



Blue Cross Blue Shield of Louisiana

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Viscocanalostomy and Canaloplasty

Policy # 00280

Original Effective Date: 11/16/2010

Current Effective Date: 11/20/2013

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 the use of canaloplasty as a method to reduce intraocular pressure in patients with chronic primary open-angle glaucoma to be **eligible for coverage** under the following conditions:

- Medical therapy has failed to adequately control intraocular pressure, AND
- The patient is not a candidate for any other intraocular pressure lowering procedure (e.g. trabeculectomy or glaucoma drainage implant) due to a high risk for complications.

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 canaloplasty under all other conditions, including angle-closure glaucoma, to be **investigational***.

Based on review of available data, the Company considers viscocanalostomy to be **investigational***.

Background/Overview

Glaucoma surgery is intended to reduce intraocular pressure (IOP) when the target IOP cannot be reached with medications. Due to complications with established surgical approaches such as trabeculectomy, alternative surgical treatments such as transluminal dilation by viscocanalostomy and canaloplasty are being evaluated for patients with glaucoma.

Surgical procedures for glaucoma aim to reduce IOP resulting from impaired aqueous humor drainage in the trabecular meshwork and/or Schlemm's canal. In the primary (conventional) outflow pathway from the eye, aqueous humor passes through the trabecular meshwork, enters a space lined with endothelial cells (Schlemm's canal), drains into collector channels, and then into the aqueous veins. Increases in resistance in the trabecular meshwork and/or the inner wall of Schlemm's canal can disrupt the balance of aqueous humor inflow and outflow, resulting in an increase in IOP and glaucoma risk.

Surgical intervention may be indicated in patients with glaucoma when the target IOP cannot be reached pharmacologically. Trabeculectomy (guarded filtration surgery) is the most established surgical procedure for glaucoma, allowing aqueous humor to directly enter the subconjunctival space. This procedure creates a subconjunctival reservoir with a filtering "bleb" on the eye, which can effectively reduce IOP, is associated



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with numerous and sometimes sight-threatening complications (e.g., leaks, hypotony, choroidal effusions and hemorrhages, hyphemas or bleb-related endophthalmitis) and long-term failure. Other surgical procedures (not addressed in this policy) include trabecular laser ablation and deep sclerectomy, which removes the outer wall of Schlemm's canal and excises deep sclera and peripheral cornea.

More recently the Trabectome™[‡] an electrocautery device with irrigation and aspiration, has been used to selectively ablate the trabecular meshwork and inner wall of Schlemm's canal without external access or creation of a subconjunctival bleb. Intraocular pressure with this ab interno procedure is typically higher than the pressure achieved with standard filtering trabeculectomy. Aqueous shunts may also be placed to facilitate drainage of aqueous humor. Complications of anterior chamber shunts include corneal endothelial failure and erosion of the overlying conjunctiva.

Alternative nonpenetrating methods that are being evaluated for glaucoma are viscocanalostomy and canaloplasty. Viscocanalostomy is a variant of deep sclerectomy and unroofs and dilates Schlemm's canal without penetrating the trabecular meshwork or anterior chamber. A high-viscosity viscoelastic solution, such as sodium hyaluronate, is used to open the canal and create a passage from the canal to a scleral reservoir. It has been proposed that viscocanalostomy may lower IOP while avoiding bleb-related complications.

Canaloplasty was developed from viscocanalostomy and involves dilation and tension of Schlemm's canal with a suture loop between the inner wall of the canal and the trabecular meshwork. This ab externo procedure uses the iTrack™[‡] illuminated microcatheter (iScience Interventional) to access and dilate the length of Schlemm's canal and to pass the suture loop through the canal. An important difference between viscocanalostomy and canaloplasty is that canaloplasty attempts to open the entire length of Schlemm's canal, rather than one section of it.

Since aqueous humor outflow is pressure-dependent, the pressure in the reservoir and venous system are critical for reaching the target IOP. Therefore, some procedures may be unable to reduce IOP below the pressure of the distal outflow system used, e.g., below 15mm Hg, and are not indicated for patients for whom very low IOP is desired (e.g., those with advanced glaucoma). Health outcomes of interest are the IOP achieved, reduction in medications, ability to convert to trabeculectomy if the procedure is unsuccessful, complications, and durability of the procedure.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

The iTrack (iScience Interventional) received 510(k) marketing clearance from the FDA in 2004 as a surgical ophthalmic microcannula that is indicated for the general purpose of "fluid infusion and aspiration, as well as illumination, during surgery." In 2008 the iTrack received FDA-clearance for the indication of "catheterization and viscodilation of Schlemm's canal to reduce IOP in adult patients with open angle glaucoma."

Rationale/Source

Viscocanalostomy

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A 2010 meta-analysis by Chai and Loon compared the safety and efficacy of viscocanalostomy with the gold standard of trabeculectomy. Ten randomized controlled trials with a total of 458 eyes (397 patients) with medically uncontrolled glaucoma were included in the analysis. The number of eyes in each study ranged from 20 to 60, with follow-up ranging from 6 months to 4 years. The majority of eyes (81%) had primary open angle glaucoma, while 16.4% had secondary open angle glaucoma, and 1.7% had primary angle closure glaucoma. Meta-analysis found that trabeculectomy had a significantly better pressure-lowering outcome. The difference in intraocular pressure between the treatments was 2.25 mm Hg at 6 months, 3.64 mm Hg at 12 months, and 3.42 mm Hg at 24 months. Viscocanalostomy had a significantly higher relative risk (RR) of perforation of Descemet's membrane (RR: 7.72). In contrast, viscocanalostomy had significantly fewer postoperative events compared with trabeculectomy (hypotony RR: 0.29, hyphema RR: 0.50, shallow anterior chamber RR: 0.19, and cataract formation RR: 0.31). Although viscocanalostomy had a better risk profile, most of the adverse events associated with trabeculectomy were considered to be mild and reversible.

One of the studies included in the systematic review was a randomized trial with 4-year follow-up by Gilmour et al. from 2009. Patients (n=43) with open angle glaucoma were randomized to viscocanalostomy (25 eyes) or trabeculectomy (25 eyes) and prospectively followed at regular intervals for up to 60 months. A successful outcome was defined as IOP less than 18 mm Hg with no medications; a qualified success was defined as IOP less than 18 mm Hg with or without topical treatment. One patient in each group was lost to follow-up. At baseline, patients had a mean IOP of 25 mm Hg and were using an average of 1.4 medications. At mean follow-up of 40 months (range, 6 to 60 months), 10 patients (42%) in the trabeculectomy group had achieved success compared to 5 patients (21%) in the viscocanalostomy group. Although 19 patients (79%) in both groups achieved qualified success, fewer trabeculectomy patients required additional topical treatment (50% vs. 83%, respectively) to achieve qualified success. There were more early postoperative complications in the trabeculectomy group (e.g., hypotony, wound leak, choroidal detachment), but these did not affect the outcome. At one month, conjunctival blebs were observed in 19 (79%) of the trabeculectomy group and 16 (64%) of the viscocanalostomy group. At 12 months, blebs were observed in 19 (79%) of the trabeculectomy group and 14 (56%) of the viscocanalostomy group. The proportion of patients with conjunctival blebs at final follow-up and the statistical significance of these differences were not reported. It was reported that more bleb manipulations (7 vs. 1) and antimetabolites (5 vs. 1) were needed in the trabeculectomy group. The three patients who required cataract surgery were all in the viscocanalostomy group.

In 2003, Kobayashi et al. reported a within-subject safety and efficacy comparison of trabeculectomy (with mitomycin C) and viscocanalostomy in 25 patients with bilateral primary open-angle glaucoma who had IOP greater than 22 mm Hg under medical therapy. Patients were randomly assigned to receive trabeculectomy in one eye and viscocanalostomy (with removal of the internal wall of Schlemm's canal) in the other eye. Follow-up was performed at 1 and 3 days, 1 and 2 weeks, and 1, 2, 3, 4, 5, 6, 9, and 12 months after surgery. Throughout follow-up, the mean IOP decreased significantly more in trabeculectomy-treated eyes (e.g., from 24.8 to 12.6 mm Hg at 12 months) than in viscocanalostomy-treated eyes (from 25.0 to 17.1 mm Hg). At 12 months, significantly more trabeculectomy-treated eyes achieved an intraocular pressure less than 20 mm Hg without medication (88% vs. 64%, respectively). The mean IOP reduction was 48.9% in trabeculectomy-treated eyes and 30.5% in viscocanalostomy-treated eyes. Overall success, defined as IOP



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less than 20 mm Hg and IOP reduction greater than 30% with or without glaucoma medication, was not significantly different between the two groups (96% for trabeculectomy and 92% for viscocanalostomy). Although trabeculectomy had a greater IOP-lowering effect, there were fewer complications with viscocanalostomy (1 microperforation of Descemet's membrane compared with four cases of shallow anterior chamber and five cases of hypotony with IOP <4 mm Hg).

Stangos et al. reported the effect of the learning curve on the surgical outcome of viscocanalostomy from a retrospective series of 180 consecutive cases performed by two surgeons at a single center in Europe. Overall success, defined as no visual field deterioration with an IOP of 20 mm Hg or less and IOP reduction of 30% or greater compared to baseline values, improved from 64% to 91% when comparing the first 45 to the last 45 cases of the series. Complete success, defined as no medications required, improved from 38% to 73%. Surgical complications were not significantly different between the first and last 45 cases (16 vs. 10, respectively).

Canaloplasty

In 2007, Lewis et al. reported interim data analysis from a company-sponsored multicenter (15 centers) safety/efficacy study on canaloplasty using the iTrack microcatheter. Catheterization of the canal was achieved in 83 of 94 patients enrolled (88%); tension sutures were successfully placed in 74 patients (79%) with a mean IOP of 24 mm Hg. At 3-month follow-up, 57 patients (77% of 74 implanted) had an IOP of 16 mm Hg, and at 12 months, 48 patients (65%) had a mean IOP of 15 mm Hg. Ten ocular adverse events (11%) were reported, including hyphema (3%), elevated IOP (3%), Descemet's membrane detachment, hypotony, choroidal effusion, and exposed closure suture (1% each). Eleven patients (12%) had a subconjunctival bleb, six of which resolved by three months. The study design included 5-year follow-up. These results were limited by the lack of randomization and high loss to follow-up.

Lewis et al. reported 2-year and 3-year results from the multicenter study in 2009 and 2011, respectively. Enrolled in the follow-up study were 157 patients with a diagnosis of primary open-angle glaucoma, pigmentary glaucoma, exfoliative glaucoma, and a baseline IOP of 16 mm Hg or higher before surgery, with a historical IOP of 21 mm Hg or higher. Exclusion criteria were neovascular disease, uveitis, peripheral anterior synechiae, angle recession, and developmental or secondary glaucoma (except for pigmentary and exfoliative glaucoma). At baseline, the mean IOP was 23.8, and patients were on an average 1.8 medications; 21% of eyes were on 3 or more antiglaucoma medications, and 12 eyes (7.6%) were on no medications. Twenty-five eyes (15.9%) were pseudophakic. Canaloplasty (with or without cataract surgery) was successful in 133 eyes (85%). Eyes that did not have placement of a tensioning suture were viscodilated to the extent possible by catheterizing the canal from both ostia. At three years postoperatively, 134 study eyes (85% follow-up) had a mean IOP of 15.2 mm Hg and mean glaucoma medication use of 0.8 medications; 4 eyes (3%) were on 3 or more antiglaucoma medications, and 66 eyes (49.3%) were on no medications. Another 7 patients (4.4%) had additional glaucoma surgery. Six eyes lost 2 or more lines of corrected visual acuity related to glaucoma progression. With qualified success defined as achieving IOP of 18 mm Hg or lower (with 0 to 2 medications), success was achieved in 69 of the 89 eyes (77.5%) that had successful suture implantation alone and 24 of the 27 eyes (89%) with successful suture placement combined with phacoemulsification. Early surgical/postoperative complications included microhyphema (12%), hyphema (10%), elevated intraocular pressure (6%), Descemet's membrane detachment (3%),



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suture extrusion (1%), and hypotony (1%). Late postoperative complications included cataract (12.7%), transient IOP elevation (6.4%), and partial suture extrusion through the trabecular meshwork (0.6%).

Interim 1-year results from a company-sponsored multicenter study were reported in 2008 for 40 patients who had combined canaloplasty and cataract surgery (potential overlap in patients from the study described above). Inclusion criteria included: a glaucoma diagnosis of primary open-angle glaucoma (POAG), pigmentary glaucoma, exfoliation glaucoma, or POAG with narrow but not occludable angles after laser iridectomy; a treated IOP of 16 mm Hg or higher at baseline; and a historical untreated IOP of 21 mm Hg or higher. Of the 54 eyes enrolled, successful circumferential catheterization was achieved in 44 eyes (81%), and sutures were successfully placed in 40 eyes (74%). The 14 eyes (26%) that did not have sutures placed were due to the microcatheter entering a collector channel or meeting other resistance during catheterization; successful suture placement was reported to increase with surgeon experience. Two eyes were considered failures, with one conversion to trabeculectomy. Clinical results were reported for 25 patients (46% of 54) who were both due for and reported for 12-month follow-up. Of these, three eyes (12%) had low subconjunctival blebs at 12 months. No case of suture erosion through the trabecular meshwork or sclera was noted during follow-up. IOP was reduced from a mean of 24 mm Hg to 13 mm Hg at six months (reported for 42 eyes; 40 were reported to be successfully treated) and remained under 14 mm Hg in the 25 patients who were evaluated at 12 months. The number of antiglaucoma medications decreased from a mean of 1.5 medications to a mean of 0.1 at 1 month and 0.2 at 12 months. This trial is ongoing, and longer follow-up on a larger number of patients is needed.

Koerber et al. reported on 15 of the patients who participated in the multicenter trial described above who had bilateral POAG and received canaloplasty in one eye and viscocanalostomy in the contralateral eye. Qualifying preoperative IOPs were 18 mm Hg or greater with historical IOPs of at least 21 mm Hg. For the canaloplasty eye, the baseline IOP averaged 26.5 mm Hg on 2.1 medications. All patients had successful suture placement. Follow-up at 18 months showed IOP of 14.5 on 0.3 medications. For the viscocanalostomy eye, the baseline eye averaged 24.3 mm Hg on 1.9 medications; follow-up at 18 months showed an average IOP of 16.1 on 0.4 medications. The reduction in IOP from baseline was significantly greater with canaloplasty (12.0 mm Hg) than with viscocanalostomy (8.2 mm Hg). There was no loss in visual acuity and no adverse events from either procedure. The authors noted that this study effectively compares the additional effects of the two major additional maneuvers associated with canaloplasty: first, 360 degrees viscodilation of Schlemm's canal, as opposed to partial dilation achieved with viscocanalostomy, and second, prolonged opening and tensioning of Schlemm's canal with suture placement.

Bull et al. reported an industry-sponsored 3-year prospective, multicenter study of 109 open-angle glaucoma patients (109 eyes) who underwent canaloplasty or combined cataract-canaloplasty surgery. All patients had documented visual field loss and met criteria for the diagnosis of glaucoma and failure of prior medical or laser therapy. A tensioning suture was successfully placed in 98 eyes (89.9%) and 96 eyes (88.1%) completed the 3-year follow-up. Of the 13 patients who did not complete follow-up, 4 (3.7%) had undergone additional glaucoma surgery; these patients were not included in the analysis. In eyes treated with canaloplasty with a successful tensioning suture, IOP decreased from 23 mm Hg on 1.9 medications to 15.1 mm Hg on 0.9 medications. In eyes treated with combined cataract-canaloplasty surgery with a



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successful tensioning suture, IOP decreased from 24.3 mm Hg on 1.5 medications to 13.8 mm Hg on 0.5 medications. For the 11 eyes that had canaloplasty without suture placement, IOP decreased from 24.4 on 1.9 medications to 15.6 on 1.2 medications. Late postoperative complications included cataracts (19.1%) and transient IOP elevation (1.8%). Patients who received additional glaucoma surgery were excluded from further analysis (instead of being counted as treatment failures), limiting interpretation of these findings.

Grieshaber et al. reported a prospective series of 60 consecutive black South African patients with POAG who underwent canaloplasty. The mean preoperative IOP was 45 mm Hg. At 12-month follow-up, the IOP was 15 mm Hg (n=54), and at 36 months, the IOP was 13.3 mm Hg (n=49). Eleven patients (18%) were lost to follow-up at three years. With qualified success defined as achieving IOP of 21 mm Hg or lower (with or without medications), success was achieved in 40 of 49 patients (82%). When defined as an IOP of 16 mm Hg or less without medications, 47% of eyes met criteria for complete success. There were no severe complications in this series.

Mosaed and colleagues published a comparative effectiveness review of newer (Trabectome and canaloplasty) and older (trabeculectomy and Baerveldt shunt) surgeries for glaucoma in 2009. Twelve-month outcomes (intraocular pressure adjunctive medications and complications) were compared after glaucoma-only and combined glaucoma-phacoemulsification surgeries. The review found that Trabectome and canaloplasty provided modest IOP reduction (to about 16 mm Hg) with minimal intraoperative or postoperative complications. Results of Baerveldt glaucoma implant IOP reduction were comparable to trabeculectomy (about 12 mm Hg), but typically this shunt required more postoperative IOP-lowering medication (average of 1.3 vs. 0.5 medications, respectively) to achieve a success rate comparable to trabeculectomy. Patients treated with Trabectome required more medications (average of 1.5) to control IOP than patients treated with canaloplasty (average of 0.6). The authors concluded that Trabectome and canaloplasty are reasonable surgical therapy choices for patients in which IOPs in the mid-teens seem adequate; although trabeculectomy remains the most effective IOP-lowering procedure, it also has the highest serious complication rates.

Clinical Input Obtained Through Specialty Medical Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests regarding viscocalostomy, input was received from one specialty medical society and three academic medical centers while this policy was under review in 2011. Although some considered viscocalostomy to be medically necessary in a select group of patients who would be at risk for suffering a blinding complication with trabeculectomy, the input was mixed. Notably, one reviewer considered outcomes with viscocalostomy to be inferior to other currently used non-penetrating techniques.

In response to requests regarding canaloplasty, input was received from one specialty medical society and two academic medical centers while this policy was under review in 2011. The American Academy of Ophthalmology provided a statement indicating that the case series cited are sufficient to show efficacy of



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canaloplasty to lower IOP to treat open angle glaucoma. Other reviewers considered canaloplasty to be investigational but medically necessary for a select group of patients (e.g., patients who are at risk for infection or hypotony, who have surface disease that would preclude the creation of good trabeculectomy bleb, or that would not be able to cover a glaucoma drainage device implant).

Ongoing Clinical Trials

A search of the online site: Clinicaltrials.gov in July 2013 found 2 randomized trials comparing canaloplasty to trabeculectomy. NCT01228799 enrolled 60 patients and was completed December 2012. No publications have been submitted to date. NCT00854256 has an expected enrollment of 60 patients with completion in 2014. NCT01726543 will compare canaloplasty with non-penetrating deep sclerectomy. This study has an estimated enrollment of 80 patients with completion in 2014.

Summary

A number of small randomized trials have been conducted that compare viscocanalostomy with trabeculectomy. Meta-analysis of these trials indicates that trabeculectomy has a greater intraocular pressure-lowering effect than viscocanalostomy. Although trabeculectomy is associated with greater postoperative risk, most of the adverse events are mild and reversible. Reduction in IOP has also been shown to be greater with canaloplasty than viscocanalostomy in a small within-subject comparison. The clinical input obtained for viscocanalostomy in 2011 was mixed. Overall, the evidence is insufficient to evaluate health outcomes with this procedure in comparison with currently accepted alternatives. Therefore, viscocanalostomy is considered investigational.

Positive 2- to 3-year outcomes have been reported for canaloplasty, along with a systematic review that found that Trabectome and canaloplasty provided modest IOP reduction (to about 16 mm Hg) with minimal intraoperative or postoperative complications. When combined with clinical input, the evidence is sufficient for canaloplasty to be considered medically necessary in the subset of patients for whom medical therapy has failed to adequately control intraocular pressure and in whom other surgical procedures (e.g. trabeculectomy or a glaucoma drainage implant) are contraindicated.

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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	66174, 66175
HCPCS	No code
ICD-9 Diagnosis	365.10 thru 365.24
ICD-9 Procedure	No code

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11/04/2010	Medical Policy Committee review
11/16/2010	Medical Policy Implementation Committee approval. New policy.
12/31/2010	Coding Updated
09/01/2011	Medical Policy Committee review
09/14/2011	Medical Policy Implementation Committee approval. Title changed from "Canaloplasty for Primary Open Angel Glaucoma" to "Viscocalostomy and Canaloplasty". Coverage for canaloplasty revised to be eligible under specified conditions. Viscocalostomy added as investigational.
11/01/2012	Medical Policy Committee review
11/28/2012	Medical Policy Implementation Committee approval. No change to coverage.
11/07/2013	Medical Policy Committee review
11/20/2013	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	11/2014

*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
- 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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