Does HIV Coinfection Affect HCV Reimbursement Decisions?

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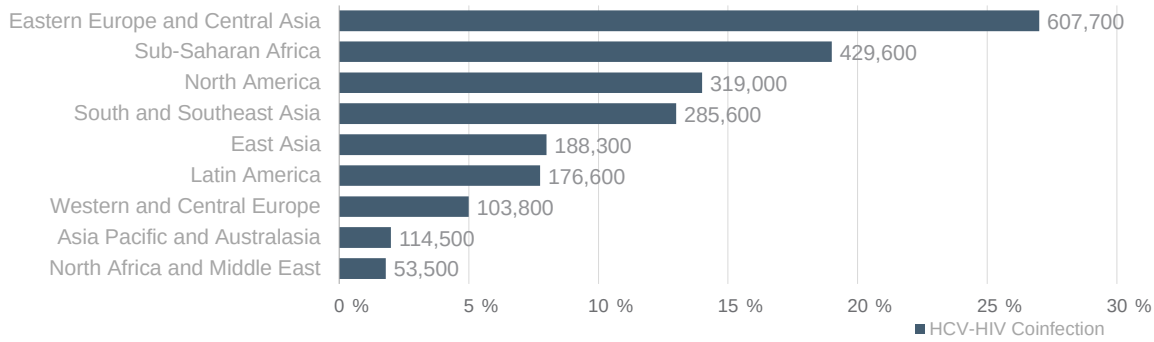
Background and Research Objective

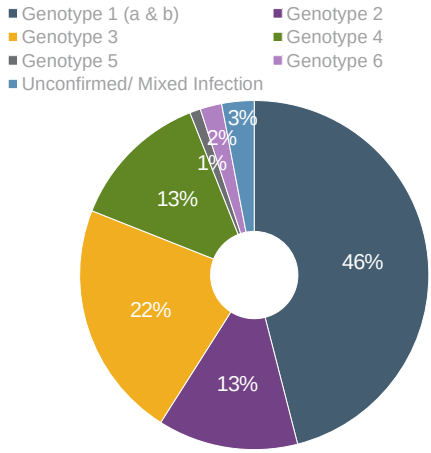
Global Disease Burden by Region, 2017



- Thirty-seven million people are infected with human immunodeficiency virus (HIV). Approximately 115 million people have hepatitis C virus (HCV) infection.
- The odds of contracting HCV infection are 6 times higher among patients with HIV.

Platt, Lucy, et al. "Prevalence and Burden of HCV Co-Infection in People Living with HIV: A Global Systematic Review and Meta-Analysis." The Lancet Infectious Diseases, vol. 16, no. 7, 24 Feb. 2016, pp. 797–808., doi:10.1016/s1473-3099(15)00485-5.

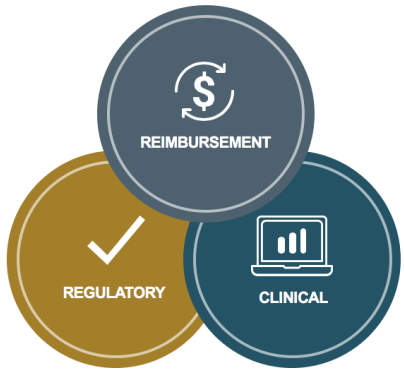
HCV Genotypes and Targeted Therapies by Drug Class



Therapy by Drug Class	Targeted Genotype
Interferons	
peginterferon alfa-2a	genotype 1
peginterferon alfa-2b	genotype 1, 2, or 3
Protease inhibitors (in combination with peginterferon + ribavirin)	
telaprevir	genotype 1
simeprevir	genotype 1 or 4
Polymerase inhibitors (in combination with peginterferon + ribavirin)	
sofosbuvir	genotype 1
Interferon-free regimens	
simeprevir + sofosbuvir	genotype 1 or 4
sofosbuvir-velpatasvir	genotypes 1 to 6
Nucleoside analogues	
ribavirin	genotype 1, 2, or 3

Gower, Erin, et al. "Global Epidemiology and Genotype Distribution of the Hepatitis C Virus Infection." Journal of Hepatology, vol. 61, no. 1, Nov. 2014, doi:10.1016/j.jhep.2014.07.027.

Health Technology Assessment



Agencies Covered
Canadian Agency for Drugs and Technologies in Health (CADTH)
Gemeinsamer Bundesausschuss (G-BA)
Haute Autorité de Santé (HAS)
National Institute for Health and Care Excellence (NICE)
Pharmaceutical Benefits Advisory Committee (PBAC)
Scottish Medicines Consortium (SMC)

Objective: To assess whether including HIV-coinfected patient subgroup analyses play a role in receiving positive reimbursement decisions in health technology assessment (HTA) submissions for HCV treatments.

Methodology

Does HIV Coinfection Affect HCV Reimbursement Decisions?

Data-Selection Process

Data extracted from the Context Matters Platform between 2009 and 2018

All HCV reimbursement decisions among adult and pediatric populations

(n = 456)

Adult HCV patients, including those with HIV coinfection

(n = 434)

Selected agencies:

CADTH, G-BA, HAS, NICE, PBAC, SMC

(n = 325)

Excluding abbreviated and non-submissions

(n = 312)

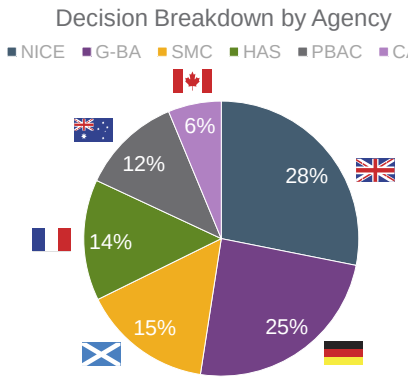
Positive and negative reimbursement decisions

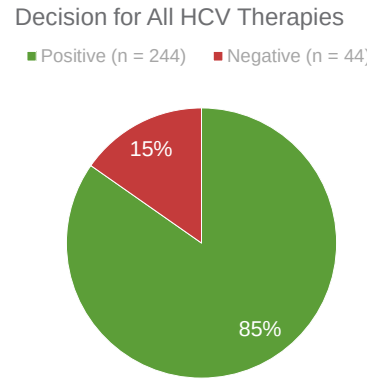
(n = 288)

Results and Conclusion

Does HIV Coinfection Affect HCV Reimbursement Decisions?

Distribution of All Reimbursement Decisions

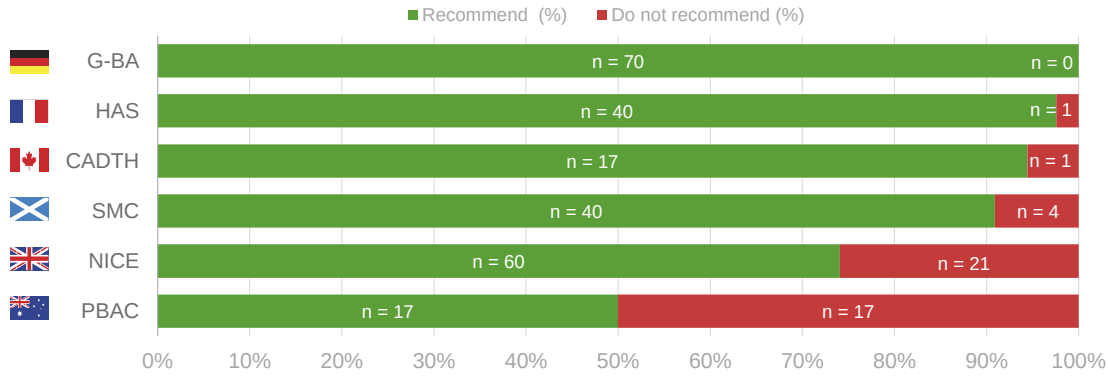




Of the 6 HTA agencies, NICE and G-BA assessed HCV therapies at higher rates, while CADTH had the lowest rate.

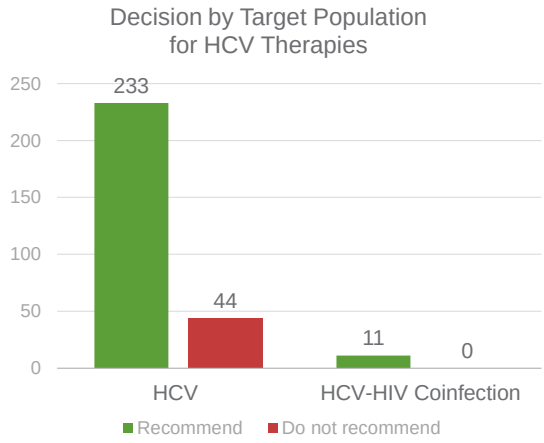
Among all HCV therapies that were evaluated for reimbursement, approximately 85% received positive decisions between 2009 and 2018.

Distribution of Reimbursement Decisions by Agency



G-BA made the most positive HCV decisions (100% [n = 70]), followed by HAS (97.6% [n = 40]), and CADTH (94.44% [n = 17]).

Relationship Between Reimbursement Decision and Type of Therapy



- **Fisher's exact test demonstrated that there is no significant relationship between receiving positive reimbursement decisions and HTA submissions for HCV therapies that included an HIV-coinfected subgroup (p = 0.1558).**

Target Population for HCV Therapy	Reimbursement Decision		Total
	Recommend (%)	Do not recommend (%)	
HCV	84.12	15.88	277
HCV-HIV Coinfection	100	0	11

Timeline of First Reimbursement Approvals of Therapies for Patients with HCV and HCV-HIV Coinfection

Why Were HCV Therapies Recommended for HIV-Coinfected Patients?

Grounds for Approval by Drug Class, by Population

	Interferons	Interferon-free Regimens
Drugs	Pegasys *(peginterferon alfa-2a + ribavirin)*	Viekirax *(ombitasvir-paritaprevir-ritonavir ± ribavirin or dasabuvir)* Harvoni *(ledipasvir-sofosbuvir)*
Population	• Genotype 1 HCV with HIV coinfection	• Genotype 1 HCV with HIV coinfection
Reasons for Reimbursement	• Cost-effective • Dominant ICERs (< £12,000/QALY) • Curative therapy	• Hint of an additional clinical benefit over comparators (peginterferon alfa + ribavirin)

Grounds for Approval by Drug Class, by Population (Cont'd)

	Protease Inhibitors (+ peginterferon + ribavirin)	Polymerase Inhibitors (+ peginterferon + ribavirin)
Drugs	Galexos, Olysio *(simeprevir)*	Sovaldi *(sofosbuvir)*
Population	• Genotype 1 or 4 HCV with HIV coinfection	• Genotypes 1 to 6 HCV with HIV coinfection • Genotypes 1 to 6 HCV with HIV coinfection (except genotype 3)
Reasons for Reimbursement	• Similar efficacy (sustained virological response rate) as seen in HCV patients • Higher efficacy and better safety profile • Short treatment duration • Lower cost over comparator (telaprevir + peginterferon alfa-2a), higher QALY gains	• Indication of a minor benefit over the comparator, peginterferon alfa-2a + ribavirin • Higher efficacy: virological levels • Better safety profile in most difficult-to-treat patients (genotypes 1, 4, 5, and 6) and cirrhotic patients, no drug interactions

Conclusion and Key Takeaways

1

All HCV therapies for patients coinfected with HIV were recommended.

2

Expanding the HCV demographic to include HIV-coinfected patients for HCV therapies does not reduce the rate of positive reimbursement decisions.

3

Whether or not including an HIV-coinfected subgroup increases the rate of receiving positive decisions is not clear given the small sample size.

Thank you!

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