Lung and Lobar Lung Transplant

Policy # 00414
Original Effective Date: 05/21/2014
Current Effective Date: 08/17/2016

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.

When Services Are 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 lung transplantation for carefully selected patients with irreversible, progressively disabling, end-stage pulmonary disease unresponsive to maximum medical therapy, including but not limited to one of the conditions listed below to be eligible for coverage.

Based on review of available data, the Company may consider a lobar lung transplant from a living or deceased donor for carefully selected patients with end-stage pulmonary disease including but not limited to one of the conditions listed below to be eligible for coverage.

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Based on review of available data, the Company may consider lung or lobar lung retransplantation after a failed lung or lobar lung transplant in patients who meet criteria for lung transplantation to be eligible for coverage.
Lung and Lobar Lung Transplant

Policy # 00414
Original Effective Date: 05/21/2014
Current Effective Date: 08/17/2016

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

Based on review of available data, the Company considers lung or lobar lung transplantation in all other situations to be investigational.*

Background/Overview
A lung transplant consists of replacing all or part of diseased lungs with healthy lung(s). Transplantation is an option for patients with end-stage lung disease.

End-stage lung disease may be the consequence of a number of different etiologies. The most common indications for lung transplantation are chronic obstructive pulmonary disease (COPD), idiopathic pulmonary fibrosis, cystic fibrosis, alpha-1 antitrypsin deficiency, and idiopathic pulmonary arterial hypertension. Prior to the consideration for transplant, patients should be receiving maximal medical therapy, including oxygen supplementation, or surgical options, such as lung-volume reduction surgery for COPD. Lung or lobar lung transplantation is an option for patients with end-stage lung disease despite these measures.

A lung transplant refers to single-lung or double-lung replacement. In a single-lung transplant, only 1 lung from a deceased donor is provided to the recipient. In a double-lung transplant, both the recipient’s lungs are removed and replaced by the donor’s lungs. In a lobar transplant, a lobe of the donor’s lung is excised, sized appropriately for the recipient’s thoracic dimensions, and transplanted. Donors for lobar transplant have primarily been living-related donors, with 1 lobe obtained from each of 2 donors (e.g., mother and father) in cases for which bilateral transplantation is required. There are also cases of cadaver lobe transplants. Combined lung-pancreatic islet cell transplant is being studied for patients with cystic fibrosis.

Since 2005, potential recipients have been ranked according to the Lung Allocation Score (LAS). Patients 12 years of age and older receive a score between 1 and 100 based on predicted survival after transplantation reduced by predicted survival on the waiting list; the LAS takes into consideration the patient’s disease and clinical parameters. In 2010, a simple priority system was implemented for children younger than age 12 years. Under this system, children younger than 12 years with respiratory lung failure and/or pulmonary hypertension who meet criteria are considered “priority 1” and all other candidates in the age group are considered “priority 2”. A lung review board has the authority to adjust scores on appeal for adults and children.

FDA or Other Governmental Regulatory Approval
Centers for Medicare and Medicaid Services (CMS)
Lung transplantation is covered under Medicare when performed in a facility that is approved by Medicare as meeting institutional coverage criteria. The Centers for Medicare and Medicaid Services have stated that under certain limited cases, exceptions to the facility-related criteria may be warranted if there is justification and the facility ensures safety and efficacy objectives.
Lung and Lobar Lung Transplant

Policy # 00414
Original Effective Date: 05/21/2014
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Rationale/Source
The most recent literature search was performed for the period of October 2012 through December 22, 2014. Due to the nature of the population, there are no randomized controlled trials (RCTs) that compare lung transplantation with alternatives. Systematic reviews are based on case series and registry data. The extant RCTs compare surgical technique, infection prophylaxis, or immunosuppressive therapy and are not germane to this policy. The following is a summary of the evidence based on registries, case series, and expert opinion.

Survival
The Registry of the International Society for Heart and Lung Transplantation (ISHLT) contains data from 42,069 adult recipients who received lung transplantation (including lung retransplantation) before 2012. Reports from 132 transplant centers around the world were obtained on 3,640 lung transplants performed in 2011. The overall median survival of patients who underwent lung transplantation between June 1994 and June 2011 was 5.6 years. In the first 30 days after transplantation, the major reported causes of mortality were graft failure and noncytomegalovirus (non-CMV) infections while non-CMV infections became the major cause of death for the remainder of the first year. Beyond the first year, the most common reported causes of mortality were bronchiolitis obliterans, graft failure (lung rejection or bronchiolitis obliterans) and non-CMV infections. Over time, the proportion of patients who died from malignancies increased; malignancies accounted for 15% of all deaths between 5 and 10 years after transplant. Authors of a 2009 review of the current status of lung transplantation observed that while transplantation can prolong survival, survival statistics for lung transplantation are not as favorable as in patients receiving other solid organ transplants.

In 2009, Thabut et al reported on a comparison of patients undergoing single- and double-lung transplantation for idiopathic pulmonary fibrosis. A retrospective review was conducted of 3,327 patients with data in the United Network for Organ Sharing (UNOS) registry. More patients underwent single-lung as compared to double-lung transplant (64.5% vs 35.5%, respectively). Median survival time was greater for the double-lung group at 5.2 years (95% confidence interval [CI], 4.3 to 6.7 years) versus 3.8 years (95% CI, 3.6 to 4.1 years; p<0.001). After adjustment for baseline differences, however, survival times were not statistically different. The authors concluded that overall survival did not differ between the 2 groups: single-lung transplants offered improved short-term survival but long-term harm, whereas double-lung transplant increased short-term harm but was associated with a long-term survival benefit.

Patient Selection
In 2008, Kozower et al performed a retrospective cohort study using data from 5 academic medical centers to evaluate the impact of a new lung allocation score on short-term outcomes after lung transplantation. (This lung allocation score was implemented in May 2005 by the Organ Procurement and Transplantation Network [OPTN].) This new score changed lung allocation from a system based on waiting time to an algorithm based on the probability of survival for 1 year on the transplant list and survival 1-year posttransplantation. Results were compared for 170 patients who received transplants on the basis of the new lung allocation scores (May 4, 2005 to May 3, 2006) with those of 171 patients who underwent transplants the preceding year before implementation of the scoring system. Waiting time decreased from 681 to 445.6 days (p<0.001). Recipient diagnoses changed, with an increase (15% to 25%) in idiopathic
Lung and Lobar Lung Transplant

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Pulmonary fibrosis cases and decreases in emphysema (46% to 34%) and cystic fibrosis (23% to 13%). Hospital mortality and 1-year survival were the same between groups (5.3% vs 5.3% and 90% vs 89%, respectively). Presumably due to increased severity of illness, the incidence of primary graft dysfunction and postoperative intensive care unit length of stay increased in the year after implementation of the scoring system; graft dysfunction grew from 14.8% (24/170) to 22.9% (39/171); (p=0.04) and length of stay rose from 5.7 to 7.8 days.

In 2010, Yusen et al reviewed the effect of the LAS on lung transplantation by comparing statistics for the period before and after its implementation in 2005. Other independent changes in clinical practice, which may affect outcomes over the same period of time, include variation in immunosuppressive regimens, an increased supply of donor lungs, changes in diagnostic mix, and increased consideration of older recipients. Deaths on the waiting list declined following implementation of the LAS system, from approximately 500 per 5000 patients to 300 per 5000 patients. However, it is expected that implementation of LAS affected patient characteristics of transplant applicants. One-year survival posttransplantation did not improve after implementation of the LAS system: patient survival data before and after are approximately 83%. Long-term survival data are not yet available for comparison. In 2014, Shafii et al reported on a retrospective evaluation of the LAS and mortality in 537 adults listed for lung transplantation and 426 who underwent primary lung transplantation between 2005 and 2010. Patients on the waitlist who had a higher LAS had a higher rate of mortality (p<0.001). In the highest quartile of LAS, ranging from 47 to 95, within 1 year of listing, there was a 75% mortality rate. Higher LAS was also associated with early posttransplant survival (p=0.05) but not late posttransplant survival (p=0.4). When other predictive factors of early mortality were accounted for, pretransplant LAS was not independently related to posttransplant mortality (p=0.12).

Pediatric Considerations

In 2012, Benden et al reviewed pediatric lung transplants that have been reported to the international registry. Pediatric patients are defined as those younger than 18 years of age. The authors noted an increase in the number of pediatric lung transplants in recent years; there were 126 transplants in 2010 compared with 73 in 2000. In contrast to adult patients, the most common indication for pediatric patients was cystic fibrosis, accounting for 54% of lung transplants in 6- to 11-year-olds and 72% of lung transplants in 12- to 17-year-olds that occurred between 1990 and June 2011. Survival has improved in the recent era, and 5-year survival is not significantly different from adult recipients. The half-life, estimated time at which 50% of recipients have died, was 4.7 years for children and 5.3 years for adults. For children receiving allografts between 2002 and June 2010, the 5-year survival rate was 54% and 7-year survival was 44%. Patients aged 1 to 11 years had a significantly better survival rate than those between the ages of 12 and 17 years (half-life of 6.2 years and 4.3 years, respectively). In the first year after lung transplantation, non-CMV infection and graft failure were the 2 leading causes of death. Bronchiolitis obliterans syndrome was the major cause of death beyond 3 years after transplantation.

Potential Contraindications

Malignancy

Malignancies are common after lung transplantation with 21% and 40% of patients reporting 1 or more malignancies at 5 and 10 years posttransplantation, respectively. Skin cancer occurred most frequently and lymphoproliferative disorders were the malignancies most associated with morbidity posttransplantation.
Lung and Lobar Lung Transplant

Policy # 00414
Original Effective Date: 05/21/2014
Current Effective Date: 08/17/2016

A 2012 study reported on outcomes in patients with lung cancer who were lung transplant recipients. Ahmad et al identified 29 individuals in the UNOS database who underwent lung transplantation for advanced bronchoalveolar carcinoma (BAC). These patients represented 0.13% of the 21,553 lung transplantations during the study period. BAC and general lung transplant recipients had similar survival rates: the 30-day mortality rate was 7% versus 10% (p=0.44) and 5-year survival rate was 50% versus 57% (p=0.66).

HIV
Solid organ transplant for patients who are HIV-positive has been controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be of research interest at some transplant centers, the minimal data regarding long-term outcome in these patients primarily consist of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease.

As of October 2013, the OPTN policy on HIV status in recipients states: “A 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. These criteria may be extrapolated to other organs:
- CD4 count greater than 200 cells/mL 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 regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART.

Other Infections
Infection with *Burkholderia cenocepacia* is associated with increased mortality in some transplant centers, a factor that may be taken into account when evaluating overall risk for transplant survival. Two articles published in 2008 evaluated the impact of infection with various species of *Burkholderia* on outcomes for lung transplantation for cystic fibrosis. In a study published by Murray et al, multivariate Cox survival models assessing hazard ratios (HRs) were applied to 1026 lung transplant candidates and 528 transplant recipients. Of the transplant recipients, 88 were infected with *Burkholderia*. Among transplant recipients infected with *B cenocepacia*, only those infected with nonepidemic strains (n=11) had significantly greater posttransplant mortality than uninfected patients (HR=2.52; 95% CI, 1.04 to 6.12; p=0.04). Transplant recipients infected with *Burkholderia gladioli* (n=14) also had significantly greater posttransplant mortality than uninfected patients (HR=2.23; 95% CI, 1.05 to 4.74; p=0.04). When adjustments for specific species/strains were included, lung allocation scores of *Burkholderia multivorans*-infected transplant candidates were comparable with uninfected candidate scores, and scores for patients infected with nonepidemic *B cenocepacia* or *B gladioli* were lower. In a smaller study of 22 patients colonized with *Burkholderia cepacia* complex who underwent lung transplantation in 2 French centers, the risk of death by
univariate analysis was significantly higher for the 8 patients infected with \textit{B cepacia} than for the other 14 colonized patients (11 of whom had \textit{B multivorans}).

In 2012, Shields et al reported on infections in 596 consecutive lung transplant recipients treated at a single center occurring in the first 90 days after transplantation. A total of 109 patients (18\%) developed 138 \textit{Staphylococcus aureus} infections. The most common type of infection was pneumonia (66 of 138, 48\%) followed by tracheobronchitis (36/138 [26\%]) and bacteremia (17/138 [12\%]). Thirteen of 109 (12\%) patients with \textit{S aureus} infection died within 90 days of the onset of infection. The 1-year mortality rate was higher for patients with \textit{S aureus} pneumonia (19/66 [29\%]) but not \textit{S aureus} tracheobronchitis (8/36 [22\%]) compared with uninfected patients (85/487 [17\%]).

Pinney et al published a retrospective review of invasive fungal infection rates in lung transplantation patients without cystic fibrosis treated at a single center. Patients were followed for a median of 34 months. Invasive fungal infections were identified in 22 of 242 (9.1\%) patients. \textit{Aspergillus} infections were most common, occurring in 11 of 242 (4.5\%) of patients. There were also 7 cases (3\%) of \textit{Candida} infection. Survival rates did not differ significantly in patients with invasive fungal infections compared with the entire cohort of patients. For example, 3-year survival was 50\% among patients with invasive fungal infection and 66\% in the entire cohort (p=0.66). The authors did not compare survival in patients with invasive fungal infections with survival only in those without invasive fungal infections.

In 2013, Lobo et al reported on 13 lung transplant patients with \textit{Mycobacterium abscessus} in cystic fibrosis. Survival rates were 77\%, 64\%, and 50\% after transplant at 1, 3, and 5 years, respectively. These results were not significantly different when compared with 154 cystic fibrosis patients treated with lung transplantation who did not have \textit{M abscessus} (p=0.8).

**Coronary Artery Disease**

Castleberry et al reported on a retrospective cohort study of lung transplantation with concurrent coronary bypass (CAB) or preoperative percutaneous coronary intervention (PCI). Of 898 lung transplants performed during the period between 1997 and 2010, 49 patients also had concurrent CAB and 38 patients had preoperative PCI. All of the intervention groups, including revascularization, had similar rates of perioperative mortality, overall unadjusted survival, and adjusted hazard ratio for cumulative risk of death. Postoperative major adverse cardiac event rates were also similar among groups, although postoperative length of stay, intensive care unit time and need for ventilator support increased in patients receiving concurrent CAB with lung transplantation.

In 2011, Sherman et al reported on outcomes in 27 patients with coronary artery disease (CAD) at a single center who underwent lung transplantation and coronary revascularization. Patients needed to be otherwise considered good candidates for transplantation and have discrete coronary lesions (at least 50\% in the left main artery or at least 70\% in other major vessels) and preserved ejection fraction. Thirteen patients had single-lung transplantation and 14 had double-lung transplantation. Outcomes were compared with a control group of 81 patients without CAD who underwent lung transplantation; patients were matched for age, diagnosis, lung allocation score and type of procedure. During a mean follow-up of 3 years, 9 of 27 (33\%) patients with CAD and 28 of 81 (35\%) without CAD died (p=0.91). Bronchiolitis obliterans and
infection were the primary causes of death. There was no significant difference between groups in a composite outcome of adverse cardiac events (defined as acute coronary syndrome, redo revascularization, or hospital admissions for heart failure) (p=0.80).

**Lobar Lung Transplantation**

Several case series have reported outcomes after lobar lung transplants in both children and adults. In 2005, Barr et al reported on experience performing living donor lobar lung transplants in the United States. Ninety patients were adults and 43 were children. The primary indication for transplantation (86%) was cystic fibrosis. At the time of transplantation, 67% of patients were hospitalized and 20% were ventilator dependent. Overall recipient actuarial survival at 1, 3, and 5 years was 70%, 54%, and 45%, respectively. There was not a statistically significant difference in actuarial survival between adults and children who underwent transplantation. Moreover, survival rates were similar to the general population of lung transplant recipients. The authors also reported that rates of postoperative pulmonary function in patients surviving more than 3 months posttransplant were comparable with rates in cadaveric lung transplant recipients.

In 2014 Date et al reported on a retrospective study comparing 42 living-donor lobar lung transplants and 37 cadaveric lung transplants. Survival rates at 1 and 3 years were not significantly different between the groups (89.7 and 86.1% vs 88.3 and 83.1%, respectively, p=0.55), despite living-donor lobar lung transplant patients having poorer health status preoperatively. In 2012, a program in Japan reported on 14 critically ill patients who had undergone single living-donor lobar lung transplants; there were 10 children and 4 adults. Patients were followed for a mean 45 months. The 3-year survival rate was 70% and the 5-year survival was 56%. Severe graft dysfunction occurred in 4 patients. Mean forced vital capacity (FVC) was found to be lower in patients experiencing severe graft dysfunction compared with the other patients, mean FVC was 54.5% and 66.5%, respectively. The authors stated that this suggests size mismatching in the patients with severe graft dysfunction. Also in 2012, Inci et al published data on 23 patients in Switzerland who received bilateral lobar lung transplants. The mean age was 41 years (range, 13-66). Survival at 1 and 2 years was 82% and 64%, respectively; survival rates were comparable with 219 patients who underwent bilateral lung transplantation during the same time period (p=0.56).

A review article by Date stated that, as of 2011, approximately 400 living-donor lobar lung transplants have been performed worldwide. Procedures in the United States decreased after 2005 due to changes in the lung allocation system. The author stated that size matching between donor and recipient is important and that, to some extent, size mismatching (oversized or undersized grafts) can be overcome by adjusting surgical technique.

In 2014 Slama et al reported on a comparison of outcomes in 138 cadaveric lobar lung transplants (for size discrepancies) to 778 patients who received cadaveric whole-lung transplants, 239 of whom had downsizing by wedge resection of the right middle lobe and/or the left lingula. Survival in the lobar lung transplant group at 1 and 5 years was 65.1% and 54.9% versus 84.8% and 65.1% in the whole lung and downsized by wedge resection group (p<0.001). The lobar lung transplantation group experienced significantly inferior early postoperative outcomes, but in patients who were successfully discharged, survival rates were similar to standard lung transplantation (p=0.168).
Lung and Lobar Lung Transplant

Policy #: 00414
Original Effective Date: 05/21/2014
Current Effective Date: 08/17/2016

Retransplantation

Registry data and case series reports have demonstrated favorable outcomes with lung retransplantation in certain populations, such as in patients who meet criteria for initial lung transplantation. The ISHLT Registry contains data on 970 retransplantation patients for the period of January 1995 to June 2012 (2.6% of all lung transplantations during this period). Lung retransplantation occurred most commonly for bronchiolitis obliterans syndrome in 568 patients, while 402 patients received retransplantation for other reasons. In an analysis of lung transplantation during the period of January 1999 to June 2011, retransplantation was associated with an increased risk of death within 1 year after lung transplantation (HR=1.69; 95% CI, 1.38 to 2.07; p<0.001). However, for patients surviving at least 1 year, the risk of death was no longer associated with retransplantation.

In 2013, Kilic et al evaluated data on 390 adult lung retransplantation patients from the UNOS database.

Patients received lung retransplantation during the period May 2005 to December 2010, which was after the LAS selection criteria were implemented. Patients with reduced functional status were found to have poorer outcomes than patients with better functional status before retransplantation. Using the Karnofsky scale to stratify patients into functional status groups, the authors found the overall 1-year survival of 56% for patients requiring total assistance before retransplantation was significantly lower than the overall 1-year survival of 82% for patients who only required some assistance before retransplantation (p<0.001). The 1-year mortality rate after risk adjustment was also increased significantly for patients requiring total assistance before retransplantation (odds ratio, 3.72; p=0.02). While additional patient selection criteria may be useful for lung retransplantation, current LAS criteria are now used.

Summary of Evidence

The literature on lung and lobar lung transplantation, which consists of case series and registry data, demonstrates that lung and lobar lung transplantation provides a survival benefit in appropriately selected patients and thus may be considered medically necessary. It may be the only option for some patients with end-stage lung disease.

The literature on lung retransplantation is limited but is accumulating in registry data. As in lung transplantation, lung retransplantation may be the only option for patients with failed lung transplantation.

References

Lung and Lobar Lung Transplant

Policy # 00414
Original Effective Date: 05/21/2014
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Lung and Lobar Lung Transplant

Policy #      00414
Original Effective Date:  05/21/2014
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Policy History
Original Effective Date:  05/21/2014
Current Effective Date:  08/17/2016
05/01/2014   Medical Policy Committee review
05/21/2014   Medical Policy Implementation Committee approval. New policy.
08/06/2015   Medical Policy Committee review
08/19/2015   Medical Policy Implementation Committee approval. No change to coverage.
08/04/2016   Medical Policy Committee review
08/17/2016   Medical Policy Implementation Committee approval. No change to coverage.
01/01/2017   Coding update: Removing ICD-9 Diagnosis Codes
Next Scheduled Review Date:  08/2017

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

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Lung and Lobar Lung Transplant

Policy #  00414
Original Effective Date:  05/21/2014
Current Effective Date:  08/17/2016

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*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. 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
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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