MILLIMAN RESEARCH REPORT

2020 U.S. organ and tissue transplants: Cost estimates, discussion, and emerging issues

January 2020

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I. Overview

This 2020 report represents Milliman's triennial summary of estimated U.S. average utilization, billed charges, and resulting per member per month (PMPM) costs for organ and tissue transplants. The report covers estimates for the period ranging from 30 days prior to 180 days after admission for organ and tissue transplants treatment.

Highlights of this report include information from the following sections:

Section II

- We estimate the 2020 PMPM costs based on billed charges to be $11.22 and $16.48 for the under-65 and 65-and-over populations by age, respectively. These PMPM costs reflect average annual increases of 11.0% and 10.5%, respectively, from our 2017 report.
- There is a wide range of annual changes in utilization and billed charges by type of transplant, relative to our 2017 report. Multiple organ transplants tend to demonstrate greater year-to-year utilization volatility due to their smaller numbers. Average annual changes to billed charges vary less than utilization for the under-65 population, relative to our 2017 report.
- Hospital lengths of stay have been fairly stable for most transplants since our 2017 report, with small increases shown for most transplants.

Section IV

- Average waiting times increased for a number of transplants since our 2017 report, with heart and intestine transplant waiting times increasing by 22 and 43 days, respectively. Average waiting times for liver, pancreas after kidney, and kidney-pancreas decreased since our 2017 report, by amounts ranging from three days (liver) to 24 (kidney-pancreas).
- In general, survival rates appear to have decreased slightly from those in our 2017 report, based on the data available. Intestine and pancreas transplants appear to show greater decreases in survival rates than other transplants, in comparison to our 2017 report. We are not aware of explanations for these apparent decreases. Research into transplant outcomes is beyond the scope of this report.

Section VII:

- We highlight emerging innovations and issues to consider related to organ viability and organ availability and policy. We expect to assess and evaluate the implications of emerging innovations and solutions for organ transplant utilization and costs as those innovations and solutions continue to emerge and gain traction, and as data becomes available for assessment and evaluation.

Organ transplants include single-organ transplants such as heart, intestine, kidney, liver, lung, or pancreas, as well as a number of multiple-organ transplants, while tissue transplants include bone marrow and cornea transplants. 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.

Estimated billed charges and resulting PMPM cost estimates in this report may not be the actual amounts paid for transplant services. The use of case rates, discounts, or other negotiated reimbursement arrangements may result in significant reductions from billed charge levels. Actual charges will likely vary for private insurers, Medicare, or Medicaid. For billed charges pre- and post-transplant admission, we include the costs for all medical services associated with the transplant patient.

II. Costs PMPM, billed charges, and utilization

The table in Figure 1 summarizes the estimated U.S. average 2020 transplant costs PMPM for the under-65 and 65-and-over populations by age, based on the product of utilization and billed charges. The table in Figure 2 summarizes the estimated U.S. average 2020 billed charges per transplant.

The estimated number of transplants shown in Figure 1 reflects transplants provided to U.S. citizens and U.S. residents who are not U.S. citizens. To determine utilization rates, we assume 2020 U.S. under-65 and 65-and-over population estimates by age of 276.6 million and 56.1 million, respectively. We relied on the U.S. Census Bureau's 2017 population projections series for these 2020 population estimates. The 2017 population projections series uses official estimates of the resident population on July 1, 2016, to project the U.S. population from 2017 to 2060 and includes projections by age group.

Billed charges for pre-transplant, follow-up, outpatient (OP) immunosuppressants, and other drugs used in both our 2017 and 2020 reports cover the period from 30 days pre-transplant to 180 days post-transplant discharge for follow-up and outpatient immunosuppressant and other drugs. Note that for these categories we include the costs for all medical services associated with the transplant patient, not just those related to the transplant.

FIGURE 1: ESTIMATED U.S. AVERAGE 2020 TRANSPLANT COSTS PMPM

			Under Age 65			Ages 65 and Over		
Transplant	Total Estimated Number of Transplants	Estimated Billed Charges	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 - Allogenic	9,950	$1,071,700	8,258	29.86	$2.67	1,692	30.19	$2.70
Bone Marrow - Autologous	14,745	471,600	10,616	38.38	1.51	4,129	73.67	2.90
Cornea	53,065	32,500	18,573	67.15	0.18	34,492	615.37	1.67
Heart	3,499	1,664,800	2,869	10.37	1.44	630	11.24	1.56
Intestine	38	1,240,700	37	0.13	0.01	1	0.02	0.00
Kidney	21,963	442,500	17,131	61.94	2.28	4,832	86.21	3.18
Liver	8,219	878,400	6,411	23.18	1.70	1,808	32.26	2.36
Lung - Single	821	929,600	575	2.08	0.16	246	4.39	0.34
Lung - Double	2,011	1,295,900	1,408	5.09	0.55	603	10.76	1.16
Pancreas	126	408,800	124	0.45	0.02	2	0.04	0.00
Multiple Organ								
Heart-Lung	35	2,637,200	34	0.12	0.03	1	0.02	0.00
Intestine with Other Organs	58	1,662,900	56	0.20	0.03	2	0.04	0.01
Kidney-Heart	238	2,644,600	192	0.69	0.15	46	0.82	0.18
Kidney-Pancreas	900	713,800	895	3.24	0.19	5	0.09	0.01
Liver-Kidney	807	1,355,100	613	2.22	0.25	194	3.46	0.39
Other Multi-Organ	79	2,185,800	74	0.27	0.05	5	0.09	0.02
TOTAL					**$11.22**			**$16.48**

BILLED CHARGES

Figure 2 shows estimated U.S. average 2020 billed charges per transplant. We define the categories making up the total billed charges below.

- **30 days pre-transplant:** These billed charges include all medical costs that 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. 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; cross-matching for donor compatibility; hepatitis and HIV 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 time period defined.
- **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. Any readmissions within 180 days of the transplant discharge date are included in the "180 Days Post-Transplant Discharge" category, 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.
- **Physician services during transplant admission:** This category includes billed charges for professional services while the recipient is hospitalized for the transplant, including surgery procedures and other services identified by Current Procedural Terminology (CPT) or Healthcare Common Procedure Coding System (HCPCS) procedure codes.
- **180 days post-transplant discharge:** This category covers post-discharge facility and professional services, including any hospital readmissions. Services may also include regular lab tests, regular outpatient visits, and evaluation and treatment of complications. These services can include both those related and not related to the transplant.
- **OP immunosuppressants and other Rx:** This category includes all outpatient drugs prescribed from discharge for the transplant admission to 180 days post-transplant discharge, including immunosuppressants, other drugs related to the transplant, and other drugs not related to the transplant. Anti-anxiety medications, antifungal antibiotics, antivirals, colony-stimulating factors, gastrointestinal drugs, hypertension drugs, and post-operative pain management drugs are examples of drugs other than outpatient immunosuppressants related to the transplant that a patient could also use in treatment.

FIGURE 2: ESTIMATED U.S. AVERAGE 2020 BILLED CHARGES PER TRANSPLANT

Transplant	30 Days Pre-Transplant	Procurement	Hospital Transplant Admission	Physician During Transplant Admission	180 Days Post-Transplant Discharge	OP Immuno-Suppressants & Other Rx	Total
Single Organ/Tissue							
Bone Marrow - Allogenic	$71,300	$81,600	$537,900	$27,700	$319,300	$33,900	$1,071,700
Bone Marrow - Autologous	66,000	16,000	257,500	11,800	96,700	23,600	471,600
Cornea	NA	NA	23,300	9,200	NA	NA	32,500
Heart	49,800	131,500	1,062,600	111,100	270,300	39,500	1,664,800
Intestine	32,000	107,000	705,700	73,900	298,000	24,100	1,240,700
Kidney	32,700	113,900	152,300	26,200	85,500	31,900	442,500
Liver	46,200	104,200	490,600	59,200	140,200	38,000	878,400
Lung - Single	32,100	110,100	523,700	55,100	165,300	43,300	929,600
Lung - Double	45,000	127,700	759,800	77,200	231,500	54,700	1,295,900
Pancreas	17,900	111,800	151,000	23,900	77,700	26,500	408,800
Multiple Organ							
Heart-Lung	86,900	298,900	1,703,300	144,900	350,400	52,800	2,637,200
Intestine with Other Organs	68,100	284,900	837,500	99,000	327,200	46,200	1,662,900
Kidney-Heart	133,300	175,100	1,611,500	173,300	466,700	84,700	2,644,600
Kidney-Pancreas	37,400	185,000	295,200	39,500	124,300	32,400	713,800
Liver-Kidney	88,400	187,800	696,200	88,400	238,000	56,300	1,355,100
Other Multi-Organ	95,500	213,500	1,302,000	144,500	367,300	63,000	2,185,800

BASIS OF UTILIZATION AND BILLED CHARGE ESTIMATES

We base utilization estimates on data from the U.S. Organ Procurement and Transplantation Network (OPTN), the Scientific Registry of Transplant Recipients (SRTR), 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 approved 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. Department of Health and Human Services (HHS), nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. government.

We base the procurement and hospital billed charge estimates on 2017 and prior state hospital data available, then project trend to 2020 and normalize the state-specific data to a national average basis using Milliman area relativity research and our judgment. State data availability varies by year and states may restate prior years of data. A majority of states may not have or make hospital data available for our use.

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

Our bone marrow billed charge estimates do not reflect any charges from outpatient treatment because we lack sufficient outpatient bone marrow data.

We develop cornea hospital billed charges from 2017 and prior Wisconsin hospital outpatient data available, then project trend to 2020 and normalize the state-specific data to a national average basis using Milliman area relativity research and our judgment.

We assume no outpatient immunosuppressant charges for autologous bone marrow and cornea transplants. For all other transplants, outpatient immunosuppressant billed charges begin after our estimated date of discharge, which we base on 2017 hospital lengths of stay, trended to 2020. We base the average wholesale prices on the Medi-Span database, the MarketScan commercial database, and our judgment to project these billed charges to 2020. Average dosing regimen assumptions reflect clinical pharmacology and our judgment. We base average immunosuppressant use by drug assumptions on the Scientific Registry of Transplant Recipients 2017 Annual Data Report.

HOSPITAL LENGTHS OF STAY

The table in Figure 3 shows that estimated hospital lengths of stay have been fairly stable for most transplants since our 2017 report, with small increases shown for most transplants.

FIGURE 3: HOSPITAL LENGTHS OF STAY BY TRANSPLANT (DAYS)

Transplant	2017 Milliman Research Report, Based on State Databases Through 2014	2020 Milliman Research Report, Based on State Databases Through 2017
Single Organ/Tissue		
Bone Marrow - Allogenic	33.8	34.3
Bone Marrow - Autologous	19.8	19.8
Heart	48.6	49.2
Intestine	42.5	52.1
Kidney	6.8	6.7
Liver	20.4	21.1
Lung - Single	22.4	23.4
Lung - Double	28.3	31.4
Pancreas	10.5	10.4
Multiple Organ		
Heart-Lung	63.6	67.4
Intestine with Other Organs	75.6	77.9
Kidney-Heart	81.6	85.6
Kidney-Pancreas	10.8	11.1
Liver-Kidney	32.9	32.8
Other Multi-Organ	46.7	75.5

ANNUAL NUMBER OF TRANSPLANTS

The tables in Figures 4 to 6 show the annual number of transplants performed in the U.S. from 2016 to 2020. These numbers include all ages and transplants for U.S. citizens and U.S. residents who are not citizens. We project increases in the number of most transplants from 2019 to 2020 because of estimated population increases, even though the estimated transplant rate per million people may decrease for certain transplants.

We base Figures 4 and 5 on OPTN data as of October 31, 2019. We estimate the split of lung transplants between single and double lung using 2017 state hospital databases and our judgment. We base the bone marrow estimates in Figure 6 on HRSA data. We base the cornea estimates in Figure 6 on information from the 2018 Eye Banking Statistical Report.

FIGURE 4: SINGLE-ORGAN TRANSPLANTS PERFORMED IN THE U.S.

Year	Heart	Intestine	Kidney	Liver	Lung-Single	Lung-Double	Pancreas
2016	3,006	62	17,919	6,928	605	1,694	138
2017	2,993	43	18,656	7,156	553	1,858	152
2018	3,132	37	19,934	7,366	767	1,706	128
2019*	3,321	29	22,088	8,014	802	1,871	106
2020*	3,499	38	21,963	8,219	821	2,011	126

* Milliman estimates

FIGURE 5: MULTIPLE-ORGAN TRANSPLANTS PERFORMED IN THE U.S.

Year	Heart-Lung	Intestine with Other Organs	Kidney-Heart	Kidney-Pancreas	Liver-Kidney	Other Mutli-Organ
2016	18	75	140	798	717	35
2017	29	54	186	785	736	48
2018	32	63	199	834	667	69
2019*	43	49	220	880	704	83
2020*	35	58	238	900	807	79

* Milliman estimates

FIGURE 6: TISSUE TRANSPLANTS PERFORMED IN THE U.S.

Year	Bone Marrow - Autologous	Bone Marrow - Allogenic	Cornea
2016	12,936	8,830	49,869
2017	13,423	9,237	50,934
2018	13,531	9,511	51,294
2019*	14,251	9,668	52,136
2020*	14,745	9,950	53,065

* Milliman estimates

REGIONAL DISTRIBUTION OF TRANSPLANTS

The table in Figure 7 shows the distribution of transplants performed in the U.S. in 2019 based on the OPTN regional structure. We base the table on OPTN data as of October 31, 2019. The table reflects the U.S. Census Bureau's resident population census estimates as of July 1, 2010, projected to 2019. Regional numbers and distribution by region could change for various reasons, including changes in transplant center accreditation status and payer narrowing of networks, among other factors.

Region 2 (Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, and West Virginia) and Region 9 (New York and Western Vermont) have the highest transplants per capita in the U.S., driven by high kidney transplant utilization. Region 6 (Alaska, Hawaii, Idaho, Montana, Oregon, and Washington) has the lowest transplants per capita in the U.S.

FIGURE 7: 2019 UTILIZATION (PER 1,000,000) OF TRANSPLANTS BY OPTN REGION

Transplant	Region 1	Region 2	Region 3	Region 4	Region 5	Region 6	Region 7	Region 8	Region 9	Region 10	Region 11
Single Organ											
Heart	10.6	7.9	6.3	7.4	8.3	5.0	10.7	9.9	9.7	8.0	11.2
Intestine	0.0	0.2	0.0	0.0	0.0	0.1	0.0	0.1	0.3	0.1	0.0
Kidney	52.4	69.0	51.7	57.7	53.7	38.4	59.2	59.8	67.9	53.9	57.3
Liver	18.2	24.8	21.5	21.2	19.2	12.2	20.9	21.9	19.2	22.5	18.7
Lung (Single and Double)	4.8	10.6	4.4	7.0	6.8	2.6	6.2	7.5	6.6	10.0	7.5
Pancreas	0.3	0.5	0.2	0.2	0.1	0.0	1.0	0.3	0.3	0.1	0.2
Multiple Organ											
Heart-Lung	0.1	0.2	0.1	0.1	0.1	0.0	0.0	0.0	0.3	0.1	0.0
Intestine with Other Organs	0.0	0.3	0.2	0.0	0.0	0.1	0.0	0.1	0.2	0.5	0.0
Kidney-Heart	1.0	0.4	0.2	0.5	0.7	0.1	0.6	0.2	0.7	0.6	1.0
Kidney-Pancreas	0.4	3.4	2.4	1.2	1.7	1.0	4.4	2.0	3.0	1.7	2.7
Liver-Kidney	1.1	1.7	1.9	2.0	2.1	0.6	1.9	1.9	1.6	2.4	1.2
Other Multi-Organ	0.1	0.3	0.1	0.3	0.3	0.1	0.4	0.0	0.2	0.3	0.1

OPTN Regions:

Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Eastern Vermont

Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia

Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico

Region 4: Oklahoma, Texas

Region 5: Arizona, California, Nevada, New Mexico, Utah

Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, Washington

Region 7: Illinois, Minnesota, North Dakota, South Dakota, Wisconsin

Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, Wyoming

Region 9: New York, Western Vermont

Region 10: Indiana, Michigan, Ohio

Region 11: Kentucky, North Carolina, South Carolina, Tennessee, Virginia

BONE MARROW CLASSIFICATIONS

The table in Figure 8, based on data from the Center for International Blood and Marrow Transplant Research (CIBMTR), shows that bone marrow transplants can be classified according to graft source: bone marrow, peripheral blood stem cell, or cord blood stem cell. Generally speaking, allogeneic bone marrow cell graft use continues to increase while peripheral blood stem cells remain the dominant graft source for autologous transplants. Autologous cord blood stem cells also emerged as a graft source for ages younger than 21 (about 8%, compared to 0% in our 2017 report).

FIGURE 8: BONE MARROW TRANSPLANT GRAFT SOURCES, 2012-2016

	Graft Sources		
Age at Time of Transplant	Bone Marrow	Peripheral Blood Stem Cell	Cord Blood Stem Cell
Autologous			
Under 21	About 1%	About 91%	About 8%
21+	About 0%	About 100%	About 0%
Allogenic			
Under 21	About 57%	About 23%	About 20%
21+	About 14%	About 80%	About 6%

Source: Table 20. 2015 CIBMTR Transplant Activity Report Covering 2009-2013

ACTUAL COSTS COMPARED TO MILLIMAN COST ESTIMATES

As mentioned in Section II, "cost" means the product of utilization and billed charges. We did not research the actual reimbursement that hospitals and physicians receive for providing transplants, because such values involve proprietary contractual arrangements. Actual transplant costs PMPM may vary from our estimates for a variety of reasons that are beyond the scope of our report, including:

- The transplant cost estimates assume full insurance coverage; patient cost-sharing and benefit limitations would reduce full coverage costs.
- Costs may vary by geographic area and transplant center due to volume or incidence of complications.
- Changes in the average number of organs procured per donor and number of centers may change costs, as long as suitable donor organs and tissue can continue to be found.
- Private insurance, Medicare, Medicaid, and uninsured recipient costs may vary by transplant. For example, Medicare covers a significant portion of kidney transplants through the End-Stage Renal Disease 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 decrease with use of 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.
- Wide availability of mechanical, artificial, or cloned organs, experimental procedures becoming accepted practice, or other innovations may affect costs.

- Cost estimates may change if the OPTN data and other data relied on changes due to future data submissions or corrections.
- Administration costs and profit margins will vary, and we did not consider such information in our analysis.
- Any estimate of costs after the first year should reflect adjustments for trend, survival, and probability of re-transplantation.

ACTUAL CHARGES COMPARED TO MILLIMAN BILLED CHARGE ESTIMATES

"Charges" in this report refer to the amount billed, which may not be the actual amount paid for the transplant services due to the presence of case rates, discounts, or other negotiated reimbursement arrangements. Significant reductions from billed charge levels may be obtained and the chances for successful treatment may be maximized by directing patients to specific centers. Actual charges will likely vary for private insurers, Medicare, or Medicaid.

Negotiated case rates may combine hospital and physician charges. Procurement charges may be included in the negotiated case rate, but usually the procurement charges reflect only slight, if any, discounts from billed levels.

We have observed that case rates do not typically cover pre-transplant 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 do 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 from our estimates, which affects the amount of 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 actual use and prevalence of single and multiple outpatient immunosuppressant regimens will vary from our estimates.

The transplant billed charge estimates 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 ages 65 and over.

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

III. Primary diagnoses

The table in Figure 9 summarizes the most common primary indications for the organ and tissue transplants noted. Organ indications reflect data from the 2017 OPTN/SRTR Annual Report. The bone marrow indications reflect 2016 North American data from the CIBMTR 2018 Summary Slides. Cornea data relies on the 2018 Eye Banking Statistical Report.

Since our 2017 report, the order of the top indications generally remained the same for most transplants, while the magnitude of the top indications changed slightly for most transplants. In comparison to our 2017 report, the most common primary diagnosis and prevalence was the same for all transplants listed except liver transplants (with alcoholic liver disease replacing hepatitis C virus as the most common diagnosis and prevalence).

FIGURE 9: INDICATIONS FOR TRANSPLANT

Organ or Tissue	Most Common Primary Diagnosis and Prevalence	Second-Most-Common Primary Diagnosis and Prevalence	Third-Most-Common Primary Diagnosis and Prevalence
Single Organ/Tissue			
Bone Marrow - Allogenic	Acute Myelogenous Leukemia (38%)	Myelodysplastic Syndrome/ Myeloproliferative Disease (21%)	Acute Lymphocytic Leukemia (15%)
Bone Marrow - Autologous	Multiple Myeloma (62%)	Non-Hodgkin's Lymphoma (25%)	Hodgkin's Disease (7%)
Cornea	Endothelia Dystrophies^ (35%)	Repeat Corneal Transplant (12%)	Other Causes of Endothelial Dysfunction (11%)
Heart	Cardiomyopathy (60%)	Coronary Artery Disease (26%)	Congenital Disease (10%)
Intestine	Short Gut Syndrome: Other (62%)	Short Gut Syndrome: Congenital (10%)	Pseudo-obstruction (10%)
Kidney	Diabetes (28%)	Hypertension (21%)	Glomerulonephritis (18%)
Liver	Alcoholic Liver Disease (23%)	Malignancy (Hepatocellular carcinoma) (17%)	Hepatitis C Virus (12%)
Lung (Single and Double)	Restrictive Lung Disease - Idiopathic Pulmonary Fibrosis (57%)	Obstructive Lung Disease - COPD/Emphysema (27%)	Cystic Fibrosis (11%)
Pancreas	Diabetes Mellitus - Type I (65%)	Unknown/Other (35%)	NA
Multiple Organ			
Kidney-Pancreas	Diabetes Mellitus - Type I (83%)	Diabetes Mellitus - Type II (12%)	Unknown/Other (5%)

IV. Waiting times and survival rates

WAITING TIMES

The table in Figure 10 summarizes transplant waiting times in days by organ, based on data from the 2014 and 2017 OPTN/SRTR Annual Reports. The waiting times reflect a patient who has been registered on a waiting list and accounts for all of the events that can happen to the patient after wait listing, such as receiving a transplant, being removed from the waiting list, and dying. We do not show data for bone marrow transplants because we were unable to find a data source for tissue transplant waiting times.

The waiting times shown in Figure 10 are estimates of averages. For example, a candidate for a heart transplant has an average waiting time of 213 days.

Figure 10 also shows that waiting times vary by organ transplant over time, with waiting times for a number of transplants increasing since our 2017 report, some significantly (heart and intestine). Waiting times may also vary for other characteristics not shown.

FIGURE 10: WAITING TIMES BY TRANSPLANT

Organ	2017 Milliman Research Report, 2014 OPTN/SRTR Annual Report	2020 Milliman Research Report, 2017 OPTN/SRTR Annual Report
	Average Waiting Time in Days	
Heart	191	213
Intestine	181	224
Kidney	679	685
Liver	239	236
Lung (Single and Double)	185	186
Pancreas Alone	281	289
Pancreas after Kidney	532	514
Kidney-Pancreas	394	370

SURVIVAL RATES

The table in Figure 11 summarizes one-year, three-year, and five-year patient survival rates by transplant. The patient survival rates for organ transplants (using a 2011 through 2018 timeframe) appear to have generally decreased slightly from those in our 2017 report (which used a 2008 through 2015 timeframe). Intestine and pancreas transplants show greater decreases in survival rates in comparison to our 2017 report. We relied on OPTN/SRTR for the survival rates by organ transplant. Those survival rates reflect OPTN/SRTR data as of October 31, 2019, and December 31, 2016, for this report and for our 2017 report, respectively. OPTN/SRTR notes that data is subject to change based on future data submission or correction. We are not aware of explanations for the apparent decreases shown for survival rates, and research into transplant outcomes is beyond the scope of this report.

Bone marrow transplant survival rates are based on 2006 to 2016 CIBMTR survival rate data. Autologous and allogeneic survival rates may vary significantly by individual diagnosis, age, type of donor, and disease stage. We develop composite autologous bone marrow estimates reflecting survival rates for multiple myeloma, non-Hodgkin's lymphoma, Hodgkin's disease, and acute myelogenous leukemia, which represent more than 94% of all North American autologous bone marrow transplants in 2016.

The composite allogeneic bone marrow estimates we developed reflect survival rates for acute myelogenous leukemia, acute lymphoblastic leukemia, myelodysplasia, non-Hodgkin's lymphoma, aplastic anemia, chronic myelogenous leukemia, multiple myeloma, and Hodgkin's disease, which represent more than 91% of all allogeneic bone marrow transplants in 2016.

The CIBMTR has not reviewed or approved our composite survival estimates.

FIGURE 11: PATIENT SURVIVAL RATES BY TYPE AND YEAR OF TRANSPLANT

	One-Year		Three-Year		Five-Year	
Organ	**2017 Report***	**2020 Report***	**2017 Report***	**2020 Report***	**2017 Report***	**2020 Report***
Heart	91%	90%	85%	85%	78%	77%
Intestine	81	76	67	60	58	49
Kidney	97	95	93	88	86	78
Liver	91	89	83	80	75	72
Lung (Single and Double)	87	87	69	68	55	52
Pancreas	92	81	88	70	80	59
Heart-Lung	80	80	59	58	51	49
Kidney-Pancreas	98	96	95	89	88	81
Tissue	**2003-2013**	**2006-2016**	**2003-2013**	**2006-2016**	**2003-2013**	**2006-2016**
Bone Marrow - Autologous	90-94%	87-91%	72-76%	75-79%	61-65%	68-72%
Bone Marrow - Allogenic	65-69%	69-73%	48-52%	53-57%	46-50%	47-51%

* Milliman 2017 and 2020 U.S. organ and tissue transplant research reports

V. 2019 recipient demographics

The tables in Figures 12 and 13 highlight 2019 transplant recipient demographics. We base the demographic data and categories on OPTN/SRTR data as of October 31, 2019, for solid organs, and 2017 state hospital databases for bone marrow.

FIGURE 12: 2019 RECIPIENT DEMOGRAPHICS: SINGLE-ORGAN/TISSUE TRANSPLANTS

	Bone Marrow	Heart	Intestine	Kidney	Liver	Lung	Pancreas
Gender							
Male	58%	69%	40%	61%	64%	60%	48%
Female	42	31	60	39	36	40	52
Total	100%	100%	100%	100%	100%	100%	100%
Race							
White	63%	63%	64%	45%	71%	77%	72%
Black	12	21	24	27	7	10	16
Hispanic	14	11	12	19	16	10	10
Asian	4	3	0	7	4	2	1
Other	7	2	0	2	2	1	1
Total	100%	100%	100%	100%	100%	100%	100%
Age (At Time of Transplant)							
Under 1	0%	4%	0%	0%	2%	0%	0%
1-5	6	4	8	1	3	0	0
6-10	3	2	12	1	1	0	0
11-17	3	5	16	2	1	1	0
18-34	11	10	40	12	6	8	15
35-49	14	18	4	24	18	12	58
50-64	38	40	16	38	48	44	27
65+	25	17	4	22	21	35	0
Total	100%	100%	100%	100%	100%	100%	100%

FIGURE 13: 2019 RECIPIENT DEMOGRAPHICS: MULTIPLE-ORGAN TRANSPLANTS

	Heart-Lung	Intestine with Other Organs	Kidney-Heart	Kidney-Pancreas	Liver-Kidney	Other Multi-Organ
Gender						
Male	54%	60%	72%	62%	58%	67%
Female	46	40	28	38	42	33
Total	100%	100%	100%	100%	100%	100%
Race						
White	49%	65%	46%	49%	59%	60%
Black	27	21	35	30	13	22
Hispanic	19	12	12	17	21	14
Asian	5	0	5	3	4	3
Other	0	2	2	1	3	1
Total	100%	100%	100%	100%	100%	100%
Age (At Time of Transplant)						
Under 1	0%	9%	0%	0%	0%	0%
1-5	3	16	1	0	0	0
6-10	0	16	0	0	1	1
11-17	0	7	1	0	2	0
18-34	16	19	8	25	4	31
35-49	35	10	22	51	13	23
50-64	41	21	48	24	54	45
65+	5	2	20	0	26	0
Total	100%	100%	100%	100%	100%	100%

VI. Donor facts and data

DECEASED DONORS

Deceased donor data reflects only donors recovered by U.S. organ procurement organizations. United Network for Organ Sharing (UNOS) defines a recovered, deceased donor as one from whom at least one vascularized solid organ—heart, intestine, kidney, liver, lung, or pancreas—was recovered for transplantation. Hearts recovered for heart valves are not counted.

The table in Figure 14 summarizes deceased donor counts for transplants performed in the U.S. from 2016 to 2019, based on OPTN data as of October 31, 2019. As in Figures 1, 4, and 5 above, the heart, intestine, kidney, liver, lung, and pancreas transplants in Figure 14 do not include multiple-organ transplants with those organs. Heart-lung and kidney-pancreas transplants are the exception, as those transplants are tracked separately and only counted once. Unlike Figures 4 and 5, Figure 14 includes transplants provided to non-U.S. residents/non-U.S. citizens.

FIGURE 14: PRIMARY ORGAN TRANSPLANTS FROM DECEASED DONORS

Year	Heart	Intestine	Kidney	Liver	Lung	Pancreas	Heart-Lung	Kidney-Pancreas
2016*	3,031	67	12,544	6,668	2,314	139	18	798
2017	3,023	47	13,100	6,880	2,431	152	29	789
2018	3,161	37	13,821	7,052	2,504	128	32	835
2019**	2,794	25	12,944	6,316	2,258	88	37	738

* Single organ transplants do not include multiple organ transplants with those organs (a change from our 2017 report).
** 2019 counts based on OPTN data as of October 31, 2019, without projecting estimates for the remainder of the year.

LIVING DONORS

The most common transplants using living donors include bone marrow, kidney, and liver. A donor may live with one kidney with little danger because the remaining kidney enlarges to do the work that both kidneys previously shared. The liver can regenerate a donated segment.

Intestine, lung, pancreas, and kidney-pancreas transplants can also use living donors. 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.

Living donor data includes living donors from whom organs were transplanted in the U.S. The number of living donor transplants may differ from the number of living donors because living donors might donate segments from more than one organ, or there may be multiple donors for one transplant.

The table in Figure 15 summarizes living donor counts for transplants performed in the U.S. from 2016 to 2019, based on OPTN data as of October 31, 2019. Like As in Figures 1, 4, and 5 above, the intestine, kidney, and liver transplants do not include multiple-organ transplants with those organs. Lung, pancreas, and kidney-pancreas transplants showed no primary organ transplants from living donors in the 2016 to 2019 period. Unlike Figures 4 and 5, Figure 15 includes transplants provided to non-U.S. residents/non-U.S. citizens.

FIGURE 15: PRIMARY ORGAN TRANSPLANTS FROM LIVING DONORS

Year	Intestine	Kidney	Liver
2016	0	5,629	345
2017	1	5,811	367
2018	0	6,442	401
2019*	0	5,719	424

* 2019 counts based on OPTN data as of October 31, 2019, without projecting estimates for the remainder of the year.

VII. Emerging innovations and issues

Physicians, researchers, policy makers, insurance carriers, and other innovators are driving investigations and potential solutions for issues that include growing waitlists accompanied by shortages of donated organs, along with inefficiencies in organ allocation and use. We present a variety of emerging innovations and issues for these stakeholders to consider in the areas of organ viability, organ availability, and overall policy. As emerging solutions and efficiencies gain and sustain traction, we expect to review and quantify the implications of those innovations and solutions for procurement, transplant use, pricing and provider reimbursement, and costs.

(1) ORGAN VIABILITY

Organs from donors infected with the 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 have discarded HCV-infected organs because of concerns about infecting the recipients of such organs and high HCV transmission rates to recipients.[1,2]

Studies show that treating recipients of HCV-positive organs with new anti-HCV drugs eliminates the HCV from the recipient. While this innovation may remain controversial and may lack wide acceptance, it has the potential to increase the number of organs available for transplantation.[3,4,5,6,7,8]

Making marginal organs healthy enough 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").[9,10] The reasons for organ rejection vary and may include organ trauma, edema, inflammation, and donor comorbidities that lead to poor organ viability.[11] 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. [12,13]

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.[13,14,15,16,17] While researchers may still need to clear various technical, financial, reimbursement, and ethical hurdles associated with these innovations, such initiatives may offer greater hope in the near future for patients awaiting transplants.

Bioengineering medicine and xenotransplantation

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, as well as working with discarded human donor kidneys.[18] With xenotransplantation, the use of animal organs or cell lines facilitates regenerative tissue for use in creating a new organ.[18,19,20] The goal of this initial research may eventually progress to the use of human stem cells to create a new organ.[21,22] The use of autologous human stem cells might avoid use of immunosuppressant medicine. Complex, solid organs such as the kidney, lung, and heart remain a challenge in the field of regenerative medicine.[23]

(2) ORGAN AVAILABILITY AND POLICY

Efforts to remove financial barriers to living organ donation

In response to rulemaking outlined in the July 2019 "Advancing American Kidney Health" Executive Order, this proposed HHS/HRSA rule would amend the OPTN final rule to remove financial barriers to living organ donation by expanding the allowable costs that are reimbursable.[24,25] The proposed rule also notes the HHS Secretary's authority to reimburse travel and subsistence expenses, encompassing costs for travel to medical and clinical appointments, lodging, and meals, incurred by eligible individuals making living organ donations and other individuals accompanying the living organ donors.

As noted in the proposal, 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.[25] The total net savings or costs for full implementation of this proposal would need assessment, including the effect of the implementation of such policies in the commercial (non-Medicaid/non-Medicare) space.

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, with the longest U.S. kidney transplant chain exceeding 100 donations.[26]

VIII. Figure index

IX. Emerging innovations and issues: references

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X. Acknowledgments

The authors thank the following Milliman colleagues for their assistance in reviewing this report:

Steven G. Hanson, ASA, MAAA
Edward Jhu, FSA, MAAA
Stephen George, PharmD, MS

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