

# MEDICA®

## UTILIZATION MANAGEMENT POLICY

### TITLE: PANCREAS-KIDNEY (SPK, PAK) TRANSPLANTATION

Origination Date: January, 1995

Subsequent Endorsement Date(s): 01/1996, 02/1998, 01/1999, 01/2000, 01/2001, 03/2002, 02/2003, 01/2004, 02/2005, 04/2005, 02/2006, 02/2007, 02/2008, 02/2009, 02/2010

*This policy was developed with input from specialists in endocrinology, nephrology and transplant surgery, and endorsed by the Medical Policy Committee.*

#### **PRODUCT APPLICATION**

*This policy provides general information concerning Medica's administrative processes. It applies to all fully insured Medica Health Plans, Medica Insurance Company, and Medica Health Plans of Wisconsin products, unless a specific limitation or exception exists. For self-insured plans, consult individual plan sponsor benefit documents. If there is a discrepancy between a Utilization Management Policy and a self-insured benefit plan, the provisions of the benefit plan will govern. With respect to Medicare and Medicaid members, this policy will apply unless Medicare or Medicaid policies require different coverage.*

#### **IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**

*Medica updates its Utilization Management Policies regularly, and reserves the right to amend these policies without notice to Medica members. Medica also reserves the right to amend these policies without notice to contracted health care providers unless the amendment materially alters the policy. If the amendment materially alters the policy, Medica will disclose the change to contracted health care providers not less than 45 days prior to implementation of the policy. Medica's Utilization Management Policies contain general information only and do not guarantee coverage. Receipt of benefits is subject to all terms and conditions of the member's coverage document. Members should consult their Certificates of Coverage or Plan Documents/Summary Plan Descriptions to review the provisions relating to a specific coverage determination. If there is a conflict between a Utilization Management Policy and the applicable coverage document, the coverage document will govern. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Utilization Management Policy may call Medica's Provider Service Center toll free at 1-800-458-5512.*

*Medica's Utilization Management Policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.*

#### **PURPOSE**

To promote consistency between reviewers in utilization management decision-making by providing the criteria that determine the medical necessity of pancreas-kidney (SPK, PAK) transplantation. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

#### **BACKGROUND**

##### I. Definitions

- A. **Transplant or graft** is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual. Pancreas transplantation has been used to arrest or ameliorate secondary complications of diabetes by establishing insulin independence.
- B. There are three types of **pancreas transplantation**:
  1. Simultaneous pancreas/kidney (SPK)
  2. Pancreas after kidney (PAK)
  3. Pancreas transplantation alone (PTA).
- C. **Living donor kidney transplant** is a procedure in which a kidney of a healthy individual is removed and transplanted into a related (or unrelated) recipient.

D. **Pancreatic islet cell transplantation** is a procedure in which the insulin-producing islet cells alone (without the remainder of the pancreas) are transplanted from a donor to the same (autologous) or different (allogeneic) individual. (Refer to the Coverage Issues section for additional information.)

II. Comments

- A. For uremic diabetic patients, combined pancreas and kidney transplantation usually removes dependencies on both insulin and dialysis.
- B. Pancreas transplantation represents an alternative means of treating insulin dependence. Because organ transplantation requires commitment of the recipient to long term immunosuppression, the problems of diabetes must be of a magnitude to justify anti-rejection drugs. Thus, the main pancreas transplant applications have been in patients who are extremely labile or experience hypoglycemia unawareness syndrome. The complications of uncontrolled labile diabetes with severe metabolic instability must be judged to be more serious than being immunosuppressed.
- C. Patients with Type II Insulin Dependent Diabetes Mellitus (IDDM) may exhibit the secondary complications of diabetes, including nephropathy, retinopathy, and peripheral/autonomic neuropathy and vasculopathy. In these patients, insulin resistance may be an important factor in the pathophysiology of diabetes and a pancreas transplant may not be helpful, if residual beta cell function exists. In order to differentiate between Type I and Type II IDDM, a C-peptide determination or antibody studies may be necessary. In patients with Type I IDDM, there should be no detectable C-peptide and antibodies may be present. In patients with Type II IDDM, C-peptide levels may be normal or even elevated and antibodies are absent.

MEDICAL NECESSITY CRITERIA

I. Patient Suitability

- A. All patients should meet the institution's criteria for acceptable heart, lung, and liver function.
- B. Additional studies to determine the patient's suitability for transplant may be requested, if indicated, including, but not limited to:
  - 1. Cardiac evaluation for persons over age 40
  - 2. Pulmonary function tests
  - 3. Serology testing including, but not limited to, hepatitis A, B and C, human immunodeficiency virus (HIV), cytomegalovirus (CMV), varicella, Epstein Barr virus, herpes virus, Rapid Plasma Reagin (RPR), and Fluorescent Treponemal Antibody Absorption (FTA)
  - 4. Psychosocial evaluation and clearance
  - 5. Mammogram for women over age 40
  - 6. Prostate-specific antigen (PSA) and digital rectal exam for men over age 50
  - 7. Pelvic exam and Pap smear for women
  - 8. Dental exam with completion of required dental work prior to transplant
  - 9. Imaging studies
  - 10. Colonoscopy for persons over age 50 with removal of any polyps
  - 11. Immunizations up to date, including Hepatitis A, Hepatitis B, influenza and pneumonia
  - 12. Carotid Doppler ultrasound for individuals with known coronary artery disease
  - 13. Ankle-Brachial Index (ABI)
  - 14. Ophthalmology exam for persons with diabetes (as baseline)
- C. Patient or guardian is able to give informed consent. Patient/guardian and family/social support system are able to comply with the treatment regimen and necessary follow-up
- D. For patients with a recent (24 months) history of alcohol or other drug abuse, successful completion of a chemical dependency program and documented ongoing abstinence

II. Indications for transplantation

- A. For simultaneous pancreas kidney transplant (SPK) the following criteria must be met:
  - 1. Type I insulin-dependent diabetes, and
  - 2. Imminent or established end-stage renal disease.
- B. For sequential pancreas after kidney transplant (PAK), the following criteria must be met:
  - 1. Type I insulin-dependent diabetes, and
  - 2. Previously successful kidney transplant with stable function.

III. Indications for retransplantation

- A. Failed previous pancreas transplantation including, but not limited to, the following:
  1. Non-function of the graft, or
  2. Chronic rejection, or
  3. Chronic allograft pancreatitis, and
- B. The above criteria for initial transplantation must be met, and
- C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.

IV. Contraindications

- A. Generally, transplantation is contraindicated in the presence of a medical condition that would itself significantly shorten life expectancy or make transplant success unlikely.
- B. Contraindications include, but are not limited to:
  1. Active systemic or localized infection
  2. Active untreated or untreatable malignancy
  3. Irreversible multisystem organ failure
  4. Acquired Immunodeficiency Syndrome (AIDS)
  5. Active alcohol and/or other substance abuse
  6. Irreversible severe brain damage
  7. Current patient and/or family noncompliance, psychiatric illness or psychological condition, or a pattern of substance abuse that would make compliance with a disciplined medical regimen impossible
  8. Inability to obtain informed consent from patient or guardian
- C. Relative contraindications\* include, but are not limited to:
  1. Infection that may be aggravated/activated by immunosuppression
  2. HIV infection without AIDS and with sustained CD4 counts greater than 200/mm<sup>3</sup>
  3. Malignancy other than basal or squamous cell carcinoma of the skin in preceding five years
  4. Untreatable vascular disease
  5. Unstable cardiac disease (e.g., Angina pectoris)
  6. Chronic peptic ulcer disease, GI bleeding, diverticulitis
  7. Cachexia/severe malnutrition
  8. Body mass index equal to or greater than 40kg/m sq (*See Appendix 1*)
  9. Age greater than 70
  10. High dose systemic corticosteroid use
  11. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI.

NOTE: Additional consultation, evaluation, and/or treatment may be indicated in these situations. Refer to Medical Director.

V. Documentation Requirements

Written documentation from the medical record specifying the medical necessity according to the above criteria is required. Requested documentation may include, but is not limited to:

- A. Patient suitability studies
- B. Transplant protocol.

COVERAGE ISSUES

1. Prior authorization is required for pancreas-kidney transplantation.
2. Coverage may vary according to the terms of the member's coverage document.
3. For Medicare members, refer to the following, as applicable:
  - Centers for Medicare and Medicaid Services (CMS). *National Coverage Determination (NCD) for Pancreas Transplants (260.3)*. Available at: [http://www.cms.hhs.gov/mcd/viewncd.asp?ncd\\_id=260.3&ncd\\_version=3&basket=ncd%3A260%2E3%3A3%3APancreas+Transplants](http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=260.3&ncd_version=3&basket=ncd%3A260%2E3%3A3%3APancreas+Transplants). Accessed December 23, 2009.
  - Centers for Medicare and Medicaid Services (CMS). *Medicare Benefit Policy Manual*. Chapter 11: End Stage Renal Disease (ESRD), Section 140 - Transplantation. Available at:

<http://www.cms.hhs.gov/manuals/Downloads/bp102c11.pdf>. Accessed December 23, 2009.

4. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member's coverage document.
5. Complex cases require medical director or external review and, as necessary, discussion with the patient's physician.
6. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.
7. Coverage of pancreatic islet cell transplantation is addressed in the member's coverage document.
8. Living donor segmental pancreas transplants are investigative, and therefore are not covered.
9. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits of the member's coverage document.
10. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.
11. See also related Medica UM Policy No. III-TRA.04 *Pancreas Transplantation (Pancreas Alone)*.

#### References:

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15. Reddy KS, Stablein D, Taranto S, et al. Long-term survival following simultaneous kidney-pancreas transplantation versus kidney transplantation alone in patients with type 1 diabetes mellitus and renal failure. *Am J Kidney Dis*. February 2003;41(2):464-470.

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**APPENDIX 1 – Body Mass Index (BMI) Conversion Table**

		Body Mass Index Table																																			
		Normal				Overweight				Obese				Extreme Obesity																							
BMI	Height (inches)	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54
		<b>Body Weight (pounds)</b>																																			
58	91	96	100	105	110	115	119	124	129	134	138	143	148	153	158	162	167	172	177	181	186	191	196	201	205	210	215	220	224	229	234	239	244	248	253	258	
59	94	99	104	109	114	119	124	128	133	138	143	148	153	158	163	168	173	178	183	188	193	198	203	208	212	217	222	227	232	237	242	247	252	257	262	267	
60	97	102	107	112	118	123	128	133	138	143	148	153	158	163	168	174	179	184	189	194	199	204	209	215	220	225	230	235	240	245	250	255	261	266	271	276	
61	100	106	111	116	122	127	132	137	143	148	153	158	164	169	174	180	185	190	195	201	206	211	217	222	227	232	238	243	248	254	259	264	269	275	280	285	
62	104	109	115	120	126	131	136	142	147	153	158	164	169	175	180	186	191	196	202	207	213	218	224	229	235	240	246	251	256	262	267	273	278	284	289	295	
63	107	113	118	124	130	135	141	146	152	158	163	169	175	180	186	191	197	203	208	214	220	225	231	237	242	248	254	259	265	270	278	282	287	293	299	304	
64	110	116	122	128	134	140	145	151	157	163	169	174	180	186	192	197	204	209	215	221	227	232	238	244	250	256	262	267	273	279	285	291	296	302	308	314	
65	114	120	126	132	138	144	150	156	162	168	174	180	186	192	198	204	210	216	222	228	234	240	246	252	258	264	270	276	282	288	294	300	306	312	318	324	
66	118	124	130	136	142	148	155	161	167	173	179	186	192	198	204	210	216	223	229	235	241	247	253	260	266	272	278	284	291	297	303	309	315	322	328	334	
67	121	127	134	140	146	153	159	166	172	178	185	191	198	204	211	217	223	230	236	242	249	255	261	268	274	280	287	293	299	306	312	319	325	331	338	344	
68	125	131	138	144	151	158	164	171	177	184	190	197	203	210	216	223	230	236	243	249	256	262	269	276	282	289	295	302	308	315	322	328	335	341	348	354	
69	128	135	142	149	155	162	169	176	182	189	196	203	209	216	223	230	236	243	250	257	263	270	277	284	291	297	304	311	318	324	331	338	345	351	358	365	
70	132	139	146	153	160	167	174	181	188	195	202	209	216	222	229	236	243	250	257	264	271	278	285	292	299	306	313	320	327	334	341	348	355	362	369	376	
71	136	143	150	157	165	172	179	186	193	200	208	215	222	229	236	243	250	257	265	272	279	286	293	301	308	315	322	329	338	343	351	358	365	372	379	386	
72	140	147	154	162	169	177	184	191	199	206	213	221	228	235	242	250	258	265	272	279	287	294	302	309	316	324	331	338	346	353	361	368	375	383	390	397	
73	144	151	159	166	174	182	189	197	204	212	219	227	235	242	250	257	265	272	280	288	295	302	310	318	325	333	340	348	355	363	371	378	386	393	401	408	
74	148	155	163	171	179	186	194	202	210	218	225	233	241	249	256	264	272	280	287	295	303	311	319	326	334	342	350	358	365	373	381	389	396	404	412	420	
75	152	160	168	176	184	192	200	208	216	224	232	240	248	256	264	272	279	287	295	303	311	319	327	335	343	351	359	367	375	383	391	399	407	415	423	431	
76	156	164	172	180	189	197	205	213	221	230	238	246	254	263	271	279	287	295	304	312	320	328	336	344	353	361	369	377	385	394	402	410	418	426	435	443	

The BMI describes relative weight for height. It is calculated as weight (in kilograms) / height (in meters) squared. The National Heart, Lung, and Blood Institute (NHLBI) guidelines classify overweight as a BMI of 25 through 29.9 kg/meter squared, obesity as a BMI equal to or greater than 30 kg/meter squared, and extreme obesity as a BMI equal to or greater than 40 kg/meter squared.

Adapted from: National Heart Lung and Blood Institute. Clinical Guidelines on the Identification, Evaluation and Treatment of Overweight and Obesity in Adults. Available at: [http://www.nhlbi.nih.gov/guidelines/obesity/ob\\_home.htm](http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm).