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GILEAD | Medical Information

Vemlidy® (tenofovir alafenamide) Use in Patients Post-Orthotopic Liver Transplant

This document is in response to your request for information regarding the use of Vemlidy® (tenofovir alafenamide [TAF]) after orthotopic liver transplant (OLT) in adults with a history of chronic HBV.

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The full indication, important safety information, and boxed warnings are available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.

Summary

Product Labeling[1]

No dosage adjustment of TAF is required in patients with mild hepatic impairment (Child-Pugh A). TAF is not recommended in patients with decompensated (Child-Pugh B or C) hepatic impairment.

Clinical Data on TAF Use in Patients Post-OLT

In a prospective study of TAF monotherapy as prophylaxis against HBV recurrence after liver transplant, 100% of participants (55/55) who remained in the study at the Week 24 interim analysis had undetectable levels of HBV DNA, and 92.7% (51/55) achieved HBsAg loss. No drug-related AEs were reported.[2]

An open-label, phase 2 study compared the safety and efficacy of TAF and TDF-containing regimens in post-OLT participants with CKD.[3]

- All participants maintained viral suppression through Week 192.[3]
- At Week 48, Grade 3 to 4 AEs and SAEs occurred in fewer participants in the TAF group than the TDF group; however, safety results were similar between groups at Week 192.[4]
- Renal function showed improvement and/or stability after switching to TAF through Week 192. Additionally, therapy with TAF resulted in improvement in hip and spine BMD through Week 192.[4]

Real-World Data on TAF Use in Patients Post OLT

Renal function stabilized or improved in patients who initiated or switched to TAF post OLT.[5-8] Viral suppression was maintained and improvement in ALT level was observed.[5,6] No significant interactions were reported between TAF and post-OLT immunosuppressants.[6,7,9]

Clinical Data on TAF Use in Patients Post OLT

Prospective Study in TAF Monotherapy[2]

Study design

A prospective study conducted between October 2022 and January 2024 assessed the efficacy of TAF monotherapy as prophylaxis against HBV recurrence in participants post liver transplant (N=66). Eligible participants had an HBsAg+ status for ≥6 months and did not receive HBIG at the time of transplant. The primary endpoint of the interim analysis was the rate of undetectable HBV DNA (<50 IU/mL) at 24 weeks after liver transplant.

Overall, 4.5% of participants (3/66) were not receiving antiviral therapy before transplant. At the time of transplant, the median (range) HBV DNA level was <50 (<50–738) IU/mL, and 83.3% of participants (55/66) had undetectable levels of HBV DNA.

Interim results

After 24 weeks of TAF prophylaxis post liver transplant, there was no HBV reactivation; 100% of participants (55/55) who remained in the study had undetectable levels of HBV DNA, and 92.7% of participants (51/55) achieved loss of HBsAg. Additional laboratory and virologic changes from baseline to Week 24 are provided in Table 1.

Table 1. Changes in Laboratory and Virologic Parameters From Baseline to Week 24 (Shi et al)[2]

Parameter	Baseline (N=66)	Week 24 (n=55)[a]
HBeAg+, n (%)	13 (19.7)	0
ALT, median (range), U/L	35.5 (13–203)	22 (6–246)
AST, median (range), U/L	49.5 (20–242)	26 (13–191)

[a]A total of 11 participants discontinued the study before Week 24 (reason not reported, n=6; unscheduled injection of HBIG, n=3; death, n=2 [HCC recurrence and pneumonia]).

No drug-related AEs were reported through Week 24. No other safety data were reported.

Study GS-320-3912

Study design and demographics[3,4]

A phase 2, open-label study was conducted to evaluate the safety and efficacy of TAF (n=26) and TDF/TDF-containing regimens (n=25) as HBV prophylaxis in participants with recurrent HBV infection and CKD who were post OLT. Participants who had pretransplant history of chronic HBV and were maintained on TDF or TDF-containing regimens were included. Participants were also required to have HBV DNA <LLOQ, ALT level ≤10 × ULN, and $eGFR_{CKD\text{-}EPI}$ <90 mL/min/1.73 m^2 at screening. Eligible participants were randomly assigned in a 1:1 ratio to begin TAF or to continue a TDF-containing regimen for 48 weeks. After the randomization phase, all participants received TAF during the OLE phase, and the final analysis occurred at Week 192. OLT was performed ≥12 weeks prior to screening. The study included participants with compensated cirrhosis, and randomization was stratified by renal function at screening ($eGFR_{CKD\text{-}EPI}$ <50 mL/min/1.73 m^2 or ≥50 mL/min/1.73 m^2).

Figure 1. Study GS-320-3912: Study Design[3,4]



Note: There were 23 participants in each group who completed the study at Week 192. Three participants who were initially randomly assigned to receive TAF did not complete the OLE phase (death, n=2; AE, n=1). Two participants who were initially randomly assigned to receive TDF did not complete the randomization phase (death, n=1; AE, n=1).

Table 2. Study GS-320-3912: Baseline Demographics and Disease Characteristics[3,4]

Key Demographics and Characteristics		TAF (n=26)	TDF-Containing Regimen (n=25)
Age, mean (range), years		58 (26–76)	62 (45–77)
Male, n (%)		16 (62)	22 (88)
Race, n (%)	Pacific Islander	15 (58)	12 (48)
	Asian	7 (27)	10 (40)
ALT level, mean (SD), U/L		28 (12.6)	38 (43.7)
$eGFR_{CKD-EPI}$, median (Q1, Q3), mL/min/1.73 m^2		48.8 (44.8, 59.2)	52.2 (45, 60.3)
<50 mL/min/1.73 m^2, n (%)		15 (58)	12 (48)
Current calcineurin inhibitor use, n (%)		21 (81)	19 (76)
Years since OLT, median (Q1, Q3)		9 (3, 14)	9 (4, 12)
History of rejection, n (%)		0	2 (8)
Multiple organ transplants, n (%)		1 (4)[a]	0
HBeAg+, n (%)		1 (4)	0
HBsAg+, n (%)		2 (8)	1 (4)

[a]Renal transplant.

Results: Week 192 efficacy[3]

All participants with HBV DNA data maintained viral suppression through Week 192 (Table 3).

Table 3. Study GS-320-3912: Week 192 Efficacy[a] and Serologic Response[3]

	TAF (n=26)	TDF-Containing Regimen (n=25)
HBV DNA <20 IU/mL, n (%)	20 (100)	20 (100)
HBV DNA <20 IU/mL and target not detected, n (%)	20 (100)	20 (100)
HBeAg loss/seroconversion, n/N	1/1	0/0
HBsAg loss/seroconversion, n/N	0/2	0/1

[a]Missing=excluded from analysis.

Safety

Safety results through Week 48 (the randomization phase) and Week 192 (the OLE phase) are presented in Table 4.

Table 4. Study GS-320-3912: Safety Summary Through Week 48 and Week 192[3,4]

Safety Outcomes, n (%)		Through Week 48 (Randomized Phase)		Through Week 192 (OLE Phase)	
		TAF (n=26)	TDF-Containing Regimen (n=25)	TAF (n=26)	TDF→TAF (n=24)
Any AE		24 (92)	24 (96)	25 (96)	24 (100)
Grade 3–4 AE		2 (8)	6 (24)	6 (23)	8 (33)
Grade 3–4 AE related to study drug		0	0	0	0
SAE		3 (12)	7 (28)	8 (31)	8 (33)
SAE related to study drug		0	0	0	0
Discontinued study drug due to AE		0	1 (4)[a]	1 (4)[b]	0
Death		0	1 (4)[c]	2 (8)[d]	0
Renal or bone AEs (reported in ≥2 participants)	Decrease in bone density	3 (12)	1 (4)	1 (4)	1 (4)
	Acute kidney injury	0	0	2 (8)	5 (21)
	Nephrolithiasis	0	0	0	3 (13)
	Nocturia	0	0	0	2 (8)

[a]Discontinued due to disseminated tuberculosis.
[b]Discontinued due to acute kidney injury (considered unrelated to study drug).
[c]One participant died due to diffuse large B-cell lymphoma.
[d]One participant died due to liver failure, and another died due to cardiac arrest.

Renal safety[4]

The median change in eGFR values from baseline through Week 48 (during the randomization phase) indicated improved renal function with TAF that remained stable through Week 192 (OLE phase). Among those who were in the TDF group at baseline and then switched to TAF in the OLE phase, renal function remained stable through Week 192 (Figure 2). Changes in renal proximal tubular markers (urine RBP:Cr and β2M:Cr ratios) were similar between groups (

Figure 3). All participants had stage 2 or 3 CKD at baseline, and most participants remained stable or improved in CKD stage through Week 192.

Figure 2. Study GS-320-3912: Changes in eGFR Values Through Week 192[4]

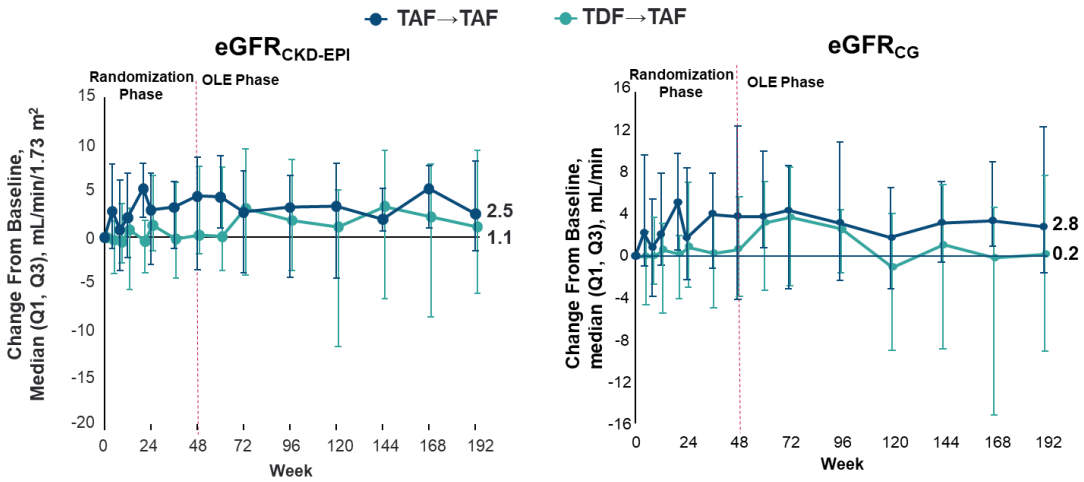
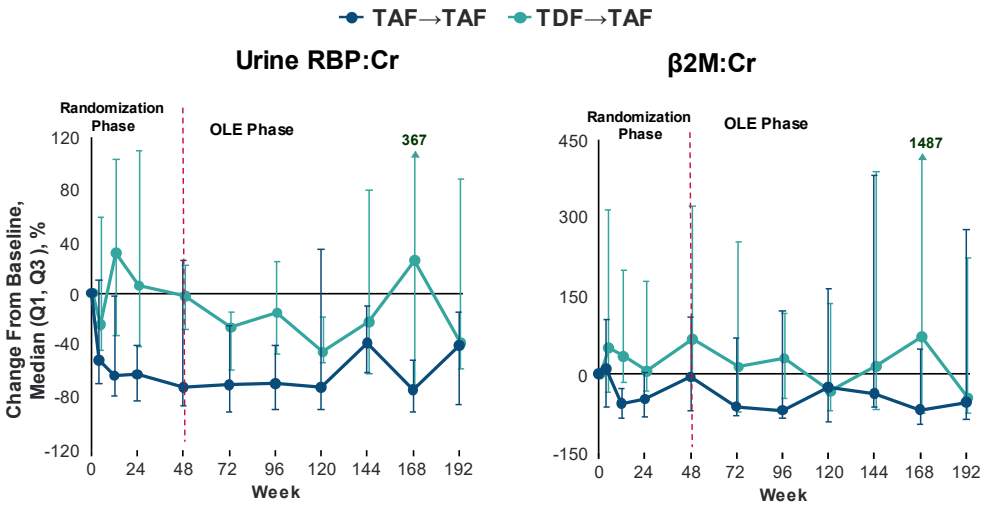


Figure 3. Study GS-320-3912: Changes in Renal Proximal Tubular Markers Through Week 192[4]

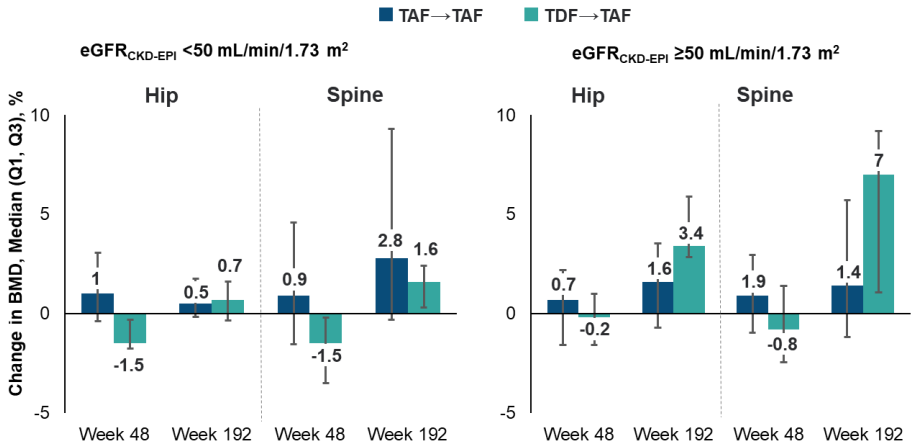


***Bone safety*[4]**

During the randomization phase (up to Week 48), improvements from baseline in hip and spine BMD measurements were observed in participants who received TAF; in comparison, declines were observed in participants who received TDF-containing regimens. During the OLE phase, improvements in hip and spine BMD were observed at Week 192 in participants who switched from TDF to TAF after Week 48.

In an analysis of bone safety according to baseline $eGFR_{CKD\text{-}EPI}$, greater decreases from baseline in hip and spine BMD measurements at Week 48 were observed in participants in the TDF-containing regimen group who had a baseline $eGFR_{CKD\text{-}EPI}$ <50 mL/min/1.73 m^2 than in those who had a baseline $eGFR_{CKD\text{-}EPI}$ ≥50 mL/min/1.73 m^2 (Figure 4). After participants were switched from TDF to TAF in the OLE phase, both $eGFR_{CKD\text{-}EPI}$ subgroups showed improvements in hip and spine BMD measurements. Improvements in BMD measurements were observed among participants in the TAF group at Week 48 and Week 192, regardless of baseline $eGFR_{CKD\text{-}EPI}$ (Figure 4).

Figure 4. Study GS-320-3912: Changes in BMD at Weeks 48 and 192 by Baseline $eGFR_{CKD\text{-}EPI}$[4]



Observed changes in bone biomarkers (C-type collagen sequence and procollagen type 1 N-terminal propeptide) were similar between groups at Week 192.

Real-World Data on TAF Use in Patients Post OLT

US, Singapore, and Japan Study[8]

Study design and demographics

A retrospective, multicenter cohort study of 298 patients with CHB who underwent a liver transplant between 2005 and 2020 was conducted to assess the change in renal function (ie, CKD stage and eGFR changes) in patients who received TAF (n=112), TDF (n=51), or ETV (n=135) monotherapy for the prevention of HBV reinfection or reactivation from receipt of an HBcAb+ graft. Laboratory data were collected at baseline and at Months 3, 6, 9, 12, 18, and 24, and the mean study follow-up duration was 21.95±4.63 months. Most patients (73.83%) were male, Asian (75.84%), had CHB prior to liver transplant (91.28%), and had received tacrolimus-based immunosuppression (94.97%). Patients in the TAF group were older (*P*=0.02) and had lower baseline eGFR (*P*=0.01) compared with the other groups.

Results

From baseline through Month 24, there were no significant changes in CKD stage distribution in the TAF and TDF groups, but there was a decrease in normal renal function from 35.56% to 18.18% in the group that received ETV (Table 5).

Table 5. Changes in CKD Distribution From Baseline Through Month 24[8]

Cohort	CKD Stage	Baseline n (%)	Month 24 n (%)	*P*-Value
TAF	1	16 (14.29)	7 (11.11)	0.55
	2	48 (42.86)	27 (42.86)	1
	3–5	48 (42.86)	29 (46.03)	0.69
TDF	1	12 (23.53)	6 (14.29)	0.26
	2	18 (35.29)	19 (45.24)	0.33
	3–5	21 (41.18)	17 (40.48)	0.95
ETV	1	48 (35.56)	22 (18.18)	0.002
	2	44 (32.59)	60 (49.59)	0.006
	3–5	43 (31.85)	39 (32.23)	0.95

At Month 24, there were no significant differences in mean eGFRs between the three groups (TAF=63.27±25.09 mL/min/1.73 m^2; TDF=63.62±26.42 mL/min/1.73 m^2; ETV=69.77±22.99 mL/min/1.73 m^2; *P*=0.15), and the TAF group had the smallest decrease in eGFR (1.46 mL/min/1.73 m^2) compared with the TDF (2.97 mL/min/1.73 m^2) or ETV groups (4.57 mL/min/1.73 m^2) from baseline through Month 24.

Stanford Health Care Study[5]

Study design and demographics

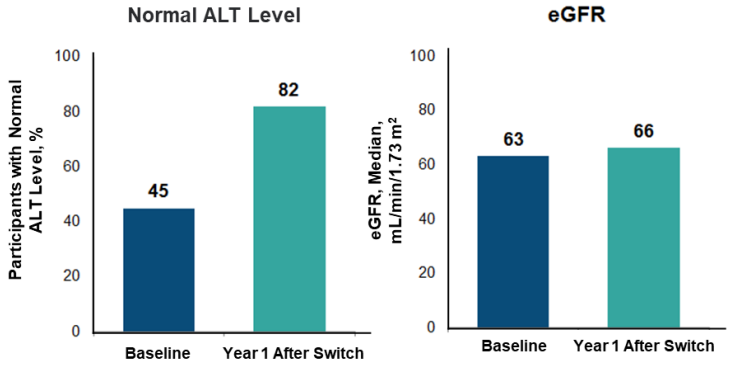
A retrospective, single-center study was conducted to determine the effect of TAF therapy on ALT levels and $eGFR_{CKD\text{-}EPI}$ in 11 patients with CHB who were treatment experienced and had undergone liver transplants. Baseline characteristics were as follows: the mean age

was 62 years, 73% of participants were male, the mean ALT level was 41.2 U/L, and the mean $eGFR_{CKD\text{-}EPI}$ was 63.9 mL/min/1.73 m^2. OAV use prior to initiation of TAF included TDF (n=9) and TDF + ETV (n=2); the mean duration of OAV treatment prior to TAF initiation was 4 years. The mean duration between OLT and TAF initiation was 5.7 years.

Results: efficacy and renal safety

After 48 weeks of TAF therapy, 100% of patients had undetectable HBV DNA. The proportion of patients with normal ALT levels and median $eGFR_{CKD\text{-}EPI}$ at baseline and Year 1 after they switched to TAF are shown in Figure 5. From baseline to 1 year after patients switched to TAF, the median change in ALT levels was -6 U/L (*P*=0.041), and the median change in $eGFR_{CKD\text{-}EPI}$ was +2.46 mL/min/1.73 m^2 (*P*=0.24); 73% of patients experienced improvement in $eGFR_{CKD\text{-}EPI}$ after they switched to TAF.

Figure 5. Normal ALT and Renal Function 1 Year After TAF Switch (Sripongpun et al)[5]



UCLA, USC, and Cedars-Sinai Study[6]

Study design and demographics

A multicenter, retrospective study of patients post OLT was conducted to compare the safety and efficacy of TAF as prophylaxis among patients who switched to TAF (n=52) with those of patients who remained on their previous HBV therapy (n=47; TDF in 33 patients [70%], ETV in 12 patients [26%], and LAM in 2 patients [4%]). The primary endpoint was the change in SCr level at Week 48.

Figure 6. Study Design (Perumpail et al)[6]

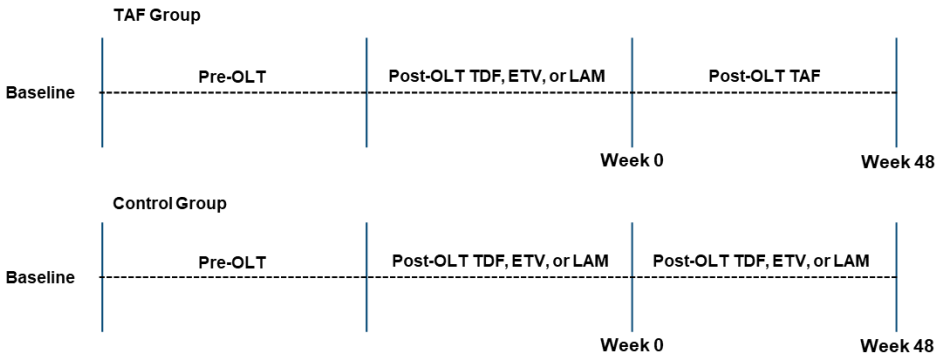


Table 6. Baseline Demographics and Disease Characteristics (Perumpail et al)[6]

Key Demographics and Characteristics		TAF (n=52)	Control (n=47)
Age, mean (SD), years		61 (9)	60 (10)
Male, n (%)		45 (87)	32 (68)
Race or ethnicity, n (%)	Asian	39 (75)	28 (60)
	White	10 (19)	11 (23)
	Latinx	2 (4)	8 (17)
	Black	1 (2)	0
SCr, mean (SD), mg/dL		1.42 (0.44)	1.12 (0.31)

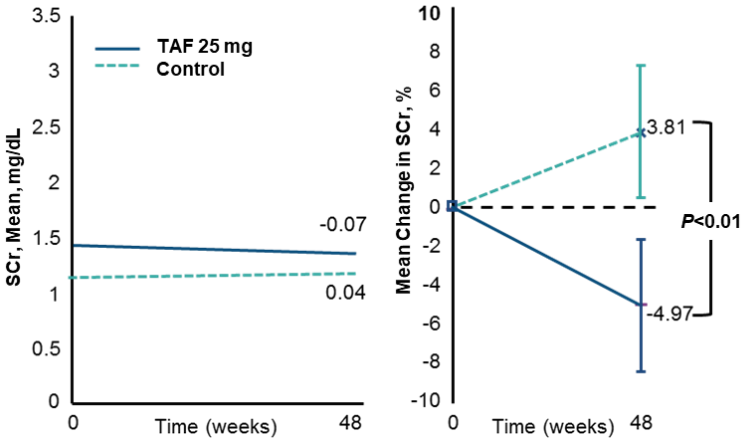
Results

All patients in both groups had undetectable HBV DNA through Week 48. There were no conversions to HBsAg+ status during the study. There were no significant drug-drug interactions with immunosuppressive agents post OLT. There were no Grade 3 or 4 laboratory abnormalities in either group.

Renal safety

In patients who required HBV prophylaxis post OLT, switching to TAF was associated with significant improvement in renal function compared with the control group (those who remained on TDF, ETV, or LAM), as shown in Figure 7.

Figure 7. Change in SCr (Perumpail et al)[6]



Long-Term, Retrospective Analysis of Outcomes[9]

Study design and demographics

A single-center, retrospective analysis of electronic medical records was performed to evaluate renal function over time, measure the impact of antiviral therapy on renal function, and assess the impact of recurrent HBsAg on liver and graft function in post-OLT patients who received oral HBV therapy (N=79). The impact of OAVs on renal function was measured by the need for hemodialysis and changes in SCr levels and CKD stage. Efficacy outcomes also included serum HBsAg status, patient survival, and graft survival.

Patients received therapy with a single HBV OAV and HBIG for 6 months post OLT. After discontinuation of HBIG, patients remained on OAV therapy, which included TAF, LAM,

ETV, TDF, or adefovir dipivoxil. TAF was administered as monotherapy; all other OAVs were administered as monotherapy or in combination regimens. No patients were receiving hemodialysis when HBIG was discontinued, and none were co-infected with HCV.

Table 7. Baseline Demographics and Disease Characteristics (Saab et al)[9]

Key Demographics and Characteristics		HBV OAV Therapy (N=79)
Age at last follow-up, mean (SD), years		65.4 (8.2)
Male, n (%)		63 (79.7)
Ethnicity, n (%)	Asian/Pacific Islander	57 (72.2)
	Non-Latinx White	15 (19)
	Latinx White	6 (7.6)
Model for End-Stage Liver Disease score, mean (SD)		29.9 (6.7)
Concomitant HCC at time of transplant, n (%)		63 (80)
Comorbidities, n (%)	Hypertension	38 (48.1)
	Diabetes	31 (39.2)
	Hyperlipidemia	13 (16.5)
Never smoker, n (%)		47 (59.5)
Time from OLT to last follow-up, mean (SD), years		6.45 (3.3)
Concurrent use of tacrolimus, %		95

Results

Ten different HBV OAV regimens were used in this cohort, and 32 patients had received TAF. At last follow-up, 30 patients were receiving TAF as monotherapy. The mean (SD) duration of therapy with TAF was 308 (159) days. TAF was associated with less decline in renal function than other therapies in this study. Patients exposed to TAF had no significant change in renal function over time (Table 8); however, those who had never received TAF had an average increase in SCr level of 0.55 mL/min (P<0.05). An increase in CKD stage (worsened renal function) was reported in 6.3% of patients who had received TAF and in 23.4% of patients who had never received TAF (P<0.05; Table 9).

Table 8. Changes in Laboratory Parameters for Patients Who Received TAF (Saab et al)[9a]

Laboratory Parameters	Prior to Initiation of TAF	Last Follow-Up on TAF
SCr level, mean (SD), mL/min	1.38 (0.5)	1.35 (0.4)
GFR, mean (SD), mL/min/1.73 m^2	55.5 (17.1)	55.9 (17.9)
AST level, mean (SD), IU/L	19.9 (5.9)	26.3 (38.3)
ALT level, mean (SD), IU/L	18.2 (9)	21.8 (26.1)

[a]The mean (SD) time on TAF was 308 (159) days. Changes in laboratory parameters were statistically nonsignificant.

Table 9. Change in Renal Function During Therapy (Saab et al)[9]

Parameter, n (%)		TAF (n=32)	Never Received TAF (n=47)	*P*-Value
Change in CKD stage[a]	Worse	2 (6.3)	11 (23.4)	<0.05
	Same	26 (81.3)	28 (59.6)	–
	Better	4 (12.5)	8 (17)	–
Increase in SCr level by >0.3 mL/min[a]		2 (6.3)	9 (19.5)	<0.05

[a]Change was measured from before initiation of TAF to end of TAF therapy in patients who had received TAF and from HBIG withdrawal to the last follow-up in patients who had never received TAF.

Six patients required dialysis after HBIG was discontinued; none of these patients were receiving TAF. An association between the recurrence of HBsAg and decreased patient survival was observed in the overall study population.

Greek Study[7]

Study design and demographics

A single-center, real-world study in Greece was conducted to evaluate renal function and serum phosphorus levels in HBV-infected patients post OLT who switched from TDF to TAF (TDF→TAF; n=17) or who remained on TDF (n=30). In the TDF→TAF group, indications for switching included GFR <60 mL/min/1.73 m^2, serum phosphorus levels <2.5 mg/dL, and dual-energy x-ray absorptiometry derived T-score <-2.5 SD. A subgroup of the TDF group (TDF-CKD; n=14) did not switch to TAF at their physician's discretion, despite having low GFR and/or hypophosphatemia. The mean (SD) follow-up period was 13.7 (6.5) months in the TDF→TAF group and 35.5 (22.7) months in those who remained on TDF (*P*<0.001).

Table 10. Baseline Demographics and Disease Characteristics (Sinakos et al)[7]

Key Demographics and Characteristics	TDF→TAF (n=17)	TDF (n=30)
Age, mean (SD), years	62.6 (9.9)	60.3 (9.2)
Male, n (%)	16 (94.1)	19 (63.3)
Time from OLT, mean (SD), months	93.1 (61.3)	105.6 (75)
Current mycophenolate mofetil use, n (%)	12 (70.6)	22 (73.3)
Current everolimus use, n (%)	8 (47.1)	8 (26.7)
Current tacrolimus use, n (%)	5 (29.4)	11 (36.7)
Current cyclosporine use, n (%)	3 (17.6)	12 (40)

Table 11. Baseline Renal Function (Sinakos et al)[7]

Renal Parameter	TDF→TAF (n=17)	TDF (n=30)		*P*-Value
		TDF (n=16)	TDF-CKD (n=14)	
$eGFR_{MDRD}$, mean (SD), mL/min	63.2 (14.1)	79.1 (12.7)	67.2 (11.8)	0.003
SCr level, mean (SD), mg/dL	1.27 (0.2)	1.02 (0.16)	1.06 (0.2)	0.002
Serum phosphorus level, mean (SD), mg/dL	2.7 (0.7)	3.1 (0.4)	3.1 (0.6)	0.129

Results

There were no significant changes in renal function markers (ie, GFR, SCr, or serum phosphorus) between the TAF and TDF or TDF-CKD groups by the end of follow-up. In the TAF group, radionuclide technique-based GFR levels returned to normal in 7 of 14 patients (50%; OR: 1.75; 95% CI: 0.34–8.79), and serum phosphorus levels returned to normal in 3 of 8 patients (37.5%; OR: 0.6; 95% CI: 0.05–6.79). Changes in SCr levels and $eGFR_{MDRD}$ were not significantly different according to age category (>65 or <65 years) or current calcineurin inhibitor use.

Safety

There were no recurrences of HBV or graft failure in either group. At the end of follow-up, there were no significant changes between the TAF and TDF group regarding levels of transaminases or concentrations of immunosuppressants. TAF was well tolerated.

References

1. Enclosed. Gilead Sciences Inc, VEMLIDY® (tenofovir alafenamide) tablets, for oral use. U.S. Prescribing Information. Foster City, CA.
2. Shi Y, Liu W, Fan J, Ding Z, Huang X, Zhou J. Tenofovir Alafenamide Monotherapy is Effective in Suppressing Hepatitis B Virus After Liver Transplantation [Poster 2563]. Paper presented at: American Association for the Study of Liver Diseases (AASLD); November 15-19, 2024; San Diego, CA.
3. Gane EJ, George B, Ray-Chaudhuri D, et al. Safety and Efficacy at 4 Years in Post-Liver Transplant Patients With Chronic Kidney Disease Receiving Tenofovir Alafenamide for HBV Prophylaxis [Poster 803]. Paper presented at: American Association for the Study of Liver Diseases (AASLD) The Liver Meeting Virtual; 12-15 November, 2021.
4. Gane EJ, Dagooc R, Ray-Chaudhuri D, et al. Evaluation of Renal and Bone Safety at 4 Years in Post-Liver Transplant Patients With Chronic Kidney Disease Receiving Tenofovir Alafenamide for HBV Prophylaxis [Poster SAT368]. Paper presented at: EASL The International Liver Congress; 22-26 June, 2022; London, UK.
5. Sripongpun P, Mannalilhara A, Kwo P, Kim R. One-Year Effect of Tenofovir Alafenamide (TAF) on Alanine Aminotransferase (ALT) Levels and Renal Safety in Post Liver Transplant Chronic Hepatitis B Patients [Poster 546]. Paper presented at: APASL; 18-20 April, 2019; Tokyo, Japan.
6. Perumpail RB, Khemichien S, Lakhoo K, et al. Tenofovir Alafenamide for Hepatitis B Virus Prophylaxis Post-Liver Transplantation is Associated with Improved Renal Function: An Interim Analysis of a Multicenter Real-World Experience [Presentation 049]. Paper presented at: EASL; 10-14 April, 2019; Vienna, Austria.
7. Sinakos E, Panas P, Fragkou N, et al. Tenofovir Alafenamide Prophylaxis Post-Liver Transplantation: a Real-World Study in Patients With Chronic Kidney Disease. *Acta Gastro-Enterologica Belgica.* 2022;85(2):331-337. https://www.ncbi.nlm.nih.gov/pubmed/35709777
8. Liu JK, Vutien P, Huang DQ, Ishigami M, Landis CS, Nguyen MH. Renal Outcomes With Tenofovir Alafenamide in Liver Transplant Recipients. *Clinical Gastroenterology and Hepatology.* 2023;21(2):538-540. https://www.ncbi.nlm.nih.gov/pubmed/35123081
9. Saab S, Song D, Challita YP, et al. Long-term Outcomes with Oral Therapy in Liver Transplant Recipients with Hepatitis B [Accepted]. *Clinical Transplantation.* 2019;33(12):e13740.

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Abbreviations

β2M=β2-microglobulin
AE=adverse event
BMD=bone mineral density
CG=Cockcroft-Gault
CHB=chronic hepatitis B
CKD=chronic kidney disease
CKD-EPI=CKD Epidemiology Collaboration equation
ETV=entecavir
HBeAg=hepatitis B envelope antigen
HBIG=hepatitis B immunoglobulin
HBsAg=hepatitis B surface antigen
HCC=hepatocellular carcinoma
LAM=lamivudine
LLoQ=lower limit of quantification
MDRD=Modification of Diet in Renal Disease study equation
OAV=oral antiviral
OLE=open-label extension
OLT=orthotopic liver transplant
Q=quartile
RBP=retinol-binding protein
SAE=serious adverse event
TAF=tenofovir alafenamide
TDF=tenofovir disoproxil fumarate
UCLA=University of California, Los Angeles
ULN=upper limit of normal
USC=University of Southern California

Product Label

For the full indication, important safety information, and boxed warning(s), please refer to the Vemlidy US Prescribing Information available at: www.gilead.com/-/media/files/pdfs/medicines/liver-disease/vemlidy/vemlidy_pi.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎1-866-MEDI-GSI (1-866-633-4474) or 🖱 www.askgileadmedical.com

Adverse Event Reporting

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or
🖱 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🖱 www.accessdata.fda.gov/scripts/medwatch

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