

Lumasiran: Use in Kidney Transplantation

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SUMMARY

- In the lumasiran phase 3 clinical trials, patients who received a prior iKT and/or immunosuppressants at the time of study initiation were excluded from the ILLUMINATE studies.¹⁻³
- In the ILLUMINATE-C trial, patients with advanced kidney disease were included in the study. As of Month 36 of the study extension period, 5 patients received iKT and continued lumasiran treatment post-transplant.^{3,4}
- In the BONAPH1DE real-world observational study, there were 7 patients who underwent iKT and received lumasiran.⁵
 - A descriptive analysis of BONAPH1DE and ILLUMINATE-C study was performed to compare the outcomes of patients from BONAPH1DE who received lumasiran and underwent iKT with outcomes of all patients from ILLUMINATE-C who underwent iKT prior to the data cutoff date.⁵
- Case reports from published medical literature discuss the use of lumasiran in patients with PH1 who have had an iKT.⁶⁻¹⁴

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ILLUMINATE-C

ILLUMINATE-C was a phase 3, open-label, single-arm study with a 6-month primary analysis period followed by an ongoing 54-month extension period to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of lumasiran in full term infants to adult patients with advanced PH1 with an eGFR ≤ 45 mL/min/1.73m² (or elevated serum creatinine if <12 months old) and POx ≥ 20 μ mol/L. Patients enrolled in the study included those not receiving hemodialysis in Cohort A (N=6) and those receiving hemodialysis in Cohort B (N=15). Patients received subcutaneous injections of lumasiran as determined by a body weight-based dosing regimen. The primary endpoints were the percent change from baseline in POx at 6 months (Cohort A) and percent change from baseline in predialysis POx at 6 months (Cohort B).¹⁵

Patients were excluded from the study if any of the following criteria applied³:

- Had a previous liver transplant or a liver transplant was anticipated within the next 6 months of the study
- Had a previous iKT and were currently receiving immunosuppression to prevent transplant rejection.

Patient Demographics & Baseline Characteristics

A total of 21 patients were enrolled (6 in Cohort A and 15 in Cohort B). All patients completed the 6-month primary analysis period and entered the extension period. Relevant baseline characteristics are described in **Table 1**.¹⁵

Table 1. Select Baseline Characteristics.¹⁵

Baseline Characteristic	Cohort A (N=6)	Cohort B (N=15)	All Treated (N=21)
Median age at consent (range), years	9 (0-40)	6 (1-59)	8 (0-59)
Plasma oxalate ^a , median (range) $\mu\text{mol/L}$	57.9 (22.7-134.0)	103.7 (56.3-167.0)	100.9 (22.7-167.0)
eGFR ^b , median (range), mL/min/1.73 m ²	N=5 16.5 (8.6-34.1)	NA	N=5 16.5 (8.6-34.1)
Number of dialysis sessions per week, median (range)	NA	6 (3-7)	NA

Abbreviations: eGFR = estimated glomerular filtration rate; NA = not applicable.

^aUpper limit of normal = 12.11 $\mu\text{mol/L}$ (1.09 mg/mL) as determined based on data from 75 healthy adults.

^beGFR value was available for 5 patients in Cohort A. eGFR was calculated with the Modification of Diet in Renal Disease Study equation for those aged ≥ 18 years and the Schwartz bedside formula for those aged 1 to <18 years.

Isolated Kidney Transplantation Data

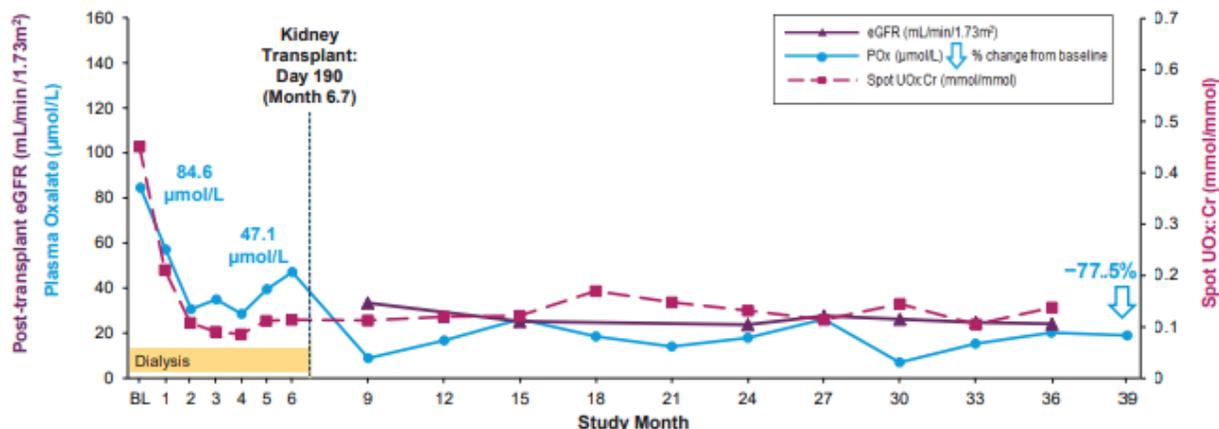
Of the 15 patients enrolled in Cohort B (on hemodialysis at study start), 5 patients underwent iKT as of Month 36 (**Figures 1-5**). Transplant decisions were made at the clinical discretion of the individual investigators.^{4,16}

The baseline POx values of the 5 patients ranged from 84.6 to 152.3 $\mu\text{mol/L}$. Prior to iKT, all 5 patients experienced reductions in POx from baseline ranging from -37.5 to -87.8 $\mu\text{mol/L}$. Further reductions post-transplant indicated improved POx clearance with functioning kidney grafts.¹⁶

Patient 1

Patient 1 was 44 years of age at the time of study entry and had a pyridoxine-responsive genotype. The patient received an iKT on Study Day 190 (Month 6.7). The percent reduction from baseline in POx was 77.5% at Month 39 (**Figure 1**).¹⁶

Figure 1. Patient 1: POx, UOx:Cr, and Post-transplant eGFR through Month 39.¹⁶



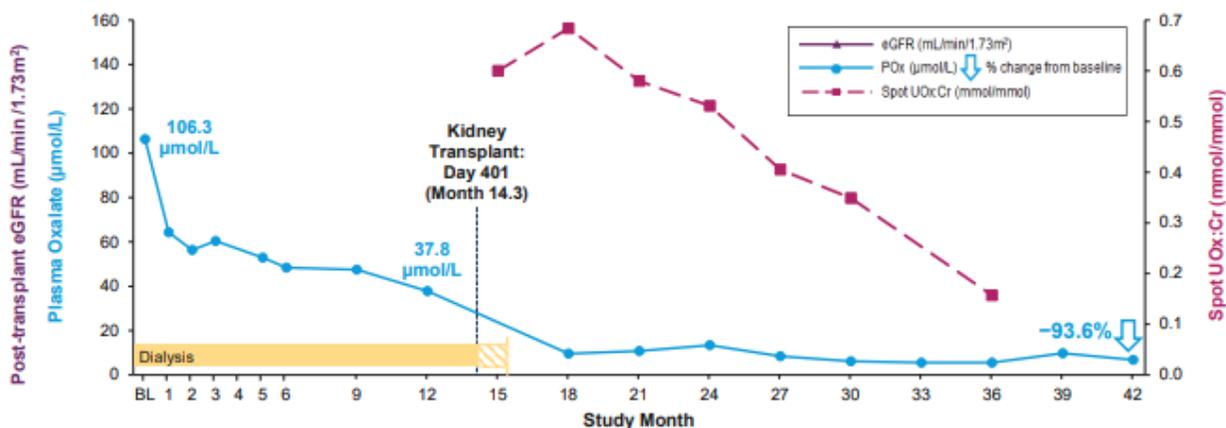
Abbreviations: BL = baseline; eGFR = estimated glomerular filtration rate; POx = plasma oxalate; UOx:Cr = urinary oxalate:creatinine ratio. From Somers et al.¹⁶

Patient 1 experienced a non-serious post-transplant AE of graft failure, which resolved. A renal graft biopsy performed 6 weeks after iKT associated with this AE demonstrated evidence of BK virus nephropathy without calcium oxalate nephropathy.¹⁶

Patient 2

Patient 2 was 2 years of age at the time of study entry and had a non-pyridoxine-responsive genotype. The patient received an iKT on Study Day 401 (Month 14.3). The percent reduction from baseline in POx was 93.6% at Month 42. (Figure 2).¹⁶

Figure 2. Patient 2: POx, UOx:Cr, and Post-transplant eGFR through Month 42.¹⁶



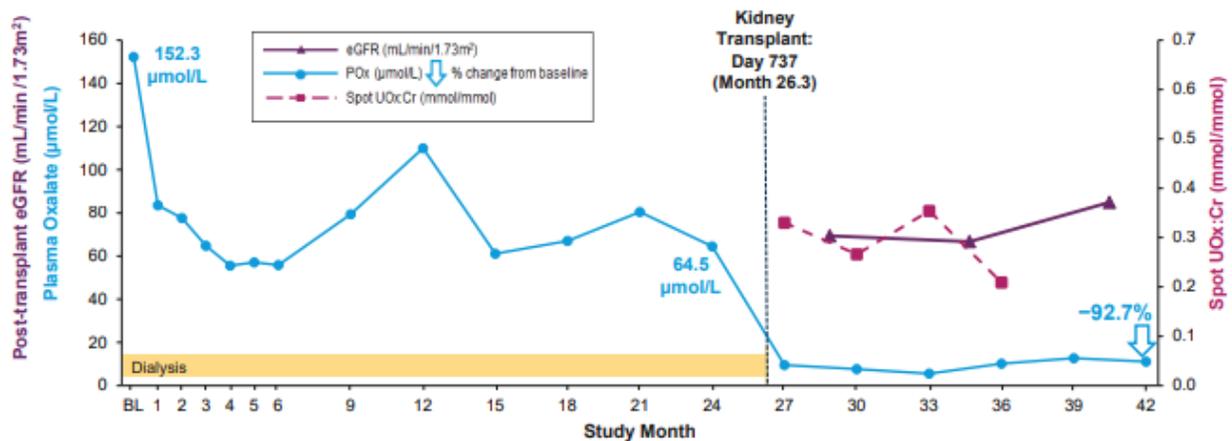
Abbreviations: BL = baseline; eGFR = estimated glomerular filtration rate; POx = plasma oxalate; UOx:Cr = urinary oxalate:creatinine ratio. From Somers et al.¹⁶

HD was stopped 36 days following iKT. The reason for continuation of dialysis after iKT was not reported. However, within the first month post-transplant, the patient experienced severe AEs of pyrexia 13 days after transplant; graft complication, urinoma, and AKI 14 days after transplant; and herpes simplex infection 21 days after transplant. The AEs were considered not related to lumasiran.⁴

Patient 3

Patient 3 was 0.9 years of age at the time of study entry and had a non-pyridoxine-responsive genotype. The patient received a iKT on Study Day 737 (Month 26.3). The percent reduction from baseline in POx was 92.7% at Month 42. (Figure 3).¹⁶

Figure 3. Patient 3: POx, UOx:Cr, and Post-transplant eGFR through Month 42.¹⁶



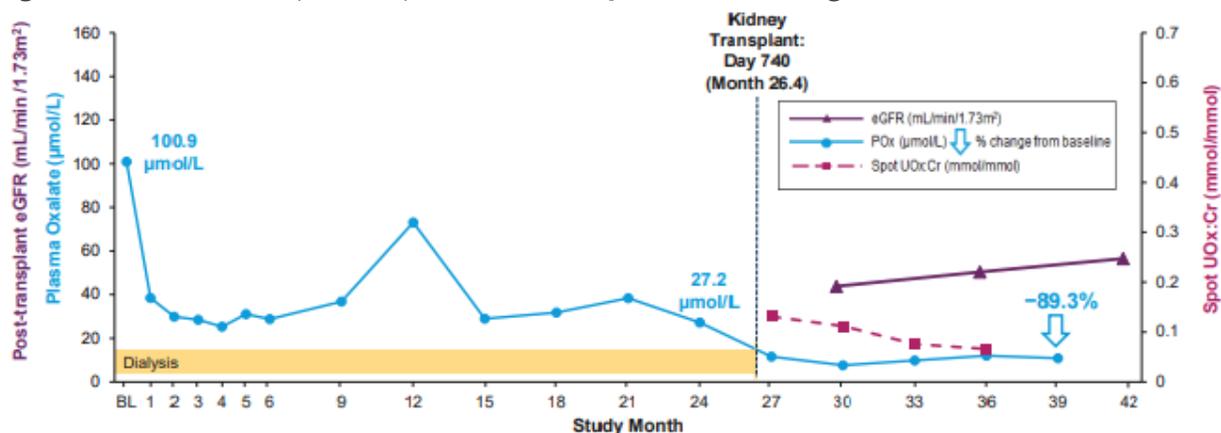
Abbreviations: BL = baseline; eGFR = estimated glomerular filtration rate; POx = plasma oxalate; UOx:Cr = urinary oxalate:creatinine ratio. From Somers et al.¹⁶

Patient 3 experienced a mild AE of UTI 14 days after transplant and recovered from the event. The AE was considered not related to lumasiran. Other complications that occurred within 3 months to 1 year after transplant and required hospitalization included a moderate AE of hypogammaglobulinemia; severe AEs of gastroenteritis, pneumonia, post-transplant lymphoproliferative disorder; and ear infection. All post-transplantation AEs were unrelated to lumasiran, and the patient's eGFR remained normal.¹⁶

Patient 4

Patient 4 was 18 years of age at the time of study entry and had a non-pyridoxine-responsive genotype. The patient received an iKT on Study Day 740 (Month 26.4). The percent reduction from baseline in POx was 89.3% at Month 42. (Figure 4).¹⁶

Figure 4. Patient 4: POx, UOx:Cr, and Post-transplant eGFR through Month 42.¹⁶



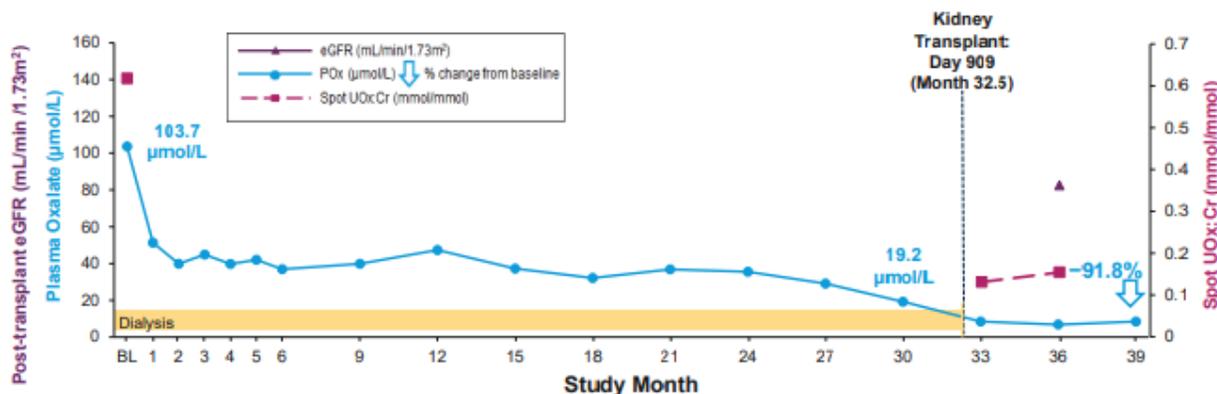
Abbreviations: BL = baseline; eGFR = estimated glomerular filtration rate; POx = plasma oxalate; UOx:Cr = urinary oxalate:creatinine ratio. From Somers et al.¹⁶

Patient 4 experienced moderate AEs of diarrhea and BK virus infection within the first month of iKT. Both AEs were considered not related to lumasiran and were not resolved at the time of the data cut.⁴

Patient 5

Patient 5 was 1 year of age at the time of study entry and had a pyridoxine-responsive genotype. The patient received an iKT at Study Day 909 (Month 32.5). The percent reduction from baseline in POx was 91.8% at Month 39. (Figure 5).¹⁶

Figure 5. Patient 5: POx, UOx:Cr, and Post-transplant eGFR through Month 39.¹⁶



Abbreviations: BL = baseline; eGFR = estimated glomerular filtration rate; POx = plasma oxalate; UOx:Cr = urinary oxalate:creatinine ratio. From Somers et al.¹⁶

Patient 5 experienced moderate AEs of *Clostridium difficile* infection and incision site discharge within the first month of iKT. The patient also experienced a mild AE of perinephric collection. All 3 AEs were resolved and were considered not related to lumasiran.⁴

As of Month 36, all 5 patients remained hemodialysis-free and continued treatment with lumasiran post-transplant. Overall, post-transplant AEs were frequent and included transplant-related complications that were not related to study drug. None of the patients experienced oxalate nephropathy post-transplant.¹⁶

BONAPH1DE

BONAPH1DE is an ongoing, global, longitudinal, prospective, observational real-world registry in patients with PH1. An exploratory descriptive analysis of data was performed with the data cutoff dates of January 29, 2025 for BONAPH1DE and November 6, 2023 for ILLUMINATE-C. The outcomes of patients from BONAPH1DE who received lumasiran, underwent iKT, had ≥ 1 year of post-transplant follow-up and ≥ 1 available data point post-transplant were compared with outcomes of all patients from ILLUMINATE-C who underwent iKT prior to the data cutoff date. As of January 29, 2025, 174 patients were enrolled. Inclusion criteria include patients of all ages with a diagnosis of PH1. The primary objective of BONAPH1DE is to characterize long-term real-world safety of lumasiran in patients with PH1.⁵

Baseline Characteristics

Of the 174 patients enrolled in BONAPH1DE, 30 patients had late-stage CKD. Patients in ILLUMINATE-C had lower POx levels compared with those from BONAPH1DE (**Table 2**).⁵

Table 2. Patient Baseline Characteristics.⁵

Baseline Characteristic	BONAPH1DE (n=30) ^a	ILLUMINATE-C (N=21) ^a
Dialysis category, n (%)		
Patients on dialysis	19 (63)	15 (71)
Patients not on dialysis with baseline eGFR ≤ 45 mL/min/1.73m ²	11 (37)	6 (29)
eGFR, mean (SD), mL/min/1.73m ²		
Patients not on dialysis with baseline eGFR ≤ 45 mL/min/1.73m ²	n=11 18.9 (15.5)	n=5 ^b 19.8 (9.6)
POx, mean (SD), μ mol/L		
Patients on dialysis	n=10 185.4 (348.6)	n=15 108.4 (29.5)
Patients not on dialysis with baseline eGFR ≤ 45 mL/min/1.73m ²	n=9 110.5 (108.0)	n=6 64.7 (41.3)

Abbreviations: eGFR = estimated glomerular filtration rate; SD = standard deviation.

^aNumber of patients unless indicated otherwise in the table.

^bIn ILLUMINATE-C, eGFR was calculated based on the Schwartz Bedside Formula in patients < 18 years of age at screening, and ≥ 12 months of age at the time of the assessment. eGFR was calculated based on the Modification of Diet in Renal Disease formula for patients aged ≥ 18 years at screening.

Isolated Kidney Transplantation

Eight patients from BONAPH1DE underwent iKT, 1 patient was excluded because they did not receive lumasiran. The mean age at study enrollment was 23.1 (range 2.0-48.0) years. Four of the 7 patients started lumasiran at 15.5 months (range 6.2-23.8) prior to iKT. Five patients from ILLUMINATE-C underwent iKT and received lumasiran. The mean patient age at study entry was 13.2 (range 0.9-44) years. Overall, the mean eGFR increased and POx decreased in both studies (**Table 3**).⁵

Table 3. Overall eGFR and POx Outcomes Following iKT.⁵

Laboratory values	BONAPH1DE (n=7)	ILLUMINATE-C (n=5)
eGFR ^a mean (SD), mL/min/1.73m ²		
After iKT	56.1 (39.9)	71.1 (38.2)
Time measured after iKT, mean (range), months	14.5 (0.0-62.0)	14.6 (1.0-26.0) ^b
POx, mean (SD), μmol/L		
Prior to iKT	60.7 (23.1) ^c	52.9 (26.0)
After iKT	14.2 (17.3)	11.7 (5.5)
Time measured after iKT, mean (range), months	9.7 (0.0-43.0)	11.0 (0.0-29.0)

Abbreviations: eGFR = estimated glomerular filtration rate; iKT = isolated kidney transplant; POx = plasma oxalate; SD = standard deviation.

^aPer definition of late-stage CKD for inclusion in analysis, patients either required HD or did not require HD and had a baseline eGFR ≤45 mL/min/1.73m².

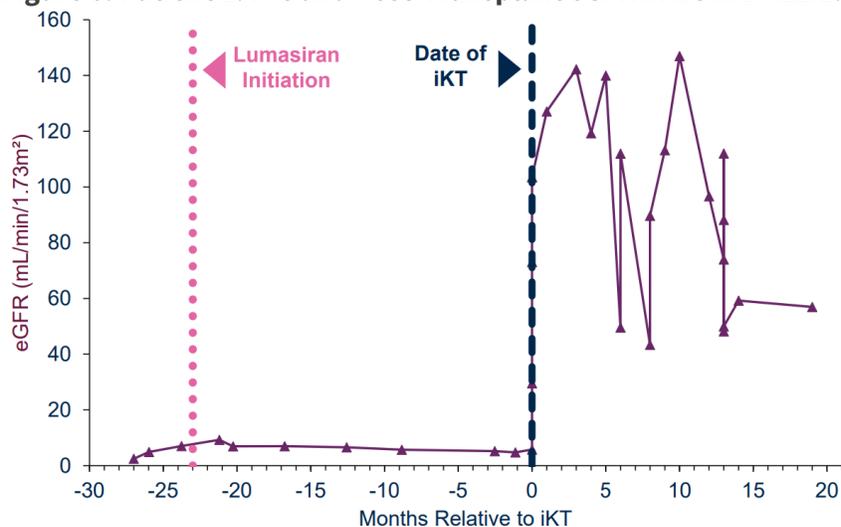
^bOne patient had no eGFR values obtained post-iKT.

^cData prior to iKT was only available for 2 patients.

Treatment with lumasiran following iKT resulted in a sustained reduction in POx in 2 case studies of similarly aged patients from BONAPH1DE and ILLUMINATE-C.⁵

Patient 1 was a male patient aged 2.9 years of age at the time of iKT from BONAPH1DE (**Figure 6** and **Figure 7**). Patient 2 was a female patient aged 2.5 years at the time of iKT from ILLUMINATE-C. Following iKT, Patient 2 received continuous venovenous hemodiafiltration for prophylactic purposes from POD 0-2 and POD 3-4 due to a serious adverse event of obstructive acute renal failure unrelated to lumasiran, and acute intermittent HD on POD 17-35 due to acute renal injury unrelated to lumasiran. HD did not resume through data cutoff date (**Figure 8** and **Figure 9**).⁵

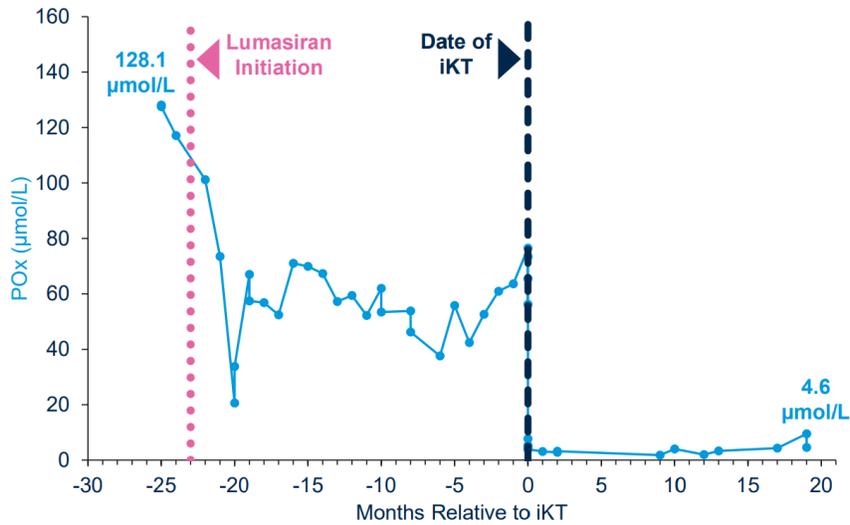
Figure 6. Patient 1: Pre and Post-Transplant eGFR in BONAPH1DE.⁵



Abbreviations: eGFR = estimated glomerular filtration rate; HD = hemodialysis; iKT = isolated kidney transplant.

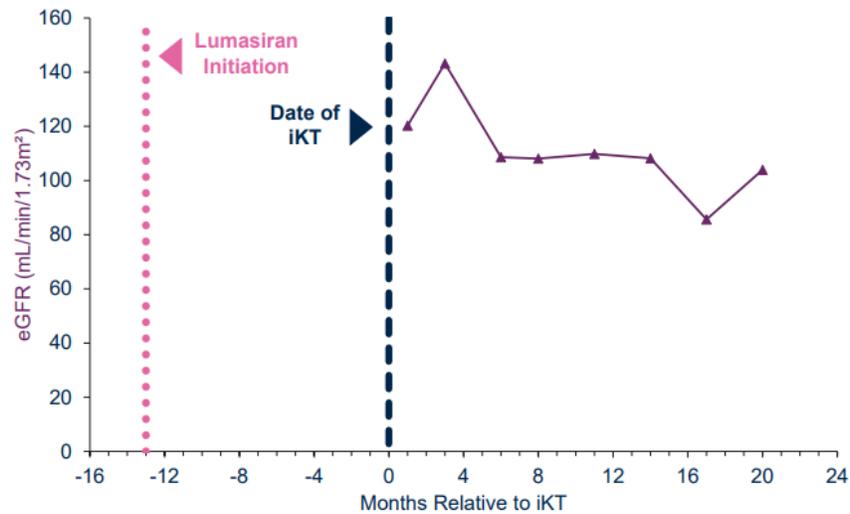
From Lieske et al.⁵

Figure 7. Patient 1: Pre and Post-Transplant POx in BONAPH1DE.⁵



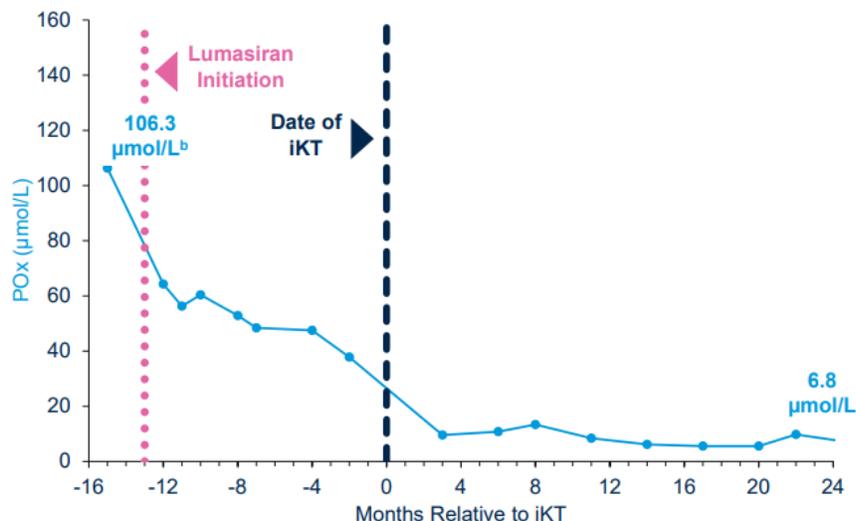
Abbreviations: iKT = isolated kidney transplant; POx = plasma oxalate.
 Baseline POx value is an average of multiple values obtained prior to initiation of lumasiran and is graphed to show POx levels prior to lumasiran initiation and not months relative to iKT.
 From Lieske et al.⁵

Figure 8. Patient 2: Pre and Post-Transplant eGFR in ILLUMINATE-C.^{5,a}



Abbreviations: eGFR = estimated glomerular filtration rate; iKT = isolated kidney transplant.
^aeGFR values were not available prior to iKT as the patient was receiving HD up to the date of iKT.
 From Lieske et al.⁵

Figure 9. Patient 2: Pre and Post-Transplant POx in ILLUMINATE-C.⁵



Abbreviations: iKT = isolated kidney transplant; POx = plasma oxalate.

Baseline POx value is an average of multiple values obtained prior to initiation of lumasiran and is graphed to show POx levels prior to lumasiran initiation and not months relative to iKT.

From Lieske et al.⁵

CASE REPORTS

The following information provides an overview of published case reports regarding patients with PH1 who underwent iKT while receiving treatment with lumasiran. It is not intended to be an all-inclusive list or summary of relevant publications, abstracts, and manuscripts.

Bahbah H, Azzam A, Hamed A, Aldaoud N, Alshami A. Hidden in CAKUT: Post-Transplant Diagnosis of Primary Hyperoxaluria Type 1 and Rescue Management Using Lumasiran. *Pediatr Transplant.* 2025;29(3):e70079. doi:10.1111/petr.70079⁶

- A pediatric patient with recurrent UTI's due to CAKUT received iKT at the age of 7 years. After PH1 was diagnosed, the patient was treated with potassium citrate, pyridoxine, and hyperhydration. 7.5 months after iKT, the patient started lumasiran with HD. The patient had reduced POx and improvement in kidney function (HD was stopped) and had persistent medullary nephrocalcinosis and renal calculi.

Moretti MI, Leporati M, Mazzucchelli R, et al. Plasma Glycolate Levels Contribute to Drive the Decision of Isolated Kidney Transplantation in Dialyzed Patients with End-Stage Kidney Disease due to Primary Hyperoxaluria Type 1 Treated with Lumasiran: A Case Report. *Case Rep Nephrol Dial.* 2025;15(1):141-149. Published 2025 May 23. doi:10.1159/000546144⁷

- A case report detailed a 36-year old male patient with PH1 c.33dupC homozygous gene mutation who underwent iKT combined with lumasiran. Two years after transplantation, graft function was without lithiasis or nephrocalcinosis. 24-h UOx ranged from 0.55 to 1.2 mmol/day and POx remained stable at 12 µmol/L. Allograft biopsies through 22 months showed negligible oxalate crystal deposits.

Martin-Higueras C, Borghese L, König J, et al. RNA interference medication and transplantation procedures in patients with primary hyperoxaluria type 1 (PH1). *Nephrol Dial Transplant*. Published online October 3, 2025. doi:10.1093/ndt/gfaf202⁸

- One patient was diagnosed at age 58 with AKF and a history of kidney stones. The patient received dialysis and pyridoxine. The patient had iKT and lumasiran was initiated shortly before surgery and continued thereafter. Kidney function remained preserved. UOx and POx fluctuated and remained elevated.
- One patient was diagnosed at age 43 when requiring HD. The patient received pyridoxine and HD and started lumasiran treatment at age 51. iKT was performed at age 52 with the kidney working well initially until declining later due to oxalate deposit and renal artery stenosis. Lumasiran was stopped 6 months after transplant with the patient continuing alkaline citrate and pyridoxine.
- One infant went into AKF at 4 months of life and received PD and HD. Nedosiran was given from month 14 to 31 and lumasiran was added at month 27 and continued thereafter without nedosiran. The patient received iKT at age 4, which was complicated by borderline rejection and oxalate deposit. Treatment with pyridoxine, lumasiran, and nedosiran were continued.

Choi M, et al. Recovery from severe heart failure in a patient with primary hyperoxaluria type 1 after treatment with lumasiran, pyridoxine, and kidney transplant. *AIMCC*. 2024;3(6). doi:10.7326/aimcc.2023.1428⁹

- A case report detailed the treatment outcomes of a 29-year-old male patient with PH1, severe cardiomyopathy, and heart failure was started on lumasiran after being diagnosed with kidney failure and receiving combined PD and HD.
- Serial echocardiograms demonstrated an improvement in LVEF from 35% after initiation of HD to $43.8 \pm 3.2\%$ after the initiation of lumasiran therapy.
- The patient received an iKT. Therapy with oral pyridoxine daily and subcutaneous lumasiran every 3 months was continued. There were no signs of rejection or oxalate deposition in allograft biopsy specimens collected 1 month post-transplant.
- At 6 months post-transplant, the patient's kidney function remained stable. At 8 months post-transplant, POx was 9.5 $\mu\text{mol/L}$ and cardiac function improved to NYHA class I.

Bacchetta J, et al. Lumasiran, isolated kidney transplantation, and continued vigilance. *N Engl J Med*. 2024;390(11):1052-1054. doi:10.1056/NEJMc2312941¹⁰

- Sellier-Leclerc et al. detailed the treatment outcomes of 5 patients with PH1 who underwent iKT and received lumasiran and proactive management during the immediate postoperative period. Patients were followed up for at least 6 months.¹²
- Bacchetta et al. reported data from at least 23 months of follow-up for each patient. All grafts continued to function at the time of the report, and no patients had nephrocalcinosis. In 4 of the patients, UOx:Cr was normalized or near normalized. Additional details regarding the treatment outcomes of individual patients are provided in the publication and supplement.^{10,17}

Lombardi Y, et al. Stiripentol and lumasiran as a rescue therapy for oxalate nephropathy recurrence after kidney transplantation in an adult patient with primary hyperoxaluria type 1. *Am J Kidney Dis*. 2023;82(1):113-116. doi:10.1053/j.ajkd.2022.12.005¹¹

- A case report detailed the treatment outcomes of an 51-year old adult patient with PH1 that

received iKT after HD. High UOx values persisted after treatment with pyridoxine and Stiripentol, and compassionate use lumasiran was granted and initiated at day 78 post-transplant. POx and UOx decreased.

- Systematic screening biopsies were performed at 3 months and 12 months post-transplant and showed a complete disappearance of previously existing oxalate crystals. At last follow-up on day 423, the patient was symptom free; serum creatinine was stable with an eGFR of 69 mL/min/1.73m²; and serum oxalate concentration was 20.2 μmol/L with a UOx:Cr ratio of 83 μmol/mmol.

Sellier-Leclerc A-L, et al. Isolated kidney transplantation under lumasiran therapy in primary hyperoxaluria type 1: a report of five cases. *Nephrol Dial Transplant.* 2023;38(2):517-521. doi:10.1093/ndt/gfac295¹²

- A retrospective report detailed 5 cases of patients with PH1 (median [range] age at transplantation: 26 [3-45]) that underwent iKT while on lumasiran therapy (median [range]: 13 [5-17] months of therapy before iKT).
- Three of these patients received grafts from living donors, and all received intensive postoperative management which varied across treatment plans. Postoperative management across patients included (but was not limited to) hyperhydration, pyridoxine, dialysis, potassium citrate, immunosuppression with various agents, and lumasiran treatment. After a follow-up of at least 6 months, the 5 patients showed no indications of recurrent oxalate nephropathy nor signs of lactic acidosis with lumasiran treatment, with POx levels ranging from not detected to 21 μmol. Two patients were followed up to 12 months. Additional details regarding the treatment outcomes of individual patients are provided in the publication.

Joher N, et al. Early post-transplant recurrence of oxalate nephropathy in a patient with primary hyperoxaluria type 1, despite pretransplant lumasiran therapy. *Kidney International.* 2022;101(1):185-186. doi:10.1016/j.kint.2021.10.022¹³

- A case report detailed the treatment outcomes of a 39-year-old female patient who was started on lumasiran after receiving HD. Serum oxalate concentrations normalized, allowing for an iKT.
- On Day 25 post-transplant, the patient was treated for acute rejection. Preventive measures for the recurrence of oxalate nephropathy were maintained, including lumasiran on the seventh week post-transplant. There were no reports of adverse events or drug interactions.

Stone HK, et al Primary hyperoxaluria diagnosed after kidney transplant: A review of the literature and case report of aggressive renal replacement therapy and lumasiran to prevent allograft loss. *Am J Transplant.* 2021;21(12):4061-4067. doi:10.1111/ajt.16762¹⁴

- A case report detailed the treatment outcomes of a 7-year-old male pediatric patient diagnosed with PH1 following iKT.
- Following the diagnosis of PH1, the patient received aggressive renal replacement therapy and lumasiran was initiated on day 34 post-transplant. In the first 5 months of lumasiran treatment, UOx decreased by 65.9%. UOx continued to decline since discontinuing hemodialysis, although levels remained above the upper limit of normal.

OXLUMO PRESCRIBING INFORMATION – RELEVANT CONTENT

The **USE IN SPECIFIC POPULATIONS** provides the following information¹⁸:

Renal Impairment

No dose adjustment is necessary in patients with renal impairment including patients with kidney failure treated with hemodialysis. OXLUMO has not been studied in patients on peritoneal dialysis.

The **CLINICAL PHARMACOLOGY** section provides the following information¹⁸:

Pharmacokinetics

Table 3. Pharmacokinetic Parameters of Lumasiran

Excretion	
Primary Pathway	Less than 26% of the administered dose of lumasiran is excreted unchanged into the urine within 24 hours with the rest excreted as inactive metabolite.

ABBREVIATIONS

ACR = acute cellular rejection; AE = adverse event; AKF = acute kidney failure; AKI = acute kidney injury, BL = baseline; CAKUT = congenital anomalies of the kidney and urinary tract; eGFR = estimated glomerular filtration rate; HD = hemodialysis; iKT = isolated kidney transplant; LVEF = left ventricular ejection fraction; M = month; NA = not applicable; NT-proBNP = N-terminal prohormone of brain natriuretic peptide; NYHA = New York Heart Association; PD = peritoneal dialysis; PGly = plasma glycolate; PH1 = primary hyperoxaluria type 1; POx = plasma oxalate; RNAi = RNA interference; UOx = urinary oxalate; UOx:Cr = urinary oxalate:creatinine ratio; UTI = urinary tract infection.

Updated 5 January 2026

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