

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA75; Interferon alfa and ribavirin for treating chronic hepatitis C, TA106; Peginterferon alfa and ribavirin for treating mild hepatitis C, and TA200; Pegylated interferons, peginterferon alfa, ribavirin and alfa interferon for treating hepatitis C**

This guidance was issued in: TA75 (January 2004); TA106 (August, 2006); TA200 (September, 2010)

The review date for this guidance is: TA75 and TA106 (no date given); TA200 (July, 2013)

**Background**

At the GE meeting of 1 Oct 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list' until the start of the development of the clinical guideline.
<b>Rationale for selecting this proposal</b>	<p>No new evidence has been identified that is likely to fundamentally change the recommendations in TAs 75, 106 and 200. However, the recommendations for the use of peginterferons and ribavirin are now very fragmented (with elements being updated in subsequent guidance) and will be even more so once the ongoing technology appraisal of the use of the drugs in children has been published, which will update recommendation 1.6 in TA106. It would therefore be beneficial to bring the current TA recommendations together as part of the wider clinical context, and that is best done through a guideline.</p> <p>The new evidence is related to 4 small studies comparing the effectiveness of peginterferon alfa-2a with peginterferon alfa-2b, and studies investigating the role of polymorphisms in the interleukin 28 gene. Consideration of both these issues would be better accommodated in the context of the ongoing clinical guideline. It is therefore proposed that the current recommendations of TAs 75, 106 and 200 are transferred to the 'static guidance list' until the start of the development of the clinical guideline for the management of hepatitis C.</p>

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

<b>Recommendation post consultation:</b>	The guidance should be transferred to the 'static guidance list' until the start of the development of the clinical guideline.
--	--

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Foundation for Liver Research	Agree	I would agree that further consideration of Peg Interferon and Ribavirin therapy should be deferred until the assessment of the new antiviral agents including Sofosbuvir have been completed.	Comment noted.
British Society of Gastroenterology	Agree	I think that the proposal is entirely sensible and we should support the development of a NICE clinical guideline on HCV once the forthcoming TAs are completed.	Comment noted.
NHS Bracknell & Ascot CCG	Agree	I would agree with the proposal paper, however, as Hepatitis C (chronic and mild) is currently commissioned by NHSE rather than CCGs, I would expect my Specialised Commissioning colleagues in NHSE to have a stronger view on this proposal paper.	Comment noted.
Royal College of Nursing	Agree	Nurses caring for people with hepatitis C reviewed the documents on behalf of the RCN.  The RCN agrees with the proposal to move the technology appraisal guidance to the static list. It is considered that this proposal is prudent and should be welcomed in light of the rapid developments currently within Hepatitis C treatments and management which could render a new guidance out of date before publication.	Comment noted.

<b>Respondent</b>	<b>Response to proposal</b>	<b>Details</b>	<b>Comment from Technology Appraisals</b>
Medicines and Healthcare Products Regulatory Agency	No comment	We don't have any information to pass on with regards to this proposal.	Comment noted.
Royal College of Physicians	Agree	Our experts believe that it is sensible to move the existing guidance to the static list. As they stand, the combination of IFN/RBV and PI Technology Appraisals (TAs) allow clinicians to give appropriate treatment with currently licensed drugs, while awaiting the outcome of new TAs and clinical guidelines.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
British HIV Association	Agree	<p>The Association fully supports the NICE assessment that there is no new evidence that would lead to a change in the existing recommendations for TA75, TA106 or TA200. BHIVA also supports the NICE recommendations for the use of peginterferons and ribavirin being now very fragmented, and that it would be beneficial to bring all of the existing recommendations together in the context of wider clinical practice; and that the best place for this to take place would be within a clinical guideline.</p> <p>BHIVA also agrees that there is no evidence to warrant an update within the technology appraisals programme and that TA200 should be moved to the static list of technology appraisals, and that TA75 and TA106 should remain on the static list until any new data are available.</p> <p>BHIVA has NICE-accredited process Guidelines for the management of hepatitis viruses in adults infected with HIV 2013, which have recently been published<sup>1</sup> and many of these points are covered within these guidelines.</p>	Comment noted.
MRC Clinical Trials Unit	No comment	We have no comments on this appraisal.	Comment noted.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Janssen	Agree	Janssen agree with the perspective of NICE and believe that TA200 should be moved to the static list of technology appraisals, and that TA75 and TA106 should remain on the static list until the development of the clinical guideline commences.	Comment noted.
Merck, Sharp & Dohme	Agree	MSD agrees that there is no evidence to warrant an update within the technology appraisals programme, and agree that TA200 should be moved to the static list of technology appraisals, and that TA75 and TA106 should remain on the static list.	Comment noted.
Royal College of Pathologists	No comment	We are happy with the decision to move these guidelines to the static list and so has no comments to make	Comment noted.
Roche	Agree	We have no new data to submit for TA200 and agree with moving this technology appraisal to the static list	Comment noted.

**No response received from:**

<u>Patient/carer groups</u> <ul style="list-style-type: none"> <li>Action on Hepatitis C</li> <li>Addaction</li> </ul>	<u>General</u> <ul style="list-style-type: none"> <li>Allied Health Professionals Federation</li> <li>Board of Community Health Councils in Wales</li> </ul>
--	--

- Addiction Today (Addiction Recovery Network)
- Adfam
- Afiya Trust
- African Health Policy Network
- Alliance
- AVERT
- Black Health Agency
- British Liver Trust
- Compass UK
- Drugscope
- Equalities National Council
- The Gay Men's Health Charity
- Haemophilia Alliance
- Haemophilia Society
- Hepatitis A-Z
- Hepatitis C Trust
- Muslim Council of Britain
- Muslim Health Network
- NAM publications
- National AIDS Trust
- National Hepatitis C Resource Centre
- Positively UK
- Rehabilitation for Addicted Prisoners Trust (RAPt)
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Transplant Support Network

#### Professional groups

- Association of Anaesthetists of Great Britain and Ireland
- Association of Nurses in Substance Abuse

- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- Drugs Action Scotland
- Healthcare Improvement Scotland
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Scottish Medicines Consortium

#### Comparator manufacturers

- Merck, Sharp & Dohme (boceprevir)

#### Relevant research groups

- Centre for Sexual Health & HIV Research
- Cochrane Hepato-biliary Group
- Health Research Authority
- National Institute for Health Research
- Research Institute for the Care of Older People

#### Assessment Group

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

#### Associated Guideline Groups

<ul style="list-style-type: none"> <li>• Association of Surgeons of Great Britain and Ireland</li> <li>• British Association for Services to the Elderly</li> <li>• British Association for Sexual Health and HIV</li> <li>• British Association for the Study of the Liver</li> <li>• British Geriatrics Society</li> <li>• British Infection Association</li> <li>• British Liver Nurses Forum</li> <li>• British Viral Hepatitis Group</li> <li>• Haemophilia Nurses Association</li> <li>• Health Protection Agency</li> <li>• Hepatitis Nurse Specialist Forum</li> <li>• Infection Control Nurses Association</li> <li>• Royal College of Anaesthetists</li> <li>• Royal College of General Practitioners</li> <li>• Royal College of Surgeons</li> <li>• Royal Pharmaceutical Society</li> <li>• Royal Society of Medicine</li> <li>• UK Clinical Virology Network</li> <li>• United Kingdom Clinical Pharmacy Association</li> <li>• UK Haemophilia Centre Doctors' Organisation</li> </ul> <p><u>Others</u></p> <ul style="list-style-type: none"> <li>• Department of Health</li> <li>• NHS England</li> <li>• NHS South Devon and Torbay CCG</li> <li>• Welsh Government</li> </ul>	<ul style="list-style-type: none"> <li>• National Clinical Guidelines Centre</li> </ul> <p><u>Associated Public Health Groups</u></p> <ul style="list-style-type: none"> <li>• Public Health England</li> <li>• Public Health Wales NHS Trust</li> </ul>
--	--

**GE paper sign-off:** Elisabeth George, Associate Director – Technology Appraisals Programme

**Contributors to this paper:**

Technical Lead: Christian Griffiths

Project Manager: Andrew Kenyon

19 11 2013