at the scoping workshop agreed that sofosbuvir in combination with ribavirin, with or without peginterferon alfa (subject to ongoing NICE appraisal ID 654) should be considered a comparator subject to NICE appraisal. The following comparators have also been included for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal: • Simeprevir in combination with peginterferon alfa and ribavirin (for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal [ID668]) • Simpeprevir in combination with sofosbuvir with or without ribavirin for people with hepatitis genotypes 1 or 4, subject to ongoing appraisal [ID668]) Best supportive care (watchful waiting) (genotypes 1-6) (when interferon based regimens are inappropriate because of contraindications or intolerance)

Section	Consultees	Comments	Action
	Royal College of Nursing	Seems appropriate	Comment noted.
	Terence Higgins Trust	No comment	No changes required.
	UKCPA	Comparators are appropriate for now but ? if Sofosbuvir should be added based on the likely arrival of NICE Guidance on these agents by 2014/15.	Comment noted. Attendees at the scoping workshop agreed that sofosbuvir in combination with other medicinal products should be considered a comparator subject to NICE appraisal.
Outcomes	Gilead Sciences	Gilead believes that one of the outcomes is not relevant to SOF/LDV FDC, namely: • rapid virological response (leading to shortened treatment duration) This should be removed from the Outcomes list.	Comment noted. Attendees at the scoping workshop agreed that rapid virological response is not a relevant outcome for interferon free regimens. This has been removed from the scope.
	Merck, Sharp and Dohme	No comment	No changes required.
	Royal College of Nursing	Evidence is required on whether Rapid Virologic Response (RVR) rate is relevent for this medication combination for the stated duration.	Comment noted. Attendees at the scoping workshop agreed that rapid virological response is not a relevant outcome for interferon free regimens. This has been removed from the scope.

Section	Consultees	Comments	Action
	Terence Higgins Trust	No comment	No changes required.
	UKCPA	Standard outcomes no objections to those outlines.	Comment noted.
Economic analysis	Gilead Sciences	Gilead agrees that the time horizon should be such as to capture the full differences in costs or outcomes between the technologies being compared, and given the long term consequences / benefits a lifetime analysis is likely to be required.	Comment noted. NICE recommends using a lifetime time horizon when the technology leads to differences in survival or benefits that persist for the remainder of a person's life. Please see Guide to the methods of technology appraisal (2013) for further details.
	Merck, Sharp and Dohme	No comment	No changes required.
	Royal College of Nursing	Seems appropriate	Comment noted. No changes required.
	Terence Higgins Trust	We would suggest that costs should extend beyond NHS and personal social services and should consider other financial impacts on the individuals' and/or carers' increased ability to gain employment and the wider societal impacts.	The NICE reference case stipulates that NHS and PSS should be used in the reference case. Please see Guide to the methods of technology appraisal (2013) for further details.
	UKCPA	Agree that the time horizon for estimating clinical and cost effectiveness should be sufficiently long enough to accurately reflect differences in cost between other comparators	Comment noted. No changes required.

Section	Consultees	Comments	Action
Equality and Diversity	Gilead Sciences	In addressing the appraisal NICE should be aware that HCV adversely affects certain populations who could be considered at risk of being disadvantaged in terms of accessing the healthcare system and therefore at risk of inequity of access to innovative new treatments. For example: - Certain immigrant populations - Prison population - Intravenous drug users	Comments noted. Attendees at the scoping workshop were in agreement that any guidance should ensure it does not exclude these patient groups unless there is evidence on the risk of harm due to drug interaction.
	Merck, Sharp and Dohme	No comment	No changes required.
	Royal College of Nursing	Not aware of any at this stage.	No changes required.
	Terence Higgins Trust	No comment	No changes required.
	UKCPA	No comments- satisfied with content	No changes required.
Innovation	Gilead Sciences	OF/LDV FDC meets the 5 criteria for step-change innovation as laid out by the Kennedy Report, such that: • SOF/LDV FDC significantly and substantially improves the way that a current need is met (superior clinical efficacy vs. NICE-recommended SoC coupled with a placebo-like side effect profile and a treatment option for the significant proportion of patients who are unsuitable for interferon) • SOF/LDV FDC meets a need which the NHS has identified as being important, as evidenced by the recent NHS Outcomes Framework that reflects the government commitment to reducing mortality due to liver disease in the under-75s • The following information is provided as commercial-in-confidence: SOF/LDV FDC has a robust evidence set providing research on the populations in which the product is effective (clinical trials across GT1 and GT3 and incorporating relevant subgroups) • SOF/LDV FDC has demonstrated an appropriate level of	Comment noted. No changes required. Innovation will be considered as part of the appraisal process.

Section	Consultees	Comments	Action
		effectiveness (superior clinical efficacy vs. NICE-recommended SoC, and an increase in the proportion of patients suitable for treatment) • SOF/LDV FDC will have a marketing authorisation for the indication under review In further detail, SOF/LDV FDC represents a breakthrough treatment for HCV, offering: • Superior clinical efficacy vs. NICE-recommended SoC (even amongst cirrhotic patients who are typically the most difficult to treat) • The first complete all-oral non-IFN-based treatment regimen • The following information is provided as commercial-in-confidence: Data demonstrating high efficacy in reducing graft re-infection pre- and post-liver transplant, which is an area of great unmet need. • A side effect profile similar to placebo and superior to the current SoC • Shorter treatment duration (8-12 weeks with SOF/LDV, compared with up to 48 weeks with current SoC) The implications are as follows: • Significantly greater proportion of HCV patients can achieve a cure (93%-99% demonstrated in recent clinical trials) • Decreased treatment-emergent side effects and discontinuations compared to NICE-approved SoC, which could result in decreased healthcare costs associated with managing the potentially severe side effects • Improved QoL for patients as demonstrated by a reduced treatment side effect profile and decreased duration of treatment • As this is an infectious disease with the potential for cure, by improving cure rates together with increasing numbers of patients eligible for treatment, there is the potential to positively impact on the overall	

Section	Consultees	Comments	Action
		epidemiology and long-term burden to the NHS of HCV All of this means that there is an urgent need for timely patient access to SOF/LDV FDC, re-iterating the need for timely NICE review and guidance. Given the urgent need for those patients with life-threatening liver disease, Gilead wishes to ensure that the timing of NICE guidance aligns with the anticipated accelerated regulatory review timelines for SOF/LDV FDC. We therefore strongly support an STA submission in 2014 to support this alignment. Health related benefits that are unlikely to be included in the QALY calculation include the reduction in onward transmission of the hepatitis C virus through rapid clearance of the virus from the body due to effective treatment, together with the potential for reversal of liver fibrosis once cured of HCV. Onward transmission Data to support this are the rapid reductions in HCV RNA to <LLOQ (lower limit of quantitation) regardless of GT, which are sustained post-treatment in the majority of patients (as per the clinical trials) together with public health information regarding rates of transmission from individuals infected with HCV. As this is an infectious disease with the potential for cure, by improving cure rates together with increasing numbers of patients eligible for treatment, there is the potential to positively impact on the overall epidemiology and long-term burden to the NHS of HCV. Therefore additional benefits exist from a public health perspective that are not fully captured in the QALY calculation.	
	Merck, Sharp and Dohme	No comment	Comment noted. No changes required.

Section	Consultees	Comments	Action
	Royal College of Nursing	Seems appropriate	Comment noted. No changes required. Innovation will be considered as part of the appraisal process.
	Terence Higgins Trust	This is a highly innovative treatment which is administered orally unlike current treatments which are all injections. Additionally, current treatments have severe side effects including depression, weakness, flu like symptoms, aches, coughs and itching. Reduced side effects in addition to the psychological benefits from an oral treatment will be of great importance to individuals. Ease of application and reduced effects on daily life with less need of support from others will be a significant improvement for people taking the treatment. The course of treatment down to 12 weeks from 24-48 weeks is a notable advancement and is likely to result in improved treatment fidelity and completion rates.	Comment noted. No changes required. Innovation will be considered as part of the appraisal process.
	UKCPA	This product is innovative in that it can be used in the absence of interferon and possibly ribavirin which will undoubtedly result in greater patient tolerability and possibly less intensive specialist follow up. The duration of treatment will also likely to be less that current standard of acre for Genotype 1 HCV again resulting in greater patient satisfaction and reduced follow up.	Comment noted. No changes required. Innovation will be considered as part of the appraisal process.
Other considerations	Gilead Sciences	No comment	No changes required.
	Merck, Sharp and Dohme	If evidence allows then the subgroup of cirrhotic patients should be considered.	Comment noted. Consultees at the scoping workshop were in agreement that people with cirrhosis is an important clinical subgroup which should be examined separately

Section	Consultees	Comments	Action
	Royal College of Nursing	Seems appropriate	Comment noted.
	Terence Higgins Trust	If evidence allows we would suggest that the following sub-groups are considered: • Co-infection with HIV If evidence allows we would suggest that sustained virological response at 12 and 24 weeks is considered. Treatment fidelity should be a core consideration so that comparison with the new treatment and existing treatments can be drawn. Current treatment regimes expand between 24-48 weeks, with severe side effects, new treatment that have fewer side effects and higher fidelity rates would be highly innovative. Incomplete treatment evidently incurs costs for the NHS without the benefit of effective treatment. Therefore improved completion rates overall should also be considered.	Comment noted.

Section	Consultees	Comments	Action
	UKCPA	Would promote including HIV co-infected population and previous treatment failures.	Comment noted. Attendees at the scoping workshop agreed that people with HIV co-infection should be included as a subgroup, if evidence allows. The 'Other considerations' section of the scope has been updated accordingly. Response to previous treatment (non-response, partial response, relapsed) is also included as a potential subgroup.
NICE Pathways **[Delete section if not relevant]**	Gilead Sciences	No comment	No changes required
	Merck, Sharp and Dohme	[see response to 'Additional comments on the draft scope']	No changes required
	Royal College of Nursing	No comment	No changes required
	Terence Higgins Trust	No comment	No changes required
	UKCPA	No comment	No changes required

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

Section	Consultees	Comments	Action
Questions for consultation	Gilead Sciences	The following information is provided as commercial-in-confidence: [redacted]	Comment noted. Consultees at the scoping workshop were in agreement that subgroups should include the following: • Genotype • Co-infection with HIV • People with and without cirrhosis • People who have received treatment pre- and post-liver transplantation • Response to previous treatment (non-response, partial response, relapsed) • People who are intolerant to or ineligible for interferon treatment If evidence allows the impact of treatment on reduced onward HCV transmission will also be considered.
	Merck, Sharp and Dohme	No comment	No changes required
	Royal College of Nursing	No comment	No changes required
	Terence Higgins Trust	No comment	No changes required
	UKCPA	No comment	No changes required

Appendix D - NICE's response to consultee and commentator comments on the draft scope and provisional matrix

Section	Consultees	Comments	Action
Additional comments on the draft scope.	Gilead Sciences	None	No changes required
	Merck, Sharp and Dohme	In the related NICE recommendations and NICE pathways section we would like to make NICE aware of a clinical guideline on liver disease and quality standard on prisons: physical conditions and diseases that are currently under development.	Comment noted. No changes required.
	Royal College of Nursing	None	No changes required
	Terence Higgins Trust	No comment	No changes required
	UKCPA	None	No changes required

The following consultees/commentators indicated that they had no comments on the draft remit and/or the draft scope

Department of Health
Slough CCG, Bracknell & Ascot CCG and Windsor, Ascot & Maidenhead CCG

NATIONAL INSTITUTE FOR HEALTH CARE EXCELLENCE

Single Technology Appraisal (STA)

Ledipasvir-sofosbuvir for treating chronic hepatitis C

Response to consultee and commentator comments on the provisional matrix of consultees and commentators (pre-referral)

Version of matrix of consultees and commentators reviewed: Provisional matrix of consultees and commentators sent for consultation					
Summary of comments, action taken, and justification of action:					
	Proposal:	Proposal made by:		Action taken: Removed/Added/Not included/Noted	Justification:
1.	Remove Action on Hepatitis C	NICE Secretariat		Removed	This organisation has disbanded.
2.	Add HIV i-Base	NICE Secretariat		Added	This organisation has an area of interest directly related to this appraisal and meets the selection criteria to participate in this appraisal. HIV i-Base has been added to the matrix of consultees and commentators under 'patient' groups.
3.	Remove Transplant Support Network	NICE Secretariat		Removed	This organisation has disbanded.

4.	Remove Health Protection Agency	NICE Secretariat		Removed	This organisation has disbanded.
5.	Add Association of Surgeons of Great Britain and Ireland	NICE Secretariat		Added	This organisation has an area of interest directly related to this appraisal and meets the selection criteria to participate in this appraisal. Association of Surgeons of Great Britain and Ireland has been added to the matrix of consultees and commentators under 'professional' groups.
6.	Remove British Association for the Study of the Liver Nurses Forum	NICE Secretariat		Removed	This organisation is a sub-group of British Association for the Study of the Liver who are already listed on the matrix of consultees and commentators under 'professional groups'
7.	Remove Commissioning Support Appraisals Service	NICE Secretariat		Removed	This organisation has disbanded.

8.	Remove Research Institute for the Care of Older People	NICE Secretariat		Removed	This organisation's interests are not closely related to the appraisal topic and as per our inclusion criteria. Research Institute for the Care of Older People has not been included in the matrix of consultees and commentators.