

AWMSG ADVICE SUPERSEDED BY NICE GUIDANCE (TA363)

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Final Appraisal Recommendation

Advice No: 0915 – April 2015

**Ledipasvir/sofosbuvir (Harvoni[®]▼)
90 mg/400 mg film-coated tablets**

Submission by Gilead Sciences Limited

Recommendation of AWMSG

Ledipasvir/sofosbuvir (Harvoni[®]▼) is recommended as an option for restricted use within NHS Wales for the treatment of chronic hepatitis C in adults with hepatitis C virus genotype 1 and 4 without cirrhosis or with compensated cirrhosis for up to 12 weeks.

Ledipasvir/sofosbuvir (Harvoni[®]▼) is not recommended for use within NHS Wales outside of this subpopulation/these circumstances.

Key factor(s) influencing the recommendation:

- The cost effectiveness data presented in the submission were insufficient for AWMSG to recommend use beyond 12 weeks.
- No economic data were provided for genotype 1 or 4 patients with decompensated cirrhosis or who are pre-/post liver transplant.
- Similarly, no economic data were provided for genotype 3 patients with cirrhosis and/or prior treatment failure

In reaching the above recommendation AWMSG has taken account of the appraisal documentation prepared by the AWMSG Secretariat (reference number 1887), which includes the AWMSG Secretariat Assessment Report (ASAR), the Preliminary Appraisal Recommendation (PAR) and the applicant company's response to the PAR, clinical expert opinion (where available), the views of patients/patient carers (where available) and the lay member perspective.



NICE has accredited the process used by the All Wales Medicines Strategy Group (AWMSG) to produce its final appraisal recommendation. Accreditation is valid for 5 years from October 2011. More information on accreditation can be viewed at www.evidence.nhs.uk.

For full details on our accreditation visit: www.nice.org.uk/accreditation.

This recommendation has been ratified by the Minister for Health and Social Services and will be considered for review every three years.

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All Wales Medicines Strategy Group. Final Appraisal Recommendation – 0915:
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