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Clinical Expert Summary
Daclatasvir (Daklinza®▼) 30 mg and 60 mg film-coated tablets

Daclatasvir (Daklinza®▼) in combination with other medicinal products for the treatment of chronic hepatitis C virus (HCV) infection in adults.

1. Existing guidelines

No guidelines were highlighted. The clinical expert stated that there is intention to develop a national policy with regards to the use of the new treatments for hepatitis C. This policy will be influenced by the National Institute for Health and Care Excellence (NICE) recommendation for sofosbuvir and the affordability of the new treatments (as they signify a significant clinical advance from previous therapies). It is unknown when this policy might be ready.

2. Disease prevalence/incidence

There were between 600 and 700 laboratory reports of hepatitis C in Wales in 2013. Over 400 patients were treated for hepatitis C in 2011 and 2012. It was noted that due to the lack of funding for a hepatitis database it is not possible to provide accurate data on the number of individuals under the care of specialist hepatitis services in Wales. Therefore, prevalence data from the "Hepatitis C in the UK: 2014 report[1]" published by Public Health England was provided.

3. Current treatment options

Patients with HCV genotype 1 are treated with a combination of pegylated interferon and ribavirin +/- a protease inhibitor (i.e. telaprevir or boceprevir). Patients with HCV genotypes 2, 3, 4, 5 and 6 are treated with a combination of pegylated interferon and ribavirin for 16–48 weeks.

4. Unmet needs

Current treatment regimens for hepatitis C combine direct acting antiviral (DAA) agents with pegylated interferon and ribavirin. There are a significant number of patients infected with hepatitis C that are intolerant or ineligible for interferon treatment (including a significant number of patients that have been previously treated with interferon that have either relapsed or not responded). The new DAA agents allow clinicians to treat patients with interferon-free regimens providing a much needed treatment modality for these patients. In addition pegylated interferon and ribavirin is a relatively toxic treatment combination that is associated with a significant number of adverse events (AEs), some of which are permanent (e.g. development of autoimmune disease) and the need to combine injections with oral medication. The new DAA agents provide a much needed all-oral, relatively non-toxic treatment combination that is highly efficacious (with response rates as good as or better than interferon-containing regimens). The new treatments potentially increase the number of infected patients that can be treated safety and effectively.

5. Knowledge of product in given indication

Daclatasvir can be combined with sofosbuvir for the treatment of patients with hepatitis C (regardless of genotype) for 12–24 weeks. The selection of patients for this combination will be based on affordability as clinically, this combination is superior to interferon-containing regimens due to fewer AEs, easier administration and response rates that are equivalent or better than current regimens.

It should be noted that one expert involved in compiling this response declared a personal specific interest in relation to daclatasvir for the indication under consideration.

REFERENCES

1 Public Health England. Hepatitis C in the UK: 2014 report. Jul 2014. Available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/337115/HCV_in_the_UK_2014_24_July.pdf. Accessed Nov 2014.