

MILLIMAN REPORT

2025 U.S. organ and tissue transplants:

Estimated costs and utilization, emerging issues, and solutions

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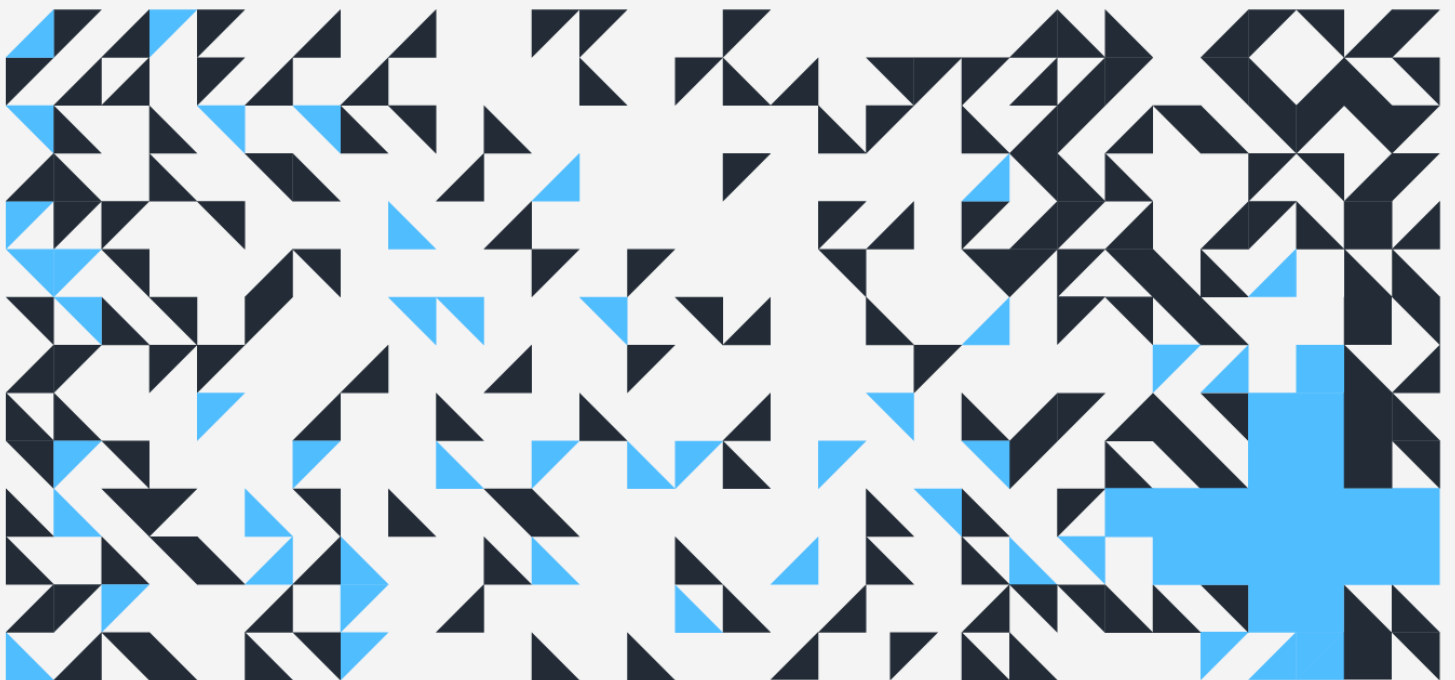


Table of contents

1. OVERVIEW	1
2. COSTS PMPM, BILLED CHARGES, AND UTILIZATION	3
COMPONENTS OF BILLED CHARGES.....	3
BASIS OF UTILIZATION AND BILLED CHARGES	6
HOSPITAL LENGTHS OF STAY	6
ANNUAL NUMBER OF TRANSPLANTS	7
3. EMERGING ISSUES AND POTENTIAL SOLUTIONS	8
BENCHMARKING AND CONTEMPORARY MARKET INTELLIGENCE	8
ORGAN TRANSPLANT DISTRIBUTION AND INEQUALITIES	8
ORGAN AVAILABILITY.....	10
ORGAN VIABILITY	11
BONE MARROW TRANSPLANT DEVELOPMENTS	12
SECURING THE U.S. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK ACT.....	12
4. OTHER DATA AND POTENTIAL ANALYSIS OPPORTUNITIES	13
ACTUAL MARKET PRICES WILL VARY FROM MILLIMAN BILLED CHARGES	13
ACTUAL COSTS COMPARED TO MILLIMAN COSTS	13
BILLED CHARGE COMPONENT DETAILS	14
OTHER POTENTIAL DATA ANALYSES	14
BACKGROUND ON DATA SETS	15
5. FIGURE INDEX	16
ACKNOWLEDGMENTS	17

1. Overview

This 2025 report represents Milliman's periodic summary of estimated U.S. average utilization, billed charges, and resulting costs per member per month (PMPM) for organ and tissue transplants. Since the last report (released in February 2020), we expanded the underlying data used to produce the cost estimates. Any comparisons to the 2020 report should note that the 2020 projections (released in February 2020) were developed without considering the impact of COVID-19 on transplants. The short- and long-term effects of COVID-19 on transplant use, costs, demand, and other aspects are outside the scope of this report.

The report covers estimates for the period ranging from 30 days prior to 180 days after admission for organ and tissue transplants treatment. Organ transplants include single-organ transplants (heart, intestine, kidney, liver, lung, and pancreas), several multiple-organ transplants, and tissue transplants (bone marrow and cornea). We split the bone marrow estimates by donor method: autologous (where the donor is the recipient) and allogeneic (where the donor may be related or unrelated to the recipient).

Highlights of this report include:

- We estimate the 2025 costs PMPM based on billed charges to be \$14.43 and \$25.42 for the under age 65 and age 65 and over populations, respectively. These costs PMPM reflect average annual increases of 5.2% and 9.1%, respectively, from our 2020 report.
- Average annual utilization generally varied more than average annual billed charges for the under age 65 population, relative to our 2020 report. Estimated hospital lengths of stay have also changed for most transplants since our 2020 report, with estimated U.S. average 2025 billed charges, utilization, costs PMPM, and hospital lengths of stay by transplant summarized in Figure 1 on page 2.
- We also describe emerging issues and potential solutions to consider related to benchmarking and market intelligence, organ distribution and inequalities, organ availability and viability, and developments specific to bone marrow transplants. We continue to monitor and be available to assess the implications of those emerging issues and solutions on the transplant space.

Key elements related to the underlying methodology include:

- We used the Milliman Consolidated Health Cost Guidelines™ Sources Database (CHSD) and the 100% Medicare Limited Data Set (LDS) for the underlying basis of the cost estimates, with those data sets covering a much wider nationwide range of organ and tissue transplantation cost records than prior reports.
- The estimated billed charges and resulting cost PMPM estimates in this report are not the actual amounts paid for transplant services. The use of negotiated reimbursement arrangements will result in potentially significant reductions from billed charge levels. Actual charges will vary for private insurers, Medicare, and Medicaid.
- Other areas for potential review and uncovering insight into market opportunities and gaps may include:
 - Costs by transplant diagnosis or at the graft source level for bone marrow transplants
 - Average waiting time and/or survival rate analyses, including research into transplant outcomes
 - Donor source (deceased/living) studies

FIGURE 1: ESTIMATED U.S. AVERAGE 2025 BILLED CHARGES, UTILIZATION, COSTS PMPM, AND HOSPITAL LENGTHS OF STAY BY TRANSPLANT

TRANSPLANT	ESTIMATED BILLED CHARGES	UNDER AGE 65		AGES 65 AND OVER		ALL AGES
		ESTIMATED ANNUAL UTILIZATION PER 1,000,000	ESTIMATED COSTS PMPM	ESTIMATED ANNUAL UTILIZATION PER 1,000,000	ESTIMATED COSTS PMPM	ESTIMATED HOSPITAL LENGTH OF STAY (DAYS)
SINGLE ORGAN/TISSUE						
BONE MARROW – ALLOGENEIC	\$1,261,800	25.92	\$2.73	38.36	\$4.03	33.3
BONE MARROW – AUTOLOGOUS	577,000	30.39	1.46	89.95	4.33	20.3
CORNEA	57,000	60.38	0.29	582.99	2.77	N/A
HEART	1,918,700	11.99	1.92	12.89	2.06	40.6
INTESTINE	1,729,500	0.17	0.02	0.03	0.00	63.2
KIDNEY	446,800	75.85	2.82	115.27	4.29	7.5
LIVER	1,017,800	31.10	2.64	37.59	3.19	20.2
LUNG – SINGLE	1,810,700	2.08	0.31	5.41	0.82	25.7
LUNG – DOUBLE	2,346,500	5.47	1.07	14.27	2.79	38.2
PANCREAS	609,400	0.23	0.01	0.02	0.00	14.6
MULTIPLE ORGAN						
HEART-LUNG	\$4,060,100	0.23	\$0.08	0.05	\$0.02	74.7
INTESTINE WITH OTHER ORGANS	1,996,400	0.14	0.02	0.02	0.00	73.1
KIDNEY-HEART	3,650,500	1.25	0.38	1.66	0.50	65.8
KIDNEY-PANCREAS	947,200	2.95	0.23	0.06	0.00	11.5
LIVER-KIDNEY	1,870,900	2.15	0.34	3.62	0.56	35.3
OTHER MULTIPLE ORGAN	3,198,800	0.43	0.11	0.21	0.06	83.6
TOTAL		\$14.43		\$25.42		

2. Costs PMPM, billed charges, and utilization

The table in Figure 2 on page 4 summarizes the estimated U.S. average 2025 transplant costs PMPM for the under age 65 and age 65 and over populations, based on the product of utilization and billed charges. The table in Figure 3 summarizes the estimated U.S. average 2025 billed charges per transplant.

The estimated billed charges and resulting cost PMPM estimates in this report may not be the actual amounts paid for transplant services, as discussed further in Section 4 of this report below. The use of various negotiated reimbursement arrangements may result in significant reductions from billed charge levels and charge levels that vary by market and payer (e.g., private insurers, Medicare, or Medicaid).

The estimated number of transplants shown in Figure 2 reflects transplants provided to U.S. citizens and U.S. residents who are not U.S. citizens. To determine utilization rates, we assume 2025 U.S. under-65 and 65+ population estimates by age of 275.9 million and 62.1 million, respectively. We relied on the U.S. Census Bureau's American Community Survey (ACS) one-year estimates and data profiles for these 2025 population estimates.

Consistent with our 2020 report, billed charges for pretransplant, follow-up, outpatient (OP) immunosuppressants, and other drugs used cover the period from 30 days pretransplant to 180 days posttransplant discharge for follow-up and outpatient immunosuppressant and other drugs. We include the costs for all medical services associated with the transplant patient for these components of care, not just those related to the transplant.

COMPONENTS OF BILLED CHARGES

Figure 3 on page 5 shows detailed estimated U.S. average 2025 billed charges per transplant. We summarize the components of care making up the total billed charges below and provide more detail about some of these components in Section 4.

- **30 days pretransplant:** These billed charges include all medical costs a transplant patient may incur for services during the 30 days prior to the transplant hospital admission, which may also include costs for medical services not related to the transplant.
- **Procurement:** This category includes donated organ or tissue recovery services, which may include retrieval, preservation, transportation, and other acquisition costs.
- **Hospital transplant admission:** This component covers billed facility charges for the transplant only.
- **Physician services during transplant admission:** This piece includes billed charges for professional services while the recipient is hospitalized for the transplant, including surgical procedures and other services identified by Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) codes.
- **180 days posttransplant discharge:** This category covers post-discharge facility and professional services, including any hospital readmissions.
- **Outpatient (OP) immunosuppressants and other Rx:** This component includes all OP drugs prescribed from discharge for the transplant admission to 180 days posttransplant discharge, including immunosuppressants and other drugs (related and unrelated to the transplant).

FIGURE 2: ESTIMATED U.S. AVERAGE 2025 TRANSPLANT COSTS PMPM, BILLED CHARGES, AND UTILIZATION

TRANSPLANT	TOTAL ESTIMATED NUMBER OF TRANSPLANTS	ESTIMATED BILLED CHARGES	UNDER AGE 65			AGES 65 AND OVER		
			ESTIMATED NUMBER OF TRANSPLANTS	ESTIMATED ANNUAL UTILIZATION PER 1,000,000	ESTIMATED COSTS PMPM	ESTIMATED NUMBER OF TRANSPLANTS	ESTIMATED ANNUAL UTILIZATION PER 1,000,000	ESTIMATED COSTS PMPM
SINGLE ORGAN/TISSUE								
BONE MARROW – ALLOGENEIC	9,535	\$1,261,800	7,151	25.92	\$2.73	2,384	38.36	\$4.03
BONE MARROW – AUTOLOGOUS	13,975	577,000	8,385	30.39	1.46	5,590	89.95	4.33
CORNEA	52,889	57,000	16,660	60.38	0.29	36,229	582.99	2.77
HEART	4,109	1,918,700	3,308	11.99	1.92	801	12.89	2.06
INTESTINE	48	1,729,500	46	0.17	0.02	2	0.03	0.00
KIDNEY	28,092	446,800	20,929	75.85	2.82	7,163	115.27	4.29
LIVER	10,916	1,017,800	8,580	31.10	2.64	2,336	37.59	3.19
LUNG – SINGLE	909	1,810,700	573	2.08	0.31	336	5.41	0.82
LUNG – DOUBLE	2,398	2,346,500	1,511	5.47	1.07	887	14.27	2.79
PANCREAS	64	609,400	63	0.23	0.01	1	0.02	0.00
MULTIPLE ORGAN								
HEART-LUNG	67	\$4,060,100	64	0.23	\$0.08	3	0.05	\$0.02
INTESTINE WITH OTHER ORGANS	40	1,996,400	39	0.14	0.02	1	0.02	0.00
KIDNEY-HEART	448	3,650,500	345	1.25	0.38	103	1.66	0.50
KIDNEY-PANCREAS	819	947,200	815	2.95	0.23	4	0.06	0.00
LIVER-KIDNEY	818	1,870,900	593	2.15	0.34	225	3.62	0.56
OTHER MULTIPLE ORGAN	131	3,198,800	118	0.43	0.11	13	0.21	0.06
TOTAL					\$14.43			\$25.42

FIGURE 3: ESTIMATED U.S. AVERAGE 2025 BILLED CHARGES PER TRANSPLANT BY COMPONENT OF CARE

TRANSPLANT	30 DAYS PRETRANSPLANT	PROCUREMENT	HOSPITAL TRANSPLANT ADMISSION	PHYSICIAN DURING TRANSPLANT ADMISSION	180 DAYS POSTTRANSPLANT DISCHARGE	OP IMMUNO- SUPPRESSANTS AND OTHER RX	TOTAL
SINGLE ORGAN/TISSUE							
BONE MARROW – ALLOGENEIC	\$94,300	\$97,400	\$669,300	\$18,900	\$314,200	\$67,700	\$1,261,800
BONE MARROW – AUTOLOGOUS	77,900	36,100	275,500	11,500	129,800	46,200	577,000
CORNEA*	N/A	18,900	28,600	9,500	N/A	N/A	57,000
HEART	67,000	214,500	1,220,400	105,200	277,400	34,200	1,918,700
INTESTINE	43,100	170,300	1,019,800	86,200	379,400	30,700	1,729,500
KIDNEY	30,900	135,400	142,500	22,100	88,200	27,700	446,800
LIVER	60,600	175,500	552,100	60,600	141,500	27,500	1,017,800
LUNG – SINGLE	72,100	240,300	1,039,700	108,200	297,500	52,900	1,810,700
LUNG – DOUBLE	93,600	257,700	1,403,800	140,400	386,100	64,900	2,346,500
PANCREAS	27,200	119,600	279,000	30,200	126,800	26,600	609,400
MULTIPLE ORGAN							
HEART-LUNG	\$101,400	\$486,900	\$2,677,300	\$223,100	\$527,400	\$44,000	\$4,060,100
INTESTINE WITH OTHER ORGANS	82,400	409,600	971,500	110,000	373,700	49,200	1,996,400
KIDNEY-HEART	202,100	287,600	2,247,800	202,100	624,700	86,200	3,650,500
KIDNEY-PANCREAS	56,800	258,400	394,300	47,300	156,100	34,300	947,200
LIVER-KIDNEY	122,200	278,300	971,800	112,800	329,000	56,800	1,870,900
OTHER MULTIPLE ORGAN	146,400	337,400	1,960,200	183,600	495,200	76,000	3,198,800

* Cornea transplantation cost data was not available for the following components of care: 30 days pretransplant, 180 days posttransplant discharge, and OP immunosuppressants and other Rx.

BASIS OF UTILIZATION AND BILLED CHARGES

We base utilization estimates on data from the U.S. Organ Procurement and Transplantation Network (OPTN) as of November 12, 2024, the U.S. Health Resources and Services Administration (HRSA), and the Eye Bank Association of America. None of the entities on which we relied for data have reviewed or confirmed our estimates. The content of this report is the responsibility of the authors alone and does not necessarily reflect the views or policies of the U.S. government or other entities, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government or other entities.

We based the procurement and hospital billed charge estimates on the data available and described in Section 4 below, then project trend to 2025 and adjust (i.e., normalize) the data to a national average basis using Milliman area relativity research and our judgment.

We develop billed charge estimates for 30 days pretransplant, physician during transplant, 180 days posttransplant discharge, and non-immunosuppressant drugs based on Milliman proprietary claim data.

We develop outpatient immunosuppressant billed charges after our estimated date of discharge, which we base on 2022 hospital lengths of stay, trended to 2025. We base the average wholesale prices on the Medi-Span database, the MarketScan commercial database, and our judgment to project these billed charges to 2025. Average dosing regimen assumptions reflect clinical pharmacology and our judgment. We base average immunosuppressant use by drug assumptions on data through June 30, 2024, and based on data from OPTN as of October 4, 2024.

HOSPITAL LENGTHS OF STAY

Figure 4 shows estimated hospital lengths of stay underlying the projected billed charges in this report. We estimate the hospital lengths of stay by transplant without variation by age, based on experience available through 2022 and adjust to 2025 based on emerging trends and evolving experience.

Experience varies by transplant, such that certain transplants may indicate reductions in hospital stays over time while other transplants may demonstrate flat or increasing lengths of stay, with lower-volume transplants subject to higher volatility over time. Hospital lengths of stay may be highly variable due to the influence of factors that may include different surgery complexities, risks of rejection and complications, and levels of post-operative care and recovery time; varying patient ages, health conditions, and adjustment times to immunosuppressive medications; differences in recovery times between living and deceased donor transplants; and varying protocols and standards by hospital for post-transplant care.

FIGURE 4: ESTIMATED 2025 HOSPITAL LENGTHS OF STAY BY TRANSPLANT (DAYS)

TRANSPLANT	ESTIMATED 2025 HOSPITAL LENGTH OF STAY	TRANSPLANT	ESTIMATED 2025 HOSPITAL LENGTH OF STAY
SINGLE ORGAN/TISSUE		MULTIPLE ORGAN	
BONE MARROW – ALLOGENEIC	33.3	HEART-LUNG	74.7
BONE MARROW – AUTOLOGOUS	20.3	INTESTINE WITH OTHER ORGANS	73.1
HEART	40.6	KIDNEY-HEART	65.8
INTESTINE	63.2	KIDNEY-PANCREAS	11.5
KIDNEY	7.5	LIVER-KIDNEY	35.3
LIVER	20.2	OTHER MULTIPLE ORGAN	83.6
LUNG – SINGLE	25.7		
LUNG – DOUBLE	38.2		
PANCREAS	14.6		

ANNUAL NUMBER OF TRANSPLANTS

Figures 5 to 7 show the annual number of transplants performed (or estimated to be performed) in the United States from 2022 to 2025. These numbers include all ages and transplants for U.S. citizens and U.S. residents who are not citizens. We base Figures 5 and 6 on OPTN data as of November 12, 2024. We estimate the split of lung transplants between single and double lung using 2022 CHSD and 100% Medicare LDS (further discussed in Section 4 below) and our judgment. In Figure 7, we base the bone marrow estimates on 2021 HRSA data, while we base the cornea estimates on information from the 2023 Eye Banking Statistical Report.

FIGURE 5: SINGLE-ORGAN TRANSPLANTS PERFORMED IN THE UNITED STATES

YEAR	HEART	INTESTINE	KIDNEY	LIVER	LUNG – SINGLE	LUNG – DOUBLE	PANCREAS
2022	3,599	43	23,878	8,524	822	1,789	74
2023	3,990	46	25,599	9,570	730	2,190	59
2024*	4,153	47	26,289	10,470	809	2,427	69
2025*	4,109	48	28,092	10,916	909	2,398	64

* Milliman estimates.

FIGURE 6: MULTIPLE-ORGAN TRANSPLANTS PERFORMED IN THE UNITED STATES

YEAR	HEART-LUNG	INTESTINE WITH OTHER ORGANS	KIDNEY-HEART	KIDNEY-PANCREAS	LIVER-KIDNEY	OTHER MULTIPLE ORGAN
2022	51	38	384	804	777	119
2023	54	42	414	806	807	120
2024*	64	43	430	810	774	124
2025*	67	40	448	819	818	131

* Milliman estimates.

FIGURE 7: TISSUE TRANSPLANTS PERFORMED IN THE UNITED STATES

YEAR	BONE MARROW – ALLOGENEIC	BONE MARROW – AUTOLOGOUS	CORNEA
2022^	9,401	13,456	49,597
2023^	9,724	14,320	50,925
2024^*	9,515	14,167	51,817
2025^*	9,535	13,975	52,889

^ Milliman estimates (bone marrow).

* Milliman estimates (cornea).

3. Emerging issues and potential solutions

In this section, we present a variety of emerging innovations and issues for transplant stakeholders (e.g., hospitals, physicians, researchers, policymakers, insurance carriers, patients, and other innovators) to continue to consider, assess, and quantify, in the areas of benchmarking and contemporary market intelligence, organ transplant inequalities, organ availability, and organ viability, along with issues unique to bone marrow transplants. As emerging innovations, solutions, and efficiencies gain and sustain traction, Milliman is well-positioned to support efforts to better understand and project the implications for stakeholders on transplant use and costs across the following critical areas:

- Benchmarking and contemporary market intelligence
- Organ transplant distribution and inequalities
- Organ availability and viability
- Bone marrow transplant developments

BENCHMARKING AND CONTEMPORARY MARKET INTELLIGENCE

Contractual benchmarking / reviews and value-based contracting

Benchmarking is critical to assessing the reasonableness of current contracts in the transplant market and understanding any gaps, exposures, or market misalignment that may exist. Such reviews and updates may serve to realign contract terms, covered services, and definitions while mitigating emerging risks (e.g., use of chimeric antigen receptor T cell (CAR-T) therapies or high-cost drugs). Such assessments may also diagnose exposures and gaps in current reimbursement arrangements (e.g., case rates or other bundling), leading to updates that may reduce vulnerability to transplant cost volatility.

Actuarial contract analysis will be necessary under CMS' Increasing Organ Transplant Access Model (IOTA), a 6-year, mandatory model that begins on July 1, 2025. This model is designed to assess if two-sided performance-based payment in kidney transplantation will increase access to kidney transplants. The payment model goals are intended to improve access equity, decrease costs, and enhance end-stage renal disease quality of care for participating transplant hospitals. It is not yet known if commercial payers will adopt this same approach for kidney and other organ transplants.

Market-level utilization and cost experience assessments and projections

Customized experience analyses and projections by market may be valuable as actual utilization and costs (and their emerging trends) will vary by enrolled population, geographic area (at an OPTN region level or state level), and transplant center due to differences in provider reimbursement and varying volume and/or incidence of complications. Other factors to consider in emerging trend and experience might include changes in transplant center accreditation status, payer redefining (i.e., narrowing) of networks, and population movement. Tools are available to estimate and compare transplant utilization and expected charges across geographies and markets (commercial, Medicare, and Medicaid).

Analyses to identify markets that may be saturated or underserved, including disparities between the rates of transplantation and the demographic proportions in the population, may enhance understanding of certain market prospects and improve market positioning. Such assessments may also help guide decision-making that potentially drives changes in transplants and promotes greater accountability and transparency in organ distribution. Transplant recipient demographic splits by organ or tissue by age, gender, and/or race may also lend insight to transplant market opportunities and gaps.

ORGAN TRANSPLANT DISTRIBUTION AND INEQUALITIES

Improving access, reducing racial disparities, and kidney transplant focus

Accessing health services can be challenging and complicated by racial inequalities, with organ transplantation not immune to this concern. Achieving equity in the organ transplantation system has led to recommendations intended to create a fairer and more equitable system for donors and recipients.

Major gaps continue to exist in our knowledge about patients who need a transplant, but never enter the organ transplant pathway, with more research needed in this area to help identify opportunities to reduce inequalities related to access. While equity has been a goal of the transplantation system, stated goals and intentions have not always aligned with stakeholder actions for change in disadvantaged populations (i.e., ethnic minorities, individuals with disabilities, and/or lower-income individuals). In its 2023 report, “Realizing the Promise of Equity in the Organ Transplantation System,” the National Academies of Sciences, Engineering, and Medicine (NASEM) provided “expert recommendations to improve fairness, equity, transparency, and cost-effectiveness in the donor organ system.”

The NASEM has also suggested modifications to the distribution allocation process, as it appears that continuous distribution of organs has not been fully realized. Geographic barriers remain a factor in the OPTN distance to donor calculation and the NASEM recommended adjustments to that calculation to help reduce inequality in transplantation.

Kidney transplantation has been one area of particular focus:

- The United Network for Organ Sharing (UNOS), in its 2023 “6 Month Waiting Time Modification / 1 Year Race-Neutral eGFR Calculations Monitoring Report,” evaluated metrics associated with two community-driven policies aimed to address inequities for Black kidney candidates by requiring transplant programs to use calculations that did not include race variables and providing a pathway for waiting time modifications for Black kidney candidates who were affected by transplant program use of race-inclusive calculations.
- The NASEM has recommended eliminating the pre-dialysis waiting time variable in the kidney allocation calculation as an initiative to improve the volume of transplants. In the kidney allocation calculation, the pre-dialysis waiting time starts on the date the patient begins regularly administered dialysis and accumulates points. Elimination of the accrual pre-dialysis wait time may save more lives and preemptively get patients transplanted prior to being on dialysis, saving lives and money.

Artificial intelligence (AI) and big data

Questions loom related to how to leverage and optimize AI and big data to improve donor-recipient matching and predict outcomes. While considering such questions, stakeholders may concurrently work to ensure transparency and accountability in the organ transplant process and mitigate biases that could emerge in the use of AI and big data.

“Acuity circles” policy for liver and intestinal transplantation

This allocation policy was projected to increase equity and provide more consistent transplant access for the most urgent transplant candidates by minimizing the effect of donation service area and regional boundaries. Continuing trends, as documented in the findings in previous monitoring reports, appear to support several key modeling predictions and demonstrate an improvement compared with the previous policy in many important areas.

- Liver transplant gender disparities
Gender disparities may have historically existed between men and women requiring liver transplants due to certain limitations and inequities inherent in the Model for End-Stage Liver Disease (MELD) transplant scoring system that determines a patient's transplant urgency. MELD 3.0 (implemented in July 2023) built upon prior models with the goal to reduce disparities in organ allocation for those (particularly women) who may have faced disadvantages under prior models and to close the gap in access to liver transplants between men and women.
- Lung allocation equity
Effective September 2024, a new OPTN policy is intended to promote equity in lung priority by standardizing the six-minute walk test for lung allocation, with specific requirements for lung transplant programs to perform an oxygen titration test ahead of that six-minute walk test for lung candidates. This policy change may not necessarily change total lung transplant counts or costs but may reallocate lungs to different transplant candidates.

ORGAN AVAILABILITY

Default policy change to “opt out”

While significant energy has been directed at expanding donor registration pools to increase the number of organs available for transplant, opting out as the default policy alternative is garnering more interest, requiring an individual to explicitly opt out of organ donation (rather than opting in). Laws that would make organ donation the default option at the time of death, such that individuals must explicitly “opt out” of organ donation, have the potential to increase donation. A potential drawback to consider with such policies is the effect such policies could have on living donor transplants (currently a substantial source of kidney transplants in the United States and a growing source of liver transplants).

Streamlining “opt in” policies

If opt-in policies remain the default donor registration approach (i.e., donors must explicitly sign up to donate organs), then increased organ supply could develop with new or revised approaches that could include:

- Use of apps and online/digital platforms may provide information that facilitates donor registration. Simplified and more integrated processes may also make it easier for individuals to register as organ donors through such online platforms or via routine interactions with public services (e.g., driver's license renewals or tax filings).
- Training and educating healthcare providers and professionals on the importance of organ donation and how to approach families about donation in a sensitive and effective manner may help increase registration and donation.
- Public awareness and media campaigns may reach broader audiences, educate the public about the importance of organ donation and its life-saving potential, dispel myths and misconceptions about the process, and encourage (and increase) donor registration. Collaboration with community and religious leaders to address cultural and religious concerns about donation and to promote its acceptance may also raise awareness and support for donation.

Use of organs from donors infected with HCV and HIV

Hepatitis C virus (HCV): Facilities and providers may not use organs otherwise fit for transplant because the donor is infected with HCV. Facilities and providers may have historically discarded HCV-infected organs because of concerns about infecting the recipients of such organs and high HCV transmission rates to recipients. If HCV-positive organs emerge as a safe and effective option for most transplant candidates, particularly as newer antiviral drugs make it possible for patients to be successfully treated for HCV infections transmitted via organ transplant, such an approach has the potential to increase the number of organs available for transplantation.

HIV: As of November 2024, new rules from HHS allow those with HIV to receive a kidney or liver from a donor who is also infected with the virus (transplants where both donor and recipient were HIV-positive had only previously been allowed as part of a research study). While this rule change (as issued) is limited to kidney and liver transplants, HHS is soliciting comment on whether research rules on HIV-to-HIV organ transplants may need revising for other organs, potentially increasing the number of organs available for transplantation.

Efforts to remove financial barriers to living organ donation

Proposed laws are emerging to protect living donors and help ensure such donors receive adequate medical care, financial support, and job protection during the donation and recovery process. These measures aim to encourage more people to become living donors. Proposed HHS/HRSA rules would amend the OPTN final rule to remove financial barriers to living organ donation by expanding the allowable costs that are reimbursable.

Proposals have also noted that reimbursement of lost wages and child and elder care expenses could increase the number of living organ donor transplants, and more patients receiving transplants may save on total Medicare and Medicaid expenses. Estimates of total net savings or costs for full implementation of such proposals would need assessment and validation, including the effect of the implementation of such policies in the commercial (non-Medicaid/non-Medicare) market.

Kidney paired donation (KPD) or paired kidney exchange

Kidney paired donation (KPD), or paired kidney exchange, is an emerging approach to living donor kidney transplants to expand the donor pool and reduce recipient time on waiting lists. KPDs occur when patients with incompatible donors swap kidneys to receive a compatible kidney, resulting in multiple live donor transplants, improved organ compatibility, and increased overall transplant quality. A “kidney chain” describes exchanges involving more than two recipients and kidney transplant chains may exceed 100 donations.

ORGAN VIABILITY

Rejuvenation of marginal organs for transplantation

Even with the significant disparity between the number of patients waiting for an organ and the number of organs available, some donated organs (particularly lungs) may be rejected for transplantation because the organs may not be suitable for transplantation (i.e., “marginal”). The reasons for organ rejection vary and may include organ trauma, edema, inflammation, and donor comorbidities that lead to poor organ viability. Transplant centers may hesitate to use marginal organs because their use could contribute to increased health risks (e.g., rejection, stroke) for the organ recipient following the transplant.

Researchers are studying organs rejected for transplantation and using new processes, technologies, and innovations to repair and rejuvenate those organs to make them healthy enough for use in transplants. While researchers may still need to clear various technical, financial, reimbursement, and ethical hurdles associated with these innovations, such initiatives may offer greater hope soon for patients awaiting transplants.

Preservation, organ perfusion machines use and reimbursement, and improved organ transportation

Researchers are studying new ways to preserve organs for longer periods of time, which could potentially increase the number of available organs for transplant.

Most of this research involves the use of perfusion machines that keep the donated organ viable for transplantation. Innovations in perfusion technology and related devices may be able to facilitate broader geographic sharing of organs, as use of emerging systems may allow for transportation of certain organs thousands of miles to recipients.

Monitoring the use and reimbursement associated with perfusion machines will be important, particularly if their use becomes more widespread. The machines also have the potential to increase available donors by supporting the use of donation after circulatory death (DCD) hearts by reviving and supporting the recovery of non-beating hearts.

Drone delivery of certain organs that tolerate less time on ice (e.g., hearts and lungs) may also represent an emerging opportunity to increase transplants, assuming landing gear can be created to protect fragile organs. The opportunity for drone use in the transplant space may be to carry organs to locations for repairs needed to make the organ ready for transplant and expand the pool of organs available for use.

Xenotransplantation and gene editing

With xenotransplantation, the use of animal organs or cell lines facilitates regenerative tissue for use in creating new organs, with the goal to eventually progress to the use of human stem cells to create a new organ. Xenografts have the potential advantages of lower cost and increased availability, though the efficiency of these organs is not as great as human organs, and the immunosuppression make them less viable than allogenic or autologous human organs.

Recent porcine xenotransplant cases have provided insight and advancements to making more organs available for transplantation and use of this biomedical engineering technique will need to be priced into the services provided by transplant centers. Innovations that may continue progress in reducing human rejection, mitigating the spread of pig viruses to people, and decreasing other complications will also need to be quantified.

Other bioengineering medicine

Other innovations are also emerging in attempts to address the shortage of donated organs. Emerging strategies related to bioengineering medicine include using body tissue together with 3D molding and printing and working with discarded human donor kidneys. Scientists are also working on bioartificial organs, which are semisynthetic organs grown from human cells that can perform the functions of the organ they replace. Complex, solid organs such as the kidney, lung, and heart appear to remain a challenge in the field of regenerative medicine.

Scientists are also investigating the use of stem cells to repair or regenerate damaged organs and tissues, potentially eliminating the need for a transplant, while the use of autologous stem cells might avoid use of immunosuppressant medicine.

Research also continues around immune tolerance induction to develop methods to induce immune tolerance in transplant recipients, which would reduce or eliminate the need for lifelong immunosuppressive drugs. In a related topic, personalized medicine and genomic advances may allow for tailoring of immunosuppressive therapies to individual patients, as well as improved matching of donors and recipients and accuracy in predicting transplant outcomes.

Post-transplant acute allograft rejection surveillance

Donor-derived cell-free DNA (dd-cfDNA) laboratory monitoring is an innovation that offers patients non-invasive detection of the graft (organ) cell death in the bloodstream as an alternative to more invasive and costly biopsy procedures. Such diagnostics are used on a regular basis while patients live with their transplants and, without these diagnostic tools, timely and accurate detection of graft rejection cannot occur to possibly preserve the organ. Among the factors in assessing the diagnostic to use, payer coverage decisions should consider patient and clinical choice.

BONE MARROW TRANSPLANT DEVELOPMENTS

Beyond any of the above issues and solutions that bone marrow transplants may share with solid organ transplantation, additional developments and emerging issues and solutions specific to bone marrow transplants warrant monitoring for their use and effects on the transplant market.

Alternatives to traditional bone marrow transplants and matching that may warrant monitoring and impact bone marrow transplant use and costs include:

- Haploidentical transplants (a type of allogeneic transplant), which allow use of a family member as a half-match donor to increase the number of potential donors for patients.
- Cord blood transplants (given cord blood's richness in stem cells) may be another alternative to bone marrow transplants. Such blood can be collected and stored at birth and may be easier to match than bone marrow.
- Reduced-intensity transplants (i.e., non-myeloablative transplants) use lower doses of chemotherapy and radiation pretransplant to make the procedure more viable for older patients and those with other health issues.
- Micro-transplantation involves transplanting stem cells from a donor's blood without the need for immune suppression in the recipient.

Other medical advancements whose emerging effects and risks may need evaluation include:

- Use of gene therapy in conjunction with bone marrow transplants to treat certain genetic disorders.
- CAR-T cell therapy (a patient's own immune cells are genetically modified to fight cancer) used in conjunction with bone marrow transplants and any accompanying risks of such therapies (e.g., the potential secondary T-cell cancer risk for patients treated with CAR-T cell therapy).

SECURING THE U.S. ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK ACT

A key factor overarching all transplant-related issues is the pending effect of the Securing the U.S. Organ Procurement and Transplantation Network (OPTN) Act, signed into law in September 2023. This Act allows for the award of multiple grants, contracts, or cooperative agreements to operate the OPTN (moving away from sole reliance on UNOS) to improve management and outcomes of the U.S. organ donation system and encourage participation from various contractors. This Act also grants the HRSA statutory authority to improve management of the U.S. organ transplantation system. Congressional funding levels will shape the scope and pace of work completed.

4. Other data and potential analysis opportunities

ACTUAL MARKET PRICES WILL VARY FROM MILLIMAN BILLED CHARGES

“Charges” in this report refer to the amounts billed based on the information available. Billed charges are unlikely to equal the actual amount paid for the transplant services due to the presence of negotiated reimbursement arrangements such as case rates, prescribed fee schedules, discounts, or other agreements in place.

We did not research the actual reimbursement that hospitals and physicians receive for providing transplants because such values involve proprietary contractual arrangements. Significant reductions from billed charge levels may be achieved and the chances for successful treatment may be improved by directing patients to specific centers. Actual charges will also vary for private insurers, Medicare, or Medicaid.

The transplant billed charge estimates also do not reflect differences in charges due to patient age. Billed transplant charges may vary for pediatric patients, adults under the age of 65, and patients of ages 65 and over.

Negotiated case rates may bundle certain services (e.g., hospital and physician) into one charge. Procurement charges may be included in negotiated case rates, but procurement charges usually reflect only slight, if any, discounts from billed levels. Case rates may not typically cover pretransplant medical services and maintenance therapy outpatient immunosuppressants. Some case rates may include follow-up costs within a specified period, such as the first 90 days after discharge.

Some transplant centers address charge variation by developing separate payment rates by diagnosis or by patient disease state. We did not adjust our billed charge estimates to reflect diagnosis, disease state, or other variables specific to a given situation.

An outlier provision may provide additional payment beyond the case rate after a specified number of days in the hospital or after a certain level of billed charges. The outlier provision may pay for hospital days at a discount from billed charges or at a per diem rate. Centers may also have outlier payments for physician services.

Actual outpatient immunosuppressant charges will vary from our billed charge estimates for several reasons:

- Actual hospital lengths of stay will vary and affect the time that outpatient immunosuppressants are required.
- Drug discounts will vary and yield different estimates.
- Actual dosing regimens will vary from the dosing regimens assumed.
- The use and prevalence of outpatient immunosuppressant regimens will vary from our estimates.

Charges may continue after the first year and may include continued testing and evaluation, medical services for transplant rejection, and outpatient immunosuppressants.

ACTUAL COSTS COMPARED TO MILLIMAN COSTS

As mentioned in Section 2 above, “cost” means the product of utilization and *billed* charges. Actual transplant costs PMPM may vary from our estimates for a variety of reasons beyond the scope of our report. Any estimate of costs after the first year should reflect adjustments for trend, survival, and probability of re-transplantation. Reasons for variations from these report estimates that may warrant further exploration and may be supportable with research include:

- The cost estimates assume full insurance coverage. Patient cost-sharing and benefit limitations would reduce full coverage costs (with shifts in costs to the patient).
- Costs may vary by transplant, geographic area, and transplant center due to differences in volume, complexity, and/or baseline diagnoses coupled with incidence and severity of complications, among other factors:
 - Transplants such as intestine and multiple organ transplants may demonstrate greater annual volatility in their utilization and costs due to their smaller volumes and fewer centers performing such transplants
 - Complexity (e.g., donor procurement costs and technology and care intensity needs) will vary by transplant
 - Single and double lung transplant cost differences (as an example) may be driven, at least in part, by the diagnoses underlying each recipient group

- Changes in the average number of organs procured per donor and the number of centers may change costs, if suitable donor organs and tissue can continue to be found.
- Private insurance, Medicare, Medicaid, and uninsured transplant costs may vary. For example, Medicare covers a significant portion of kidney transplants through the End-Stage Renal Disease (ESRD) program.
- Federal and state legislative efforts and private initiatives may change utilization and costs.
- Changes in selection criteria may affect costs.
- Costs may vary by underlying diagnosis and/or disease state.
- Medical management may reduce costs, particularly with respect to hospital charges. Costs may also decrease with use of other cost-control mechanisms such as greater donor and recipient selectivity by centers, critical pathways to reduce inpatient lengths of stay, and aggressive use of outpatient therapies and other more cost-effective treatments.
- Cost estimates may change if the OPTN data and other supporting data changes due to future data submissions or corrections.
- Wide availability of mechanical, artificial, or cloned organs, experimental procedures becoming accepted practice, or other innovations may affect costs.
- Administration costs and profit margins will vary. We did not consider such information in our analysis.

BILLED CHARGE COMPONENT DETAILS

Additional details underlying certain components that comprise total billed charges include the following:

- **30 days pretransplant:** These billed charges could include a history of the candidate, which may note indications and contraindications for the transplant; comprehensive physical, psychological, and laboratory evaluations, including blood and tissue typing and serum and cell compatibility matching; crossmatching for donor compatibility; hepatitis and HIV (human immunodeficiency virus) screening; antibody screening; medical and psychological testing; lab tests; and x-rays. Due to the period between evaluation and transplant, evaluation costs are exceedingly difficult to identify in claim databases, which are our primary source of billed charge data. Therefore, it is not practical to separate these billed charges into those related and not related to the transplant because of the short 30-day timeframe.
- **Hospital transplant admission:** Any readmissions within 180 days of the transplant discharge date are included in the “180 Days Post-Transplant Discharge” component, whether related to the transplant or not. Hospital services include room and board and ancillary services such as use of surgical and intensive care facilities, inpatient nursing care, pathology and radiology procedures, drugs, supplies, and other facility-based services. Hospital services may also include use of immunosuppressive and other drugs provided during the hospital stay.
- **180 days posttransplant discharge:** Services also include regular lab tests, regular outpatient visits, and evaluation and treatment of complications, and may be related and unrelated to the transplant.
- **Outpatient (OP) immunosuppressants and other Rx:** Antianxiety medications, antifungal antibiotics, antivirals, colony-stimulating factors, gastrointestinal drugs, hypertension drugs, and postoperative pain management drugs are examples of drugs other than OP immunosuppressants related to the transplant that a patient could also use in treatment.

OTHER POTENTIAL DATA ANALYSES

While this report has focused on estimates for average utilization, billed charges, and the resulting costs PMPM for organ and tissue transplants in the United States, we highlight below additional data analyses that could be developed to provide further insight into the transplant market.

Primary diagnoses and bone marrow graft sources

Organ and tissue transplants tend to have a few primary indications and diagnoses that remain relatively stable and make up most of the total transplants for the organ or tissue. Bone marrow transplants can be further classified according to graft source (bone marrow, peripheral blood stem cell, or cord blood stem cell), with autologous cord blood stem cells emerging as a graft source for ages younger than 21.

Costs will vary by underlying diagnosis and/or disease state, perhaps significantly. Where the diagnosis or disease state is critical (e.g., pharmaceuticals in development and potentially being positioned as an alternative to bone marrow transplants for certain cancers), further investigation into transplant charge differences by diagnosis and disease state may provide clarity unaddressed by the scope of this report.

Waiting times

Waiting times reflect a patient who has been registered on a waiting list and accounts for all events that can happen to the patient after wait-listing, such as receiving a transplant, being removed from the waiting list, and dying. Longitudinal studies of transplant waiting times by organ may highlight wait time variations as well as where improvements have occurred or, in the case of increasing waiting times, where work needs to be done and needs remain unaddressed. Waiting times may also vary for characteristics that a separate review may be able to quantify (e.g., changing demographic characteristics of the underlying wait-listed individuals).

Survival rates

Patient survival rate studies by transplant and timeframe (e.g., one-, three-, and five-year) may be another review tool to better understand where improvements may be emerging and where opportunities for improvement remain. Where survival rates may be decreasing over time, research into transplant outcomes and underlying factors may be able to clarify drivers of the indicated outcomes.

Donor data and analytics

With demand for transplants continuing to grow, the supply of transplants via donation continues to be a critical issue, as noted among the emerging issues and solutions in the prior section of this report. Studies of donor transplants (deceased and/or living) over time may indicate emerging trends and areas for missed opportunities and potential growth.

Living donor transplants are typically smaller in number relative to deceased donations and primarily include kidney, liver, and bone marrow. A donor may live with one kidney with little danger because the remaining kidney enlarges to do the work that both kidneys previously shared, while the liver can regenerate a donated segment.

Among other transplants with living donation, living lung donors have a segment of one lung removed for transplants. Lung lobes do not regenerate the donated segment, but the average decrease in the living donor's lung capacity generally yields minimal physical limitations for the donor. Intestine, pancreas, and kidney-pancreas transplants can also use living donors.

BACKGROUND ON DATA SETS

We used the Milliman CHSD and the 100% Medicare LDS for the underlying basis of the cost estimates. The CHSD data set includes commercial market members' claims and enrollment across all states, with several national and regional health plans contributing their claims detail and annual enrollment (over 52 million commercially insured lives). The CHSD data set also includes 30 International Classification of Diseases (ICD) codes, filtered to transplant-related categories to create a transplant database. The 100% Medicare LDS includes Part A experience for all Medicare beneficiaries with 25 ICD codes, filtered to transplant-related categories to create a transplant database.

5. Figure index

FIGURE 1: ESTIMATED U.S. AVERAGE 2025 BILLED CHARGES, UTILIZATION, COSTS PMPM, AND HOSPITAL LENGTHS OF STAY BY TRANSPLANT	2
FIGURE 2: ESTIMATED U.S. AVERAGE 2025 TRANSPLANT COSTS PMPM, BILLED CHARGES, AND UTILIZATION	4
FIGURE 3: ESTIMATED U.S. AVERAGE 2025 BILLED CHARGES PER TRANSPLANT BY COMPONENT OF CARE	5
FIGURE 4: ESTIMATED 2025 HOSPITAL LENGTHS OF STAY BY TRANSPLANT (DAYS)	6
FIGURE 5: SINGLE-ORGAN TRANSPLANTS PERFORMED IN THE UNITED STATES	7
FIGURE 6: MULTIPLE-ORGAN TRANSPLANTS PERFORMED IN THE UNITED STATES	7
FIGURE 7: TISSUE TRANSPLANTS PERFORMED IN THE UNITED STATES	7

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