BlueCross BlueShield of Louisiana

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Posterior Tibial Nerve Stimulation for Voiding Dysfunction

Policy # 00415
Original Effective Date: 04/16/2014
Current Effective Date: 07/16/2014

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 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 posterior nerve stimulation (PTNS) in patients with non-neurogenic overactive bladder (OAB) syndrome to be **eligible for coverage.**

Patient Selection Criteria
Coverage eligibility will be considered for posterior nerve stimulation (PTNS) in patients with non-neurogenic overactive bladder (OAB) syndrome when all of the following criteria are met:

- Patients must have symptoms of overactive bladder (OAB) syndrome for at least 3 months; and
- Patients must have failed behavioral therapies (see Background/Overview); and
- Unless contraindicated, patients must have failed medication therapy e.g., oral anti-muscarinics and/or transdermal oxybutynin.

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 the use of posterior tibial nerve stimulation (PTNS) when patient selection criteria are not met to be **investigational.***

Based on review of available data, the Company considers posterior tibial nerve stimulation (PTNS) in all other situations to be **investigational.***

Background/Overview

Posterior tibial nerve stimulation is a technique of electrical neuromodulation used for treating voiding dysfunction. The tibial nerve is stimulated using a fine-needle electrode inserted slightly above the ankle, and low-voltage electrical current is delivered. The recommended course of treatment is 12 weekly 30-minute sessions followed by an individualized maintenance schedule.

Altering the function of the posterior tibial nerve with PTNS is believed to improve voiding function and control. While the posterior tibial nerve is located near the ankle, it is derived from the lumbar-sacral nerves (L4-S3), which control the bladder detrusor and perineal floor. Voiding dysfunction includes urinary frequency, urgency, incontinence, and nonobstructive retention. Common causes of voiding dysfunction are pelvic floor dysfunction (eg, from pregnancy, childbirth, surgery), inflammation, medication (eg, diuretics and

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anticholinergics), obesity, psychogenic factors, and disease (eg, multiple sclerosis [MS], spinal cord injury, detrusor hyper-reflexia, diabetes with peripheral nerve involvement).

The procedure for PTNS consists of the insertion of a needle above the medial malleolus into the posterior tibial nerve followed by the application of low-voltage (10 mA, 1-10 Hz frequency) electrical stimulation (ES) that produces sensory and motor responses (ie, a tickling sensation and plantar flexion or fanning of all toes). Noninvasive PTNS has also been delivered with surface electrodes. The recommended course of treatment is an initial series of 12 weekly office-based treatments followed by an individualized maintenance treatment schedule.

Posterior tibial nerve stimulation is less invasive than traditional sacral nerve neuromodulation, which has been successfully used in the treatment of urinary dysfunction but requires implantation of a permanent device. In sacral root neuromodulation, an implantable pulse generator that delivers controlled electrical impulses is attached to wire leads that connect to the sacral nerves, most commonly the S3 nerve root that modulates the neural pathways controlling bladder function.

"Failed behavioral therapies" is defined as continued symptoms that impact function or quality of life following at least 12 weeks of behavioral treatment. Behavioral therapy may be individualized to the specific patient, but generally consists of the following two components:

- Bladder training, including timed voiding and inhibition of urge impulses;
- Pelvic floor muscle training, including instruction and monitoring by health professional and regular practice by the patient.

Fluid management, such as restriction of fluid and/or caffeine intake, may also be a part of behavioral treatment.

Weight loss has established efficacy in reducing symptoms of overactive bladder (OAB), but is not generally considered part of behavioral treatment.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
In July 2005, the Urgent®‡ PC Neuromodulation System (Uroplasty Inc.) received 510(k) marketing clearance from the FDA for percutaneous tibial nerve stimulation to treat patients suffering from urinary urgency, urinary frequency, and urge incontinence. The device was cleared as a class II ‘‘nonimplanted, peripheral nerve stimulator for pelvic floor dysfunction” because it was considered to be substantially equivalent to the previously cleared percutaneous Stoller afferent nerve system (PerQ SANS System) in 2001 (K992069, UroSurge Inc.).

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination (NCD).

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Rationale/Source

Overactive Bladder

Systematic Reviews

An updated TEC Assessment on PTNS for treatment of voiding dysfunction was published in December 2013 and concluded that PTNS as treatment for voiding dysfunction meets the TEC criteria for treatment of voiding dysfunction. The Assessment included the 6 randomized controlled trials (RCTs) discussed next and had the following conclusion:

> Evidence from randomized placebo-controlled trials supports the clinical efficacy of PTNS applied in the standard 12-week regimen. No concurrently controlled evidence exists from a trial over longer periods of time in maintenance therapy. Although the lack of controlled evidence on maintenance PTNS raises concern whether short-term efficacy is maintained over the long term, the available 12- to 36-month evidence appears consistent with maintained efficacy in relieving symptoms of OAB and urinary voiding dysfunction. Adverse event rates, assuming accurate ascertainment, appear limited.

In 2012 and 2013, several other systematic reviews of the literature on PTNS for treating OAB were published. Only one of these systematic reviews, however, conducted pooled analyses of study results. This review, by Burton et al, conducted a pooled analysis of data from 4 trials (2 of which were abstracts) comparing PTNS with sham treatment. They found a significantly higher risk of successful treatment with PTNS (risk ratio [RR], 7.02; 95% confidence interval [CI], 1.69 to 29.17) compared with a control intervention. The CI was wide, indicating a lack of precision in the pooled estimate. The SUmiT trial, discussed next, contributed 220 of 289 patients (76%) in the pooled analysis.

Also in 2012, the Agency for Healthcare Research and Quality (AHRQ) Effective Health Care Program published a comparative effectiveness review on the broader topic of nonsurgical treatments for urinary incontinence in adult women. The review identified 4 reports of RCTs comparing PTNS and no active treatment in patients with OAB. Two of the 4 articles reported 12-week results of the sham-controlled SUmiT trial; one of these included a subgroup of SUmiT participants and was only published as an abstract. The AHRQ report included a pooled analysis of data from 3 studies that found statistically significantly greater improvement in urinary incontinence in the PTNS group compared with the control group (RR = 1.9; 95% CI, 1.1 to 3.2). This pooled analysis included a total of 405 patients; 220 in the SUmiT trial, 150 in the SUmiT trial subanalysis and 35 in a trial by Finazzi-Agro et al. A limit of the analysis in the AHRQ review was that the 150 patients in the SUmiT subanalysis were included twice. The AHRQ report did not discuss evidence on the efficacy of PTNS beyond 12 weeks.

Randomized Controlled Trials

Two key RCTs that evaluated percutaneous tibial nerve stimulation for treating patients diagnosed with OAB syndrome have been published. In 2009, Peters et al published an industry-sponsored nonblinded comparison of PTNS and extended-release tolterodine (Detrol LA) in women with OAB syndrome (the OrBIT trial). The study included 100 patients (50 per group); more than 90% were women. Study participants were identified at 11 centers between June 2006 and September 2008. Subjects had to have symptoms of OAB, with at least 8 voids per 24 hours; the mean daily voids for those entering the study

were 12.3. A total of 87 of the 100 (87%) patients completed the study, and voiding diary data were available for 84 patients, 41 of 50 (82%) in the PTNS group and 43 of 50 (86%) in the tolterodine group.

The primary outcome was the noninferiority of PTNS in the mean reduction in the number of voids per 24 hours after 12 weeks of treatment. Noninferiority was defined as no more than a 20% difference in the mean void reduction. Study findings showed noninferiority of PTNS based on results for 84 patients. The decrease in number and standard deviation (SD) of voids per day was 2.4 (4.0) in the PTNS group and 2.5 (3.9) in the tolterodine group.

The study also reported a number of secondary outcomes, and findings on these were mixed. There were no statistically significant differences in the PTNS and tolterodine groups for other symptoms recorded in the voiding diary; this includes mean change in episodes of nocturia (-0.7 and -0.6, respectively), episodes of moderate to severe urgency per day (-2.2 and -2.9, respectively), and episodes of urge incontinence per day (-1.0 and -1.7, respectively). In other secondary outcomes, 35 of 44 patients (79.5%) in the PTNS group and 23 of 42 (54.8%) in the tolterodine group reported symptom improvement or cure. This difference was statistically significant ($p = 0.01$), favoring the PTNS group. However, the proportion of patients reporting symptom improvement (excluding the 3 patients reporting that they were cured) did not differ significantly between groups, 34 of 44 (77.3%) of those receiving PTNS and 21 of 42 (50%) receiving tolterodine. For the adverse event data, responses were obtained in person for the PTNS group in conjunction with their weekly treatment sessions and over the phone for the medication group, using standard checklists. It is not clear how response to treatment or quality-of-life data were collected. Limitations of the OrBIT trial included the lack of blinding of patients and providers and the lack of comparative data beyond the end of the initial 12-week treatment period. Moreover, there was no sham or placebo group to mitigate the potential bias due to subjective outcomes. In addition, the authors did not clearly define criteria for “improvement” or “cure”, a key secondary outcome, and did not report the extent of compliance with medical therapy and used different methods of data collection in the 2 groups for adverse event outcomes and possibly also for other self-report outcomes.

In 2010, MacDiarmid et al reported 1-year follow-up data for patients from the OrBIT trial who had been assigned to the PTNS group and had responded to the initial course of treatment, defined as reporting symptom improvement at 12 weeks. Thirty-three of the 35 responders were included. They received a mean of 12.1 (SD = 4.9) additional treatments between the 12-week and 12-month visits, and there was a median of 17 days between treatments. Data were available for 32 of the 33 (97%) participants at 6 months and 25 of the 33 (76%) participants at 12 months. The mean reduction in number of voids per day from baseline (the original primary outcome of the study) was 3.2 (SD = 3.7) at 6 months and 2.8 (SD = 3.7) at 12 months. Other voiding diary outcomes at 12 months, based on 25 responses, were mean changes in nocturia episodes of -0.8, in episodes of moderate to severe urgency per day of -3.7, and in episodes of urge incontinence per day of -1.6. As previously noted, this analysis was limited in that no data from the tolterodine group were available to compare long-term outcomes. Another limitation was not all patients in the PTNS group were included in the follow-up analysis, only PTNS responders were eligible. A potential bias is that the initial subjective outcome measure may be subject to the placebo effect. Moreover, patients in the PTNS group who responded to initial treatment may be particularly susceptible to a placebo response and/or may represent those with the best treatment response. Thus, these individuals may also be

susceptible to a placebo response during maintenance treatments, especially treatments offered on an as-needed basis.

The second key RCT on OAB syndrome, also industry-sponsored, was published by Peters et al in 2010. This study, known as the SUmiT trial, had a sham-comparison group. Prior to conducting the trial, the researchers performed a pilot study in healthy volunteers to determine the adequacy of a sham PTNS intervention. Findings were that 10 of 30 volunteers (33%) correctly identified the sham procedure. This percentage is below the 50% that could be expected by chance; the investigators concluded that the procedure was a feasible sham. The SUmiT trial included patients with OAB syndrome. Eligibility criteria included a score of at least 4 on the Overactive Bladder Questionnaire short form for urgency, self-report bladder symptoms lasting at least 3 months, and having failed conservative care. Data were collected from 23 centers in the U.S. A total of 220 patients were randomly assigned, 110 to the PTNS group and 110 to the sham group. Both groups received 12 weekly 30-minute intervention sessions. In the sham group, a blunt (placebo) instrument was used to simulate the location and sensation of needle electrode insertion in active treatment. An inactive PTNS surface electrode was used and also 2 active transcutaneous electrical nerve stimulation (TENS) surface electrodes. The TENS unit was used to deliver low-level sensation to simulate the PTNS intervention. The 12-week course of treatment was completed by 103 of 110 (94%) in the PTNS group and 105 of 110 (95%) in the sham group.

The primary study outcome was response to treatment based on a single-item global response assessment (GRA) variable at 13 weeks. Possible responses were that symptoms were markedly worse, moderately worse, mildly worse, the same, slightly improved, moderately improved, or markedly improved. The proportion of patients who responded to treatment based on the GRA (ie, answered that symptoms were moderately or markedly improved) was 60 of 110 (54.5%) in the PTNS group and 23 of 110 (20.9%) in the sham group; this difference was statistically significant ($p < 0.001$). Intention-to-treat (ITT) analysis was used for the primary end point only. Several secondary outcomes also favored the PTNS group. The mean reduction in a symptom severity score (a lower score indicates less severity) was 36.7 (SD = 21.5) in the PTNS group and 29.2 (SD = 20.0) in the sham group ($p = 0.01$). Similarly, the mean reduction in a quality-of-life scale, the SF-36 (a higher score indicates higher quality of life), was 34.2 (SD = 21.3) in the PTNS group and 20.6 (SD = 20.6) in the sham group ($p = 0.006$).

For the 4 voiding diary variables used, there was a statistically significant difference between groups favoring PTNS. The mean change from baseline in the number of voids per day was -2.4 (SD = 2.5) in the PTNS group and -1.5 (SD = 2.4) in the sham group (difference between groups, 0.9 voids per day; $p = 0.01$). The mean change in nocturia episodes was -0.7 (SD = 1.2) in the PTNS group and -0.3 (SD = 1.4) in the sham group (difference between groups; 0.4 nighttime voids; $p = 0.04$). The mean change in moderate to severe urgency per day was -3.7 in the PTNS group and -2.0 in the sham group (difference between groups, 1.7 episodes; $p < 0.001$). Finally, the mean change in urge incontinence episodes was -1.3 in the PTNS group and -0.3 in the sham group (difference between groups, 1 episode per day; $p < 0.002$). (Standard deviations were not reported for the latter 2 outcomes.)

Advantages of the SUmiT trial were that it included a sham comparison and the primary end point analysis was ITT. A limitation was that the primary outcome, the GRA, was a single-item subjective measure. For the

more objective measures, the voiding diary variables, there was statistically significantly greater benefit with PTNS compared with sham treatment; however, the clinical significance of the difference between the PTNS and sham groups was unclear, eg, on average, there was 1 fewer episode of urge incontinence a day in the PTNS group. In addition, as in the OrBIT trial, the SUmiT trial only reported comparative data immediately following the initial course of treatment; the study did not evaluate the long-term effectiveness of PTNS. Unlike medication which can be taken on an ongoing basis, PTNS involves an initial 12-week course of treatment followed by maintenance therapy, which to date has not been well defined. Therefore, the assumption cannot be made that short-term treatment effects will be maintained.

As with the OrBIT trial, there was a SUmiT extension study including only those patients who had been assigned to the PTNS group and initially responded to treatment. That is, the extension study did not collect additional follow-up data from patients in the PTNS group who failed to meet the 12-week primary effectiveness end point or from patients assigned to the sham-control group. Among the 110 patients assigned to the PTNS group, 60 were initial responders and 50 of these entered the extension study. Data were available on 34 patients at 24 months and 29 patients at 36 months. After enrolling in the extension study, patients underwent a 14-week transitional protocol consisting of 2 treatments with a 14-day interval, 2 treatments with a 21-day interval and then 1 treatment after another 28 days. Following this 14-week period, a personal treatment plan was developed for each patient. PTNS treatments were delivered based on the patient's reporting of symptoms; patients knew that PTNS sessions were available to them as needed when their symptoms increased. Between 6 and 36 months, patients received a median of 1.1 PTNS treatments per month. In a per protocol analysis, compared with baseline, 28 of 29 patients (97%) who completed the 36-month follow-up met the primary efficacy end point of moderate or marked improvement in overall bladder symptoms on the GRA. In addition, compared with baseline, all voiding diary measures were significantly improved in this group of patients at every 6-month follow-up. As mentioned previously in the discussion of the OrBIT extension study, the SUMIT extension study was limited by a lack of follow-up data on the control group and a lack of follow-up data on all participants in the treatment group.

Several other RCTs have been published; none reported on the efficacy of PTNS beyond 12 weeks. Three trials used a parallel group design. In 2010, Finazzi-Agro et al from Italy conducted a double-blind RCT that included 35 female patients who had urge incontinence and detrusor overactivity on urodynamic testing. Patients were randomly assigned to 30-minute PTNS sessions 3 times per week for 4 weeks (n = 18) or sham treatment (n = 17). One patient dropped out of the PTNS group and 2 dropped out of the sham group; analysis was not ITT. The primary outcome, percent responders at 4 weeks (defined as at least 50% reduction in incontinent episodes) was attained by 12 of 17 (71%) in the PTNS group and 0 of 15 (0%) in the sham group. Also in 2010, Schreiner et al in Brazil randomized 51 women older than 60 years who complained of urge urinary incontinence to 12 weeks of conservative treatment (Kegel exercises and bladder training) alone (n = 26) or conservative treatment plus 12 weekly sessions of PTNS (n = 25). The response rate at 12 weeks, defined as a reduction of at least 50% in the number of incontinence episodes reported by the patient in a bladder diary, was 76% in the PTNS group and 27% in the conservative treatment only group (p = 0.001). Blinding was not discussed.

In 2012, Gungor Ugurlucan et al in Turkey published findings of an RCT comparing transvaginal ES (n = 38) and PTNS (n = 21) in women with OAB.The ES protocol consisted of 20-minute treatments 3 times a

week for 6 to 8 weeks. PTNS was performed with an Urgent PC device used for twelve 30-minute weekly sessions. A total of 52 of 59 (88%) patients completed the study. The authors assessed numerous outcome variables and did not specify primary outcomes or adjust p values for multiple comparisons. Four bladder diary variables were reported. From baseline to the end of the treatment period, the groups did not differ significantly at the $p < 0.05$ level in mean change in urgency episodes, nocturia or incontinence episodes. For example, the mean number of urgency episodes was 2.9 (SD = 4.1) at baseline and 1.6 (SD = 0.5) after treatment in the ES group and 2.0 (SD = 3.1) at baseline and 1.3 (SD = 0.5) after treatment in the PTNS group ($p = 0.54$). There was a statistically significant difference in daytime frequency. The mean daytime frequency was 7.8 (SD = 2.7) at baseline and 5.8 (SD = 1.9) after treatment in the ES group and 7.6 (SD = 2.6) at baseline and 7.4 (SD = 2.9) in the PTNS group ($p = 0.03$). The authors reported that a significantly higher proportion of patients in the ES group described themselves as cured, but they did not provide proportions or p values.

One randomized trial, published in 2013, used a crossover design. This study, by Vecchioli-Scaldazza et al in Italy, included 40 women with OAB. The treatments were PTNS (twice weekly for 6 weeks) and medication (oral solifenacin succinate 5 mg/d for 40 days), given in random order, with a 6-week wash-out period between treatments. Group A received medication first and group B received PTNS first. The primary efficacy outcome was reduction in the number of voids in a 24-hour period. Thirty of the 40 patients (75%) completed the study. The number of daily voids significantly decreased after each treatment compared with before treatment. In group A, the mean number of daily voids premedication was 11.6 (SD = 1.6) and postmedication was 10.0 (SD = 2.1) ($p = 0.004$). The mean number of voids pre-PTNS was 11.5 (SD = 1.1) and post-PTNS, 8.5 (SD = 2.3) ($p < 0.001$). In group B, the mean number of voids premedication was 11.4 (SD = 1.4) and postmedication, 10.4 (SD = 1.8) ($p = 0.008$). The mean number of voids pre-PTNS was 11.4 (SD = 1.4) and post-PTNS, 9.4 (SD = 1.9) ($p < 0.001$). In addition, secondary outcomes including nocturia urge incontinence and voided volume significantly improved after each treatment compared with pretreatment values. The authors did not directly compare the efficacy of medication and PTNS.

Neurogenic Bladder

In 2011, 2 case series evaluating PTNS in patients with MS were published. One study, by Gobbi et al in the United Kingdom included twelve 30-minute treatment sessions with the Urgent PC device. The study included 21 patients with MS who had lower urinary tract symptoms unresponsive to anticholinergics. Overall, urinary symptoms significantly improved at the end of treatment. For example, median daytime frequency decreased from 9 to 6 episodes per day ($p = 0.04$) and median nocturia decreased from 3 to 1 episode per night ($p = 0.002$). The other case series was conducted in France by de Seze et al and used a different protocol. Participants underwent 1 in-clinic treatment session and were then given a TENS device for in-home tibial nerve stimulation; they were told to use the device 20 minutes a day for 3 months. A total of 70 individuals with MS and OAB refractory to medication participated in the study. Compared to baseline, there was a statistically significant reduction in OAB symptoms. For example, the proportion of continent patients increased from 26% to 45% ($p = 0.005$). Both studies were limited by lack of control groups and lack of long-term follow-up; the French study used a different device and different protocol than in the other PTNS studies.

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Clinical Input Received through Physician Specialty 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, input was received through 3 physician specialty societies and 1 academic medical center while this policy was under review in 2012. Clinical input was mixed. There was no consensus or near-consensus that the policy should be changed. The range of opinions included that PTNS should be considered investigational, that it should be considered for use in medically refractory patients as second-line treatment and that the evidence is sufficient to consider this treatment to be medically necessary.

Summary
Posterior tibial nerve stimulation is a technique of electrical neuromodulation used for treating voiding dysfunction. The RCTs reported short-term (up to 12 weeks) improvements on measures of urinary incontinence. Up to 36 months of data are available for some patients enrolled in RCTs who responded to an initial course of treatment. A TEC Assessment published in 2013 found sufficient evidence of short-term efficacy. The Assessment noted the lack of long-term controlled efficacy data, but concluded that the available 12- to 36-month follow-up data on PTNS responders in the SUmiT and OrBIT trials appeared consistent with maintaining efficacy over the long term. Other systematic reviews of the evidence have found short-term improvements with PTNS and have not evaluated long-term effectiveness. Thus, given the findings of the 2013 TEC Assessment and support from the American Urological Association guideline, PTNS may be considered medically necessary for women with OAB who meet criteria, and investigational in other situations.

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2013 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

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

Code Type	Code
CPT	64566, 64999
HCPCS	No codes
ICD-9 Diagnosis	596.51, 788.20 thru 788.29, 788.30 thru 788.39, 788.41, 788.63
ICD-9 Procedure	04.92

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04/16/2014 Medical Policy Implementation Committee approval. New policy.
07/10/2014 Medical Policy Committee review
07/16/2014 Medical Policy Implementation Committee approval. Coverage changed from investigational to eligible for coverage with criteria for selected patients with non-neurogenic overactive bladder. Posterior tibial nerve stimulation is investigational when Patient Selection Criteria are not met and in all other situations.
Next Scheduled Review Date: 07/2015

*****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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