Providence Health Plan
P.O. Box 4327
Portland, OR 97208 – 4327
ProvidenceHealthPlan.com

Health Equity Coverage Recommendation Form

Title:	**Health Equity in Organ Transplants**
Date of Last Review:	9/1/26

Research Section

Background

According to the Centers for Disease Control and Prevention (CDC), an organ transplant is a lifesaving procedure in which tissue, or an organ is transferred from one area of a person's body to another area, or from one person (the donor) to another person (the recipient). In the United States, the most commonly transplanted organs are the kidney, liver, heart, lungs, pancreas, and intestines. On any given day there are around 100,000 people on the active waiting list for organs, but only approximately 15,000 deceased organ donors in 2022, with each providing on average 2.5 organs. Living donors provide on average only around 6,000 organs per year.[1]

Inequities discussed on the Office of Minority Health Website:[2]

***Organ Transplants and Black/African Americans*:**[3]

- African Americans make up the largest BIPOC group in need of an organ transplant.
- Of the total candidates currently waiting for a transplant, 27.8% were non-Hispanic Black/African Americans.
- Non-Hispanic Black/African Americans received 22.8% of the organ transplants performed in 2024.
- In 2024, non-Hispanic Black/African Americans comprised 12.6% of organ donors.

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- Of the organs recovered from non-Hispanic Black/African Americans, 17.0% came from living donors as compared to 30.0% of the organs recovered from non-Hispanic whites

***Organ Transplants in Asian Americans*:**[4]

- Of the total candidates currently waiting for a transplant, 8.2% were non-Hispanic Asian Americans. Non-Hispanic Asian Americans received 5.8% of the organ transplants performed in 2024
- In 2024, non-Hispanic Asian Americans comprised 3.1% of organ donors. Of the organs recovered from non-Hispanic Asian Americans, 43.2% came from living donors as compared to 30.0% of the organs recovered from non-Hispanic whites

***Organ Transplants and Hispanic/Latino Americans*:**[5]

- Of the total candidates currently waiting for a transplant, 22.6% were Hispanic/Latino. Hispanics/Latinos received 18.9% of the organ transplants performed in 2024
- In 2024, Hispanics/Latinos comprised 15.4% of organ donors. Of the organs recovered from Hispanics/Latinos, 32.2% came from living donors as compared to 30.0% of the organs recovered from non-Hispanic whites

Review of current, peer-reviewed evidence from established sources

According to Ebele and Young (2019)[6] African Americans have a 2- to 4-fold greater incidence of end-stage kidney disease (ESKD) than white Americans, which has long raised the possibility of a genetic cause for this disparity. Recent advances in genetic studies have shown a causal association of polymorphisms at the apolipoprotein L1 gene (APOL1) with the markedly increased risk for the nondiabetic component of the overall disparity in ESKD in African Americans. Although APOL1-associated kidney disease is thought to account for a substantial proportion of ESKD in African Americans, not all the increased risk for ESKD is accounted for, and a complete cataloging of disparities in genetic causes of ESKD eludes our current understanding of genetic-associated kidney disease.

Kidney transplantation offers better mortality and quality of life outcomes to patients with end-stage renal failure compared to dialysis according to Zhang and Mathur (2023).[7] Specifically, living donor kidney transplantation is the best treatment for end-stage renal disease, since it offers the greatest survival benefit compared to deceased donor kidney transplant or dialysis. However, not all patients from all racial/ethnic backgrounds enjoy these benefits. While Black and Hispanic patients bear the predominant disease burden within the United States, they represent less than half of all kidney transplants in the country. Other factors such as cultural barriers that proliferate myths about transplant,

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financial costs that impede altruistic donation, and even biological predispositions create a complex maze and can also perpetuate care inaccessibility. Therefore, blanket efforts to increase the overall donation pool may not extend access to vulnerable populations, who may require more targeted attention and interventions. This review uses US kidney transplantation data to substantiate accessibility differences amongst racial minorities as well as provide examples of successful institutional and national systemic level changes that have improved transplantation outcomes for all.

Goyes et al. (2021)[8] notes that non-Hispanic white Americans and Hispanic Americans on a wait list for liver transplantation were reviewed over a period of five years. On competing risk analysis, Hispanic patients had a higher risk of being removed from the waitlist for death or clinical deterioration compared to their counterpart (SHR 1.23, 95% CI 1.13-1.34; P < 0.001).

Another compounding factor that may be contributing to this disparity is the issue of obesity and reported Body Mass Index rates. It has been well established that obesity is more prevalent amongst certain populations including Black and Hispanic individuals, women, and individuals with a lower socioeconomic status.[9, 10] This is important to note because many transplant programs have BMI maximums as part of their patient eligibility criteria which is used to determine which patients are deemed eligible for organ transplant. Generally, patients who have a BMI over the set maximum do not qualify for organ transplantation. BMI maximums have traditionally been set due to concerns around obesity contributing to surgical risks, postoperative complications, graft dysfunction, and increased frailty. However, data suggesting that patient and graft survival is affected by obesity is not consistent, and obese patients with End Stage Renal Disease have been found to have better survival after kidney transplantation compared to remaining on dialysis.[11]

Studies have also shown some limitations of using BMI classifications as predictors of short-term mortality in lung transplant recipients. Given the limitations of BMI as a classifier of phenotype and predictor of outcomes, the recommendation has been made that authors of lung transplant guidelines and clinicians should continue to work to take into account estimates of muscle mass and adiposity in their decision making that relates to body composition and transplant candidacy. They should not solely rely on weight or BMI as an estimate of body composition to help determine lung transplant candidacy or to predict pretransplant and post-transplant outcomes.[12] A recent retrospective analysis was completed which looked at 222 patients with interstitial pulmonary fibrosis (IPF) who underwent lung transplantation. These patients were grouped by BMI scores into 4 separate groups; underweight patients (BMI ≤18.5 kg/m^2), group-2 of normal weight patients (BMI 18.5–25 kg/m^2), group-3 of over-weight patients (BMI 25–29.9 kg/m^2) and group-4 of obese patients (BMI ≥30 kg/m^2). Following transplantation Kaplan–Meier analysis was performed and showed that mortality was not statistically significant between the groups indicating that Body Mass Index does not impact long-term survival of patients with IPF undergoing lung transplantation.[13]

A similar study was conducted looking at 70,302 patients who required a heart transplant. These patients were grouped by BMI scores into 4 separate groups; <30 (n=53,569), 30-34.9 (n=12,610), 35-36.9 (n=1,981), 37-39.9 (n=1,131), and ≥40 (n=386). Analysis of this group determined

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that carefully selected patients with a BMI of 35-36.9 can safely undergo heart transplant. Additionally, potential candidates with a BMI of 36-39.9 may also be considered for listing given that this group was found to have similar survival to patients with a BMI of 30-35.[14] Another retrospective cohort analysis of 23,009 patients also determined that improved quality of life and survival from a heart transplantation outweighed the risks associated with a BMI of 35 to 39.9 kg/m2.[15]

Outcomes and eligibility criteria also differ widely between different transplant programs. For example, some institutions such as Loyola Medicine do not include BMI maximums as part of their eligibility criteria for kidney transplants. Loyola Medicine has done away with BMI maximums in part due to the introduction of robotic surgery. Robotic assisted kidney transplant surgery is designed to help patients with obesity get transplants and minimize their chances of wound infection. The infection rate of the wound is about 5% for individuals with a normal BMI (between 19-25 Kg/m^2) or overweight (BMI is 26-30 Kg/m^2). Generally, it is found that using traditional kidney transplant methods that wound infection rates significantly increased at BMI >30 Kg/m^2 to rates in the 30% to 40%. With robotic surgery though, the main incision is now moved to the upper part of the abdomen, and it is significantly smaller, decreasing infection rates to those observed in individuals with normal BMI at 5%.[16]

The American Medical Association has noted that BMI alone is an imperfect clinical measure and recognizes issues with using BMI as a measurement due to its "historical harm, its use for racist exclusion, and because BMI is based primarily on data collected from previous generations of non-Hispanic white populations". The AMA has also noted that due to significant limitations associated with the widespread use of BMI in clinical settings that it be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors. It was noted that while BMI is significantly correlated with the amount of fat mass in the general population, it loses predictability when applied on the individual level. The AMA also recognizes that relative body shape and composition differences across race/ethnic groups, sexes, genders, and age-span is essential to consider when applying BMI as a measure of adiposity and that BMI should not be used as a sole criterion to deny appropriate insurance reimbursement.[17,18]

Review of clinical practices guidelines from professional associations and societies in regard to these findings

CDC- Transplant Safety:[19]

- Every organ donor can save as many as eight lives and enhance 75 more.
- While rare, an infection can be transmitted through an organ transplant from a donor to a recipient. This occurs in <1% of all transplants.
- Several safety measures are in place to lessen the risk of disease transmission to ensure that every usable organ is used safely.

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American Medical Association[17,18]

- BMI is significantly correlated with the amount of fat mass in the general population but loses predictability when applied on the individual level.
- Relative body shape and composition heterogeneity across race and ethnic groups, sexes, genders and age-span is essential to consider when applying BMI as a measure of adiposity.
- The use of BMI should not be used as a sole criterion to deny appropriate insurance reimbursement.

Do any of these findings relate to any of our current policies?

Providence Health Plan currently uses BMI maximums as part of criterion for prior authorization approval in the Company **Organ Transplantation** policy.

Summary

Medical Policy:

BIPOC populations are disproportionately affected by the need for organ donation while the percentage of organs donated by marginalized groups remains lower than that of non-Hispanic Caucasians. Furthermore, there is also evidence that marginalized populations have an increased risk of being removed from organ donation wait lists due to death and clinical deterioration.

There is a lack of clinical practice guidelines or evidence on why marginalized groups experience a need for organ donation at a higher rate than their white counterparts. The cause of the higher prevalence of organ failure in these populations is likely multifactorial and complex, including both genetic and environmental factors.

Obesity is more prevalent amongst certain populations including Black and Hispanic individuals, women, and individuals with a lower socioeconomic status. This is important to note because many transplant programs have BMI maximums as part of their patient eligibility criteria which is used to determine which patients are deemed eligible for organ transplant. Generally, patients who have a BMI over the set maximum do not qualify for organ transplantation. BMI maximums have traditionally been set due to concerns around obesity contributing to

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surgical risks, postoperative complications, graft dysfunction, and increased frailty. However, data suggesting that patient and graft survival is affected by obesity is not consistent.

The American Medical Association has also noted that due to significant limitations associated with the widespread use of BMI in clinical settings that it should be used in conjunction with other valid measures of risk such as, but not limited to, measurements of visceral fat, body adiposity index, body composition, relative fat mass, waist circumference and genetic/metabolic factors. The AMA also determined that while BMI is significantly correlated with the amount of fat mass in the general population, it loses predictability when applied on the individual level. It was also recognized that relative body shape and composition differences across race/ethnic groups, sexes, genders, and age-span are essential to consider when applying BMI as a measure of adiposity and that BMI should not be used as a sole criterion to deny appropriate insurance reimbursement.

Based on the above recommendations by the American Medical Association regarding BMI as being an imperfect clinical measure and the fact that data suggesting that patient and graft survival is affected by obesity is inconsistent, Providence Health Plan will remove BMI as a prior authorization criterion for the company version of the Organ Transplantation medical policy. Each transplant center has its own specific guidelines for organ transplant based on national policies, hospital's specific eligibility criteria, and in-house physician expertise. As such, Providence Health Plan will defer to institutional eligibility and transplant board member approval to guide eligibility determinations for organ transplant patients in relation to BMI.

Pharmacy Policy:

Pharmacoequity, coined by Dr Utibe Essien, emphasizes that all individuals should have access to the highest-quality medications needed to manage their health, regardless of race, ethnicity, or socioeconomic status.[20] Ways to improve this on the pharmacy insurer side includes tailoring formularies and copay structures to improve affordability and reduce barriers (including prior authorization requirements) for underserved populations. An equity audit was completed on the medications most commonly used for organ transplantation. Many medications do not require prior authorization, including tacrolimus, cyclosporine, prednisone, mycophenolate, azathioprine 50 mg, sirolimus, everolimus, Simulect (basiliximab), Anti-thymocyte Globulin: Thymoglobulin and Atgam, Nulojix (belatacept), and valganciclovir. Medications that do require prior authorization include: posaconazole, voriconazole, Mavyret, sofosbuvir/velpatasvir, ledipasvir/ sofosbuvir, Vosevi®, Sovaldi®, Zepatier®, Harvoni®, Livtencity, and Prevymis (for Commercial and Medicare only). Posaconazole and voriconazole require prior authorization as we only cover for individuals that are severely immunocompromised, such as a hematopoietic stem cell transplant recipient with graft-versus-host disease or a lung transplant or high-risk non-lung solid organ transplant recipient. The Hepatitis C Direct-Acting Antiviral

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class generally requires prior authorization, however for Medicaid, a prior authorization is not needed for these agents if the patient has hepatitis C and is treatment-naïve. Livtencity® (maribavir) can be covered if an individual has had a hematopoietic stem cell or solid organ transplant with cytomegalovirus (CMV). Prevymis® (letermovir) is only coverable for prophylaxis of CMV infection after allogeneic hematopoietic stem cell transplant (HSCT) or kidney transplant. These therapies are very costly and it is important to ensure utilization aligns with guideline-recommended therapy. The formulary/tiering placement for all therapies was evaluated and there are no recommendations for updates to pharmacy policy at this time.

Recommendation:	No recommended health equity updates to policies at this time. We will continue to review data and professional organization recommendations for future health equity updates.

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CORE Revision History Section

DATE	SUMMARY OF CHANGES
08/20/2024	Initial review.
08/28/2025	Annual review. Recommendation made to remove BMI from eligibility criterion for Organ Transplant medical policy
8/24/26	Annual review. No changes.

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