



Restrictions for reimbursement of interferon-free direct acting antiviral therapies for HCV infection in Europe

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*contributed equally



Disclosure statement

- Nothing to disclose

Background

- Interferon-free HCV DAAs have cure rates of >90%, fewer side effects & shorter treatment duration
- List price of DAA therapies has led governments to place restrictions on reimbursement criteria
- Prior evidence on reimbursement restrictions:
 - Marshall et al. 2016 (Canada)
 - Barua et al. 2015 (US)
- Restrictions do not align with AASLD-IDSA, CASL or EASL clinical guidelines

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Aims

- To review the availability of interferon-free DAA therapy among EU/EEA countries and Switzerland
 - sofosbuvir + ribavirin (Sovaldi®)
 - sofosbuvir/ledipasvir + ribavirin (Harvoni®)
 - sofosbuvir/velpatasvir + ribavirin (Epclusa®)
 - ombitasvir/paritaprevir/ritonavir + dasabuvir + ribavirin (Viekirax®)
 - elbasvir-grazoprevir + ribavirin (Zepatier®)
 - sofosbuvir + daclatasvir + ribavirin (Daklinza®)
- To review national criteria for interferon-free DAA therapy reimbursement among EU/EEA countries and Switzerland

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Methods

- Primary outcomes
 - Minimum fibrosis stage required (No restriction; \geq F2; \geq F3; or F4, METAVIR or equivalent)
 - Drug and/or alcohol use restrictions (Prioritised; No restrictions; Additional restrictions)
 - Prescriber-type restrictions (No restriction; Specialist only)
 - HIV-HCV co-infection restrictions (Prioritised; Eligible)
- Data collection
 - November 2016 to August 2017
 - Ministry of Health websites; online drug formularies
- Data were organized with descriptive statistics with Excel; Two authors independently cross-checked categorisation of outcomes and documentation

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Results - Reimbursement of interferon-free DAAs for HCV infection in Europe

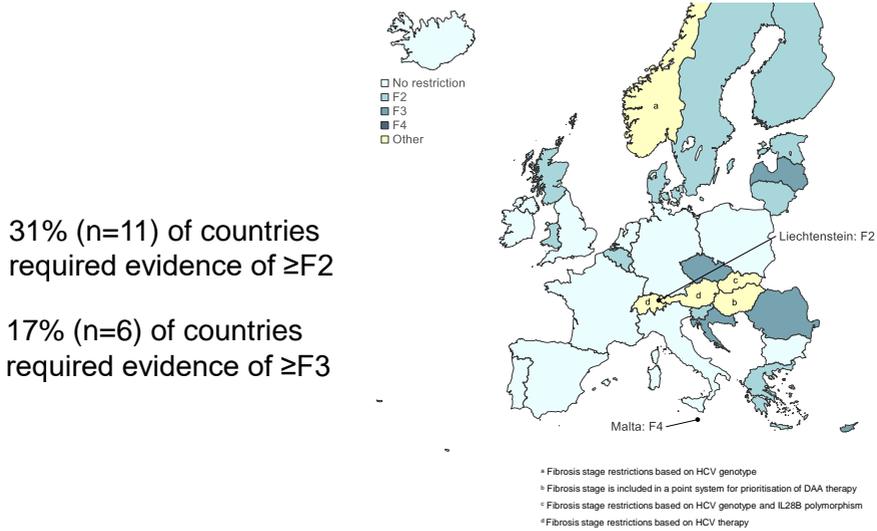
- All European countries/jurisdictions reimbursed DAAs (n=35)
- Most common DAAs reimbursed were PrOD \pm RBV (94%; n=33) and elbasvir/grazoprevir \pm RBV (91%, n=32)

	HCV DAA Therapy					
	ABR \pm RBV	ABR \pm OELON	SOALTE \pm TELAVIR	PrOD \pm RBV	EB/GZ \pm RBV	ABR \pm A, DCI, RBV
Austria						
Belgium						
Bulgaria						
Croatia						
Cyprus						
Czech Republic						
Denmark						
England						
Estonia						
Finland						
France						
Germany						
Greece						
Hungary						
Iceland						
Ireland						
Italy						
Latvia						
Liechtenstein						
Lithuania						
Luxembourg						
Malta						
Netherlands						
N. Ireland						
Norway						
Poland						
Portugal						
Romania						
Scotland						
Slovakia						
Slovenia						
Spain						
Sweden						
Switzerland						
Wales						

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UNSW
Key findings

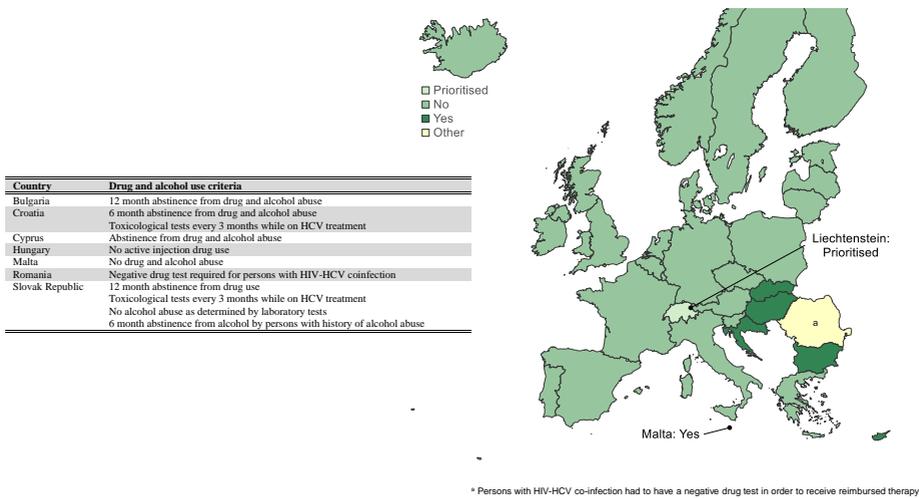
Results - Minimum fibrosis stage required for reimbursement of interferon-free DAA treatment naïve patients with HCV infection in Europe



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Key findings

Results - Drug and alcohol restrictions for reimbursement of interferon-free DAAs for patients with HCV infection in Europe

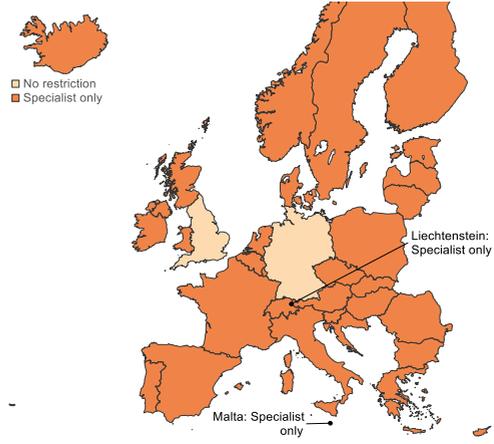


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UNSW | Key findings

Results - Prescriber-type restrictions for reimbursement of interferon-free DAAs for patients with HCV infection in Europe

94% (n=33) of countries required specialists to prescribe DAA therapy

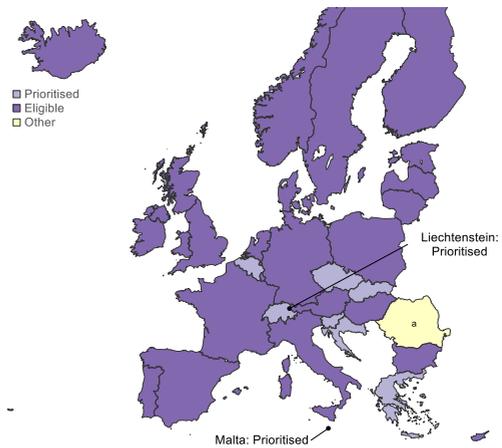


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UNSW | Key findings

Results – HIV co-infection restrictions for reimbursement of interferon-free DAAs for patients with HCV infection in Europe

97% (n=34) of countries had no additional restrictions for persons with HIV-HCV co-infection



* Persons with HIV-HCV co-infection had to have a negative drug test in order to receive reimbursed therapy

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Discussion

- Findings highlighted considerable variability in DAA therapy restrictions across Europe, particularly with respect to fibrosis stage
- Restricting DAA prescribing to specialists is a considerable barrier to broad access
- Implications for health policy makers and health service delivery with evidence of some countries not following the European HCV treatment guidelines by EASL
- Implications for meeting WHO Global Health Sector Strategy on Viral Hepatitis targets

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Discussion continued



Australia

~230,000 Australians have chronic HCV
(pop. ~23 mil)

Listed on PBS since March 1, 2016:

- No disease stage restrictions
- No drug or alcohol use restrictions
- GPs can prescribe
- 38,460 treated from March 2016 - 2017 – approximately 17% of persons estimated to have chronic HCV infection

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Monitoring hepatitis C treatment uptake in Australia. Issue #7. July 2017. The Kirby Institute. UNSW Sydney



Acknowledgements

Study Authors

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