



## Research article

# Cost and availability of antiviral therapy for Chronic Hepatitis B viral infection in Vietnam: A Nationwide retrospective study

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## ABSTRACT

Hepatitis B remains a significant global health burden, especially in low- and middle-income countries. This study aims to analyse the cost and availability of hepatitis B treatment drugs in Vietnam. This retrospective cross-sectional study analysed data from successful bids for hepatitis B antivirals in Vietnam between 2018 and 2022, including 1,963 drug packages from 242 bidders across 61 provinces. We classified hepatitis B viral (HBV) drugs using the Anatomical Therapeutic Chemical (ATC) Index with Defined Daily Doses (DDDs) and calculated average prices per DDD in USD. Descriptive statistical analysis was performed using Microsoft Excel. We included in this analysis a total of 160.2 million DDDs of HBV drugs, totalling USD \$43.2 million. Tenofovir disoproxil fumarate (TDF) was the most prescribed antiviral, accounting for 82.2% of total DDD, following by Entecavir (ETV) (9.8% of DDD) and Lamivudine (LMV) (6%). Overall, the price of HBV antivirals decreased steadily by approximately 11.67% per year during the study period, with TDF had the highest decrease by 23%. There were significant price variations or different antiviral drugs. TDF was the most commonly used medication with a reasonable price, while TAF's limited consumption may be due to its higher cost. With the transition from TDF to TAF, further research on cost-effectiveness is needed to optimise hepatitis B management. Policymakers can use these findings to improve accessibility and affordability of hepatitis B antiviral therapy in Vietnam.

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## INTRODUCTION

Hepatitis B is a viral infection that can silently progress into a chronic stage, leading to liver cirrhosis and hepatocellular carcinoma (HCC). Despite the availability of safe and effective vaccines since 1982, chronic hepatitis B remains a major global health burden as of the 2019 with 296 million people living with chronic hepatitis B worldwide and 18 million cases in the Southeast Asia region [1, 2]. In 2019, hepatitis B was responsible for an estimated 820,000 deaths, mainly from cirrhosis and HCC [2].

Vietnam is highly endemic for hepatitis B virus (HBV) infections, primarily transmitted from mother to child during infancy (90%) [3]. The prevalence of chronic HBV infection in Vietnam was 9.2% (2019), with the Central Highlands, Northwest, and South-Central Coast regions having the highest rates (11.1%, 11.1%, 11.4%, respectively) [4]. In 2017, it was estimated that there are around 7.8 million individuals with chronic hepatitis B in Vietnam, leading to approximately 80,000 cases of liver cirrhosis and HCC, and around 40,000 deaths annually.

Current HBV treatment can effectively inhibit viral replication, reduce the viral load, liver inflammation, fibrosis, and risk of cirrhosis and HCC [5]. As of the 2015, there were seven drugs recommended for the treatment of hepatitis B by the World Health Organization (WHO), including nucleoside analogues (NAs) antiviral drugs such as lamivudine (LMV), adefovir (ADV), tenofovir disoproxil fumarate (TDF), telbivudine (TBV), entecavir (ETV) and two immune modulators, interferon alpha-2a (IFN-a) and pegylated interferon alpha-2a (PEG-IFN-a) (commonly referred to as interferons - IFNs) [6]. Tenofovir alafenamide (TAF) was included in the updated revision of WHO guideline in 2023 [7].

In 2019, responding to the WHO's call for the elimination of viral hepatitis, Vietnam adopted the goal to reduce new hepatitis B infection and mortality rates by 90% and 65%, respectively, by 2030 [8]. However, only about 10% of people with hepatitis B in Vietnam are currently diagnosed, and of those diagnosed, only about 30% receive treatment [9]. To achieve the goal of eliminating HBV, the accessibility and the affordability of HBV treatment need to be expanded. Our study aims to analyse the availability and pricing of hepatitis B treatment drugs in Vietnam for providing useful information for policy makers in the goal of eliminating viral hepatitis in the country.

## MATERIALS AND METHODS

### Ethics

This study did not involve human subjects and did not require institutional review board (IRB) approval.

### Study setting

By the end of 2022, Vietnam had 1,150 public hospitals structured into three levels: central, provincial, and district [10]. The bidding process for supplying medications to public health facilities in Vietnam adheres to guidelines set by the Vietnam Ministry of Health (VMH) [11]. Each year, health facilities establish a procurement plan based on drug usage from the previous 12 months and estimated demand for the upcoming year before initiating a drug bidding process.

Information regarding the price and characteristics of HBV antivirals procured in Vietnam were obtained from the successful bids for medicines during the five-year period from 2018 and 2022 for hospitals and provincial departments of health, as published on the website of the Drug Administration of Vietnam (DAV), the regulatory authority under the VMH [12]. We

downloaded the databases of winning bids from 2018 to 2022 by searching on the official homepage of the DAV. The data for each tender included the name of the active ingredient, brand name/generic name, dosage and package, route of administration, registration identification, manufacturer, country of origin of the manufacturer, measuring unit, bid quantity, unit price, total expense, time of bidding, and healthcare facilities/hospital names.

### **Study design**

We conducted a retrospective cross-sectional study analysing all records of medications from winning bids containing antiviral agents active against HBV following both the national guidelines and WHO guidelines. The analysis excluded antiretroviral drugs for HIV treatment procured through centralised bidding and supported by the Global Fund. We classified all HBV antivirals using the 2023 Anatomical Therapeutic Chemical (ATC) Index with Defined Daily Doses (DDDs) [13]. The ATC classification system is a widely recognised tool used to categorise active medical substances according to their therapeutic and pharmacological properties. The DDDs, which are defined as the assumed average maintenance dose per day for a drug used for its main indication in adults, provide a standard unit of measurement for drug utilisation and comparison the consumption of different drugs across different populations and health systems [14]. For combination products, where the ATC code identifies the main ingredient, the DDD for the combination product was considered equivalent to the DDD for the main active ingredient [15]. By classifying the HBV antivirals (both single and multi-ingredient medications) using the ATC Index with DDDs, we can compare the utilisation of

different antiviral agents in the treatment of HBV in Vietnam. This approach was used in our previous publications [16].

We classified the manufacturers according to their country of origin to evaluate the market shares between domestic and international manufacturers of HBV antivirals and gain insights into the domestic manufacturing capacity in Vietnam.

### **Price calculation**

The “price” of each antiviral drug in the analysis was defined as the monetary value of the winning product in each successful bid, calculated based on the unit of DDDs. We calculated the total number of DDD purchased by dividing the bid quantity per transaction by DDD value of each sample. The average price per DDD of an HBV antiviral medication was determined by dividing the bidding price for that drug by the total number of DDD. Then, the ratio of the highest to the lowest price per DDD of each antiviral over the period (high/low ratio) was performed to assess the variation in the price of HBV antiviral drug. All prices were adjusted for inflation using CPI to reflect the 2022 price value and converted from VND to USD according to the annual average official exchange rates of the World Bank in 2022 (1 USD = 23,650 VND) [17].

### **Statistics**

All descriptive statistical analyses were conducted using Microsoft Excel (Office 365, version 1909, Microsoft Corporation, Redmond, Washington, United States of America).

## **RESULTS AND DISCUSSIONS**

### **RESULTS**

Our analysis included 1,963 HBV drug packages that were successfully tendered from 242 bidders, including the central procurement unit, national/provincial/district

**Table 1:** Characteristics of procurement records from 61 provinces (2018-2022)

	2018	2019	2020	2021	2022	Total
<b>Number of procurement records</b>	715	296	291	363	298	1963
<b>Number of bidders</b>	123	82	92	119	104	241
<b>Number of provinces</b>	55	36	36	39	37	61
<b>Number of manufacturers</b>	34	30	29	24	22	52
<b>Number of formulations</b>	62	48	47	42	35	98
<b>Number of HBV drugs DDD</b>	38,751,844	29,847,706	17,037,519	41,169,091	33,381,741	160,187,902
<b>Total expenditure (\$USD)</b>	18,723,694	7,561,303	3,746,980	7,508,700	5,651,023	43,191,701

hospitals, across 61 out of 63 provinces in Vietnam. The packages were sourced from 98 formulations made by 52 manufacturers over a five-year period from 2018 to 2022 (Table 1).

We identified five drugs for HBV which are recommended for the treatment of chronic hepatitis B (CHB), according to both the Vietnamese and WHO guidelines: ETV (J05AF10), TAF (J05AF13), TDF (J05AF07), IFN- $\alpha$  (L03AB05) (only approved by Vietnamese guidelines for children over one year old), and PEG-IFN- $\alpha$  (L03AB11) (only approved by Vietnamese guidelines for adults). Additionally, four single multi-active ingredient drugs, namely ADV (J05AF08), LMV (J05AF05), IFN- $\alpha$  (L03AB04), and an unclassified ACT drug, ADV+LMV, were not included in the HBV treatment recommendations. ADV+LMV is not identified by an ATC code, and as a result, the DDD for this combination product is based on the DDD of the main active ingredient, which is ADV.

Over the five-year period, the annual

average budget for all HBV treatment drugs in this analysis was approximately USD \$8.64 million, with a total of 32.04 million DDDs (Table 1).

The most commonly used drug over the five-year period was TDF, accounting for 76.99% to 86.50% of the total DDDs. It also had the highest total expense, ranging from 53.74% to 69.12%. In contrast, TAF was one of the least purchased HBV antivirals, accounting for less than 1% of the total DDD and a total budget of less than 7%, with no hospital procuring it in 2019. ETV made up only 8.15% to 13.87% of the total DDD of HBV drugs used, but its purchasing cost was relatively high, ranging from 18.89% to 39.24%. IFNs were only available in the first year of the study period, accounting for 0.48% of the total DDD, but 12.12% of the total budget for HBV antivirals (Figure 1).

Despite its high resistance rate, LMV remained widely used in Vietnam, accounting for 8.43% and 10.50% of the total DDD of HBV treatment drugs in 2018 and 2019, respectively. However, its usage gradually

HBV drugs	2018		2019		2020		2021		2022		Total %	Total %
	% DDDs	% Budget	% DDDs	% Budget	% DDDs	% Budget	% DDDs	% Budget	% DDDs	% Budget	DDD	Budget
ADV	2.42%	0.78%	0.28%	0.06%	0.10%	0.02%	0.00%	0.00%	0.00%	0.00%	0.65%	0.35%
ETV	8.15%	18.89%	9.17%	23.91%	10.01%	23.04%	8.53%	24.21%	13.87%	39.24%	9.83%	23.72%
IFN	0.48%	12.12%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.12%	5.26%
LMV	8.43%	8.66%	10.50%	8.39%	3.26%	6.99%	4.81%	3.24%	2.23%	2.05%	6.04%	6.66%
TAF	0.01%	0.03%	0.00%	0.00%	0.13%	0.83%	0.99%	6.28%	0.23%	1.64%	0.32%	1.39%
TDF	76.99%	53.74%	79.84%	66.89%	86.50%	69.12%	85.67%	66.28%	83.67%	57.07%	82.15%	59.99%
ADV+LMV	3.53%	5.78%	0.21%	0.75%	0.00%	0.00%	0.00%	0.00%	0.00%	0.00%	0.89%	2.64%
<b>Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>	<b>100.00%</b>

**Figure 1:** Distribution of hepatitis B antiviral drug utilization and spending in Vietnam (2018-2022), expressed as column-wise percentages of total DDDs and total budget.

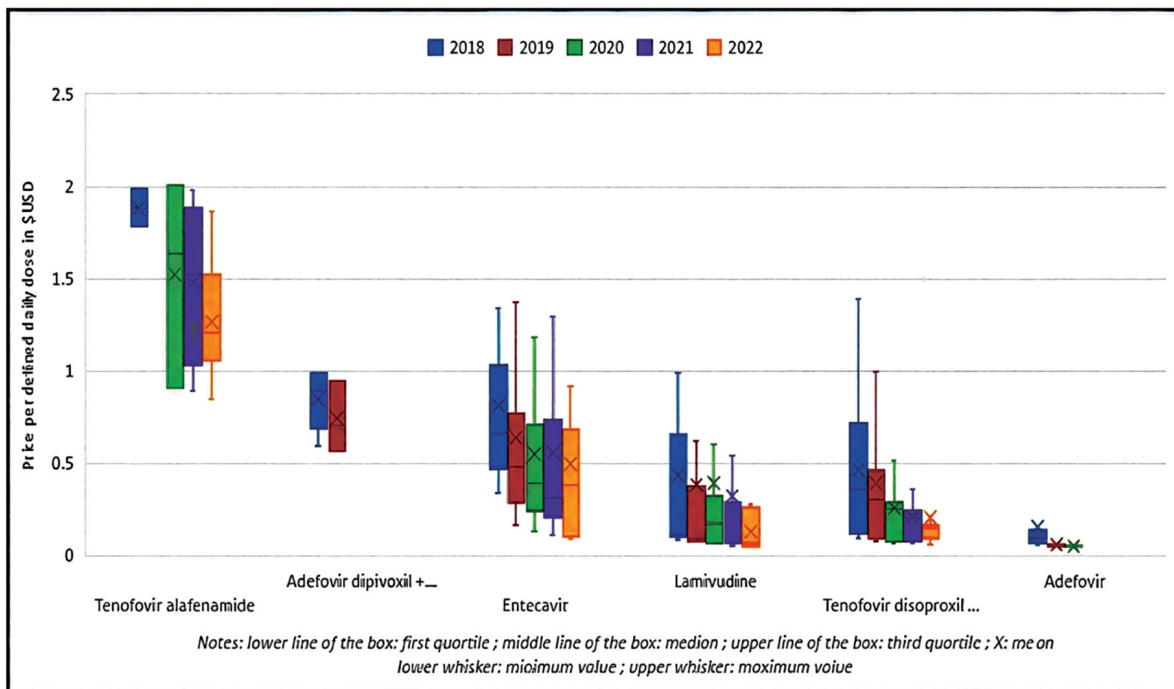
decreased, representing only 2.05% of the total DDD in 2022. ADV accounted for a small proportion of the total HBV drugs, with 2.42% of the total DDD in 2018. Its usage decreased over the next two years and was no longer be utilised as an active agent in 2021 and 2022. Similarly, the HBV drug combination of ADV-LMV was only procured in small quantities during the first two years (3.53% and 0.21% in 2018 and 2019, respectively) (Figure 1).

*Color gradients represent the value intensity in each column, where red indicates high relative values, yellow indicates intermediate values, and green represents low relative values. The following abbreviations are used: ADV - adefovir; ETV - entecavir; IFN - interferon; LMV - lamivudine; TDF - tenofovir disoproxil fumarate; TAF - tenofovir alafenamide; and ADV+LMV - a combination of adefovir and lamivudine.*

The average price per DDD varied across different drugs. IFNs had a significantly higher average price compared to NA antiviral drugs, with an average of USD \$12.23 per DDD in 2018. Among the NA antiviral drugs, TAF had the highest cost, with an average price of USD \$1.788 per DDD in the same year. The average cost per

DDD of ETV was USD \$0.65, which was higher than that of LMV at USD \$0.30 per DDD. TDF had the relatively lowest average price per DDD at USD \$0.20 (just slightly higher than ADV at USD \$0.15). The price variation per DDD was considerable for TDF (High/Low ratio ranging from 21.22 to 33.45) and entecavir (High/Low ratio ranging from 11.71 to 27.55) over the years, while the range for LMV narrowed from 2018 to 2022 (Appendix 1). Overall, the price of HBV antivirals decreased steadily by approximately 11.67% per year during the study period (decreasing 23.04% for TDF, 20.20% for ADV, 14.25% for ADV-LMV, 7.14% for entecavir, 3.65% for TAF and 1.64% for LMV annually) (Figure 2).

Domestic manufacturers from 32 out of 48 companies supplied 98.10% (157,141,171/160,187,902) of the total HBV drugs. International manufacturers contributed only 1.90% in terms of quantity but accounted for 14.12% of the total budget (USD \$6,096,953). India was the largest international country supplying 1.10% of the total DDDs (n = 1,746,660). Six out of the 23 manufacturers of TDF are foreign manufacturers, but they only account for 1.13% of the total DDDs of TDF. PEG-IFN-a, the most expensive HBV treatment



**Figure 2:** Price per DDD changes of HBV NA antivirals from 2018 to 2022

drug, was mainly imported from Switzerland (71.64% of its total DDDs) (Table 2).

HBV treatment drugs from Vietnam and India were the most affordable, with TDF priced at USD \$0.19 and USD \$0.39, respectively, which were extremely low compared to other countries. Similarly, entecavir from Vietnam was priced at USD \$0.52, which was less than half the price of the brand from Bangladesh and only about 1/4 and 1/8 of the price of the brands from Canada and the United States, respectively. IFNs from Switzerland were almost twice as expensive as that of Vietnam. The price of TAF was approximately four times higher in Vietnam and India compared to TDF, but lower or comparable when imported from Bangladesh and Ireland. Conversely, LMV had a significantly higher price compared to other NA drugs in the United Kingdom, Belgium, and Poland, when compared with its prices in Vietnam and India (Table 2).

**DISCUSSION**

This study was the largest nationwide investigation on the cost and availability of HBV antiviral drugs in Vietnam as of the year 2022. Among the medications procured, TDF accounted for approximately 80% of the total Defined Daily Doses (DDD) across the five-year study period (2018-2022). This dominance in procurement volume is illustrated in Figure 1 and Table 2, which consistently show TDF as the most widely purchased antiviral drug for hepatitis B treatment at the national level. However, substantial variation in the unit prices of TDF was observed across provinces and procurement rounds. Several factors may explain this price heterogeneity. First, TDF is available from both originator and generic manufacturers, with different pricing strategies and production standards. Second, differences in procurement volumes across provinces may affect negotiated prices, with

**Table 2:** The shares and cost of HBV antivirals by country of origin in Vietnam market from 2018-2022

	<b>%Total DDD</b>	<b>%Total expense</b>	<b>Cost per DDD in \$USD</b>
<b>Vietnam</b>	<b>98.08%</b>	<b>85.50%</b>	<b>0.23</b>
Adefovir	0.65%	0.36%	0.15
Entecavir	9.32%	18.27%	0.52
Interferons	0.05%	1.54%	8.81
Lamivudine	5.95%	4.64%	0.21
Tenofovir alafenamide	0.15%	0.49%	0.89
Tenofovir disoproxil fumarate	81.96%	60.21%	0.19
<b>India</b>	<b>1.10%</b>	<b>2.22%</b>	<b>0.53</b>
Lamivudine	0.01%	0.01%	0.19
Tenofovir alafenamide	0.16%	0.85%	1.39
Tenofovir disoproxil fumarate	0.93%	1.36%	0.39
<b>United States</b>	<b>0.27%</b>	<b>3.93%</b>	<b>3.90</b>
Entecavir	0.27%	3.93%	3.90
<b>Canada</b>	<b>0.22%</b>	<b>1.73%</b>	<b>2.06</b>
Entecavir	0.22%	1.73%	2.06
<b>United Kingdom</b>	<b>0.12%</b>	<b>1.98%</b>	<b>4.35</b>
Lamivudine	0.12%	1.98%	4.35
<b>Bangladesh</b>	<b>0.11%</b>	<b>0.49%</b>	<b>1.16</b>
Entecavir	0.10%	0.43%	1.11
Tenofovir alafenamide	0.00%	0.02%	1.52
Tenofovir disoproxil fumarate	0.01%	0.04%	1.74
<b>Switzerland</b>	<b>0.07%</b>	<b>3.86%</b>	<b>14.48</b>
Interferons	0.07%	3.86%	14.48
<b>Belgium</b>	<b>0.01%</b>	<b>0.15%</b>	<b>4.05</b>
Lamivudine	0.01%	0.15%	4.05
<b>Ireland</b>	<b>0.01%</b>	<b>0.07%</b>	<b>1.87</b>
Tenofovir alafenamide	0.01%	0.07%	1.87
<b>Poland</b>	<b>0.00%</b>	<b>0.07%</b>	<b>4.04</b>
Lamivudine	0.00%	0.07%	4.04
<b>Turkey</b>	<b>0.00%</b>	<b>0.00%</b>	<b>2.22</b>
Tenofovir disoproxil fumarate	0.00%	0.00%	2.22
<b>Grand Total</b>	<b>100.00%</b>	<b>100.00%</b>	<b>0.26</b>

larger-volume purchases potentially benefiting from bulk discounts. Third, the number of participating bidders and the competitiveness of each procurement round likely influenced price outcomes. Finally, formulation and packaging variations (e.g., number of tablets per pack, tablet strength) may have contributed to differences in unit price calculations. To further explore drug price differences, we grouped HBV antivirals by generic categories and sources (domestic vs. international). A summary of these groups, including total procurement volume and unit costs, is provided in **Appendix 2**.

The availability of recommended HBV antiviral medications in Vietnam aligned with WHO guidelines for prioritised treatment, which advocated for the use of TDF and ETV. Our estimated annual costs for TDF (USD \$73) were 3 times lower than those of HIV treatment with the first line regimen (USD \$211.42). This cost could be reduced to USD \$29.2 per year with the calculation using the lowest price (USD \$0.08 per DDD). This information will provide policymakers with valuable insights to ensure the equitable and reasonable allocation of domestic funding resources in the context of HBV management in Vietnam [4].

TAF is a newer formulation of tenofovir with improved renal and bone safety profiles compared to TDF [18]. The limited consumption of TAF may be attributed not only to its higher cost (USD \$237.35 per year), which was more than three times higher than the average price of TDF, but also to the fact that TAF was not yet included in the national health insurance benefit package during the study period. The decreased use of other regimens (IFN-based and LMV) may reflect a shift towards oral antiviral agents with a high genetic barrier to resistance, such as TDF and entecavir.

Comparing the average price per DDD of hepatitis B antiviral drugs produced by different countries, drugs from Vietnam were generally lower compared to several other nations. This affordability may be attributed to various factors, including local production capabilities, regulatory frameworks, and pricing policies [19]. Additionally, beyond the scope of our research, the average price per DDD of HBV treatment drugs in the United States for the year 2018 ranged from USD \$5.33 to USD \$1,050 [20], which was significantly higher compared to the prices observed in our study during the same year. These price differences could potentially facilitate the expansion of HBV treatment in Vietnam and contribute to reducing the burden of liver cirrhosis and HCC in the country, as Vietnam faces a significant cancer burden. In 2022, the estimated number of new cancer cases in Vietnam was 180,480, and the estimated number of cancer-related deaths was 120,184, corresponding to approximately 0.18% and 0.12% of the population, respectively, with only about 5% of global cancer financial resources being allocated to Vietnam [21]. Understanding these pricing differences can guide policymakers in setting benchmark prices, identifying potential inefficiencies or overpricing in the bidding process, and negotiating more cost-effective procurement contracts, while also informing strategies to promote local production and explore other cost-saving measures to enhance accessibility and affordability of hepatitis B antiviral therapy in Vietnam.

Our study has some limitations. Firstly, our estimation was based on procurement data from public health facilities in different provinces at different time points, which may not capture the actual consumption and pricing discrepancies of drugs. However, our study included a large number of

manufacturers, representing the majority of available formulations of HBV antivirals in the country.

### CONCLUSION

Our study sheds light on the pricing and availability of HBV antiviral therapy in Vietnam. TDF emerged as the most commonly used medication with a reasonable price among HBV treatments. Given the transition from TDF to TAF, further research is warranted to assess the cost-effectiveness of this switch and provide evidence for policy development, ensuring the affordability and accessibility of HBV antivirals in Vietnam.

The findings of the study can guide policymakers in expanding access to and optimising the affordability of hepatitis B antiviral therapy, contributing to the goal of eliminating viral hepatitis and reducing the prevalence of liver cirrhosis and HCC in Vietnam on a national scale.

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### CONFLICT OF INTEREST

None.

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