



Market access and uptake of new antiviral drugs for the treatment of hepatitis

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November 14, 2013

The new therapies & diagnostics have the potential to completely change the HCV treatment paradigm in 2014-2017



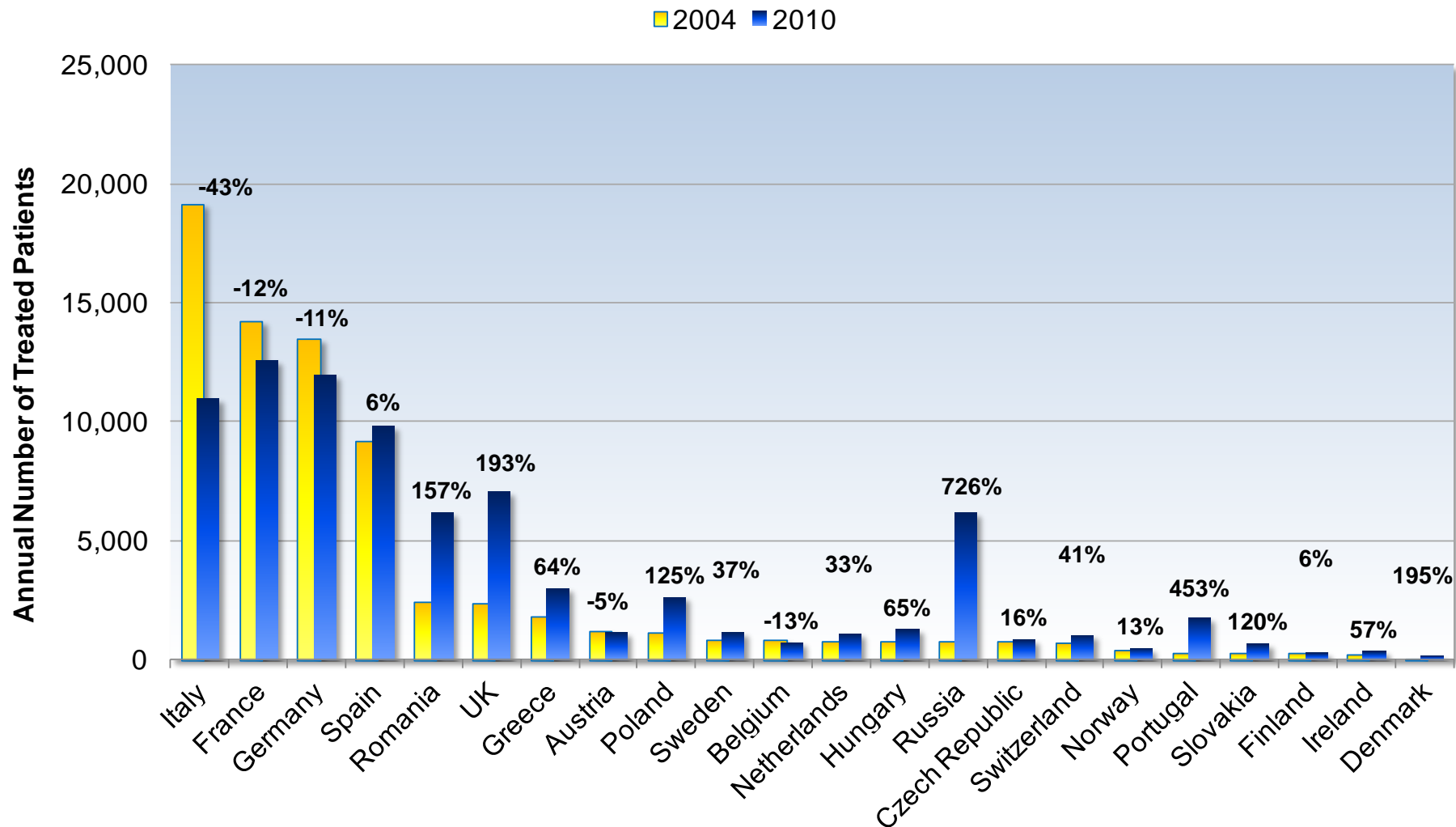
Therapies

- » simeprevir (TMC-435)
- » sofosbuvir (GS-7977)
- » ABT-333/ ABT-450/r/ ABT-267
- » faldaprevir (BI-201335)
- » daclatasvir (BMS-790052)
- Higher cure rates
- Shorter duration of treatment
- Fewer side effects
- All oral therapies

Point of Care New Diagnostics

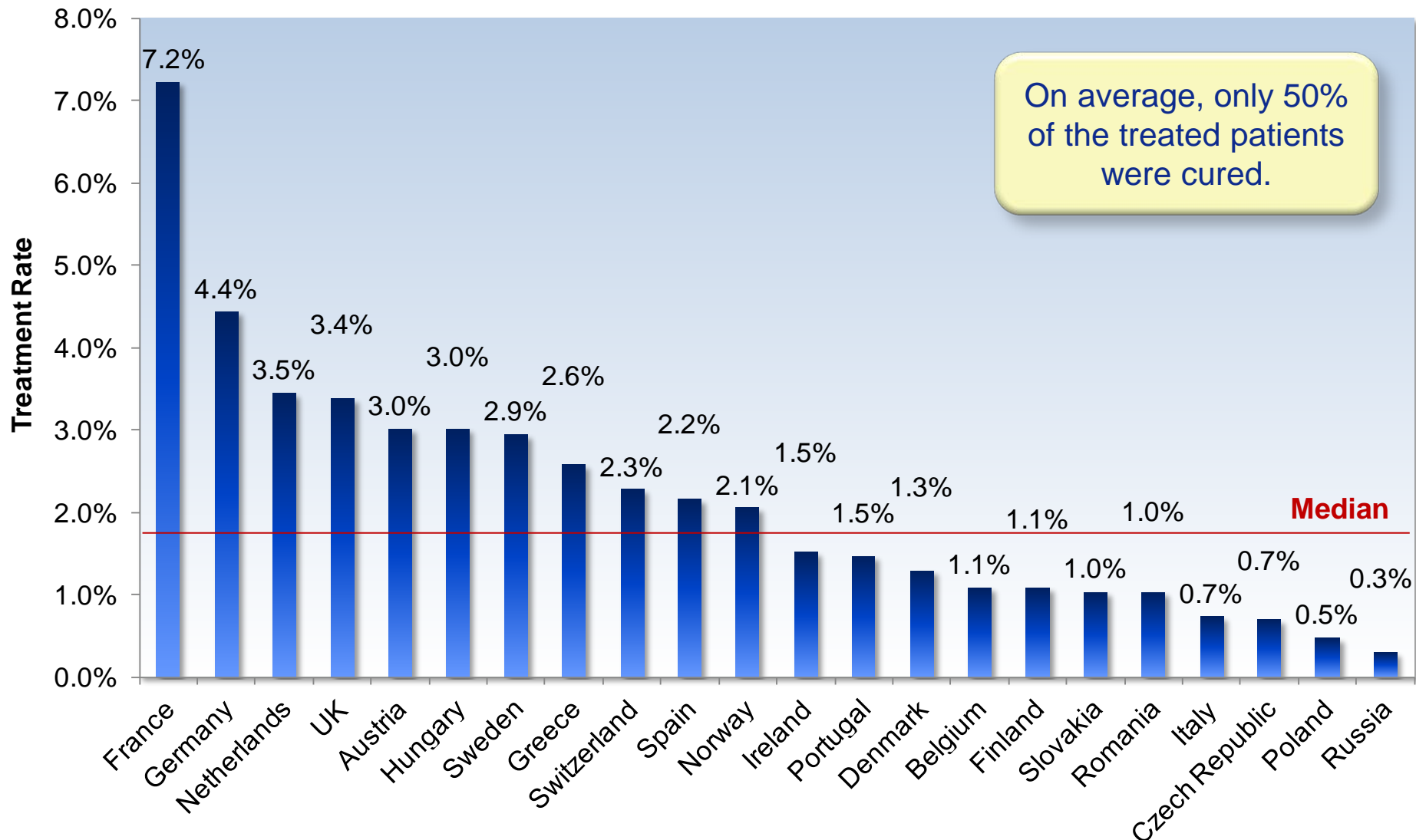
- » Immunoassays – MBio
- » Qualitative RNA tests – Daktari, Mbio, Wave 80
- » Quantative RNA tests – Alere, Daktari, Iquum, Wave 80
- » Genotyping – Celera, Wave 80, Cepheid
- Testing done in the field of office
- Rapid results
- Potential for lower cost

Even before the launch of the protease inhibitors, there was considerable variability in the number of treated HCV patients



The number of treated patients declined in 2013 across most countries in anticipation of new therapies.

HCV treatment rate has historically been low due to its low priority, efficacy, side-effects of current therapies

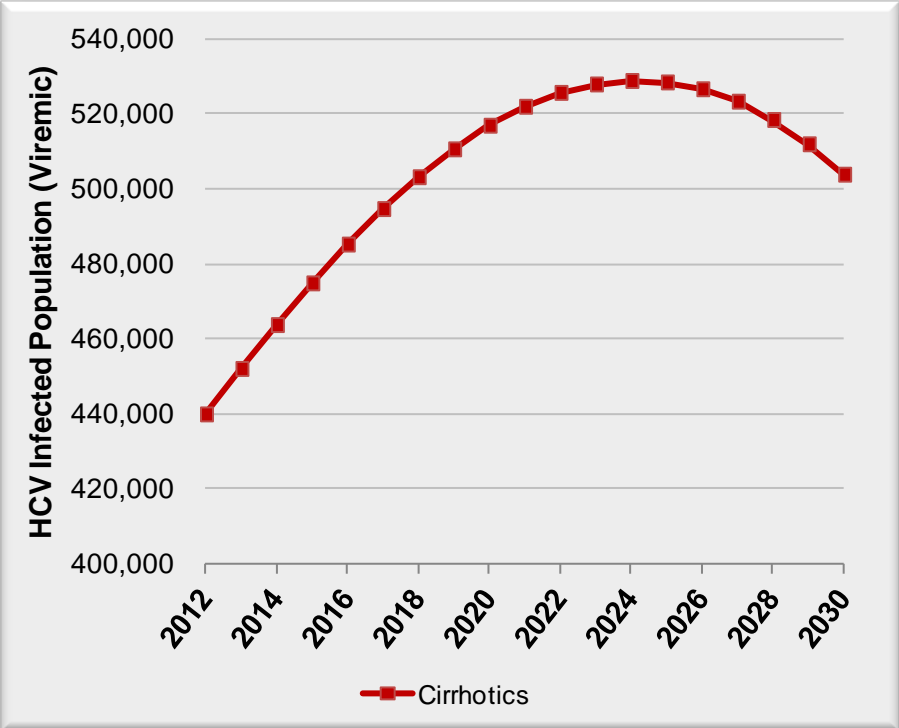


However, the HCV infected patients are aging and progression to late stage liver diseases

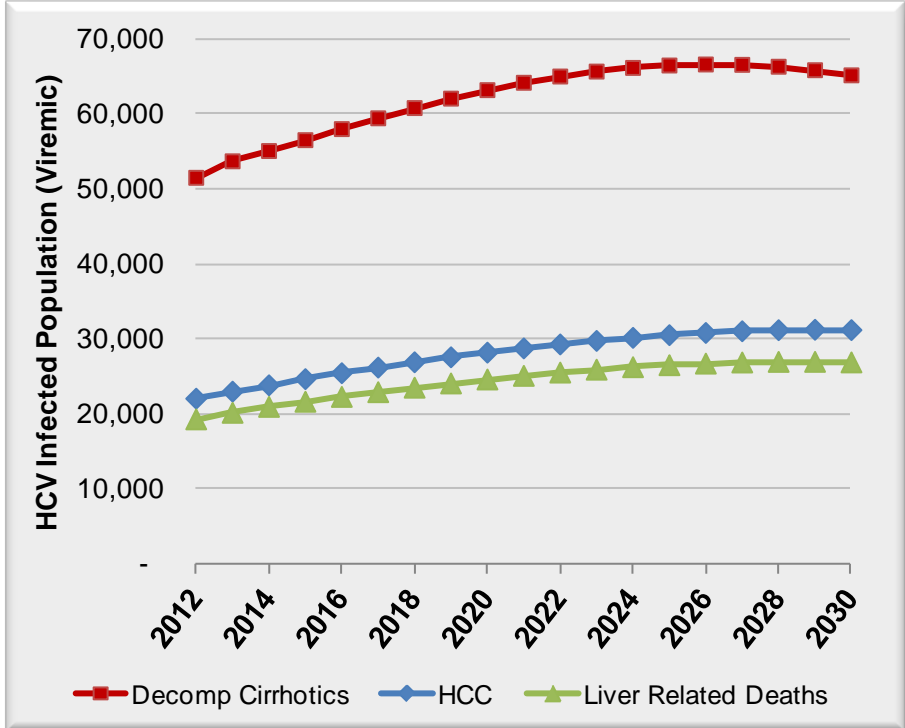


The number of HCV related cirrhotic cases will increase by 20%, decompensated cirrhosis by 30%, HCC by 40%, and liver related deaths by 40%.

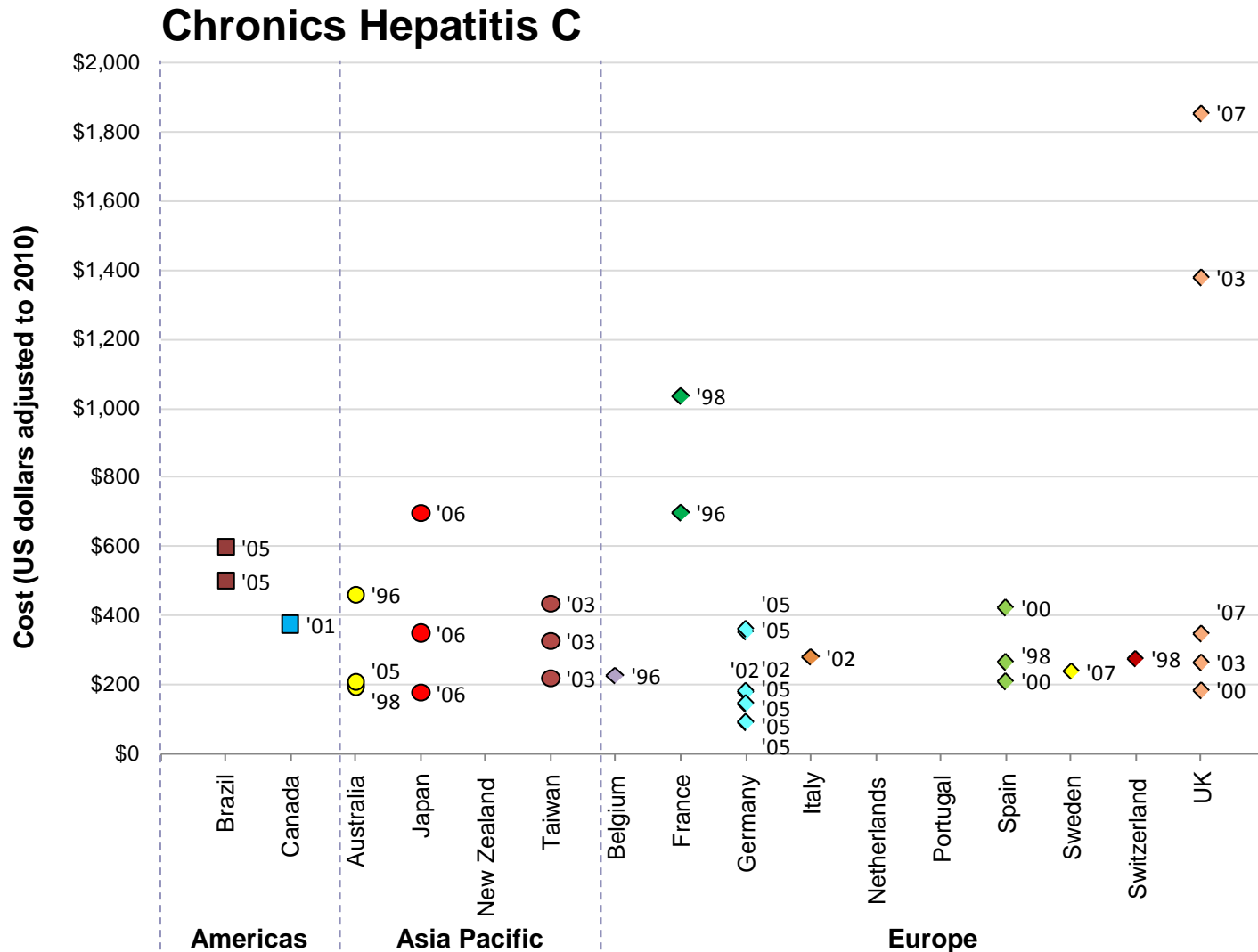
HCV Related Cirrhotic Cases



HCV Related Decomp Cirrhosis, HCC, & Liver Related Deaths

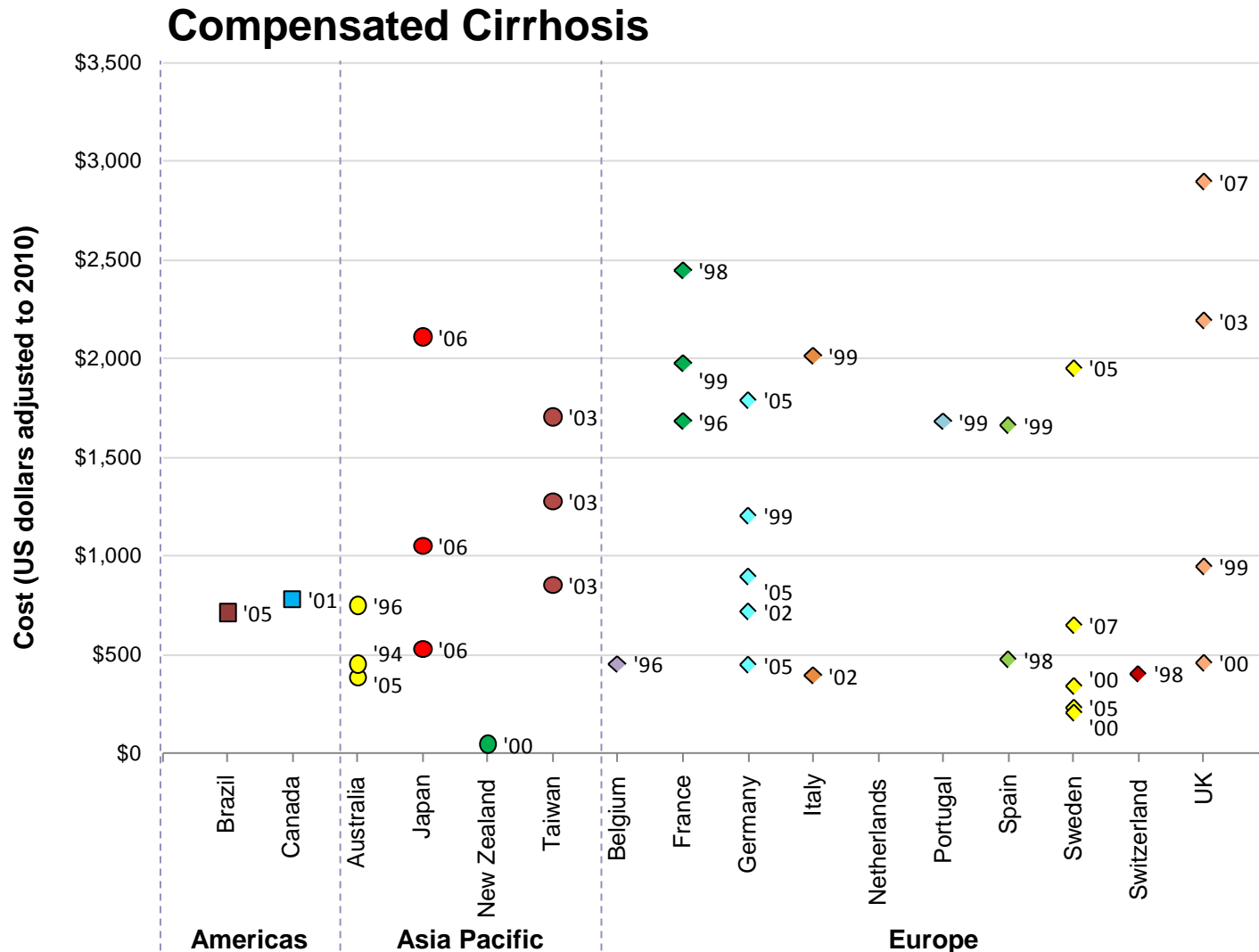


A patient with fibrosis will cost the healthcare system \$200-700 annually



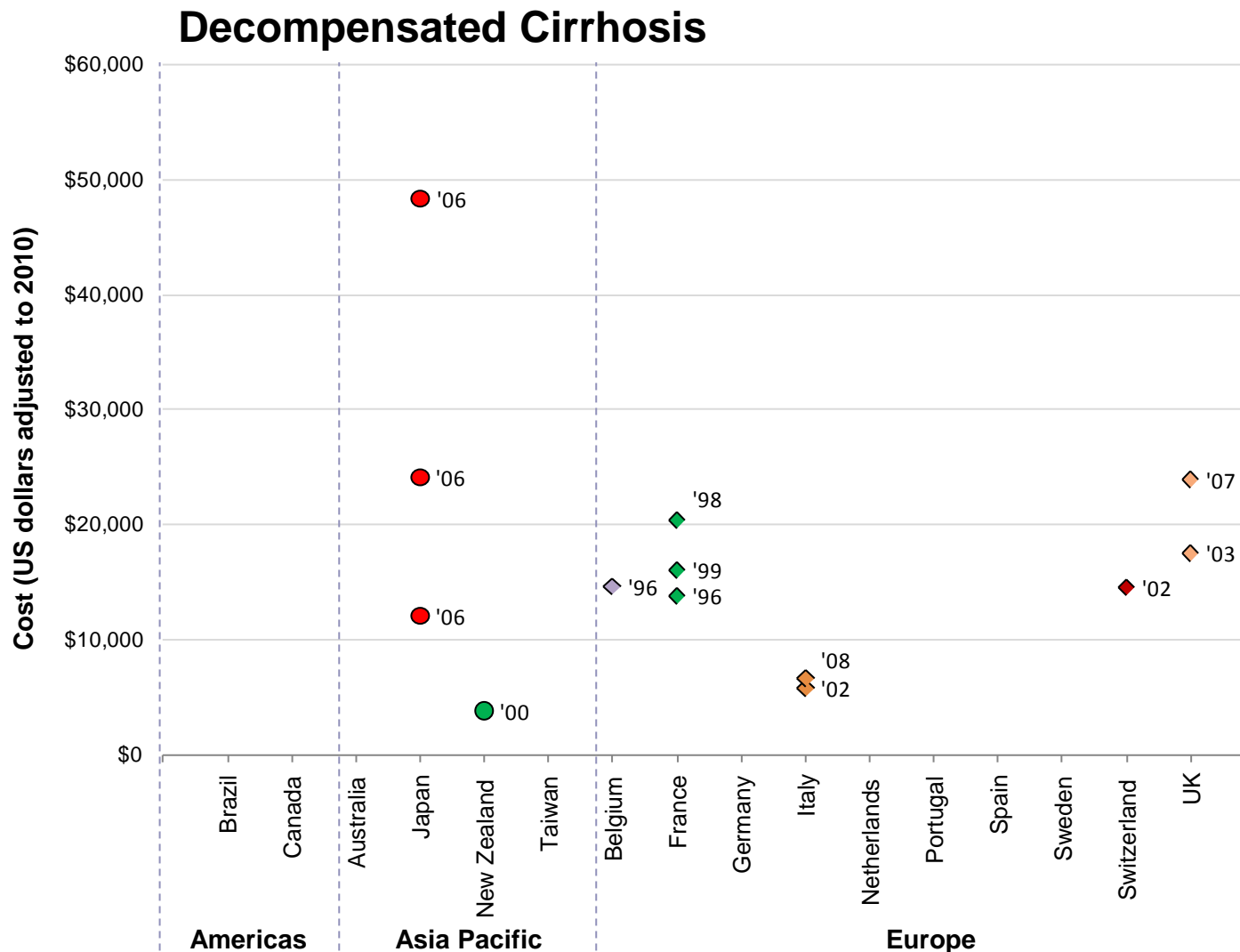
Source: El Khoury AC, Wallace C, Klimack WK, Razavi H. Economic burden of hepatitis C-associated diseases: Europe, Asia Pacific, and the Americas. *J Med Econ* 2012 Mar 30;15(5):887-96.

A patient with compensated cirrhosis will cost the healthcare system \$500-\$2,000 annually



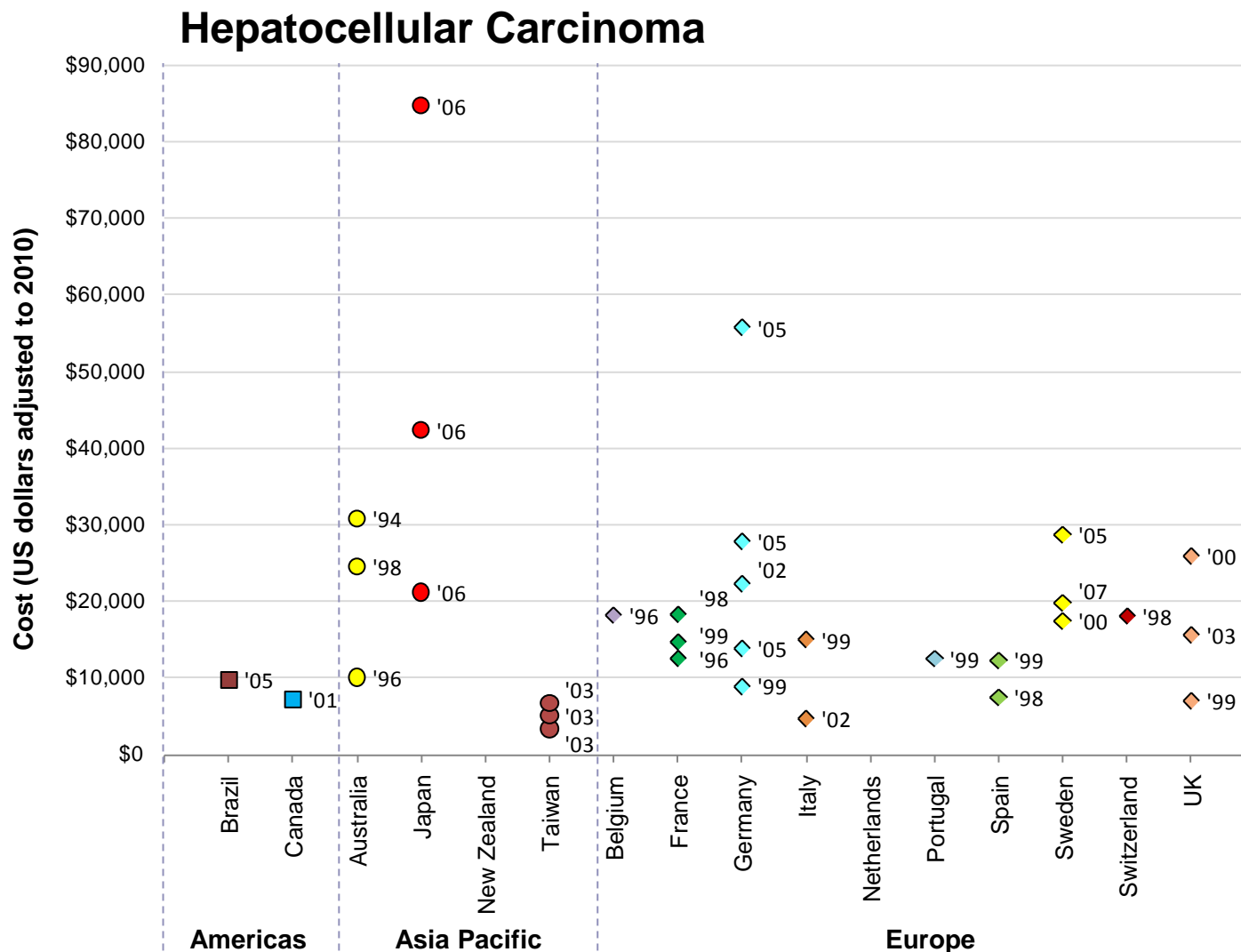
Source: El Khoury AC, Wallace C, Klimack WK, Razavi H. Economic burden of hepatitis C-associated diseases: Europe, Asia Pacific, and the Americas. *J Med Econ* 2012 Mar 30;15(5):887-96.

A patient with compensated cirrhosis will cost the healthcare system \$5,000-\$20,000 annually



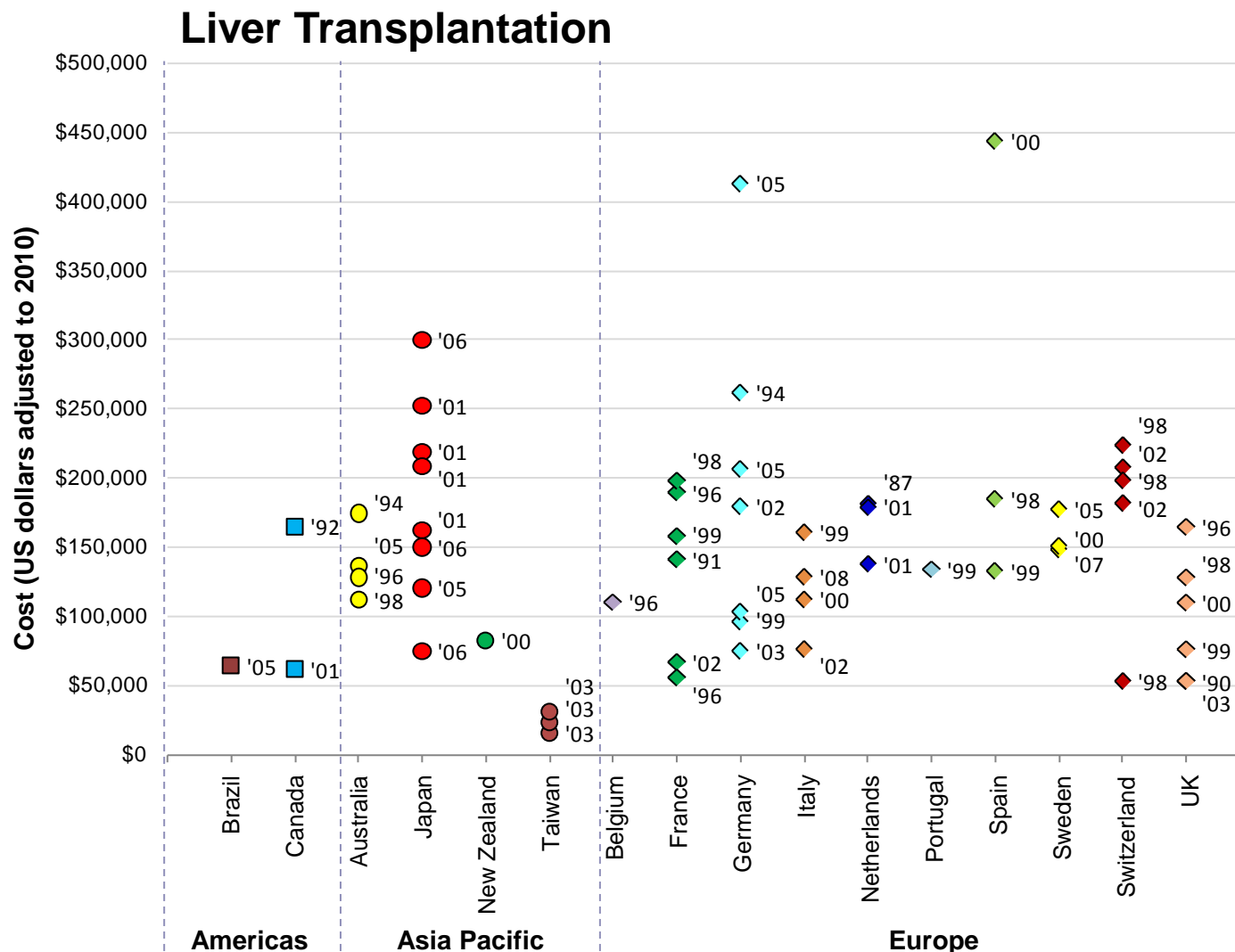
Source: El Khoury AC, Wallace C, Klimack WK, Razavi H. Economic burden of hepatitis C-associated diseases: Europe, Asia Pacific, and the Americas. *J Med Econ* 2012 Mar 30;15(5):887-96.

A patient with HCC will cost the healthcare system \$5,000- \$25,000 annually



Source: El Khoury AC, Wallace C, Klimack WK, Razavi H. Economic burden of hepatitis C-associated diseases: Europe, Asia Pacific, and the Americas. *J Med Econ* 2012 Mar 30;15(5):887-96.

A liver transplantation will cost the healthcare system \$50,000-\$250,000



Source: El Khoury AC, Wallace C, Klimack WK, Razavi H. Economic burden of hepatitis C-associated diseases: Europe, Asia Pacific, and the Americas. *J Med Econ* 2012 Mar 30;15(5):887-96.

Drug prices – determines access but there are many factors that influence the final price



- The pharmacoeconomic

Lifetime Cost of a Male 30-35 years old (in the US)

Stage of HCV Progression	F0	F1	F2	F3	Cirrhosis	Decomp Cirrhosis	HCC	Liver Trans.
Lifetime Cost	\$76,000	\$95,800	\$124,800	\$144,700	\$163,100	\$205,900	\$89,000	\$384,000

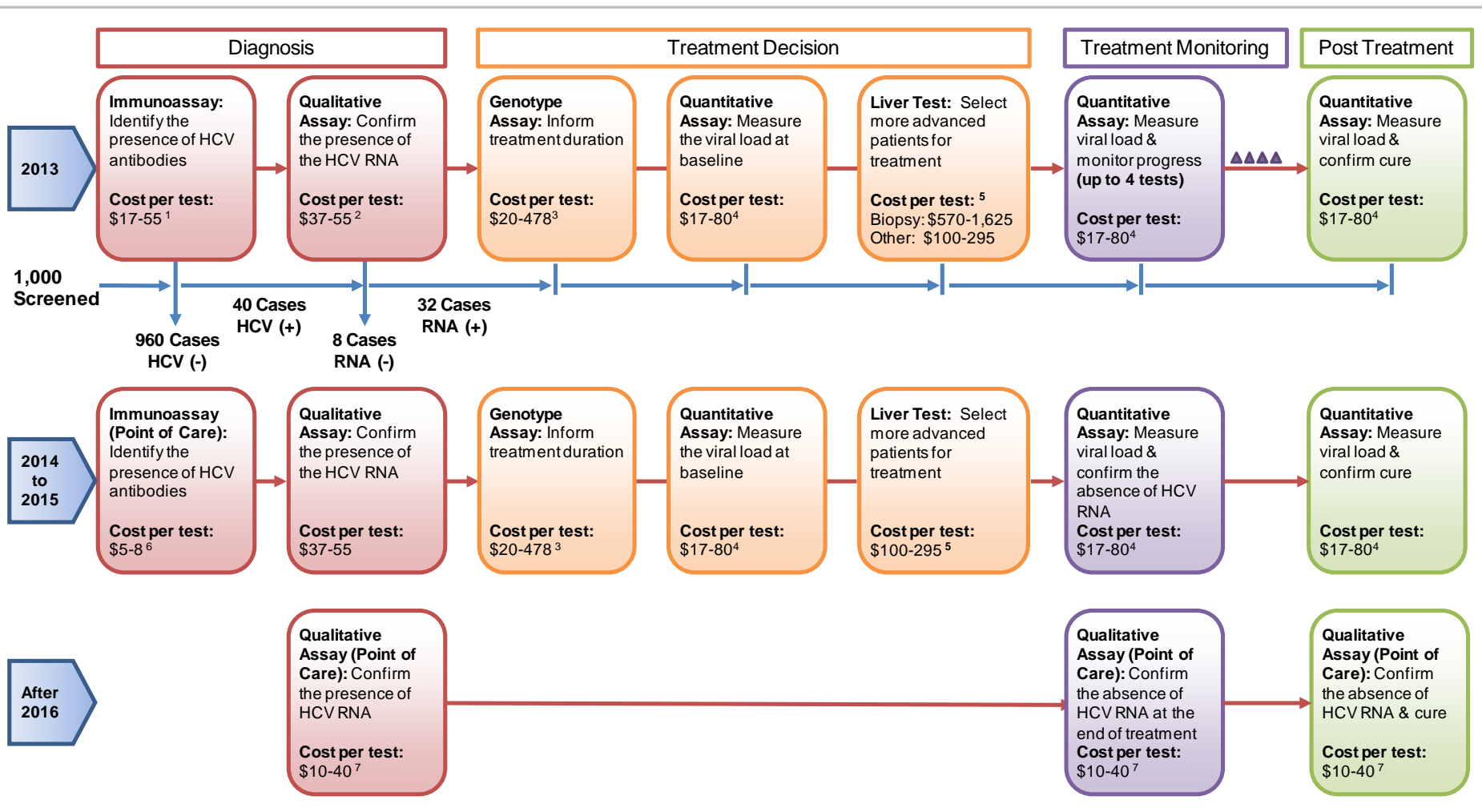
- Reference pricing
 - » Romania uses the minimum drug price any of the following countries – Austria, Belgium, Bulgaria, Czech Republic, Germany, Greece, Hungary, Italy, Lithuania, Poland, Slovakia, and Spain.
- Rebates



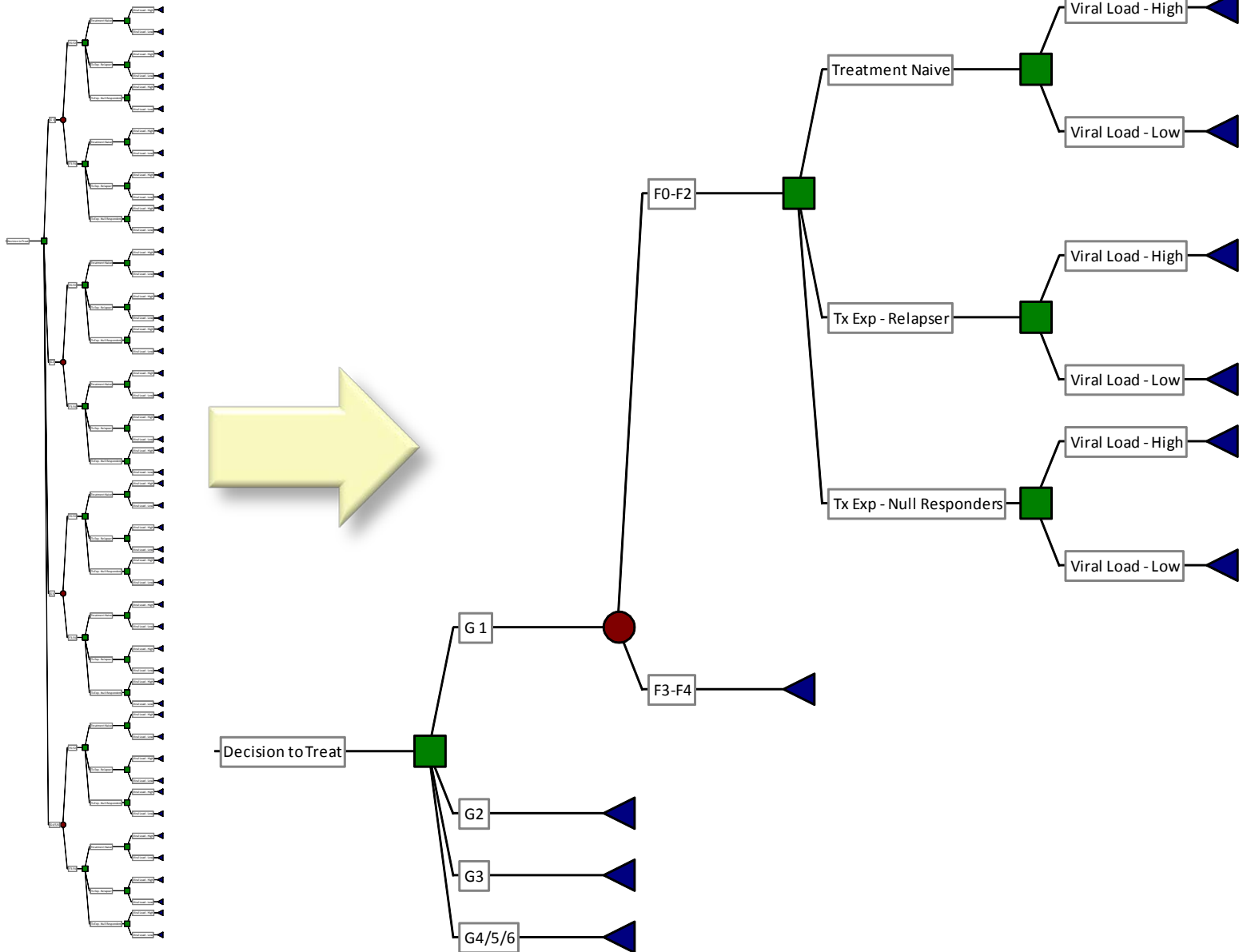
The drug price is only part of the story

- Add-on support
 - » Reimburse the countries for the cost of diagnosis
 - » Provide medical education for physician and nurses
 - » Patient hotline to help with side effects/ compliance
- Reimbursements
 - » Patient assistant programs

Access is also determined by the complexity of needed diagnostics and treatment



Treating HCV is not a simple task



How do we provide access to the new therapies and diagnostics?



- Education of the stakeholders – Governments, companies, and patients
- National and international guidelines
- Simplifying treatment and diagnosis