

## Budget Impact Analysis of a Stratified Treatment Cascade for Hepatitis C Direct Acting Antiviral Treatment in an Asian Middle-Income Country through the Use of Compulsory and Voluntary Licensing Options

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**Abstract :** Objective: A scaled-up treatment cascade with direct-acting antiviral (DAA) therapy is necessary to achieve global WHO targets for hepatitis C virus (HCV) elimination in Malaysia. Recently, limited access to Sofosbuvir/Daclatasvir (SOF/DAC) is available through compulsory licensing, with future access to Sofosbuvir/Velpatasvir (SOF/VEL) expected through voluntary licensing due to recent agreements. SOF/VEL has superior clinical outcomes, particularly for cirrhotic stages, but has higher drug acquisition costs compared to SOF/DAC. It has been proposed that a stratified treatment cascade might be the most cost-efficient approach for Malaysia whereby all HCV patients are treated with SOF/DAC except for patients with cirrhosis who are treated with SOF/VEL. This study aimed to conduct a five-year budget impact analysis from the provider perspective of the proposed stratified treatment cascade for HCV treatment in Malaysia. Method: A disease progression model that was developed based on model-predicted HCV epidemiology data in Malaysia was used for the analysis, where all HCV patients in scenario A were treated with SOF/DAC for all disease stages while in scenario B, SOF/DAC was used only for non-cirrhotic patients and SOF/VEL was used for the cirrhotic patients. The model projections estimated the annual numbers of patients in care and the numbers of patients to be initiated on DAA treatment nationally. Healthcare costs associated with DAA therapy and disease stage monitoring was included to estimate the downstream cost implications. For scenario B, the estimated treatment uptake of SOF/VEL for cirrhotic patients were 25%, 50%, 75%, 100% and 100% for 2018, 2019, 2020, 2021 and 2022 respectively. Healthcare costs were estimated based on standard clinical pathways for DAA treatment described in recent guidelines. All costs were reported in US dollars (conversion rate US\$1=RM4.09, the price year 2018). Scenario analysis was conducted for 5% and 10% reduction of SOF/VEL acquisition cost anticipated from the competitive market pricing of generic DAA in Malaysia. Results: The stratified treatment cascade with SOF/VEL in Scenario B was found to be cost-saving compared to Scenario A. A substantial portion of the cost reduction was due to the costs associated with DAA therapy which resulted in USD 40 thousand (year 1) to USD 443 thousand (year 5) savings annually, with cumulative savings of USD 1.1 million after 5 years. Cost reductions for disease stage monitoring were seen in year three onwards which resulted in cumulative savings of USD 1.1 thousand. Scenario analysis estimated cumulative savings of USD 1.24 to USD 1.35 million when the acquisition cost of SOF/VEL was reduced. Conclusion: A stratified treatment cascade with SOF/VEL was expected to be cost-saving and can results in a budget impact reduction in overall healthcare expenditure in Malaysia compared to treatment with SOF/DAC. The better clinical efficacy with SOF/VEL is expected to halt patients' HCV disease progression and may reduce downstream costs of treating advanced disease stages. The findings of this analysis may be useful to inform healthcare policies for HCV treatment in Malaysia.

**Keywords :** Malaysia, direct acting antiviral, compulsory licensing, voluntary licensing

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