

ILC 2017: European countries restrict access to life-saving treatment for Hepatitis C virus

A review of recent reimbursement data showed considerable variability in access to direct-acting antiviral therapy based on amount of liver scarring and substance use

April 20, 2017, Amsterdam, The Netherlands: Data presented today demonstrate that there are considerable restrictions in the reimbursement of direct-acting antiviral (DAA) therapy across European countries, particularly with respect to the severity of liver fibrosis (scarring of the liver) and prescribing by specialists. The study, presented at The International Liver Congress™ 2017 in Amsterdam, The Netherlands, showed that there was evidence that some countries were not following the most recent European HCV treatment guidelines, published by the European Association for the Study of the Liver (EASL) in 2016.¹

HCV is one of the most widespread transmissible diseases.² It can cause both acute and chronic infection, with about 55–85% HCV-infected individuals developing chronic infection.³ HCV is a leading cause of chronic liver disease, end-stage cirrhosis and liver cancer.⁴ It is estimated to infect over 71 million people worldwide, of whom 784,000 die each year.^{5,6} Until the approval of the DAAs, HCV was treated with pegylated interferon and ribavirin, which caused serious adverse effects in more than 80% of patients, and fewer than 50% were able to finish the course of therapy.² These new drugs have revolutionised treatment and mean that HCV is now curable, with a cure rate of 95% or higher.⁷ Although the DAAs are highly effective, they are expensive and unaffordable if prescribed for all patients.¹ Most countries therefore limit access to these drugs.

“The availability of simple, tolerable DAA-based therapies for HCV with high cure rates is one of the greatest clinical advances in recent decades,” said Ms Alison Marshall, PhD candidate, Kirby Institute, UNSW Sydney, Australia, and author of the study. “While all European countries included in our study reimbursed some form of DAA treatment, there was restricted access based on fibrosis stage, substance use, and type of prescriber, meaning that some patients are encountering considerable barriers to the life-saving treatment they need. In particular, restricting DAA prescribing to specialists is a major impediment to ensuring broad access to HCV therapy. These findings have important implications for health policy makers and the delivery of health services across Europe.”

Information from online reimbursement documents for EU/EEA countries (including England, Northern Ireland, Scotland, and Wales as separate jurisdictions) and Switzerland were reviewed from November 2016 to March 2017. Primary outcomes were reimbursement restrictions based on the stage of fibrosis, drug or alcohol use, type of prescriber (e.g. specialists), and HIV-HCV co-infection.

The European countries with complete data (34/35) all reimbursed DAAs. The most common DAAs reimbursed were ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin (97%) and

sofosbuvir/ledipasvir ± ribavirin (88%). For treatment naïve patients, 38% (n=13) of countries required evidence of at least moderate fibrosis ($\geq F2$)⁸ before DAAs were prescribed, nearly a quarter (24%, n=8) required at least severe fibrosis ($\geq F3$)⁸, over a quarter (26%, n=9) had no fibrosis stage restrictions, and 9% (n=3) had an additional requirement, such as genotype of HCV. In this study, 76% (n=26) of countries had no drug or alcohol use restriction, though almost one-fifth (n=6) had a drug or alcohol use limitation (e.g. abstinence required prior to treatment with DAAs). Overall, 94% (n=32) of countries had no additional restrictions for HIV-HCV co-infection, and in fact, 24% (n=8) of countries gave priority status to HIV-HCV co-infected people with fewer restrictions than for HCV mono-infected people. Further, 94% (n=32) of countries required specialists to prescribe DAA therapy.

“Restrictions to DAA access for Hepatitis C across Europe are widespread and conflicting with the EASL Clinical Practice Guidelines, thus preventing many patients from being treated. Restrictions are the consequence of current drug prices, calling for revised strategies to make these treatments available to all in need,” said Prof Francesco Negro, Divisions of Gastroenterology and Hepatology of Clinical Pathology, University Hospital of Geneva, Switzerland and EASL Governing Board Member.

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About The International Liver Congress™

This annual congress is the biggest event in the EASL calendar, attracting scientific and medical experts from around the world to learn about the latest in liver research. Attending specialists present, share, debate and conclude on the latest science and research in hepatology, working to enhance the treatment and management of liver disease in clinical practice. This year, the congress is expected to attract approximately 10,000 delegates from all corners of the globe. The International Liver Congress™ 2017 will take place from April 19 – 23, at the RAI Amsterdam, Amsterdam, The Netherlands.

About The European Association for the Study of the Liver (EASL) (www.easl.eu)

Since its foundation in 1966, this not-for-profit organisation has grown to over 4,000 members from all over the world, including many of the leading hepatologists in Europe and beyond. EASL is the leading liver association in Europe, having evolved into a major European Association with international influence, with an impressive track record in promoting research in liver disease, supporting wider education and promoting changes in European liver policy.

Contact

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Onsite location reference

Session title: Late breaker poster session

Time, date and location of session: 08:00 – 18:00, Thursday 20 April – Saturday 22 April, Hall 1

Presenter: Alison Marshall, Australia

Abstract: Restrictions for reimbursement of interferon-free direct-acting antiviral therapies for HCV infection in Europe (LBP-505)

Author disclosures

None.

References

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- 3 World Health Organization. Hepatitis C in the WHO European Region Fact Sheet. July 2015. Available from: http://www.euro.who.int/_data/assets/pdf_file/0010/283357/fact-sheet-en-hep-c.pdf?ua=1. Last accessed: April 2017.
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