

RESTRICTIONS FOR REIMBURSEMENT OF INTERFERON-FREE DIRECT ACTING ANTIVIRAL THERAPIES FOR HCV INFECTION IN EUROPE

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Background: Simple, tolerable direct-acting antiviral (DAA) HCV therapies with cure responses of >90% is one of the greatest clinical advances in recent decades. However, the high list price of DAA therapies has led some governments to restrict their reimbursement. Study aims were to: 1) review the availability of interferon-free DAA therapy among EU/EEA countries (including England, Northern Ireland, Scotland and Wales as separate jurisdictions) and Switzerland and; 2) review national criteria for DAA therapy reimbursement among EU/EEA countries and Switzerland.

Methods: Information was extracted from online reimbursement documents from November 2016 to March 2017. Reimbursement criteria were reviewed for: sofosbuvir + ribavirin, sofosbuvir/ledipasvir ± ribavirin, sofosbuvir/velpatasvir ± ribavirin, ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin, elbasvir-grazoprevir ± ribavirin, sofosbuvir + daclatasvir ± ribavirin, and sofosbuvir + simeprevir ± ribavirin. Primary outcomes were restrictions based on fibrosis stage, drug or alcohol use, prescriber-type and HIV co-infection.

Results: Of European countries with complete data (34 of 35), all reimbursed HCV DAAs, most commonly ombitasvir/paritaprevir/ritonavir ± dasabuvir ± ribavirin (97%) and sofosbuvir/ledipasvir ± ribavirin (88%). Overall, 38% (n=13) of countries required ≥F2; 24% (n=8) required ≥F3; 26% (n=9) had no fibrosis stage restrictions; 9% (n=3) had an additional requirement; and Wales had no information listed. Although 76% (n=26) of countries had no listed drug or alcohol use restriction, 18% (n=6) of countries required abstinence of substance use prior to treatment. Overall, 94% (n=32) of countries required a specialist to prescribe HCV DAAs. Lastly, 94% (n=32) of countries had no additional restrictions for HIV/HCV co-infected persons. In 24% (n=8) of countries, HIV-HCV co-infected persons were prioritised for treatment.

Conclusion: Findings highlight considerable variability in DAA therapy restrictions across Europe, particularly regarding fibrosis stage. This review has implications for health policy and health service delivery with evidence of some countries not following 2016 EASL HCV treatment guidelines.

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