**Janice K. Brewer, Governor**
**Thomas J. Betlach, Director**

*801 East Jefferson, Phoenix, AZ 85034*
*PO Box 25520, Phoenix, AZ 85002*
*Phone: 602-417-4000*
www.azahcccs.gov

AHCCCS

***Our first care is your health care***
ARIZONA HEALTH CARE COST CONTAINMENT SYSTEM

---

# Changes to Transplant Coverage
# Background Material

AHCCCS coverage criteria for several types of organ transplants for adults have changed. These difficult decisions were made as part of a public process that included Agency review, external consultant review and a public hearing. Ultimately the process culminated in a statutory change made by the legislature. The following material summarizes the results of the Agency's review of the transplant program and the proposed changes.

The AHCCCS review included an examination of member outcomes, Milliman transplant data, publications on non-transplant and transplant treatments, annual outcome reports from the United Network of Organ Sharing (UNOS) and specialty society standards. Each transplant type was reviewed to determine whether:

- Outcomes are aligned with procedure risks;
- More conservative treatments with less risk lead to similar outcomes;
- Transplants do not significantly affect the diseases they are intended to cure.

As a result of a detailed review of the AHCCCS transplant program, six specific transplant recommendations were made that ultimately were passed into law.

## Pancreas-only transplants

- More conservative treatments with less risk lead to similar outcomes
- Outcomes are not aligned with procedure risks

### *Details*

Pancreas-only transplants have never been a covered service for AHCCCS members. AHCCCS has only approved one pancreas-only transplant during the last five years. This was in response to an Administrative Law Judge (ALJ) decision. The member was transplanted and the organ lasted 48 hours before complications required the removal of the organ (the member developed a clot that forced the organ removal). There is one other case pending appeal in which AHCCCS is the secondary payor and the ALJ determined that AHCCCS is responsible for the co-pays and deductibles.

Pancreas–only transplants convert a patient dependent on daily insulin to a patient dependent on anti-rejection medications, which have more serious side effects than insulin. More conservative therapies that present less risk are available to treat diabetes.

## Pancreas-after-kidney transplants

- More conservative treatments with less risk lead to similar outcomes
- Transplants do not significantly affect the diseases they are intended to cure

***Details***
A major study examined the long-term outcomes of more than 11,000 diabetics who were listed for a transplant from 1995 to 2000. The study compared the mortality rate within 4 years of transplant for patients who underwent a pancreas-after-kidney (PAK) transplant to patients who remained on the transplant list during the entire study period without receiving an organ. Overall, the risk of dying within 4 years was higher for those who had received a PAK transplant compared to those who were waiting for a PAK transplant. The study concluded that PAK presents increased risks of mortality to the transplant recipient as compared to conservative therapy. The only transplant patients that had a higher survival rate at 4 years than those on the waiting list for that transplant type were those undergoing a simultaneous pancreas/kidney transplant. AHCCCS continues to cover that transplant type.

**Lung transplants**

- More conservative treatments with less risk lead to similar outcomes
- Transplants do not significantly affect the diseases they are intended to cure

***Details***
In 2009 the American Thoracic Society (ATS) presented information on "Technology and Outcomes Assessment in Lung Transplantation" that included data on both survival rates and quality of life in lung transplant recipients. The data showed that lung transplants do not increase the survival rate compared to matched populations who remain on the transplant waiting list but do not actually get a transplant. One of the conclusions by the ATS was that lung transplants could result in an increased quality of life but reduced life span. While not discounting the value of an increased quality of life, this procedure is more palliative than curative. Conventional therapy provided increased survival rates at less risk to patients.

**Allogeneic unrelated hematopoietic cell (bone marrow) transplants**

- Outcomes are not aligned with procedure risks
- Transplants do not significantly affect the diseases they are intended to cure

***Details***
AHCCCS has experienced poor outcome results for this particular therapy in adult members. Thirteen of fourteen AHCCCS members receiving allogeneic unrelated bone marrow transplants over the two-year study period expired within six months. The one survivor is no longer enrolled in AHCCCS and therefore, the Agency is unable to track the outcome of the transplant. Thus, the maximum cure rate for AHCCCS members during the study period for this transplant type is ~7.1%, assuming the one survivor is still alive at this time.

National studies mirror the poor outcomes for patients over 25 years of age, showing that treatment with chemotherapy and standard medical care is less risky for the patient than the bone marrow transplant procedure.

**Heart transplants for non-ischemic cardiomyopathies**

- More conservative treatments with less risk lead to similar outcomes

***Details***

For purposes of the AHCCCS transplant program, "ischemic cardiomyopathy" is defined as a cardiac abnormality of any etiology that produces irreversible ischemia of the myocardium (heart muscle) with permanent damage to the heart. This damage results in inadequate circulation of blood and oxygen. Causes of "ischemic cardiomyopathy" include congenital abnormalities, valvular disease, viral diseases, etc., if the end result is irreversible, permanent damage to the heart muscle. Members with "ischemic cardiomyopathy" are eligible for heart transplants if they meet all other coverage conditions and more conservative therapy is not effective in returning the member to a functional status.

"Non-ischemic cardiomyopathy" is defined as a condition in which the underlying cardiac abnormality has not resulted in irreversible permanent damage to the heart muscle. Members with "non-ischemic cardiomyopathy" have sufficient cardiac function to circulate adequate volumes of blood and oxygen to the heart muscle and other body organs. These patients may experience intermittent episodes of cardiac ischemia that may be treated with medications or less radical surgery than a heart transplant, such as coronary artery bypass graft (CABG) procedures, valve replacement procedures, or other procedures that preserve the patient's natural heart. These results were reported in a 2001 University of Virginia study published in the Annals of Thoracic Surgery.

**Liver transplants for Hepatitis C**

- Transplants do not significantly affect the diseases they are intended to cure

***Details***

Studies show that when a patient with Hepatitis C is transplanted, the Hepatitis C virus begins to infect the new liver within the first 24 hours after transplant. A study from Duke University published in 2009, also demonstrated that within 72 hours after transplant surgery, the blood level of the Hepatitis C virus was the same as it was prior to transplant. The return of the Hepatitis C virus is the number one cause of the new liver failing. A liver transplant will not get rid of the virus and is therefore not a cure for Hepatitis C. The transplanted liver will become infected and require continued treatment.

The required anti-rejection immunosuppressant medications are known to cause problems such as a higher risk of infection, diabetes and cancer. Additionally the member will continue to need treatment for the Hepatitis C. Although several studies suggest that even though re-infection with the Hepatitis C virus occurs, treatment may only require lower dose therapy. These studies fail to address the secondary problems caused by the immunosuppressant drugs.

## Transplant Coverage Summary

| Transplant Type | Covered for EPSDT members (under age 21) | Covered for adult members | Adult Limitations |
|---|---|---|---|
| Solid Organs | | | |
| Heart | X | X | Not covered for non-ischemic cardiomyopathy |
| Heart/Lung | X | Not covered | |
| Lung (single and double) | X | Not covered | |
| Liver | X | X | Not covered for members with a diagnosis of Hepatitis C |
| Kidney (cadaveric and live donor) | X | X | |
| Simultaneous Pancreas/Kidney (SPK) | X | X | |
| Pancreas after Kidney (PAK) | X | Not covered | |
| Visceral Transplantation<br>• intestine alone<br>• intestine with pancreas<br>• intestine with liver<br>• intestine, liver, pancreas en bloc<br>• pancreas, liver | X | Not covered | |
| Pancreas Only | X | Not covered | |
| Partial pancreas (including islet cell transplants) | Not covered | Not covered | |
| Hematopoietic Stem Cell Transplants | | | |
| • Allogeneic Related | X | X | |
| • Allogeneic Unrelated | X | Not Covered | |
| • Autologous | X | X | |
| • Tandem HSCT | X | X | Tandem HSCT is not covered if allogeneic unrelated HSCT |