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Janssen's Response to the Appraisal Consultation Document

Sofosbuvir for treating chronic hepatitis C

Please find below Janssen's comments on the second Appraisal Consultation Document (ACD) for sofosbuvir for treating chronic hepatitis C (CHC).

Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?

Cost effectiveness analysis in people with treatment-experienced genotype 1 CHC

We are concerned that the cost effectiveness of sofosbuvir plus peginterferon/ribavirin (PR) versus telaprevir+PR in this subpopulation is biased against telaprevir for the following reasons:

1. There has been no examination of the impact of a downward adjustment of the SVR12 for sofosbuvir+PR estimated for the non-cirrhotic subgroup to account for reduced efficacy in a cirrhotic subgroup. As noted in the ACD, and reflected in the SVRs applied in the manufacturer's analysis for the comparator treatments, patients with cirrhosis have a poorer SVR. Yet the manufacturer's analysis assumes 78% SVR12 regardless of cirrhosis status, compared to 70.6% and 47.2% SVR for telaprevir-treated non-cirrhotic and cirrhotic patients, respectively.

2. There has been no analysis of the impact of up to a 24 week treatment duration for sofosbuvir+PR which, in line with the Summary of Product Characteristics (SmPC), should be considered for patients with cirrhosis and/or prior null response to PR. Conversely, response guided treatment is incorporated to the telaprevir arm by applying an average treatment duration of 39.0 weeks. We note that this average treatment duration is entirely inconsistent with the telaprevir SmPC and the cited NICE STA; the latter reporting 10.7 week telaprevir treatment duration for treatment-experienced patients.

3. There has been no assessment of the impact of varying the distribution of prior relapsers, partial responders and null responders used to inform the pooled SVR estimate for telaprevir+PR. Whilst sofosbuvir+PR effectiveness amongst these previously-treated subgroups is unknown, and therefore presumably assumed equal, the distribution used in the manufacturer's basecase will determine the SVR for comparators.