Simultaneous Pancreas-Kidney (SPK) and Pancreas and Living-Donor Kidney (SPLK) Transplantation

Aetna considers simultaneous pancreas-kidney (SPK) transplantation and simultaneous cadaver-donor pancreas and living-donor kidney (SPLK) transplantation medically necessary for members with diabetes and end-stage renal disease (ESRD) who meet the transplanting institution's selection criteria. In the absence of an institution's selection criteria, Aetna considers SPK transplantation and SPLK transplantation medically necessary in persons with diabetes and ESRD when all of the following selection criteria are met, and none of the following absolute contraindications is present:

1. Member has a creatinine clearance (Clcr), calculated by the Cockcroft-Gault formula (see Appendix), of less than 20 ml/min, or a directly measured glomerular filtration rate (GFR) of less than 20 ml/min; and
2. Member has ESRD and requires dialysis or is expected to require dialysis in the next 12 months.

Aetna considers SPK and SPLK transplantation not medically necessary for persons with poorly controlled HIV infection. HIV infection is considered poorly controlled if any of the following is present:

- HIV-1 RNA (viral load) is not at undetectable levels; or
- Member has not been on stable anti-viral therapy for at least 3 months; or
- Member has opportunistic infections or neoplasms; or
- Member's CD4 count has not been 200 cells/mm3 or greater for at least 6 months.

Because of the success of protease inhibitors, the literature indicates the HIV-positive person may be a candidate for transplant if the CD4 count is more than 200 cells/mm3 for greater than 6 months, on stable anti-viral therapy more than 3 months, no opportunistic infections or neoplasms, and viral load is zero.

Aetna considers SPK and SPLK transplantation not medically necessary for members with any of the following absolute contraindications:
- Inability to adhere to the regimen necessary to preserve the transplant
- Malignant neoplasm (other than non-melanomatous skin cancer or low grade prostate cancer) that has a significant risk of recurrence
- Ongoing or recurrent active infections that are not adequately treated Persistent substance abuse
- Severe uncorrectable cardiac disease (e.g., coronary angiographic evidence of significant non-correctable coronary artery disease, refractory congestive heart failure, ejection fraction below 40%, myocardial infarction less than 3 months ago) (cardiac status should be re-evaluated annually while on waiting list)
- Unresolvable current psychosocial problems.

Aetna considers SPK and SPLK transplantation medically necessary for persons with any of the following relative contraindications if the attending physician determines and documents that the potential benefits of SPK or SPLK transplantation outweigh the risks. Relative contraindications to SPK and SPLK transplantation include:

- Chronic liver disease
- Clinical evidence of severe cerebrovascular or peripheral vascular disease (e.g., ischemic ulcers, previous amputation secondary to severe peripheral vascular disease, severe iliac disease, blindness). Adequate peripheral arterial supply should be determined by standard evaluation in the vascular laboratory including Doppler examination and plethysmographic readings of systolic blood pressure.
- Past psychosocial abnormality
- Persons with body mass index (BMI) of 35 or higher and type 2 diabetes (bariatric surgery should be considered)
- Structural genito-urinary abnormality or recurrent urinary tract infection.
- Substance abuse history (other than persistent substance abuse)
- Treated malignancy (SPK or SPLK transplantation is considered medically necessary in persons with malignant neoplasm if the neoplasm has been adequately treated and the risk of recurrence is small)
- Uncontrolled hypertension.

Note: For isolated kidney transplant, see CPB 0493 - Kidney Transplantation. For pancreas after kidney (PAK) transplant, see CPB 0601 - Pancreas Transplantation Alone (PTA) and Islet Cell Transplantation.

Background

Diabetes mellitus is the most common endocrine disease worldwide and is the leading chronic disease in children. Despite the success of exogenous insulin therapy, numerous long-term sequelae develop in patients with diabetes, including end-stage renal failure, cardiovascular disease, autonomic and somatic neuropathy, and blindness. Chronically abnormal lipid metabolism, accelerated atherosclerosis, and destruction of the microvascular system result in global vascular disease, leading to amputations and premature death from myocardial infarctions and cerebrovascular accidents. Occurring in approximately 1% of the population, diabetes accounts for more than 160,000 deaths annually in the United States.

According to the United States End-Stage Renal Disease (ESRD) Registry, diabetic patients between the ages of 20 and 45 who have to undergo dialysis as their only treatment option have less than 20% survival after 10 years. Solitary renal transplantation with continued administration of exogenous insulin for glucose control is a good option for diabetic recipients as it has 5-year survival rates approaching 70% for cadaveric renal transplants and 85% for living related donor (LRD) transplants; however, the diabetic state remains associated with poor patient survival.

Reported in 1993, the Diabetes Control and Complications Trial Study conclusively showed that tight glucose control significantly decreases nephropathy, retinopathy, and neuropathy in patients with type 1 diabetes, and this provided the impetus for combining pancreas transplantation with kidney transplantation. In selected patients and without compromising survival rates, both diabetes and ESRD
can be eliminated by simultaneous pancreas and cadaver kidney (SPK) transplantation and LRD kidney transplantation alone followed by a solitary cadaver-donor pancreas transplant (sequential pancreas after kidney [PAK] transplantation). SPK transplantation is more widely used than PAK, because SPK is a single operation and there is an "immunologic advantage" for the pancreas because the kidney can serve as a reliable marker for rejection of the pancreas. However, some advocate PAK transplantation if there is a willing LRD. Use of a well-matched living-donor kidney offers the potential benefits of shorter waiting time, expansion of the organ donor pool, and improved short-term and long-term renal graft function. SPK pancreas graft survival has historically exceeded that of solitary pancreas transplantation; however, recent improvements in solitary pancreas transplant survival rates have narrowed the advantage seen with SPK. Both SPK and PAK impose greater immunologic risks over kidney transplant alone.

The goal of these transplants is to produce a lasting normoglycemic state that enhances quality of life and prevents, arrests, or perhaps even reverses the otherwise inexorable progression of the destructive effects of diabetes. As demonstrated in a number of studies, this resumption of normal glucose homeostasis achieved provides several benefits:

I. quality of life is improved since it usually removes dependence on both insulin and dialysis;
II. recurrence of diabetic nephropathy is attenuated;
III. diabetic retinopathy is reduced;
IV. progression of diabetic neuropathy may be halted and in some cases reversed, including improvements in autonomic neuropathy, enhancing both cardiac reflex function and gastric motility in some cases; and
V. beneficially affects patient survival even though this glycemic control is given as a late intervention in a diabetic patient's lifetime.

More importantly, studies show that diabetic patients who receive a successful SPK transplant do not develop diabetic complications in their newly transplanted kidney, unlike persons with diabetes who receive a kidney transplant alone. Even diabetic vesicopathy has been shown to improve after transplantation, as well as attenuation of diabetic cardiovascular disease.

The American Diabetes Association (2003) has concluded that pancreas-kidney transplantation is indicated in patients with insulin-dependent diabetes and end stage renal disease: "Pancreas transplantation should be considered an acceptable therapeutic alternative to continued insulin therapy in diabetic patients with imminent or established end-stage renal disease who have had or plan to have a kidney transplant, because the successful addition of a pancreas does not jeopardize patient survival, may improve kidney survival, and will restore normal glycemia."

An assessment by the Institute for Clinical Systems Improvement (ICSI, 2003) stated that "[n]early all uremic diabetics are candidates for a kidney transplant and most should also receive a pancreas either simultaneously (SPK) or sequentially (PAK). For those who have a living donor for a kidney, PAK is preferable to waiting years for a cadaver SPK". The ICSI assessments notes that experience with pancreas transplant for type 2 diabetes is more limited than for type 1 diabetes. The assessment reports that approximately 6 % of pancreas transplants are done in patients with type 2 diabetes and about 94 % are done in patients with type 1 diabetes. The ICSI guideline describes an unpublished study by Elkhammas et al (1999) of SPK transplantation in 299 patients with type 2 diabetes who received pancreas transplants from 1994 to 1999. The study noted that, at 5 years, 86 % of patients survived, 73 % of pancreas grafts survived, and 75 % of kidney grafts survived.

Nath et al (2005) reported on the results of pancreas transplant in 17 patients with type 2 diabetes transplanted between 1994 through 2002. Of the 17 transplants, 7 (41 %) were a SPK, 4 (24 %) were a PAK, and 6 (35 %) were a pancreas transplantation alone (PTA). One recipient died during the peri-operative period because of aspiration. The other 16 recipients became euglycemic post-transplant and had a functional graft at 1 year post-transplant. After a mean follow-up of 4.3 years post-transplant, the patient survival rate is 71 % (12 of 17). The investigators reported that the 4 additional deaths were due to sepsis (n = 2), suicide (n = 1), and unknown cause (n = 1). The investigators noted that all 4 of these recipients were insulin-independent at the time of death, although 1 was on an oral hypoglycemic agent. The investigators reported that, of the 12 recipients currently alive, 11 remain euglycemic without
requiring insulin therapy or oral hypoglycemic agents, and 1 recipient began insulin therapy 1.2 years post-transplant.

Light and Barhyte (2005) reported on 10- to 15-year results of SPK transplants in 135 type 1 and type 2 patients who were dependent on insulin. Twenty-eight percent of the patients in the cohort had type 2 diabetes. The investigators reported that, at 5 and 10 years, pancreas survival for type 1 diabetes was 71% and 49%; for type 2 diabetes it was 67% and 56% (p = 0.52). Kidney survival at 5 and 10 years for patients with type 1 diabetes was 77% and 50%; for patients with type 2 diabetes, it was 72% and 56% (p = 0.65). Patient survival at 5 and 10 years with 85% and 63% for patients with type 1 diabetes mellitus, and was 73% and 70% for patients with type 2 diabetes (p = 0.98). The investigators concluded that the outcomes of SPK transplants are equivalent regardless of diabetes type.

The pros and cons of SPK and PAK must be weighed in each individual patient to determine proper treatment. The graft survival rate of living related kidney allografts significantly exceed that of cadaveric renal transplants because they have less immunologic disparity and comparatively minimal preservation injury. However, in the setting of diabetes, with the possibility of recurrent diabetic nephropathy and other disabling complications, the medical literature indicates that the addition of a pancreas transplant might provide benefits that outweigh the advantages of LRD renal transplantation. SPK transplantation is associated with excess initial morbidity and an uncertain effect on patient survival when compared with solitary cadaveric or living donor renal transplantation. Recent studies show rejection rates after SPK transplantation have now diminished to less than 5% within the first 6 months. The results also show that SPK has long-term transplant survival rates, which are equal to or even better than survival rates of kidneys from the very best matched live donors. Certainly, survival of SPK transplants is superior to cadaver kidney transplants alone in the diabetic population.

Largely because of these results, and because of the distinct advantages of living kidney donation, some centers have developed a new approach for uremic diabetic patients: simultaneous cadaver-donor pancreas and living-donor kidney transplantation (SPLK). As a single procedure, SPLK has obvious advantages over the standard living-donor kidney transplant followed by PAK. Moreover, because the SPLK kidney is from a living donor, there may be both short-term and long-term benefits over SPK transplantation. Potential benefits of SPLK for diabetic uremic patients include a shorter waiting time for transplantation and better early and long-term renal graft function. Generalized use of SPLK transplantation would expand the renal organ donor pool, thus benefiting all patients waiting for a kidney transplant. The main drawback to SPLK -- coordination of a living donor nephrectomy with a cadaver pancreas transplant -- is easily overcome.

With improved surgical technique and better organ preservation, the remaining obstacle was a high rejection rate of both the kidney and the pancreas. However, with the introduction of more immunosuppressant alternatives, rejection rates have now been reduced. The addition of mycophenolate mofetil (CellCept) and tacrolimus (Prograf) have been extremely helpful options in the immunosuppressive management. Furthermore, induction protocols utilizing basiliximab (Simulect) or daclizumab (Zenapax) are less complicated and have been shown to be better tolerated than the previous induction protocols with anti-lymphocyte globulin (ALG) or OKT3 (Muromonab-CD3). The reported 1-year pancreas graft survival rate for SPK transplantation is now 83%. The results of PAK have lagged behind the excellent results of SPK transplantation. During the past 3 to 4 years, the reported 1-year pancreas graft survival rate for PAK recipients has improved from 54% survival to 71%, shrinking the "immunologic advantage" of combining a cadaver pancreas with a kidney from the same donor.

Members referred for SPK transplantation, who are acceptable candidates by all criteria, should be counseled about possible living donor kidney transplantation. Since there is an extreme shortage of cadaver kidneys in the United States and because living donor kidneys have a survival advantage over cadaver kidneys, generally accepted guidelines state that persons with diabetes with ESRD referred for SPK transplantation should consider living donor kidney transplant alone (LDKTA) followed by a pancreas after kidney (PAK) procedure. Studies show that the LDKTA and PAK option carries equal pancreatic transplant success as SPK transplantation combined with the added survival advantage of
Margreiter et al (2013) systematically reviewed the relevant literature with regard to various biomarkers, imaging techniques, and pathologic evaluation of allograft tissue following pancreas transplantation. More recent studies including graft histology demonstrated the low specificity of pancreatic enzymes as a marker of acute rejection. On the other hand, most blood and serum markers are indicative of an activated immune status rather than rejection. Interestingly, the concomitantly transplanted kidney from the same donor does not seem to be a reliable surrogate marker. Although computed tomography or ultrasound-guided percutaneous biopsies of the pancreas are performed more frequently at present, the complication rate is still as high as 11%. In contrast, cystoscopic and enteroscopic biopsies of the duodenal part of the graft are associated with almost no complications. The few clinical studies dealing with the duodenum as surrogate marker for the pancreas report a high correlation between duodenum mucosal and pancreas parenchymal histology. The authors concluded that pancreatic graft parenchymal biopsy remains the gold standard in diagnosing pancreatic rejection, as clinical parameters, pancreatic enzymes, non-invasive biomarkers, and surrogate renal biopsies are not reliable tools. Endoscopically obtained duodenal cuff biopsies are a less invasive alternative to percutaneous biopsies.

Kobayashi et al (2014) studied and compared clinical and functional outcomes after simultaneous deceased donor pancreas and kidney transplantation (SPK DD), simultaneous deceased donor pancreas and living donor kidney transplantation (SPK DL), and simultaneous living donor pancreas and kidney transplantation (SPK LL). From January 1, 1996 to September 1, 2005, a total of 8,918 primary SPK procedures were reported to the International Pancreas Transplant Registry. Of these, 8,764 (98.3%) were SPK DD, 115 (1.3%) were SPK DL, and 39 (0.4%) were SPK LL. These researchers compared these 3 groups with regard to several end-points including patient and pancreas and kidney graft survival rates. The 1-year and 3-year patient survival rates for SPK DD were 95% and 90%, 97% and 95% for SPK DL, and 100% and 100% for SPK LL recipients, respectively (p ≥ 0.07). The 1-year and 3-year pancreas graft survival rates for SPK DD were 84% and 77%, 83% and 71% for SPK DL, and 90% and 84% for SPK LL recipients, respectively (p ≥ 0.16). The 1-year and 3-year kidney graft survival rates for SPK DD were 92% and 84%, 94% and 86% for SPK DL, and 100% and 89% for SPK LL recipients, respectively (p ≥ 0.37). The authors concluded that patient survival rates and graft survival rates for pancreas and kidney were similar among the 3 groups evaluated in this study.

In a Cochrane review, Montero et al (2014) noted that pancreas or kidney-pancreas transplantation improves survival and quality of life for people with type 1 diabetes mellitus and kidney failure. Immunosuppression after transplantation is associated with complications. Steroids have adverse effects on cardiovascular risk factors such as hypertension, hyperglycemia or hyperlipidemia, increase risk of infection, obesity, cataracts, myopathy, bone metabolism alterations, dermatologic problems and Cushingoid appearance; whether avoiding steroids changes outcomes is unclear. These investigators evaluated the safety and effectiveness of steroid early withdrawal (treatment for less than 14 days after transplantation), late withdrawal (after 14 days after transplantation) or steroid avoidance in patients receiving PTA, SPK or PAK. They searched the Cochrane Renal Group’s Specialised Register (to June 18, 2014) through contact with the Trials’ Search Co-ordinator. They hand-searched: reference lists of nephrology textbooks, recent publications and clinical practice guidelines; abstracts from international transplantation society scientific meetings; and sent emails and letters seeking information about unpublished or incomplete studies to known investigators. These researchers included randomized controlled trials (RCTs) or cohort studies of steroid avoidance (including early withdrawal) versus steroid maintenance or versus late withdrawal in pancreas or pancreas with kidney transplant recipients. They defined steroid avoidance as complete avoidance of steroid immunosuppression, early steroid withdrawal as steroid treatment for less than 14 days after transplantation and late withdrawal as steroid withdrawal after 14 days after transplantation. Two authors independently assessed the retrieved titles and abstracts, and where necessary the full text reports to determine which studies satisfied the inclusion criteria. Authors of included studies were contacted to obtain missing information. Statistical analyses were performed using random effects models and results expressed as risk ratio (RR) or mean difference (MD) with 95% confidence interval.
Cohort studies were not meta-analyzed, but their findings summarized descriptively. A total of 3 RCTs enrolling 144 participants met the inclusion criteria: 2 compared steroid avoidance versus late steroid withdrawal and 1 compared late steroid withdrawal versus steroid maintenance. All studies included SPK and only 1 also included PTA. All studies had an overall moderate risk of bias and presented only short-term results (6 to 12 months). Two studies (89 participants) compared steroid avoidance or early steroid withdrawal versus late steroid withdrawal. There was no clear evidence of an impact on mortality (2 studies, 89 participants: RR 1.64, 95% CI: 0.21 to 12.75), risk of kidney loss censored for death (2 studies, 89 participants: RR 0.35, 95% CI: 0.04 to 3.09), risk of pancreas loss censored for death (2 studies, 89 participants: RR 1.05, 95% CI: 0.36 to 3.04), or acute kidney rejection (1 study, 49 participants: RR 1.05, 95% CI: 0.26 to 21.50), however results were uncertain and consistent with no difference or important benefit or harm of steroid avoidance/early steroid withdrawal. The study that compared late steroid withdrawal versus steroid maintenance observed no deaths, no graft loss or acute kidney rejection at 6 months in either group and reported uncertain effects on acute pancreas rejection (RR 0.88, 95% CI: 0.06 to 13.35). Of the possible adverse effects only infection was reported by 1 study. There were significantly more UTIs reported in the late withdrawal group compared to the steroid avoidance group (1 study, 25 patients: RR 0.41, 95% CI: 0.26 to 0.66). These researchers also identified 13 cohort studies and 1 RCT that randomized tacrolimus versus cyclosporine. These studies in general showed that steroid-sparing and withdrawal strategies had benefits in lowering HbAc1 and risk of infections (BK virus and CMV disease) and improved blood pressure control without increasing the risk of rejection. However, 2 studies found an increased incidence of acute pancreas rejection (HR 2.8, 95% CI: 0.89 to 8.81, p = 0.066 in 1 study and 43.3% in the steroid withdrawal group versus 9.3% in the steroid maintenance, p < 0.05 at 3 years in the other) and 1 study found an increased incidence of acute kidney rejection (18.7% in the steroid withdrawal group versus 2.8% in the steroid maintenance, p < 0.05) at 3 years. The authors concluded that there is currently insufficient evidence for the benefits and harms of steroid withdrawal in pancreas transplantation in the 3 RCTs (144 patients) identified. The results showed uncertain results for short-term risk of rejection, mortality, or graft survival in steroid-sparing strategies in a very small number of patients over a short period of follow-up. Overall the data was sparse, so no firm conclusions are possible. Moreover, the 13 observational studies findings generally concur with the evidence found in the RCTs.

**Appendix**

The Cockcroft-Gault formula for calculation of creatinine clearance is now generally accepted as superior to actual measured creatinine clearance as determined by a 24-hour urine collection, due to inherent inaccuracies and collection difficulties. The formula is as follows:

<table>
<thead>
<tr>
<th>Cockcroft-Gault Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated creatinine clearance (ml/min) - males: 140 minus age multiplies weight (kg) divided by serum creatinine (mg/dL) multiplies 72</td>
</tr>
<tr>
<td>Estimated creatinine clearance (ml/min) - males: (140 - age) x weight (kg)</td>
</tr>
<tr>
<td>Estimated creatinine clearance (ml/min) - females: 0.85 multiplies 140 minus age multiplies weight (kg) divided by serum creatinine (mg/dL) multiplies 72</td>
</tr>
<tr>
<td>Estimated creatinine clearance (ml/min) - females: 0.85 ((140 - age) x weight (kg))</td>
</tr>
</tbody>
</table>

serum creatinine (mg/dL) x 72
<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>48160</td>
<td>Pancreatectomy, total or subtotal, with autologous transplantation of pancreas or pancreatic islet cells</td>
</tr>
<tr>
<td>48550</td>
<td>Donor pancreatectomy, with preparation and maintenance of allograft from cadaver donor, with or without duodenal segment for transplantation</td>
</tr>
<tr>
<td>48551</td>
<td>Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery</td>
</tr>
<tr>
<td>48552</td>
<td>Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each</td>
</tr>
<tr>
<td>48554</td>
<td>Transplantation of pancreatic allograft</td>
</tr>
<tr>
<td>48556</td>
<td>Removal of transplanted pancreatic allograft</td>
</tr>
<tr>
<td>50300</td>
<td>Donor nephrectomy, with preparation and maintenance of allograft, from cadaver donor, unilateral or bilateral</td>
</tr>
<tr>
<td>50320</td>
<td>Donor nephrectomy, open from living donor (excluding preparation and maintenance of allograft)</td>
</tr>
<tr>
<td>50323</td>
<td>Backbench standard preparation of cadaver donor renal allograft prior to transplantation, including dissection and removal of perinephric fat, diaphragmatic and retroperitoneal attachments, excision of adrenal gland, and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary</td>
</tr>
<tr>
<td>50325</td>
<td>Backbench standard preparation of living donor renal allograft (open or laparoscopic) prior to transplantation, including dissection and removal of perinephric fat and preparation of ureter(s), renal vein(s), and renal artery(s), ligating branches, as necessary</td>
</tr>
<tr>
<td>50327</td>
<td>Backbench reconstruction of cadaver or living donor renal allograft prior to transplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>50328</td>
<td>arterial anastomosis, each</td>
</tr>
<tr>
<td>50329</td>
<td>ureteral anastomosis, each</td>
</tr>
<tr>
<td>50340</td>
<td>Recipient nephrectomy (separate procedure)</td>
</tr>
<tr>
<td>50360</td>
<td>Renal allotransplantation, implantation of graft, excluding donor and recipient nephrectomy</td>
</tr>
<tr>
<td>50365</td>
<td>with recipient nephrectomy</td>
</tr>
<tr>
<td>50370</td>
<td>Removal of transplanted renal allograft</td>
</tr>
</tbody>
</table>
50380  Renal autotransplantation, reimplantation of kidney
50547  Laparoscopic nephrectomy; donor nephrectomy from living donor (excluding preparation and maintenance of allograft)

**Other CPT codes related to the CPB:**

90935 - 90999  Dialysis, hemodialysis, and end-stage renal disease services

**HCPCS code covered if selection criteria are met:**

S2065  Simultaneous pancreas kidney transplantation

**Other HCPCS codes related to the CPB:**

J7513  Daclizumab, parenteral, 25 mg
S9339  Home therapy; peritoneal dialysis, administrative services, professional pharmacy services, care coordination and all necessary supplies and equipment (drugs and nursing visits coded separately)

**ICD-10 codes covered if selection criteria are met:**

E10.21 - E10.29  Diabetes mellitus with renal manifestations
E11.21 - E11.29
E13.21 - E13.29
N18.5  Chronic kidney disease, Stage V
N18.6  End stage renal disease

**ICD-10 codes contraindicated for this CPB:**

A00.0 - B99.9  Infectious and parasitic diseases [ongoing or recurrent active infections that are not adequately treated]
C00.0 - C75.9, D00.0 - D09.9  Malignant neoplasms and carcinoma in situ [other than melanoma] [other than melanoma and low-grade prostate cancer]
E66.01, E66.1, E66.8, E66.9  Obesity unspecified or morbid obesity [BMI of 35 or higher]
F10.10 - F19.99  Alcohol and drug dependence and nondependent abuse [persistent substance abuse]
I05.0 - I52  Chronic rheumatic heart disease, hypertensive disease, ischemic heart disease, diseases of pulmonary circulation, and other forms of heart disease [severe uncorrectable cardiac disease]
I60.00 - I69.998  Cerebrovascular disease [severe]
I70.201 - I70.92  Atherosclerosis of the extremities
I73.0 - I73.9  Other peripheral vascular diseases
I79.8  Other disorders of arteries, arterioles and capillaries in diseases classified elsewhere
K70.0 - K74.69, K76.89  Diseases of liver
The above policy is based on the following references:


The Pennsylvania Medical Assistance Program considers HIV infection to be poorly controlled if any of the following is present:

- Member does not have sustained virologic response (SVR) with low levels of viremia; or
- Member does not have a non-detectable viral load; or
- Member has not been on stable anti-viral therapy for at least 3 months; or
- Member has opportunistic infections or neoplasms; or
- Member's CD4 count has not been 200 cells/mm3 or greater for at least 6 months.

The Pennsylvania Medical Assistance Program considers a “viral load of zero” to mean the viral load is undetectable.