Pancreas Transplant Criteria

Criteria:
Pancreas transplants are covered for members with insulin-requiring diabetes mellitus and who meet the following criteria:

1. Must have clearance from Psycho/Social necessity consult. Evaluation should include an assessment of the patient’s ability to give informed consent and comply with instruction including drug therapy, as well as assessment of the support systems in place at home or in the community (Level of Evidence: C)
2. Dental exam and clearance must be provided.
3. Must be abstinent of all illicit drugs and not abuse any drugs or alcohol. Physician documentation must specifically address this issue. Need for laboratory testing to confirm compliance may be at the discretion of the attending physician. Social alcohol use and medicinal marijuana use are acceptable.
4. Documentation of underlying co-morbidities must be provided.
5. Pertinent lab values must be provided.
7. Report of Abdominal ultrasound study must be provided.
8. Documentation of complications related to diabetes must be provided including HbA1c level, C-peptide level, and daily insulin requirements.
9. Echocardiogram and cardiac stress test results must be provided.
10. Documentation of renal function to determine qualification for appropriate pancreas transplant category must be provided.
11. Request may come in as “pancreas alone” or “simultaneous kidney/pancreas” request.
   a. Medicaid will review for the pancreas only; do not need approval for the kidney portion for a simultaneous pancreas/kidney or pancreas after kidney.

Contraindications:
Transplantation cannot be approved in the presence of the following:

1. Active smoking is not necessarily considered an absolute contraindication; however, heavy smoking (>1 pack per day) is an absolute contraindication. Complete smoking cessation is strongly encouraged. For patients who smoke tobacco and have smoking-related morbidities (coronary artery disease, symptomatic or documented cerebrovascular or peripheral vascular disease, chronic obstructive lung disease, history of non-cutaneous malignancy), complete smoking cessation is required and should be validated by urine nicotine test prior to transplant.
2. Malignancy in the last two years, with the exception of cutaneous squamous and basal cell tumors. Disseminated or incompletely treated cancer is an absolute contraindication. In cases of localized and treated cancer, the cancer-free interval required will vary depending on the stage and type of cancer. Consultation with a board-certified oncologist is required in most cases to determine if the patient’s mortality in the absence of transplantation is predicted to be higher than their risk of recurrence.

3. Incurable chronic active or unresolved infection including chronic active viral hepatitis B, hepatitis C, and uncontrolled human immunodeficiency virus (HIV).
   a. Adequately controlled HIV infection is defined by ALL OF the following:
      i. CD4 count greater than 200 cells/mm³
      ii. HIV-1 ribonucleic acid (RNA) undetectable
      iii. Stable combination anti-retroviral therapy for more than three months
      iv. Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past twelve months, including aspergillosis, tuberculosis or other mycobacterial infection, coccidiomycosis, resistant fungal infections, chronic intestinal cryptosporidiosis greater than one month, Kaposi’s sarcoma or other neoplasm.
   v. However, in cases of chronic hepatitis C viral infection without cirrhosis, transplantation may precede treatment for HCV to take advantage of organs from HCV+ donors and provided that the patient has been accepted as a good candidate for anti-HCV treatment.

4. Documented non-adherence or inability to follow through with medical therapy or any aspect of follow-up care.

5. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy.

6. Absence of a consistent or reliable social support system.

7. Substance addiction (e.g., alcohol, tobacco, or narcotics) that is either active or within the last six months and has not been evaluated for or entered into a structured rehabilitation or cessation program.

8. Fasting C-peptide > 10 ng/ml or total daily insulin requirements > 1 unit/kg. In selected circumstances, patients with a type 2 diabetes phenotype will be considered for pancreas transplantation provided they are insulin-requiring for a minimum of three to five years and meet the above C-peptide and insulin requirement criteria. For those patients who do not meet these criteria, a discussion of risks and benefits must specifically address this in the clinical documentation.

9. BMI > 35 kg/m² is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation.

10. Age ≥ 60 years is a relative contraindication. A discussion of risks and benefits must specifically address this in the clinical documentation.
11. Insufficient cardiovascular reserve with un-reconstructable coronary artery disease, refractory congestive heart failure, left ventricular ejection fraction <30 percent, or severe irreversible pulmonary hypertension (right ventricular systolic pressure/pulmonary artery systolic pressure ≥50 mm Hg confirmed by right heart catheterization); cardiac history of high probability of death with general anesthesia.

12. Chronic severe hypotension (may be marked by use of oral vasopressors such as midodrine) with evidence of significant and irreversible cardiac dysfunction.

13. Chronic lung disease requiring continuous oxygen therapy.

14. Moderate to advanced cirrhosis.

15. Life expectancy < two years because of other irreversible systemic illness or multiple co-morbidities.

Other coverage issues:

- Covered types of pancreas transplants are limited to the following:
  1. Simultaneous pancreas-kidney;
  2. Pancreas after kidney transplant;
  3. Pancreas transplants alone for members exhibiting any of the following:
     a) A history of frequent, acute, and severe metabolic complications, such as hypoglycemia, hyperglycemia, or ketoacidosis, which require medical attention;
     b) Clinical problems with exogenous insulin therapy that are so severe as to be incapacitating or causing a significant impairment in quality of life; and
     c) Consistent failure of insulin-based management to prevent either acute or chronic complications (i.e., retinopathy, peripheral or autonomic neuropathy, accelerated atherosclerosis).

- Pancreas transplants require pre-procedure review and approval.

- Covered pancreas transplants are only payable when performed in a facility that meets the requirements under 441-78.3(10).

- Donor expenses incurred directly in connection with a covered transplant are payable.

- Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery.

- Expenses of searching for a donor are not covered.

Services not covered:

- Transplantation of islet cells or partial pancreatic tissue.

- Expenses associated with organ preparation (e.g., “backbench prep”) are not separately payable and are considered paid as part of the transplant procedure.

CPT Codes:

48554
References Used:
441 IAC 78.1(20)”a”(7).
Listing Criteria for Heart Transplantation (Guidelines) (J Heart Lung Transplant 2006:25(9): 1024-1042)

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Change History:

<table>
<thead>
<tr>
<th>Change Date</th>
<th>Changed By</th>
<th>Description of Change</th>
<th>New Version Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/18/13</td>
<td>CAC</td>
<td>Re-ordering and new information added to Criteria #1-#10. Added Contraindications. Added information under References.</td>
<td>1</td>
</tr>
<tr>
<td>3/22/13</td>
<td>Policy staff</td>
<td>Additions to criteria to reflect details contained in 441 IAC 78.1(20)”a”(7).</td>
<td>2</td>
</tr>
</tbody>
</table>

Change History (cont.):

<table>
<thead>
<tr>
<th>Change Date</th>
<th>Changed By</th>
<th>Description of Change</th>
<th>New Version Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>11/21/13</td>
<td>Pancreas Transplant Specialist</td>
<td>Under criteria, change coverage for members with Type 1 diabetes to insulin-requiring diabetes. Criterion #8 change insulin resistance to complications. Add Criterion #9 on echocardiogram and cardiac stress test. Add Criterion #10 on renal function. Under Contraindications, remove #4 regarding incurable viral disease. Add #8 on fasting C-peptide. Add #9 on BMI</td>
<td>3</td>
</tr>
<tr>
<td>Change Date:</td>
<td>Changed By:</td>
<td>Description of Change:</td>
<td>New Version Number:</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
<td>-----------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>7/24/14</td>
<td>Medical Director</td>
<td>Contraindication #4 - removed Hepatitis C and added definitions i-iv of adequately controlled HIV infection.</td>
<td>4</td>
</tr>
<tr>
<td>1/16/15</td>
<td>Medical Director</td>
<td>Added last paragraph in References Used.</td>
<td>5</td>
</tr>
<tr>
<td>1/7/16</td>
<td>Pancreas Transplant Specialist</td>
<td>Added narrative to criterion #3 and #8.</td>
<td>6</td>
</tr>
<tr>
<td>12/18/16</td>
<td>Pancreas Transplant Specialist</td>
<td>Added narrative to Contraindication #1. Contraindication #4 iii added “combination” Contraindication #4 iv added “progressive multifocal leukoencephalopathy” “within the past twelve months” “other mycobacterial infection” “chronic intestinal cryptosporidiosis greater than one month”. Contraindication #9 added narrative. Added Contraindication #11. Other coverage issues #3b added “or causing a significant impairment in quality of life”. Other coverage #3c added “retinopathy, peripheral or autonomic neuropathy, accelerated atherosclerosis”. Sentence on expenses incurred for complications added “or requisite immunosuppression”.</td>
<td>7</td>
</tr>
<tr>
<td>4/11/17</td>
<td>Policy Staff</td>
<td>Services Not Covered added second bullet regarding associated expenses.</td>
<td>8</td>
</tr>
<tr>
<td>Date</td>
<td>Change History</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>----------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1/2/18</td>
<td>Changes in Contraindication #1 and #2. Added Contraindication #3v. Added Contraindications 11 through 15.</td>
<td>9</td>
<td></td>
</tr>
</tbody>
</table>

C. David Smith, MD