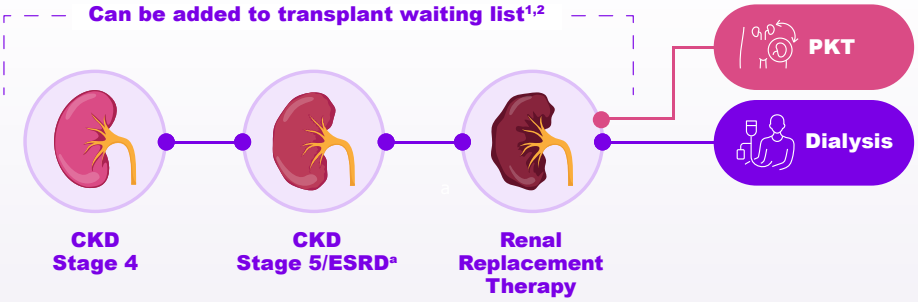
A "transplant first" treatment approach to CKD/ESRD is now recommended and promoted for appropriate patients

GUIDELINES

The 2020 KDIGO clinical practice guidelines recommend kidney transplant education begin at **CKD stage 4**[1]

- OPTN guidance recommends appropriate patients be referred for a kidney transplant and wait-listed **beginning at CKD stage 4**[2]



PKT with a living donor is the **preferred treatment** for eligible patients with ESRD[1]
PKT is performed after a **diagnosis of ESRD** and before the **initiation of dialysis**[3]

LEGISLATION

A 2019 executive order on kidney health established goals to increase the number of PKTs by 2025 and double the number of kidneys available for transplant by 2030[4]

21st Century Cures Act

- ESRD beneficiaries are allowed to enroll in Medicare Advantage (MA) plans[5]
- Organ acquisition costs for kidney transplants are excluded from MA plans[5]
- ~40,000 ESRD beneficiaries switched from a fee-for-service (FFS) plan to an MA plan in 2021[6]

CMS PAYMENT MODELS

Kidney Care Choices Model

Incorporates a quarterly capitation payment, an adjusted monthly capitation payment, and a kidney transplant incentive for appropriate CKD stages 4 and 5 and ESRD beneficiaries[7]

ESRD Treatment Choices Model

Provides incentives for transplant waitlisting and living donor transplant rates in ~30% of the nation's ESRD facilities and managing physicians[8]

[a] ESRD begins when RRT is clinically required due to kidney failure.
CKD, chronic kidney disease; CMS, Centers for Medicare & Medicaid Services; ESRD, end-stage renal disease; KDIGO, Kidney Disease: Improving Global Outcomes; OPTN, Organ Procurement and Transplantation Network; PKT, preemptive kidney transplant; RRT, renal replacement therapy.

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Economic benefits of PKT

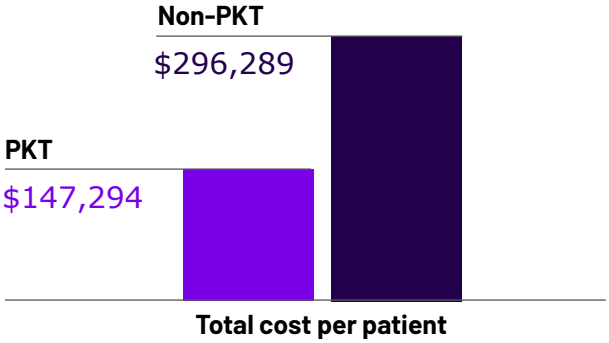
A kidney transplant may potentially reduce or eliminate dialysis costs for appropriate patients[9,10]

Per-patient Annual Spend	Medicare Beneficiary[10,a]		Privately Insured Patient	
Dialysis	~$99,000	~56% ↓	~$238,000[11,b]	~78% ↓
Kidney Transplant	~$44,000		~$52,000[12,c]	

For patients with commercial insurance, PKT potentially offers

~50% (~$149,000) medical cost savings per patient vs non-PKT[13]

Annual Commercial Costs



PKT resulted in lower health care resource utilization vs non-PKT[13]

	Pretransplant ED visit Number (% or SD)	Pretransplant hospital days Number (% or SD)	Transplant LOS (days) Number (% or SD)
PKT (n=725)	**80** (11.0%)	**1.1** (6.2)	**5.5** (4.2)
Non-PKT (n=819)	**277** (33.8%)	**3.9** (7.2)	**6.7** (6.0)
	P<0.0001		

Study Design: Recipients of first kidney transplants from 2008-2015 were identified utilizing the OptumLabs Data Warehouse, which included administrative claims data on privately insured and Medicare Advantage enrollees in the United States. Of 1,544 kidney transplant recipients (1,313 [85%] commercially insured), 725 (47%) received a PKT (565 LD + 160 DD) and 819 (54%) received a non-PKT (464 LD + 355 DD).[13]

[a] Inflation-adjusted PPPY 2021. Cost for dialysis represents hemodialysis.[10]
[b] The sample included 309,800 enrollee months, which was a balanced panel of 25 months for 12,392 enrollees with private insurance from 2012 to 2019.[11]
[c] Included 18,453 cases (9,962 kidney; 4,831 liver; 1,638 heart; 1,468 lung; and 554 pancreas) with case effective dates between January 1, 2010, and April 30, 2014, and claims paid through September 30, 2014.[12]
DD, deceased donor; ED, emergency department; LD, living donor; LOS, length of stay; PPPY, per person per year; SD, standard deviation.

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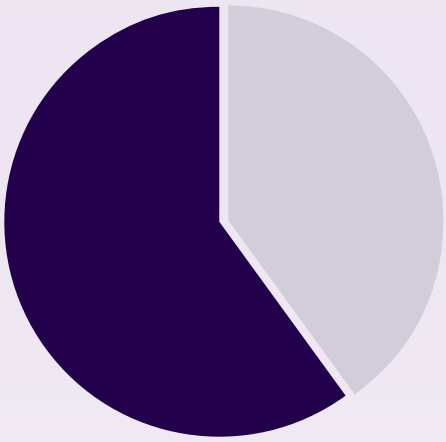
So why are so many eligible patients not gaining access to timely transplants and losing ground?

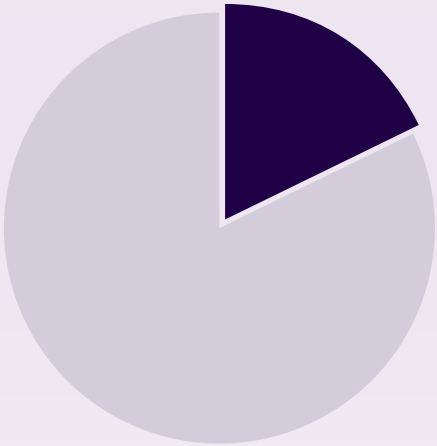
Many patients with a **top 20%** Estimated Post Transplant Survival (EPTS) status[a] were not placed on the transplant waiting list prior to dialysis[14,b]

Only 1of 5 (7,922 of 42,445) candidates with top-tier EPTS scores (those most likely to thrive after transplant) were preemptively wait-listed for transplants (2015-2017)[14,b]

Those who were preemptively wait-listed were less likely to lose their top-tier status[14,b]



61% of **patients who had initiated dialysis lost top 20% EPTS status**[a] within 30 months



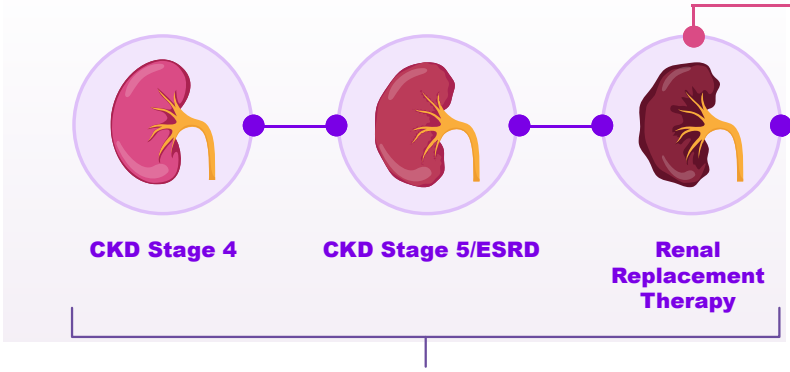
Only **18%** of **preemptively wait-listed candidates lost top 20% EPTS status**[a] within 30 months

[a] The EPTS score (0%-100%) is designed to identify candidates with the longest expected posttransplant survival and allocate the highest quality kidneys to these candidates. Candidates with top 20% EPTS status have preferential access to deceased donor kidney offers with the lowest cumulative risk factors before other candidates.[14]

[b] Limitations of the study include inherent risk of residual confounding and underlying risk factors that explain outcomes not captured in the study data; estimated risk of some patients not codified due to potential misclassification of certain clinical conditions (eg, comorbidities); missing data representing systematic differences in patient characteristics not accounted for in these analyses; and no available information on specific reasons for waiting list placement, outcomes of discussions about transplant eligibility, or patient's interestin transplantation.[14]

Consider the barriers to PKT

Lack of timely referral[2]



PKT
~3% (4,153) of patients with incident ESRD receive a **PKT**[10,b]

Dialysis
~97% (131,062) of patients with incident ESRD initiate dialysis[10,b]

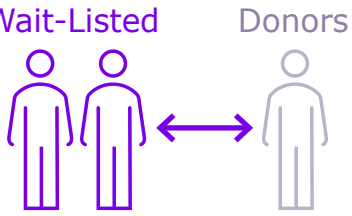
Only ~5% of kidney transplant candidates are wait-listed prior to initiating dialysis[10,a]

Lack of provider understanding of the process[2]

"*Many providers still believe that a patient needs to be on dialysis prior to being considered for transplantation*"[2]
—OPTN

Low availability of kidney donors

The ratio of wait-listed patients to donors was **~2:1** in 2023[15]



Lack of patient education[2]

Only **33%** of patients are aware of transplant options at the time of dialysis initiation, partially because nephrologists do not always discuss or emphasize transplantation[16]

Perhaps the most significant barrier to preemptive kidney transplantation is timely referral for transplant evaluation[2]
—OPTN

[a] Incident ESRD patients in 2021, USRDS ESRD and OPTN wait-listing history.[10]
[b] Incident ESRD patients in 2021, USRDS ESRD.[10]
USRDS, United States Renal Data System.

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How can we overcome these barriers?

Transplant referrals predialysis, coupled with education of key stakeholders, are crucial to successful transplants among eligible patients[2]

Mobilize physicians

Early referral by physicians allows time for appropriate patients (GFR <30 mL/min) to be educated on transplantation and to receive transplant evaluation and facilitates identification of a living donor[2]

HOW

- Raise awareness of updated practice guidelines (KDIGO 2020)
- Utilize online physician resources listed on the next page
- Share the OPTN educational guidance on patient referral for kidney transplantation

Educate patients

At CKD stage 4, inform appropriate patients that transplantation is the preferred option for kidney failure[2]

69% of patients underwent an LD kidney transplant after receiving early education[17]

Utilization of the CMS **Kidney Disease Education (KDE)** benefit resulted in[18,a]

~38% increase in pre-ESRD wait-listing

~36% increase in PKT

HOW

- Inform appropriate patients of their EPTS score and risk of kidney failure
- Utilize online patient resources listed on the next page
- Make use of the CMS KDE benefit

Increase living donor transplantation

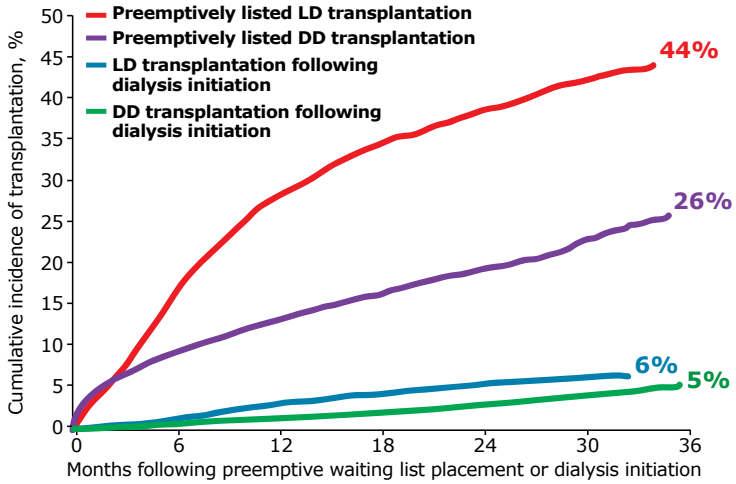
Educate providers and appropriate patients about the benefits of LD transplantation

44% of preemptively listed patients receive an LD transplant by 36 months[14,b]

HOW

- Ensure appropriate patients are wait-listed at GFR <20 mL/min
- Educate potential recipients and donors (resources listed on next page)

Cumulative Incidence of LD and DD Transplantation by Patients Who Were Preemptively Wait-Listed or Initiated Dialysis[14,b]



[a] Based on 2013-2017 US data from adults aged ≥67 years who had CKD stage 4 (n=106,465); use of KDE was examined in the 2 years prior to ESRD onset.[18]

[b] The study population was derived from the USRDS. Model censored at death and last follow-up time, December 31, 2017. Limitations of the study include inherent risk of residual confounding and underlying risk factors that explain outcomes not captured in the study data; estimated risk of some patients not codified due to potential misclassification of certain clinical conditions (eg, comorbidities); missing data representing systematic differences in patient characteristics not accounted for in these analyses; and no available information on specific reasons for waiting list placement, outcomes of discussions about transplant eligibility, or patient's interest in transplantation.[14]

GFR, glomerular filtration rate.

Access the newest resources for transplant success

The following websites can help educate and guide the process as early as **CKD stage 4** for appropriate patients

Explore Transplant

Provides an evidence-based education platform to coach appropriate patients and potential donors through the transplant decision process. Patients can also record their own stories to create awareness and highlight the living donor shortage

Rejuvenate

Offers a full range of transplant solutions to increase earlier access to care, locate donors, and reduce health care spend

Kidney Failure Risk Equation

Provides patient-specific risk equation that estimates time to kidney failure

EPTS Calculator

Calculates the EPTS score, which is designed to identify candidates with the longest expected posttransplant survival

AST Living Donor Toolkit

Helps potential living donors make an informed decision about donation

This listing is provided as a resource only and does not constitute an endorsement by Sanofi of any particular organization or its programming. Additional resources on this topic may be available and should be investigated. Sanofi does not review or control the content of non-Sanofi websites.

References: 1. Chadban SJ, Ahn C, Axelrod DA, et al. KDIGO clinical practice guideline on the evaluation and management of candidates for kidney transplantation. *Transplantation*. 2020;104 (4 suppl 1):S1-S103. doi:10.1097/TP.0000000000003136. **2.** Educational guidance on patient referral to kidney transplantation. Organ Procurement & Transplantation Network. Accessed March 13, 2024. https://optn.transplant.hrsa.gov/professionals/by-topic/guidance/educational-guidance-on-patient-referral-to-kidney-transplantation/. **3.** Yishak AA, Rubenstein K, Clark ED, Bhatia M, Vupputuri S. Early referral, living donation, and preemptive kidney transplant. *Transplant Proc.* 2022;54(3):615-621. doi:10.1016/j.transproceed.2021.11.038. **4.** Lentine KL, Mannon RB. The Advancing American Kidney Health (AAKH) Executive Order: promise and caveats for expanding access to kidney transplantation. *Kidney360.* 2020;1(6):557-560. doi:10.34067/KID.0001172020. **5.** 2021 Medicare Advantage and Part D advance notice part II fact sheet. Centers for Medicare & Medicaid Services. Accessed March 13, 2024. https://www.cms.gov/newsroom/fact-sheets/2021-medicare-advantage-and-part-d-advance-notice-part-ii-fact-sheet. **6.** ESRD enrollment in MA now exceeds 30 percent of all dialysis patients. Avalere website. Accessed March 13, 2024. https://avalere.com/insights/esrd-enrollment-in-ma-now-exceeds-30-percent-of-all-dialysis-patients. **7.** Jain G, Weiner DE. Value-based care in nephrology: the Kidney Care Choices model and other reforms. *Kidney360.* 2021;2(10):1677-1683. doi:10.34067/KID.0004552021. **8.** End-Stage Renal Disease Treatment Choices (ETC) Model fact sheet. Centers for Medicare & Medicaid Services. Accessed March 13, 2024. https://www.cms.gov/newsroom/fact-sheets/end-stage-renal-disease-treatment-choices-etc-model-fact-sheet. **9.** Optum. Kidney solutions: preemptive transplants rates and cost savings. August 2021. Accessed March 11, 2024. https://www.optum.com/content/dam/optum4/resources/pdf/optum-kidney-solutions-preemptive-transplants-rates-and-cost-savings-white-paper.pdf. **10.** United States Renal Data System. 2023 USRDS Annual Data Report: epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2023. Accessed March 11, 2024. https://usrds-adr.niddk.nih.gov/2023. **11.** League RJ, Eliason P, McDevitt RC, Roberts JW, Wong H. Assessment of spending for patients initiating dialysis care. *JAMA Netw Open.* 2022;5(10):e2239131. doi:10.1001/jamanetworkopen.2022.39131. **12.** Irwin FD, Wu C, Bannister WM, et al. A commercial transplant network's perspective of value in solid organ transplantation: strategizing for value in transplant care. *Transplant Rev (Orlando).* 2016;30(2):71-76. doi:10.1016/j.trre.2015.11.002. **13.** Dean P, Heien H, Swanson K, et al. The cost savings of preemptive kidney transplantation. *Am J Transplant.* 2017;17 (suppl 3). ATC abstract 577. **14.** Schold JD, Huml AM, Poggio ED, et al. Patients with high priority for kidney transplant who are not given expedited placement on the transplant waiting list represent lost opportunities. *J Am Soc Nephrol.* 2021;32(7):1733-1746. doi:10.1681/ASN.2020081146. **15.** Organ donation and transplantation. Health Resources & Services Administration. Accessed March 13, 2024. https://data.hrsa.gov/topics/health-systems/organ-donation. **16.** Patzer RE, Plantinga LC, Paul S, et al. Variation in dialysis facility referral for kidney transplantation among patients with end-stage renal disease in Georgia. *JAMA.* 2015;314(6):582-594. doi:10.1001/jama.2015.8897. **17.** Massey EK, Gregoor PJHS, Nette RW, et al. Early home-based group education to support informed decision-making among patients with end-stage renal disease: a multi-centre randomized controlled trial. *Nephrol Dial Transplant.* 2016;31(5):823-830. doi:10.1093/ndt/gfv322. **18.** Johansen KL, Wetmore JB, Gilbertson DT, et al. Association of use of kidney disease education benefit with ESKD-related. *J Am Soc Nephrol.* 2020;31(suppl):18. Kidney Week abstract FR-OR11.

AST, American Society of Transplantation.

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