Enc 3 Appx 3

Clinical Expert Summary Glecaprevir/pibrentasvir (Maviret®) 100 mg/40 mg film-coated tablets

Glecaprevir/pibrentasvir (Maviret®) for the treatment of chronic hepatitis C virus (HCV) infection in adults.

1. Existing guidelines

Reference was made to the All Wales Hepatitis C roll out programme guidelines, which recommend treatments for hepatitis C based on evidence and cost.

2. Disease prevalence/incidence

The All Wales Hepatitis C roll out programme is committed to treating 900 patients year on year for 5 years. If it were to be used to treat most patients with hepatitis C, that would be between 500 and 700 patients.

3. Current treatment options

The choice of treatment depends on the genotype of the hepatitis C virus (HCV) causing the infection. Available treatments listed were ritonavir/ombitasvir/paritaprevir (Viekirax®) and dasabuvir (Exviera®), elbasvir/grazoprevir (Zepatier®), sofosbuvir/ledipasvir (Harvoni®) and sofosbuvir/velpatasvir (Epclusa®) to treat infections with HCV genotypes 1 and 4 (all given with or without ribavirin). For treating infections with HCV genotypes 2, 3, 5 and 6 the available treatments are sofosbuvir/velpatasvir or sofosbuvir (Sovaldi®) plus daclatasvir (Daklinza®) with or without ribavirin.

4. Unmet needs

It was stated that some current treatments are not suitable for some patients and that some current treatments have failed to clear the virus in some patients. For example, experts referred to a lack of direct-acting antivirals available to treat genotypes 2, 3, 5 and 6 infections in people with late-stage chronic kidney disease (EGFR < 30 mL/min).

5. Knowledge of product in given indication

It was stated that glecaprevir/pibrentasvir would be incorporated into the All Wales Hepatitis C roll out programme guidelines and that its cost would determine its use in Wales.

It should be noted that one expert(s) involved in compiling this response declared a personal specific interest in relation to glecaprevir/pibrentasvir (Maviret®) for the indication under consideration.