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Allogeneic Pancreas Transplant

Policy # 00092
Original Effective Date: 11/22/1993
Current Effective Date: 01/18/2017

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Islet cell transplantation is considered in medical policy 00007.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider a combined pancreas-kidney transplant in insulin dependent diabetic patients with uremia to be **eligible for coverage**.

Based on review of available data, the Company may consider pancreas transplant after a prior kidney transplant in patients with insulin dependent diabetes to be **eligible for coverage**.

Based on review of available data, the Company may consider pancreas transplant alone in patients with severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile insulin dependent diabetes that persists in spite of optimal medical management to be **eligible for coverage**.

Based on review of available data, the Company may consider pancreas retransplant after a failed primary pancreas transplant in patients who meet criteria for pancreas transplantation to be **eligible for coverage**.

Pancreas transplantation, when the transplant recipient is HIV positive, may be considered for coverage when all of the additional criteria are met:

- CD4 count >200 cells/mm-3 for more than six months; and
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least six months; and
- Demonstrable adherence and a stable HAART regimen for at least six months; and
- Absence of AIDS-defining illness following successful immune reconstitution after HAART; and
- All other transplant criteria are met.

When Services Are Considered Investigational
Note: Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

The use of pancreas transplant when patient selection criteria are not met is considered **investigational.***

The use of pancreas transplant in HIV positive recipients when patient selection criteria and additional HIV positive patient selection criteria are not met is considered **investigational.***

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Based on review of available data, pancreas re-transplantation after two or more prior failed pancreas transplants is considered **investigational.***

Background/Overview

Transplantation of a normal pancreas is a treatment method for patients with insulin-dependent diabetes mellitus. Pancreas transplantation can restore glucose control and is intended to prevent, halt, or reverse the secondary complications from diabetes mellitus.

Achievement of insulin independence with resultant decreased morbidity and increased quality of life is the primary health outcome of pancreas transplantation. While pancreas transplantation is generally not considered a life-saving treatment, in a small subset of patients who experience life-threatening complications from diabetes, pancreas transplantation could be considered life-saving. Pancreas transplant alone (PTA) has also been investigated in patients following total pancreatectomy for chronic pancreatitis. In addition to the immune rejection issues common to all allograft transplants, autoimmune destruction of beta cells has been observed in the transplanted pancreas, presumably from the same mechanism responsible for type 1 diabetes.

Pancreas transplantation occurs in several different scenarios such as: 1) a diabetic patient with renal failure who may receive a cadaveric simultaneous pancreas/kidney transplant (SPK); 2) a diabetic patient who may receive a cadaveric or living-related pancreas transplant after a kidney transplantation (pancreas after kidney, i.e., PAK); or 3) a non-uremic diabetic patient with specific severely disabling and potentially life-threatening diabetic problems who may receive a PTA. The total number of adult pancreas transplants (pancreas and pancreas/kidney) in the U.S. peaked at 1,484 in 2004; the number has since declined. In 2011, there were 287 pancreas transplants and 795 pancreas/kidney transplants in the U.S.

According to International Registry data, the proportion of pancreas transplant recipients worldwide who have type 2 diabetes has increased over time, from 2% in 1995 to 7% in 2010. In 2010, approximately 8% of SPK, 5% of PAK, and 1% of PTA were performed in patients with type 2 diabetes.

The approach to retransplantation varies according to the cause of failure. Surgical/technical complications such as venous thrombosis are the leading cause of pancreatic graft loss among diabetic patients. Graft loss from chronic rejection may result in sensitization, increasing both the difficulty of finding a cross-matched donor and the risk of rejection of a subsequent transplant. Each center has its own guidelines based on experience; some transplant centers may wait to allow reconstitution of the immune system before initiating retransplant with an augmented immunosuppression protocol.

FDA or Other Governmental Regulatory Approval

Centers for Medicare and Medicaid Services (CMS)
Allogeneic pancreas transplant is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The CMS has made the following national coverage decision regarding pancreas transplant for Medicare recipients:

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A. General
Pancreas transplantation is performed to induce an insulin-independent, euglycemic state in diabetic patients. The procedure is generally limited to those patients with severe secondary complications of diabetes, including kidney failure. However, pancreas transplantation is sometimes performed on patients with labile diabetes and hypoglycemic unawareness.

B. Nationally Covered Indications
Effective for services performed on or after July 1, 1999, whole organ pancreas transplantation is nationally covered by Medicare when performed simultaneous with or after a kidney transplant. If the pancreas transplant occurs after the kidney transplant, immunosuppressive therapy begins with the date of discharge from the inpatient stay for the pancreas transplant.

Effective for services performed on or after April 26, 2006, pancreas transplants alone (PA) are reasonable and necessary for Medicare beneficiaries in the following limited circumstances:

1. PA will be limited to those facilities that are Medicare-approved for kidney transplantation.
2. Patients must have a diagnosis of type I diabetes:
   - Patient with diabetes must be beta cell autoantibody positive; or
   - 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 $\leq$225 mg/dL;
3. 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;
4. 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;
5. 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; and,
6. Patients must otherwise be a suitable candidate for transplantation.

C. Nationally Non-Covered Indications
The following procedure is not considered reasonable and necessary within the meaning of section 1862(a)(1)(A) of the Social Security Act:

Transplantation of partial pancreatic tissue or islet cells (except in the context of a clinical trial (see section 260.3.1 of the National Coverage Determinations Manual).

Rationale/Source
Much of the published literature consists of case series reported by single centers and registry data. The extant randomized controlled trials (RCTs) compare immunosuppression regimens and surgical techniques and therefore do not address the comparison of pancreas transplantation to insulin therapy, or SPK transplant to insulin therapy and hemodialysis.

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This policy is based in part on a 1998 TEC Assessment, which focused on pancreas graft survival and health outcomes associated with both PTA and PAK transplant. A 2001 TEC Assessment focused on the issue of pancreas retransplant. The assessments and subsequent evidence offer the following observations and conclusions:

Pancreas after Kidney (PAK) Transplant
PAK transplantation allows the uremic patient the benefits of a living-related kidney graft, if available and the benefits of a subsequent pancreas transplant that is likely to result in improved quality of life compared to a kidney transplant alone. Uremic patients for whom a cadaveric kidney graft is available, but a pancreas graft is not simultaneously available benefit similarly from a later pancreas transplant. Based on International Pancreas Registry data, at 5 years post-transplant, the patient survival rate after PAK is 83%.

In 2009, Fridell and colleagues reported a retrospective review (n=203) of a single center's experience with PAK and SPK since 2003, when current induction/tacrolimus immunosuppressive strategies became standard. Of the cases studied, 61 (30%) were PAK and 142 (70%) were SPK. One-year patient survival rates were 98% and 95% (PAK and SPK, respectively; p=0.44). Pancreas graft survival rates at 1 year were observed to be 95% and 90%, respectively (p=0.28). The authors concluded that in the modern immunosuppressive era, PAK should be considered as an acceptable alternative to SPK in candidates with an available living kidney donor.

In 2012, Bazarbachi and colleagues reviewed a single center's experience with PAK and SPK. Between 2002 and 2010, 172 pancreas transplants were performed in diabetic patients; 123 SPK and 49 PAK. The median length of time between kidney and pancreas transplantation in the PAK group was 4.8 years. Graft and patient survival rates were similar in the 2 groups. Death-censored pancreas graft survival rates for SPK and PAK were 94% and 90% at 1 year, 92% and 90% at 3 years, and 85% and 85% at 5 years (all respectively, p=0.93). Patient survival rates (calculated beginning at the time of pancreas transplantation) in the SPK versus PAK groups were 98.3% and 100% after 1 year, 96.4% and 100% after 3 years, and 94.2% and 100% after 5 years (all respectively, p=0.09).

Kleinclauss and colleagues retrospectively examined data from diabetic kidney transplant recipients (n=307) from a single center and compared renal graft survival rates in those who subsequently received a pancreatic transplant to those who did not. The comparative group was analyzed separately depending on whether they were medically eligible (KTA-E) for pancreas transplant, but chose not to proceed for financial or personal reasons, or were ineligible (KTA-I) for medical reasons. The KTA-I (n=57) group differed significantly at baseline from both the PAK group (n=175) and the KTA-E group (n=75) with respect to age, type of diabetes, and dialysis experience; kidney graft survival rates were lower than either of the other groups, with 1-, 5-, and 10-year rates of 75%, 54%, and 22%, respectively (p<0.0001). The PAK and KTA-E groups were similar in age, race, type of diabetes, and dialysis experience. The authors compared 1--, 5-, and 10-year kidney graft survival rates in PAK patients with those in the KTA-E group: 98%, 82%, and 67% versus 100%, 84%, and 62%, respectively, and concluded that the subsequent transplant of a pancreas after a living donor kidney transplant does not adversely affect patient or kidney graft survival rates.

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Simultaneous Pancreas/Kidney (SPK) Transplant

According to International Registry data through 2005, recent 5-year graft survival rates for SPK transplants were 72% for the pancreas and 80% for the kidney. Ten-year graft survival rates reached almost 60% for SPK transplants. The U.S.-based Organ Procurement and Transplant Network (OPTN) reported a 5-year survival rate of 85.5% (95% confidence interval [CI], 84.3% to 86.7%) for SPK procedures performed between 1997 and 2000.

In 2010, Mora et al described the long-term outcome of 12 patients 15 years following SPK transplant. Metabolic measures of glucose control were measured at 1, 5, 10, and 15 years following the procedure. Of this subset of patients, 6 (50%) had nondiabetic glucose challenge tests. Basal serum insulin levels declined over this period as well, from 24 µU/L to 16 µU/L at 1 and 15 years, respectively. The authors conclude that in a select group of patients whose pancreatic graft continued to function after 15 years, some glycemic control continued, albeit in a diminished fashion. It should be noted that this represents a small fraction of the 367 patients receiving the SPK transplant at this single center (12/367 SPK; 3.3%). The number of allograft survivals at 5 or more, and 10 or more years in this study was 43 (11.7%) and 28 (7.6%), respectively.

Pancreas transplant has been found to improve mortality in patients with type 1 diabetes. In 2014, van Dellen et al in the U.K. reported a retrospective analysis of data on 148 SPK patients and a wait-list control group of 120 patients. All patients had uncomplicated type 1 (insulin dependent) diabetes. (The study also included 33 patients who had PAK and 11 PTA patients.) Overall mortality was 30% (30/120 patients) on the waiting list and patients who underwent transplantation had a mortality rate of 9% (20/193 patients); the difference between groups was statistically significant ($p<0.001$). One-year mortality was 13% (n=16) on the waiting list and 4% (n=8) in the transplant group ($p<0.001$).

There are some data on outcomes in patients with type 2 compared with type 1 diabetes. In 2011, Sampaio et al published an analysis of data from the United Network for Organ Sharing (UNOS) database. The investigators compared outcomes in 6141 patients with type 1 diabetes and 582 patients with type 2 diabetes who underwent SPK between 2000 and 2007. In adjusted analyses, outcomes were similar in the 2 groups. After adjusting for other factors such as body weight; dialysis time; and cardiovascular comorbidities, type 2 diabetes was not associated with an increased risk of pancreas or kidney graft survival, or mortality compared with type 1 diabetes.

Pancreas Transplant Alone (PTA)

PTA graft survival has improved in recent years. According to International Registry data 1-year graft function increased from 51.5% in 1987-1993 to 77.8% in 2006-2010 ($p<0.001$). One-year immunologic graft loss remained higher (6%) after PTA than PAK (3.7%) or SPK (1.8%). In carefully selected patients with insulin dependent diabetes mellitus (IDDM) and severely disabling and potentially life-threatening complications due to hypoglycemia unawareness and labile diabetes that persists, despite optimal medical management, the benefits of PTA were judged to outweigh the risk of performing pancreas transplantation with subsequent immunosuppression.

Most patients undergoing PTA are those with either hypoglycemic unawareness or labile diabetes. However, other exceptional circumstances may exist where nonuremic IDDM patients have significant

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morbidity risks due to secondary complications of diabetes (ie, peripheral neuropathy) that exceed those of the transplant surgery and subsequent chronic immunosuppression. Because virtually no published evidence regarding outcomes of medical management in this very small group of exceptional diabetic patients exists, it is not possible to generalize about which circumstances represent appropriate indications for pancreas transplantation alone. Case-by-case consideration of each patient's clinical situation may be the best option for determining the balance of risks and benefits.

Noting that nephrotoxic immunosuppression may exacerbate diabetic renal injury after PTA, in 2008 Scalea et al reported a single institutional review of 123 patients who received 131 PTA for development of renal failure. Mean graft survival was 3.3 years (range, 0-11.3), and 21 patients were lost to follow- up. Mean estimated glomerular filtration rate was 88.9 pretransplantation versus 55.6 posttransplantation, with mean follow-up of 3.7 years. All but 16 patients had a decrease in estimated glomerular filtration rate, and mean decrement was 32.1 mg/min/1.73. Thirteen developed end-stage renal disease, which required kidney transplantation at a mean of 4.4 years. The authors suggested that patients should be made aware of the risk and only the most appropriate patients offered PTA. Future updates of this policy will continue to follow this clinical topic.

Pancreas Retransplantation

The OPTN reported data on transplants performed between 1997 and 2004. Patient survival rates after repeat transplants were similar to survival rates after primary transplants. Patient survival rates after repeat transplants were similar to survival rates after primary transplants. For example, the 1-year survival rate was 94.0% (95% CI, 92.6% to 95.3%) after a primary pancreas transplant and 95.6% (95% CI, 92.7% to 98.5%) after a repeat pancreas transplant. The numbers of patients transplanted was not reported, but the OPTN data stated that 1217 patients were alive 1 year after primary transplant and 256 after repeat transplants. Three-year patient survival rates were 89.5% (95% CI, 87.8% to 91.2%) after primary transplants and 89.7% (95% CI,% 85.9% to 93.5%) after repeat transplants. One-year graft survival rates were 78.2% (95% CI, 76.0% to 80.5%) after primary pancreas transplants and 70.4% (95% CI, 64.8% to 76.0%) after repeat transplants.

Data are similar for patients receiving combined kidney/pancreas transplants, but follow-up data are only available on a small number of patients who had repeat kidney/pancreas transplants so estimates of survival rates in this group are imprecise. Three-year patient survival rates were 90.0% (95% CI, 89.0% to 91.0%) after primary combined transplant and 79.9% (95% CI, 63.8% to 95.9%) after a repeat combined transplant. The number of patients who were living 3 years after transplant was 2907 after a primary combined procedure and 26 after a repeat combined procedure.

In 2013, Buron et al reported on their experience with pancreas retransplantation in France and Geneva. Between 1976 and 2008, 568 pancreas transplants were performed at 2 centers, including 37 repeat transplants. Patient survival after a repeat pancreas transplant was 100% after 1 year and 89% after 5 years. Graft survival was 64% at 1 year and 46% at 5 years. Among the 17 patients who underwent a second transplant in a later time period, ie, between 1995 and 2007, graft survival was 71% at 1 year and 59% at 5 years. In this more recently transplanted group, graft survival rates were similar to primary pancreas transplants, which was 79% at 1 year and 69% at 5 years.

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Pancreas Transplant in HIV+ Transplant Recipients
OPTN policy on Identification of Transmissible Diseases in Organ Recipients states: "Potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy."

In 2006, the British HIV Association and the British Transplantation Society Standards Committee published guidelines for kidney transplantation in patients with HIV disease. As described earlier, these criteria may be extrapolated to other organs. The guidelines recommend that any patient with end- stage organ disease with a life expectancy of at least 5 years is considered appropriate for transplantation under the following conditions:

- CD4 count greater than 200 cells/microliter for at least 6 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable HAART [highly active antiretroviral therapy] regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART.

Age
In 2013, Shah et al reviewed data on 405 patients who underwent PTA between 2003 and 2011. One-year patient survival was 100% for patients younger than age 30, 98% for patients age 30 to 39 years, 94% for patients 40 to 49 years, 95% for patients 50 to 59 years and 93% for patients age 60 or older. There was not a statistically significant difference in the rate of patient survival by age (p=0.38).

Findings were similar for 1-year graft survival; there was not a statistically significant difference in outcomes by age of the transplant recipients (p=0.10).

In addition, several 2011 studies addressed pancreas transplantation in individuals 50 years of age or older. A study by Afaneh et al reviewed data on 17 individuals at least 50 years-old and 119 individuals younger than 50 years who had a pancreas transplant at a single institution in the U.S. The 2 groups had similar rates of surgical complications, acute rejection and nonsurgical infections. Overall patient survival was similar. Three- and 5-year survival rates were 93% and 90% in the younger group and 92% and 82%, all consecutively, in the older group. Schenker et al in Germany compared outcomes in 69 individuals at least 50 years-old and 329 individuals younger than 50 years who had received a pancreas transplant. Mean duration of follow-up was 7.7 years. One-, 5-, and 10-year patient and graft survival rates were similar in the 2 groups. For example, the 5-year patient survival rate was 89% in both groups. The 5-year pancreas grant survival rate was 76% in the older group and 72% in the younger group. The authors of both studies, as well as the authors of a commentary accompanying the Schenker article, agreed that individuals age 50 years and older are suitable candidates for pancreas transplantation.

Summary
The literature, consisting primarily of case series and registry data, demonstrate graft survival rates comparable with other solid organ transplants, as well as attendant risks associated with the immunosuppressive therapy necessary to prevent allograft rejection. No randomized controlled trials have

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compared any form of pancreas transplant with insulin therapy. Pancreas transplant may be considered medically necessary in patients who are undergoing, or have undergone, kidney transplantation for renal failure. It may also be considered medically necessary as a stand-alone treatment in patients with hypoglycemia unawareness and labile diabetes, despite optimal medical therapy and in whom severe complications have developed.

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11/21/2001	Managed Care Advisory Council approval
11/18/2003	Medical Policy Committee review
01/26/2004	Managed Care Advisory Council approval
01/04/2005	Medical Director review
01/18/2005	Medical Policy Committee review. Format revision. No substance change to policy.
01/31/2005	Managed Care Advisory Council approval
02/01/2006	Medical Director review
03/15/2006	Medical Policy Committee approval. Format revision.
02/07/2007	Medical Director review
02/21/2007	Medical Policy Committee approval. Coverage eligibility unchanged.
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval.
02/04/2009	Medical Director review
02/19/2009	Medical Policy Committee approval. Clarified 2nd, 3rd and 4th criteria bullets for HIV positive transplant recipients. No change to coverage eligibility.
02/04/2010	Medical Policy Committee approval
02/17/2010	Medical Policy Implementation Committee approval. No change to coverage.
02/03/2011	Medical Policy Committee approval
02/16/2011	Medical Policy Implementation Committee approval. No change to coverage.
02/02/2012	Medical Policy Committee approval
02/15/2012	Medical Policy Implementation Committee approval. Patient selection criteria revised.
01/03/2013	Medical Policy Committee approval
01/09/2013	Medical Policy Implementation Committee approval. No change to coverage.
01/09/2014	Medical Policy Committee approval
01/15/2014	Medical Policy Implementation Committee approval. Patient selection criteria section removed.
01/08/2015	Medical Policy Committee approval
01/21/2015	Medical Policy Implementation Committee approval. Added “in patients who meet criteria for pancreas transplantation” in the criteria for pancreas retransplant after a failed primary pancreas transplant.
01/07/2016	Medical Policy Committee approval
01/22/2016	Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
01/05/2017	Medical Policy Committee approval
01/18/2017	Medical Policy Implementation Committee approval. No change to coverage

Next Scheduled Review Date: 01/2018

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	48550, 48551, 48552, 48554, 48556
HCPCS	S2065, S2152
ICD-10 Diagnosis	All related diagnoses

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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