NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C [ID731]

Specification of further work following the Appraisal Committee meeting on 1 April 2015

The Committee recommends that NICE requests further analyses from the company for ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating adults with genotypes 1a, 1b and 4 to be made available for the next Appraisal Committee meeting, as follows:

- Revised incremental cost-effectiveness analyses for the different regimens of ombitasvir/paritaprevir/ritonavir with or without dasabuvir (3D or 2D) presented separately for people with and without cirrhosis, and by treatment history. The analyses should incorporate the following:
    - The patient populations, treatment regimens and treatment durations specified in the summary of product characteristics table 1.
    - Comparison with all NICE recommended comparators (including simeprevir in combination with peginterferon plus ribavirin) using appropriate treatment durations based on the respective summaries of product characteristics specifications.
- Provide a scenario analysis, using a utility increment for sustained virological response (SVR) over the baseline utility values, estimated from the difference between pooled EQ-5D values collected at base-line and at 12 week post treatment time point in people who achieved SVR from the trials.
- Provide a scenario analysis using alternative health state utility values based on the EQ-5D data from the trials (the health state values used in the company's scenario 20 [table 127, HSU scenario 2, page 393]).
- Confirm the marketing position of AbbVie relating to 12 weeks' treatment in people with genotype 1a chronic hepatitis C with cirrhosis and provide

justification for a 12 week treatment regimen in this population, with reference to the marketing authorisation/summary of product characteristics. Comment whether a 12 week treatment with 2D plus ribavirin would be an option for some patients with genotype 4 chronic hepatitis C with cirrhosis as well. Please also provide the relevant details from the clinical guideline (published in March/April 2015) referred to in the Committee discussion that has made recommendations relating to the use/duration of 3D plus ribavirin and 2D plus ribavirin for these populations.

- Using appropriate SVR rates (for the 12 week regimen or 24 week regimen) from the TURQUOISE II trial, provide subgroup analyses to explore the effect on the incremental cost-effectiveness ratios (ICERs) of the following:
    - 12 week treatment duration of 3D plus ribavirin for people with treatment naïve genotype 1a CHC with compensated cirrhosis.
    - 12 week treatment duration of 3D plus ribavirin for treatment experienced genotype 1a CHC with compensated cirrhosis who have relapsed after achieving SVR with previous therapy.
    - 12 week treatment duration of 3D plus ribavirin for treatment experienced genotype 1a CHC with compensated cirrhosis who have achieved a partial response to previous therapy.
    - 24 week treatment duration of 3D plus ribavirin for treatment experienced genotype 1a CHC with compensated cirrhosis who had not responded to previous therapy (null responders).
- Provide probabilistic sensitivity analyses for each base-case analyses varying parameters to a meaningful degree around the value used in the base-case, with the source and rationale for each variation.
- Provide a revised fully executable economic model to check the above revisions.