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TRICARE
MANAGEMENT ACTIVITY

MB&RB

CHANGE 84
6010.54-M
AUGUST 20, 2008

PUBLICATIONS SYSTEM CHANGE TRANSMITTAL FOR TRICARE POLICY MANUAL (TPM)

The TRICARE Management Activity has authorized the following addition(s)/ revision(s) to the 6010.54-M, issued August 2002.

CHANGE TITLE: **EVOLVING TECHNOLOGY JULY 2008**

PAGE CHANGE(S): See page 2.

SUMMARY OF CHANGE(S): Changes to the TRICARE Policy Manual to implement several policy determinations on evolving health care technologies including adding coverage for pulmonary vein antrum isolation/ablation; high dose chemotherapy with autologous bone marrow or peripheral stem cell transplantation; autologous pancreatic islet cell transplantation; and, presurgical evaluation prior to electrophysiologic procedure.

EFFECTIVE DATE: As per date of individual issuance.

IMPLEMENTATION DATE: Upon direction of the Contracting Officer.

Reta Michak
Chief, Office of Medical Benefits and Reimbursement Branch

ATTACHMENT(S): 22 PAGE(S)
DISTRIBUTION: 6010.54-M

WHEN PRESCRIBED ACTION HAS BEEN TAKEN, FILE THIS TRANSMITTAL WITH BASIC DOCUMENT

REMOVE PAGE(S)	INSERT PAGE(S)
CHAPTER 4	
Table of Contents, pages i and ii	Table of Contents, pages i and ii
Section 9.1, pages 3 and 4	Section 9.1, pages 3 and 4
Section 23.1, pages 3 through 10	Section 23.1, pages 3 through 10
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CHAPTER 5	
Section 1.1, pages 5 through 7	Section 1.1, pages 5 through 7
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SUMMARY OF CHANGES

CHAPTER 4

1. Table of Contents. Reflects change/addition to the title of Section 24.7.

2. Section 9.1. This adds coverage of pulmonary vein isolation/ablation per the guideline published in the Heart Rhythm Society (HRS)/European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) 2007 Consensus Statement. This change removes the exclusion of pulmonary vein antrum isolation/ablation for treatment of atrial fibrillation.

3. Section 23.1. This adds coverage for high dose chemotherapy with autologous bone marrow or peripheral stem cell transplantation for the treatment of desmoplastic small round cell tumor may be considered on a case-by-case basis under the TRICARE provisions for treatment of rare diseases. This change removes the exclusion of HDC with ABMT or PSCT for treatment of desmoplastic small round cell tumor.

4. Section 24.7. This adds coverage for autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy for treatment of chronic pancreatitis. The exclusion is revised to: autologous islet cell transplantation when used alone and allogeneic islet cell transplantation (for the treatment of diabetes mellitus).

CHAPTER 5

5. Section 1.1. This adds presurgical evaluation prior to electrophysiologic procedure to isolate pulmonary veins for radiofrequency ablation of arrhythmia focus to the list of covered indications for multislice or multidetector row CT angiography.

CHAPTER 4

SURGERY

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24.1	Heart-Lung And Lung Transplantation
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24.7	Simultaneous Pancreas-Kidney, Pancreas-After-Kidney, And Pancreas-Transplant-Alone, And Pancreatic Islet Cell Transplantation
24.8	Kidney Transplantation
24.9	Donor Costs

e. Symptomatic incompetence of the great or small saphenous veins (symptoms as in paragraph III.G.1.a.).

2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.

3. The patient's anatomy is amenable to endovenous ablation.

H. Ambulatory Blood Pressure Monitoring (ABPM) is only covered for beneficiaries with suspected white coat hypertension and is NOT covered for any other uses. The information obtained by ABPM is necessary in order to determine the appropriate medical management of the beneficiary. Suspected white coat hypertension is considered to exist when the following is documented:

1. There is no evidence of end-organ damage;

2. Office blood pressure greater than 140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; and

3. At least two blood pressure measurements taken outside the office which are less than 140/90 mm Hg.

I. Pulmonary vein isolation/ablation (CPT[3] procedure code 93651) is covered for beneficiaries who meet the guidelines published in the Heart Rhythm Society (HRS)/ European Heart Rhythm Association (EHRA)/European Cardiac Arrhythmia Society (ECAS) 2007 Consensus Statement as follows:

1. Symptomatic Atrial Fibrillation (AF) refractory or intolerant to at least one Class 1 or 3 antiarrhythmic medication.

2. In rare clinical situations, as first line therapy.

3. Selected symptomatic patients with heart failure and/or reduced ejection fraction.

4. The presence of a Left Atrial (LA) thrombus is a contraindication.

IV. EXCLUSIONS

A. Thermogram; cephalic (CPT[3] procedure code 93760); peripheral (CPT[3] procedure code 93762) are unproven.

B. Percutaneous Myocardial Laser Revascularization (PMR) is unproven.

C. Cardiomyoplasty (Cardiac Wrap) for treatment of heart failure is unproven.

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D. Minimally Invasive CABG surgery to include Minimally Invasive Direct Coronary Artery Bypass (MIDCAB) and Port Access Coronary Artery Bypass (PACAB) are unproven.

E. Percutaneous Transluminal Angioplasty (PTA) in the treatment of obstructive lesions of the carotid, vertebral and cerebral arteries is unproven.

F. Signal-Average Electrocardiography (CPT[4] procedure code 93278) is unproven.

G. Primary percutaneous transluminal mechanical thrombectomy (CPT[4] procedure code 37184) with or without second and all subsequent vessel(s) with the same vascular family (CPT[4] procedure code 37185) is unproven.

H. Secondary percutaneous transluminal thrombectomy (CPT[4] procedure code 37186) is unproven.

I. Percutaneous transluminal mechanical thrombectomy vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance (CPT[4] procedure code 37187) is unproven.

J. Percutaneous transluminal mechanical thrombectomy, vein(s) including intraprocedural pharmacological thrombolytic injections and fluroscopic guidance, repeat treatment on subsequent day during course of thrombolytic therapy (CPT[4] procedure code 37188) is unproven.

V. EFFECTIVE DATES

A. March 1, 2001, for gamma and beta intracoronary radiotherapy (brachytherapy).

B. January 1, 2002, for TMR.

C. October 1, 2003, for ventricular assist devices as destination therapy.

D. December 1, 2003, for endovenous radiofrequency ablation/obliteration.

E. January 1, 2005, for ABPM.

F. January 1, 2007, for pulmonary vein isolation/ablation.

- END -

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b. The patient has relapsed following a course of radiation therapy, and has also failed at least one course of conventional dose chemotherapy subsequent to the failed radiation therapy; and

c. The patient is in second or third complete remission.

3. Neuroblastoma.

a. Stage III or IV, when the patient is one for whom further treatment with a conventional dose therapy is not likely to achieve a durable remission.

b. Tandem autologous peripheral stem cell transplantation for high-risk neuroblastoma (INSS Stage III with either N-MYC gene amplification or unfavorable Shimada histology or INSS Stage IV).

4. Acute lymphocytic or nonlymphocytic leukemias (e.g., myelocytic, myelogenous, myeloblastic, or myelomonoblastic);

5. Primitive Neuroectodermal Tumors (PNET)/Ewing's Sarcoma.

6. Gliofibromas (also known as desmoplastic astrocytoma; desmoplastic glioblastoma).

7. Glioblastoma multiforme.

8. Posterior fossa teratoid brain tumors.

9. Rhabdomyosarcoma and undifferentiated sarcomas.

10. Multiple myeloma. Tandem autologous stem cell transplantation is covered for the treatment of multiple myeloma.

11. Chronic myelogenous leukemia.

12. Waldenstrom's macroglobulinemia.

13. AL (Amyloid Light-Chain) Amyloidosis.

14. Wilms'tumor.

15. Trilateral retinoblastoma/pineoblastoma.

16. Osteosarcoma (osteogenic sarcoma).

17. Germ cell tumors in a second or subsequent relapse.

18. High Dose Chemotherapy (HDC) with Autologous Bone Marrow Transplantation (ABMT) or Peripheral Stem Cell Transplantation (PSCT) for the treatment of desmoplastic

small round cell tumor may be considered on a case-by-case basis under the TRICARE provisions for treatment of rare diseases.

C. Allogeneic bone marrow or allogeneic peripheral stem cell transplantation, with or without HDC, is covered in the treatment of the following disease processes when either a related or unrelated donor is used. The list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective and comparable or superior to standard care (proven).

1. Aplastic anemia.

2. Acute lymphocytic or nonlymphocytic leukemias (e.g., myelocytic, myelogenous, myeloblastic, myelomonoblastic); Chronic Myelogenous Leukemia (CML); or preleukemic syndromes.

3. Severe combined immunodeficiency; e.g., adenosine deaminase deficiency and idiopathic deficiencies.

a. Partially matched-related donor stem cell transportation (without regard for the number of mismatched antigens in determining histocompatibility) in the treatment of Bare Lymphocyte Syndrome.

b. Unrelated donor and/or related donor (without regard for mismatched antigens) with or without T cell lymphocyte depletion in the treatment of familial erythrophagocytic lymphohistiocytosis, (FEL; generalized lymphohistiocytic infiltration; familial lymphohistiocytosis; familial reticuloendotheliosis; Familial Hemophagocytic Lymphohistiocytosis; FHL) for patients whose medical records document failure of conventional therapy (etoposide; corticosteroids; intrathecal methotrexate; and cranial irradiation).

c. Partially matched-related donor stem cell transplantation (without regard for the number of mismatched antigens) in the treatment of X-linked severe combined immunodeficiency syndrome (X-Linked SCID).

4. Wiskott-Aldrich Syndrome.

5. Infantile malignant osteopetrosis (Albers-Schonberg syndrome or marble bone disease).

6. Thalassemia major.

7. Intermediate and high grade lymphoma.

8. Myeloproliferative/dysplastic syndromes.

9. Congenital mucopolysaccharidoses.

10. Congenital amegakaryocytic thrombocytopenia.

11. Metachromatic leukodystrophy.

12. Sickle cell disease.

13. Chronic Lymphocytic Leukemia (CLL) when previous therapy has failed or when the CLL is refractory to conventional therapy.

14. Hyperesinophilic Syndrome.

15. Multiple myeloma when HCD with ABMT or PSCT has failed.

16. X-linked hyper-IgM Syndrome.

17. Chediak-Higashi Syndrome.

18. Langerhans Cell Histiocytosis, refractory to conventional treatment.

19. Hodgkin's disease.

D. Unirradiated donor lymphocyte infusion (donor buffy coat infusion, donor leukocyte infusion or donor mononuclear cell infusion) is covered for patients with CML, who relapse following their first or subsequent course of HDC with allogeneic BMT. The medical record must document that the patient:

1. Is in relapse following an adequate trial of HDC with allogeneic BMT of CML; and

2. Qualified (or would have qualified) for authorization for HDC with allogeneic BMT according to the provisions set forth in this policy.

E. Allogeneic umbilical cord blood transplantation, with or without HDC, is covered in the treatment of the following disease processes when either a related or unrelated donor is used. The list of indications is not all inclusive. Other indications are covered when documented by reliable evidence as safe, effective and comparable or superior to standard care (proven).

1. Aplastic anemia.

2. Acute lymphocytic or non-lymphocytic leukemias.

3. Chronic myelogenous leukemia.

4. Severe combined immunodeficiency.

5. Wiskott-Aldrich syndrome.

6. Infantile malignant osteopetrosis.

7. Blackfan-Diamond anemia.

8. Fanconi anemia.

9. Neuroblastoma.

10. X-linked lymphoproliferative syndrome.

11. Hunter syndrome.

12. Hurler syndrome.

13. Congenital amegakaryocytic thrombocytopenia.

14. Sickle cell anemia.

15. Globoid cell leukodystrophy.

16. Adrenoleukodystrophy.

17. Kostmann's Syndrome.

18. Lesch-Nyhan disease.

19. Intermediate and high grade non-Hodgkin's lymphoma.

20. Thalassemia major.

21. Myelodysplastic Syndrome.

22. X-linked hyper-IgM Syndrome.

23. Langerhans Cell Histiocytosis, refractory to conventional treatment.

F. Syngeneic (identical twin donor) stem cell transplantation is covered for the treatment of Hodgkin's disease.

G. TRICARE will reimburse costs for donor searches.

1. Charges for donor searches must be fully itemized and billed by the transplant center.

2. Costs for donor searches will be cost-shared in accordance with established reimbursement guidelines for outpatient diagnostic testing.

3. Donor search costs may be billed at any time. There is no limit on how many searches a transplant center may request from the search printout.

H. For the purposes of TRICARE coverage, the greatest degree of incompatibility allowed between donor or recipient (for either related or unrelated donors) is a single antigen mismatch at the A, B, or Dr. locus except for:

1. Patients with undifferentiated leukemia, Chronic Myelogenous Leukemia (CML), aplastic anemia, Acute Lymphocytic Leukemia (ALL) or Acute Myelogenous Leukemia (AML), when histocompatible related or unrelated donors are not available, a 3 antigen mismatch is allowed for related donors.

2. For patients under 18 years of age with a relapsed leukemia, when histocompatible related or unrelated donors are not available, parental CD34++ stem cell transplantation with 2-3 antigen mismatch is allowed.

I. Benefits will not be allowed for stem cell harvesting and/or cryopreservation and umbilical cord blood stem cell harvesting and/or cryopreservation until the stem cell reinfusion has been completed. In the event that the patient expires prior to the stem cell reinfusion being completed, benefits for the harvesting may be allowed.

J. Benefits are allowed for Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

K. Charges for stem cell and umbilical cord blood preparation and storage shall be billed through the transplantation facility in the name of the TRICARE patient.

L. Charges for the umbilical cord blood bank may be allowed only for patients who have undergone a covered transplant.

M. Claims for services and supplies related to the HDC and transplant for beneficiaries under the age of 18 will be reimbursed based on billed charges. Claims for HDC and transplant for adult patients, 18 years and older, will be reimbursed under the Diagnostic Related Group (DRG) payment system. Outpatient institutional facility charges will be paid as billed. Professional services are reimbursed under the CHAMPUS Maximum Allowable Charge (CMAC) Methodology.

N. Transportation of the patient by air ambulance may be cost-shared when determined to be medically necessary. Benefits for advanced life support air ambulance (to include attendant) may be preauthorized by the appropriate preauthorizing authority on an individual case basis in conjunction with the preauthorization for the services themselves.

O. In those cases where the beneficiary fails to obtain preauthorization, benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for determining if the patient meets the coverage criteria. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization for HDC with ABMT or PSCT will be reimbursed only under Point of Service rules.

IV. EXCLUSIONS

Benefits will not be paid for:

A. HDC with ABMT or Autologous PSCT, Allogeneic BMT or Allogeneic PSCT, with or without HDC, or Allogeneic Umbilical Cord Blood transplantation, with or without HDC, if

the patient has a concurrent condition (other existing illness) that would jeopardize the achievement of successful transplantation.

B. Expenses waived by the transplant center (i.e., beneficiary/sponsor not financially liable).

C. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant, or research program; unproven procedure).

D. Administration of an unproven immunosuppressant drug that is not FDA approved.

E. Pre- or post-transplant nonmedical expenses (i.e., out-of-hospital living expenses, to include, hotel, meals, privately owned vehicle for the beneficiary or family members).

F. Transportation of a donor.

G. Allogeneic bone marrow transplantation for treatment of low grade non-Hodgkin's lymphoma is not a benefit.

H. Autologous umbilical cord blood transplantation therapy as this procedure is considered unproven.

I. Allogeneic bone marrow transplantation for neuroblastoma as this procedure is considered unproven.

J. Allogeneic donor bone marrow transplantation (infusion) performed with or after organ transplants for the purpose of increasing tolerance of the organ transplant is considered unproven.

K. HDC with ABMT or PSCT is not a benefit for treatment of desmoplastic small round-cell tumor.

L. HDC with ABMT or PSCT is not covered for treatment of breast cancer.

M. HDC with allogeneic BMT is not a benefit for treatment of Waldenstrom's macroglobulinemia.

N. HDC with stem cell rescue is not a benefit for the treatment of epithelial ovarian cancer.

O. HDC with allogeneic stem cell transplantation is not covered for the treatment of cold agglutinin disease.

P. Donor lymphocyte infusion if not specifically listed as covered in paragraph III.D. under POLICY above.

V. EFFECTIVE DATES

A. May 1, 1987, for HDC with ABMT or PSCT for Hodgkin's disease, non-Hodgkin's lymphoma and neuroblastoma.

B. November 1, 1987, for HDC with ABMT or PSCT for acute lymphocytic and nonlymphocytic leukemias.

C. November 1, 1983, for HDC with allogeneic bone marrow transplants using related donors.

D. July 1, 1989, for HDC with allogeneic bone marrow transplants using unrelated donors.

E. July 11, 1996, for HDC with ABMT or PSCT for multiple myeloma.

F. January 1, 1994, for HDC with ABMT and PSCT for Wilms' tumor.

G. January 1, 1995, for allogeneic umbilical cord blood transplants.

H. January 1, 1994, for HDC with ABMT or PSCT for chronic myelogenous leukemia.

I. January 1, 1996, for HDC with ABMT or PSCT for Waldenstrom's macroglobulinemia.

J. January 1, 1996, for allogeneic bone marrow transplants using related 3 antigen mismatch donors for patients with undifferentiated leukemia, Chronic Myelogenous Leukemia (CML), aplastic anemia, Acute Lymphocytic Leukemia (ALL) or Acute Myelogenous Leukemia (AML).

K. October 1, 1996, for HDC with ABMT or PSCT for AL Amyloidosis.

L. January 1, 1995, for allogeneic bone marrow transplant for hypereosinophilic syndrome.

M. May 1, 1997, for HDC with ABMT or PSCT for trilateral retinoblastoma/ pineoblastoma.

N. January 1, 1997, for HDC with ABMT or PSCT for follicular lymphoma.

O. January 1, 1997, for HDC with ABMT or PSCT for non-Hodgkin's lymphoma in first complete remission.

P. November 28, 1997, for HDC with ABMT or PSCT for Hodgkin's disease in second or third remission.

Q. January 1, 1996, for HDC with allogeneic BMT for multiple myeloma.

R. July 1, 1999, for HDC with ABMT or PSCT for germ cell tumors in a second or subsequent relapse.

S. January 1, 1998, for HDC with ABMT or PSCT for osteosarcoma (osteogenic sarcoma).

T. June 1, 1995, for allogeneic BMT for Chediak-Higashi syndrome.

U. January 1, 1998, for allogeneic peripheral stem cell transplantation.

V. June 1, 2003, for Langerhans Cell Histiocytosis, refractory to conventional treatment.

W. January 24, 2002, for allogeneic stem cell transplant for Hodgkin's disease.

X. May 19, 2005, for tandem autologous peripheral stem cell transplant for high-risk neuroblastoma.

Y. January 1, 2006, for HDC with ABMT or PSCT for desmoplastic small round cell tumor.

- END -

CHAPTER 4
SECTION 24.7

SIMULTANEOUS PANCREAS-KIDNEY, PANCREAS-AFTER-KIDNEY, AND PANCREAS-TRANSPLANT-ALONE, AND PANCREATIC ISLET CELL TRANSPLANTATION

ISSUE DATE: February 5, 1996
AUTHORITY: 32 CFR 199.4(e)(5)

I. CPT[1] PROCEDURE CODES

48160, 48550 - 48556

II. POLICY

A. Benefits are allowed for Simultaneous Pancreas-Kidney transplantation (SPK), Pancreas-After-Kidney transplantation (PAK), and Pancreas-Transplantation-Alone (PTA).

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the contractor before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and contractor authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization. Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service basis. Special cost-sharing requirements apply to Point of Service claims.

2. For Standard and Extra patients residing in a Managed Care Support (MCS) region, preauthorization authority is the responsibility of the MCS Medical Director or other designated utilization staff.

B. Simultaneous pancreas-kidney transplantation (SPK) and pancreas-after-kidney transplantation (PAK) are covered when the transplantation is performed at a Medicare-approved renal transplantation center, for patients who:

1. Are suffering from concomitant, Type I Diabetes Mellitus that is resistant to exogenous therapy and end stage chronic renal disease; and

2. Have exhausted more conservative medical and surgical treatments for Type I Diabetes Mellitus and renal disease.

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3. Have a realistic understanding of the range of clinical outcomes that may be encountered.

4. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

C. PTA is covered when performed at a Medicare approved renal transplantation center, for patients who:

1. Are suffering from Type I Diabetes Mellitus;

a. Patient with diabetes must be beta cell autoantibody positive; or

b. Patient must demonstrate insulinopenia defined as a fasting C-peptide level that is less than or equal to 110% of the lower limit of normal of the laboratory's measurement method. Fasting C-peptide levels will only be considered valid with a concurrently obtained fasting glucose less than or equal to 225 mg/Dl;

2. Patients must have a history of medically-uncontrollable labile (brittle) insulin-dependent diabetes mellitus with documented recurrent, severe, acutely life-threatening metabolic complications that require hospitalization. Aforementioned complications include frequent hypoglycemia unawareness or recurring severe ketoacidosis, or recurring severe hypoglycemic attacks;

3. Patients must have been optimally and intensively managed by an endocrinologist for at least 12 months with the most medically-recognized advanced insulin formulations and delivery systems;

4. Patients must have the emotional and mental capacity to understand the significant risks associated with surgery and to effectively manage the lifelong need for immunosuppression

5. Patients must otherwise be a suitable candidate for transplantation.

D. Services and supplies related to SPK, PAK, and PTA are covered for:

1. Evaluation of a potential candidate's suitability for SPK, PAK, and PTA whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplantation inpatient hospital and outpatient services.

3. Surgical services and related pre- and postoperative services of the transplantation team.

4. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

5. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

6. Donor costs.

7. Blood and blood products.

8. FDA approved immunosuppression drugs to include off-label uses when reliable evidence documents that the off-label use is safe, effective and in accordance with the national standards of practice in the medical community (proven). Mycophenolate Mofetil (Cellcept) and Tacrolimus (Prograf) for the prophylaxis of organ rejection in patients receiving SPK, PAK, and PTA are covered.

9. Complications of the transplantation procedure, including inpatient care, management of infection and rejection episodes.

10. Periodic evaluation and assessment of the successfully transplanted patient.

11. Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

12. DNA-HLA tissue typing in determining histocompatibility.

13. Transportation of the patient by air ambulance and the services of a certified life support attendant.

E. Autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy for the treatment of chronic pancreatitis is covered (CPT[2] procedure code 48160).

III. POLICY CONSIDERATIONS

A. For beneficiaries who fail to obtain preauthorization for SPK, PAK, and PTA benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the SPK transplantation benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization will be reimbursed only under Point of Service rules.

B. Benefits for SPK, PAK, or PTA transplantation will only be allowed for transplants performed at a Medicare-approved renal transplantation center.

C. Effective for admissions on or after October 1, 1999, SPK, PAK, and PTA transplantations shall be reimbursed under the assigned DRG. Claims for admissions prior to October 1, 1999, shall be reimbursed based on billed charges.

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D. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

E. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

F. Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard CMS 1450 UB-04 claim form in the name of the TRICARE patient.

G. When a properly preauthorized candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplant from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

H. SPKs, PAKs, or PTAs performed on an emergency basis in an unauthorized renal transplant facility may be cost-shared <u>only</u> when the following conditions have been met:

1. The unauthorized center <u>must</u> consult with the nearest Medicare-certified renal transplant center regarding the transplantation case; and

2. It must be determined and <u>documented</u> by the transplant team physician(s) at the Medicare-approved renal transplantation center that transfer of the patient (to a Medicare-approved renal transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

IV. EXCLUSIONS

A. SPKs, PAKs, and PTAs are excluded when any of the following contraindications exist:

1. Significant systemic or multisystemic disease (other than pancreatic-renal dysfunction) which limits the possibility of full recovery and may compromise the function of the newly transplanted organs.

2. Active alcohol or other substance abuse.

3. Malignancies metastasized to or extending beyond the margins of the kidney and/or pancreas.

4. Significant coronary artery disease.

B. The following are also excluded:

1. Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received TRICARE approval as an appropriate "off-label" drug indication.

4. Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

6. Autologous islet cell transplantation, when used alone, and allogeneic islet cell transplantation for the treatment of diabetes mellitus (CPT[3] procedure codes 0141T - 0143T and HCPCS codes G0341 - G0343, and S2102).

V. EFFECTIVE DATES

A. October 1, 1995, for SPK transplants.

B. January 1, 1996, for PAK and PTA transplants.

C. January 1, 2007, for autologous pancreatic islet cell transplantation as an adjunct to a total or near total pancreatectomy for treatment of chronic pancreatitis.

- END -

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9. Presurgical cardiovascular evaluation for patients with equivocal stress study prior to kidney or liver transplantation.

10. Presurgical evaluation prior to electrophysiologic procedure to isolate pulmonary veins for radiofrequency ablation of arrhythmia focus.

V. EXCLUSIONS

A. Bone density studies for the routine screening of osteoporosis.

B. Ultrafast CT (electron beam CT (HCPCS code S8092)) to predict asymptomatic heart disease is preventive.

C. MRIs (CPT[5] procedure codes 77058 and 77059) to screen for breast cancer in asymptomatic women considered to be at low or average risk of developing breast cancer; for diagnosis of suspicious lesions to avoid biopsy, to evaluate response to neoadjuvant chemotherapy, to differentiate cysts from solid lesions.

D. MRIs (CPT[5] procedure codes 77058 and 77059) to assess implant integrity or confirm implant rupture, if implants were not originally covered or coverable.

E. 3D rendering (CPT[5] procedure codes 76376 and 76377) for monitoring coronary artery stenosis activity in patients with angiographically confirmed CAD is unproven.

F. 3D rendering (CPT[5] procedure codes 76376 and 76377) for evaluating graft patency in individuals who have undergone revascularization procedures is unproven.

G. 3D rendering (CPT[5] procedure codes 76376 and 76377) for use as a screening test for CAD in healthy individuals or in asymptomatic patients who have one or more traditional risk factors for CAD is unproven.

H. CT angiography (CPT[5] procedure codes 76376 and 76377) for acute ischemic stroke is unproven.

I. CT angiography (CPT[5] procedure codes 76376 and 76377) for intracerebral aneurysm and subarachnoid hemorrhage is unproven.

J. CT, heart, without contrast, including image post processing and quantitative evaluation of coronary calcium (ultra fast or electron beam CT) (CPT[5] procedure code 0144T, HCPCS code S8092) is excluded for symptomatic patients and for screening asymptomatic patients for CAD.

K. CT, heart, without contrast material followed by contrast, material(s) and further sections, including cardiac gating and 3D image post processing; cardiac structure and morphology (CPT[5] procedure code 0145T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute Myocardial Infarction (MI); and for screening asymptomatic patients for CAD.

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L. Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts) without quantitative evaluation of coronary calcium (CPT[6] procedure code 0146T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

M. Computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts) with quantitative evaluation of coronary calcium (CPT[6] procedure code 0147T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

N. Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts) without quantitative evaluation of coronary calcium (CPT[6] procedure code 0148T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

O. Cardiac structure and morphology and computed tomographic angiography of coronary arteries (including native and anomalous coronary arteries, coronary bypass grafts) with quantitative evaluation of coronary calcium (CPT[6] procedure code 0149T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

P. Cardiac structure and morphology in congenital heart disease (CPT[6] procedure code 0150T) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

Q. CT, heart, without contrast material followed by contrast material(s) and further sections, including cardiac gating and 3D image post processing, function evaluation (left and right ventricular function, ejection fraction and segmental wall motion (CPT[6] procedure code 0151T)) is excluded for patients with typical anginal chest pain with high suspicion for CAD; patients with acute MI; and for screening asymptomatic patients for CAD.

R. Multislice or multidetector row CT angiography of less than 16 slices per sec and 1mm or less resolution is excluded.

S. Dual Energy X-Ray Absorptiometry (DXA) composition study (CPT[6] procedure code 0028T) is unproven.

VI. EFFECTIVE DATES

A. The effective date for MRIs with contrast media is dependent on the U.S. Food and Drug Administration (FDA) approval of the contrast media and a determination by the contractor of whether the labeled or unlabeled use of the contrast media is medically necessary and a proven indication.

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B. March 31, 2006, for breast MRI.

C. March 31, 2006, for coverage of multislice or multidetector row CT angiography.

D. March 1, 2007, for CPT[7] procedure codes 72291 and 72292.

E. January 1, 2007, for coverage of multislice or multidetector row CT angiography performed for presurgical evaluation prior to electrophysiological procedure to isolate pulmonary veins for radiofrequency ablation of arrhythmia focus.

- END -

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