NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Review Proposal Project (RPP) decision paper

Review of TA300; Peginterferon alfa and ribavirin for treating chronic hepatitis C in children and young people

Final recommendation post consultation
The guidance should be transferred to the 'static guidance list'.

1. Background

This guidance was issued in November 2013.

At the Guidance Executive (GE) meeting of 4 July 2017 it was agreed that we would consult on the recommendations made in the GE proposal paper. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

2. Proposal put to consultees and commentators

The guidance should be transferred to the 'static guidance list'.

3. Rationale for selecting this proposal

The marketing authorisation for peginterferon and ribavirin has not changed since the guidance was produced. There is availability of more evidence relating to long-term efficacy, safety, sub-groups and cost-effectiveness. However, this will not change current guidance as the evidence is supportive of current recommendations and it is acknowledged that further randomised controlled comparative studies are required. The guideline planned for hepatitis C is currently paused until there is stability in the availability of treatments and in the cost to the NHS of these drugs (as of 23rd September 2016). In conclusion, there is no new evidence that is likely to change the recommendations in TA300 so it would be appropriate to transfer this guidance to the static list.

4. Summary of consultee and commentator responses

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.

Respondent: Department of Health **Response to proposal:** No comment	**Comment from Technology Appraisals** No action required.

Respondent: British Association for the study of the Liver (BASL) **Response to proposal:** Agree I can confirm that BASL agrees with the proposal to move TA300 to the 'static list' of technology appraisals.	**Comment from Technology Appraisals** Comment noted. No action required.

Respondent: British Society of Gastroenterology **Response to proposal:** Agree Direct acting antiviral (DAA) therapy in adults with hepatitis C virus (HCV) infection now reliably achieves a >90% “real-world” cure rate for all HCV genotypes irrespective of stage of disease, previous treatment exposure with interferon, co-infection with HIV or renal failure [1]. However DAA therapy is not yet licensed for children and young people. The combination of Peginterferon alfa (PEG IFN) and ribavirin (RBV) has an overall sustained viral response rate of no greater than 50% in HCV-infected children and adolescents [2, 3]. However treatment of HCV genotypes 2 and 3 has shown better SVR rates between 80-100% [4] as compared to HCV genotype 1. Treatment with PEG IFN & RBV is associated with significant adverse events including haematological cytopenias, mood change and depression which can occur in more than 50% of treated cases leading to treatment discontinuation [5]. Finally treatment with PEG IFN & RBV is more inconvenient than DAA therapy, requiring subcutaneous injection and of longer duration. Currently there are ongoing studies of DAA therapy for HCV in children with promising preliminary results [6]. Thus since PEG IFN & RBV treatment of HCV-infected children has limited efficacy, well-documented toxicities, an inconvenient mode of administration and long duration of treatment for HCV in children we would agree in moving TA 300 to the static list of NICE technology assessments. Harvoni is approved for use in children with HCV by the FDA [7] and it is likely positive data supporting the use of other DDA regimens in the paediatric HCV population will become available over the next year.	**Comment from Technology Appraisals** Comment noted. Thank you for the additional information.

Respondent: Merck Sharp & Dohme UK Ltd **Response to proposal:** Agree I can confirm that MSD support the proposal to move TA300 to the static list.	**Comment from Technology Appraisals** Comment noted. No action required.

Paper signed off by: Jenniffer Prescott, 15 August 2017

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