BLUE TORCH MEDICAL TECHNOLOGIES, INC.

April 21, 2005

Marcel Salive, MD
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1849

Dear Dr. Salive:

Enclosed is our request for a national coverage policy for the assessment of the function of cavernous nerves by direct application of electrical stimulation with penile plethysmography.

The technology that is used for this diagnostic is cleared by the FDA via 510(k) for detection of the location and function of the cavernous nerves which was submitted with clinical evidence. A summary of the clinicals is included in the system Instructions for Use (IFU). Two peer-reviewed studies are included with this request and provide conflicting testimony about whether the diagnostic procedure is reasonable and necessary.

At the present time, there are twelve US hospitals performing this diagnostic test.

We understand that CMS will likely determine that the assessment of post-operative potency by direct application of electrical stimulation with penile plethysmography does not demonstrate that it results in an improvement in net health outcomes, and therefore would be non-covered.

We believe that this decision will empower our company, our patient advocates, and physician supporters to perform the testing necessary to meet reasonable and necessary criteria in the future. In the long-run, we believe that cavernous nerve stimulation will become a proven diagnostic for surgeons to assess post-surgical recovery of potency for Medicare beneficiaries. Your quick decision will help us reach this point sooner.

We appreciate your timely review of our request. If you require any additional information, please do not hesitate to contact me at 508-281-2080 or Jerry Stringham at 301-296-4334.

Sincerely,

Sharad Joshi
President

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REQUEST FOR NATIONAL COVERAGE DECISION

Request: Assessment of the function of cavernous nerves by direct application of electrical stimulation with penile plethysmography.

Benefit Category: Diagnostic Service. This service would be performed in a hospital.

A. Complete description of the item or service in question.

Through an open or laparoscopic procedure, most typically performed after a radical prostatectomy, a surgeon will stimulate the most distal end of the cavernous nerve that can be identified with the CaverMap electrical nerve stimulator (or its equivalent). A functioning and stimulated nerve will trigger blood flow either into the penis or out of the penis. A penile plethysmography sensor will have been fitted around the penis and been connected to the nerve stimulator control unit. The sensor detects slight changes in penile girth, which occur when the nerves stimulate a response to cavernous blood flow. If the nerves are intact, there is blood flow. The presence of a response, and the degree of the response, are identified to the physician. Both sides are typically tested during the process. This result is then used to indicate the likely post-operative recovery of potency.

B. A specific, detailed description of the proposed use of the item or service, including the target Medicare population and the medical condition(s) for which it can be used.

Approximately 20,000 Medicare patients undergo a radical prostatectomy each year (according to MedPAR 2002 data, ICD-9 codes 60.3 – 60.69). Most of these are nerve-sparing radical prostatectomies (performed on prostate cancer patients), where the surgeon attempts to preserve the nerve function. After completion of the nerve-sparing radical prostatectomy, the surgeon and/or patient may want to assess the diagnostic integrity of these nerves as a means to determine the future course of treatment for the patient. If the nerves are found to be non-functioning, then the patient and his physician may want to proceed more quickly to more invasive impotence therapies (such as penile implantation). If the nerves are intact, products like PDE-5 Inhibitors (such as Viagra, Levitra & Cialis) have a much greater chance of being effective. The information that could be provided with this test may help a physician provide a more realistic assessment of the chance of regaining potency and assist in the process of choosing the appropriate therapy.

C. Compilation of the supporting medical information.

Two peer-reviewed articles address the suitability of using this diagnostic test subsequent to radical prostatectomy to predict the potential recovery of potency. Both include Medicare aged patients. These are as follows:

1. Chang S, Peterson M, and Smith JA. "Intraoperative Nerve Stimulation Predicts Postoperative Potency." *Urology*, 58:594-497, 2001.

2. Kim HL, Stoffel DS, Mhoon D and Brendler CB. "A Positive CaverMap Response Poorly Predicts Recovery of Potency after Radical Prostatectomy." *Urology*, 56:561-564, 2000.

In addition, the same equipment is used to map the location of the nerves prior to or, on occasion, during surgery. This indication is unique from a post-procedural assessment test, and may not necessarily be performed on the same patient. Our request only addresses open or post-RP assessment of the cavernous nerve function.

Additional articles that describe the use of nerve stimulation to map the location of the nerves. The included articles are:

1. Klotz L, Heaton J, et al. "A Randomized Phase 3 Study of Intraoperative Cavernous Nerve Stimulation with Penile Tumescence Monitoring to Improve Nerve Sparing During Radical Prostatectomy." *Journal of Urology*, 1573-1578, Nov 2000.

2. Walsh PC, Marschke P, et al. "Efficacy of First-Generation CaverMap to Verify Location and Function of Cavernous Nerves During Radical Prostatectomy: A Multi-Institutional Evaluation by Experienced Surgeons." *Urology,* 57:491- 494, 2001.

3. Holzbeierlein J, Peterson M and Smith JA. "Variability of Results of Cavernous Nerve Stimulation During Radical Prostatectomy." *The Journal of Urology*, 165:108-110, Jan 2001.

4. Klotz L. "Cavernosal Nerve Mapping: Current Data and Applications." *BJU International*, 93:9-13, 2004.

5. Ong AM, Su, LM, et al. "Nerve Sparing Radical Prostatectomy: Effect of Hemostatic Energy Sources on the Recovery of Cavernous Nerve Function in a Canine Model." *The Journal of Urology*, 1318-1322, Oct 2004.

6. Schiff JD, Mulhall JP. "Neuroprotective strategies in radical prostatectomy" *BJU International.* 95, 11-14.

All articles are included with the electronic submission.

D. FDA Review Documents.

The equipment is the subject of numerous reviews via 510(k), earliest of these was October 27,1997 (K970971).

The FDA review document includes the Instruction for Use (IFU), which includes information from a study. The complete IFA is attached and includes the study of 25 patients. In the review of 14 patients with 12 month follow-up, 12 or 13 patients who had a positive response to nerve stimulation had recovery of erectile function at 12 months. Only 1 patient had no response to nerve stimulation. That patient and one of the 13 patients who a positive nerve stimulation response were impotent at 12 months.

This is described on pages 7-10 of the IFU, which is submitted electronically.

E. An explanation of the design, purpose, and method of using the item or equipment, including whether the item or equipment is per order and for use of a surgeon trained in radical prostatectomy.

The equipment is designed to provide a small electrical stimulus to an identifiable location. A functioning and stimulated nerve will trigger blood flow either into the penis or out of the penis. A penile plethysmography sensor will have been fitted around the penis and been connected to the nerve stimulator control unit. This equipment is designed to capture small changes in penile girth, which occur when the nerves stimulate a response to cavernous blood flow. If the nerves are intact, there is blood flow.

The equipment requires the direct supervision of a physician.

F. Rationale for inclusion of the articles.

The two studies selected provide peer-reviewed information about whether the use of the nerve stimulation technology with penile plethysmography for the purpose of this NCD is reasonable and necessary. In these studies, the physicians performed the procedure described and assessed the

relevance of the test to determine the long-term potency of the patient. It is this determination of potency that may alter physician/patient decisions about the course of treatment. These studies include patients over 65 years of age.

G. Information that examines the magnitude of the medical benefit.

A reasonable and necessary test will eliminate some post-procedural impotency treatments, and provide the patient with a better understanding of his post-operative recovery.

H. A description of any clinical trials or studies currently underway that might be relevant to a decision regarding coverage of the item or service.

There are no ***additional*** formal clinical trials or multi-center investigations underway for the use of this technology to evaluate the post-surgical potency of the RP patient. Therefore, the detailed literature listed in Section C should be complete and we would not anticipate any additional studies to emerge during the CMS review process.

The two published studies are the Chang study, which described the predictive ability of the system in 63 patients; and the Kim study, which studied the results of the system in 60 patients most directly address the issue that is the subject of this review. Both of these studies include results for patients of Medicare age. The mean age for the Kim study is 58 +/- 6.8 years, and the mean age for the Change study is 59.6 with a range of 48-72.

I. Information involving the use of a drug or device subject to FDA regulation as well as the status of current FDA regulatory review of the drug or device involved. An FDA regulated article would include the labeling submitted to the FDA or approved by the FDA for that article, together with an indication of whether the article for which a review is being requested is covered under the labeled indication(s).

The indications for use as cleared by the FDA is as follows:

”The Blue Torch Medical Technologies CaverMap™ Surgical Aid is indicated for use in the stimulation of the cavernosal and associated parasympathetic nerves during open prostatectomy and colorectal (surgical) procedures in males. The device aids the surgeon in locating these nerves. The device is designed as an adjunct to the current open prostatectomy and colorectal procedures in which a nerve sparing technique is used. The Surgical Aid is not designed to replace the surgeon’s expertise in mapping out the neurovascular bundles. Each surgeon’s skill determines whether these nerves are spared regardless of any aid.”

Additional data indicated the post-operative recovery of these nerves is included in the IFU.