ReBuilder for Peripheral Neuropathy

Executive Summary

This report summarizes the scientific evidence and clinical and payer perspectives on ReBuilder for peripheral neuropathy.

Peripheral neuropathy is a disorder of the peripheral nervous system characterized by impaired function of sensory, motor, and/or autonomic nerves resulting from many conditions. Manifestations include pain, numbness, tingling, extreme sensitivity to touch, lack of coordination, muscle weakness or paralysis, and bowel or bladder problems. Treatment relies on addressing the underlying cause and using various treatments for pain.

ReBuilder is a handheld, battery-powered nerve stimulator that delivers an electronic impulse, similar to a normal nerve signal, to specific regions of the body to alleviate pain, burning, tingling, and numbness from a variety of conditions.

A scientific evidence search yielded no original studies or technology assessments on ReBuilder for any indication. Therefore, no conclusions can be made with regard to the safety and efficacy of ReBuilder for peripheral neuropathy.

Major professional societies in neurology, neuromuscular and electrodiagnostic medicine, physical medicine and rehabilitation, and physical therapy; the Centers for Medicare and Medicaid Services; and several private national health insurers have no positions on ReBuilder for any indication.

Peripheral Neuropathy[1,2,3,4,5,6]

Overview and epidemiology. Peripheral neuropathy is a disorder of the peripheral nervous system characterized by impaired function of sensory, motor, and/or autonomic nerves. Approximately 20 million people in the United States suffer from this condition.[7] Peripheral neuropathy can occur at any age, but is more common in older adults.

Pathophysiology and etiology. Peripheral neuropathy results from damage to the cell body, nerve fiber, or to the surrounding myelin sheath of peripheral nerves. The majority of cases of peripheral neuropathy are glove-and-stocking peripheral neuropathy, which affects the distal portion of the extremities. Causes of peripheral neuropathy with symmetrical distal sensory loss and weakness include the metabolic disorders of diabetes mellitus, impaired glucose tolerance, and uremia; toxins, comprising alcohol, heavy metals, and various industrial agents; medications, such as antibiotics and chemotherapeutic agents; vitamin B deficiencies; and hereditary disorders, including Charcot-Marie-Tooth disease. Other causes of neuropathies, such as localized trauma and tumors, tend to result in asymmetric peripheral neuropathy.

[1] Schoffer K. Peripheral neuropathies. In: Bope ET, Kellerman R, Rakel RE, editors. Conn's Current Therapy 2011. 1st ed. Philadelphia: Elsevier Saunders; 2011. p. 978-85.
[2] Mayo Clinic Staff. Peripheral neuropathy. Mayo Foundation for Medical Education and Research (MFMER). November 3, 2009. Available at http://www.mayoclinic.com/health/peripheral-neuropathy/DS00131. Accessed June 24, 2011.
[3] Feldman EL. Epidemiology and classification of diabetic neuropathy. In: Basow DS, editor. UpToDate. Waltham, MA: UpToDate; 2011.
[4] Feldman EL, McCulloch DK. Treatment of diabetic neuropathy. In: Basow DS, editor. UpToDate. Waltham, MA: UpToDate; 2011.
[5] Aminoff MJ. Nervous System. In: McPhee SJ, Papadakis MA, editors. Current Medical Diagnosis and Treatment. 49th ed. New York: The McGraw-Hill Companies, Inc.; 2010. p. 921-8.
[6] Pan Y. Uremic neuropathy. Medscape Reference. Updated December 3, 2009. Available at http://emedicine.medscape.com/article/1175425-overview. Accessed June 23, 2011.
[7] The Neuropathy Association. About Peripheral Neuropathy: Facts. Available at http://www.neuropathy.org/site/PageServer?pagename=About_Facts. Accessed June 27, 2011.

Clinical manifestations. Specific clinical manifestations of peripheral neuropathy vary depending on the types of nerves affected. Dysfunction of sensory nerves may result in gradual onset of numbness and tingling in the feet and hands, which may spread upward into the legs and arms; burning, sharp, jabbing, or electric-like pain; paresthesia; dulled perception of vibration and temperature; and extreme sensitivity to touch. Other manifestations include muscle weakness or paralysis if motor nerves are affected and bowel or bladder problems if autonomic nerves are affected.

Evaluation. Evaluation of peripheral neuropathy may involve a patient history, physical examination, blood tests, electromyography, nerve biopsy, and imaging studies. A neurological examination involves checking tendon reflexes, muscle strength and tone, sensation, posture, and coordination. Blood tests may encompass vitamin levels, thyroid function, glucose levels, liver function, and kidney function. Electromyography measures the electrical signals in peripheral nerves and the transfer of those signals to muscles. Nerve biopsy enables histologic examination of a portion of a nerve to characterize its pathology. Imaging tests may entail computed tomography (CT) or magnetic resonance imaging (MRI) to look for herniated disks, tumors, or other abnormalities.

Treatment. The goals of treatment for peripheral neuropathy are to manage the condition causing the peripheral neuropathy and to relieve pain. A systematic, stepwise approach to pain relief utilizes the following pharmacologic options: simple analgesics, tricyclic antidepressants drugs, anticonvulsants, narcotics, and topical capsaicin. Other treatments that may be considered, if those options fail to relieve symptoms, include transcutaneous electrical stimulation (TENS), mexiletine (local anesthetic), duloxetine (dual reuptake inhibitor antidepressant), and tramadol (opioid).

Prognosis. In many cases, peripheral neuropathy symptoms improve with time, especially when due to an underlying condition that can be treated. If the underlying condition is corrected, the neuropathy often improves on its own.

ReBuilder[8]

Overview and background. ReBuilder (ReBuilder Medical, Incorporated; Charles Town, WV) is a handheld, battery-powered nerve stimulator that delivers an electronic impulse to specific regions of the body to alleviate symptoms such as pain, burning, tingling, and numbness. Invented by David B. Phillips, PhD,[9] and commercially available since 1987, ReBuilder is marketed as a specialized form of TENS[10] with claims that it is the only nerve stimulator that duplicates the exact waveform and frequency of a healthy peripheral nerve signal.

Theory. According to ReBuilder's proponents, peripheral neuropathy occurs when a peripheral nerve, in response to a challenge, becomes dormant to protect itself from additional damage. These proponents also believe that even if the initial cause of peripheral neuropathy is removed, the nerve does not awaken. ReBuilder aims to awaken the nerve by replicating a normal nerve signal and sending a larger waveform to the targeted area. Critics state that this theory of peripheral neuropathy goes against basic nerve anatomy and physiology.[11,12,13]

Administration. Designed for home use, ReBuilder applies signals through self adhesive electrodes directly on the skin or via silver-laced, electrically conductive socks and gloves. Each treatment session lasts 30 minutes. Most patients use ReBuilder twice a day for the first month, once a day the following month, once or twice a week for the third month, and then as needed. ReBuilder is currently available in

[8] ReBuilder Medical Inc. website. Available at http://www.rebuildermedical.com/index.php. Accessed June 21, 2011.
[9] David B. Phillips.com website. 2010. Available at http://www.davidbphillips.com/. Accessed June 22, 2011.
[10] ReBuilder Medical Technologies, Incorporated, Durable Medical Equipment website. Available at http://rebuilder-dme.com/index.php. Accessed June 22, 2011.
[11] Novella S. Nerve Nonsense – Beware of Quack Devices. NeuroLogica Blog. March 2, 2007. Available at http://theness.com/neurologicablog/index.php/nerve-nonsense-beware-of-quack-devices/. Accessed June 22, 2011.
[12] Novella S. Recognizing Dubious Health Devices. Science-Based Medicine. August 20, 2008. Available at http://www.sciencebasedmedicine.org/index.php/recognizing-dubious-health-devices/#more-190. Accessed June 22, 2011.
[13] Rutter D. Dan's Data letters #189 (page 2). Dan's Data. Last modified January 19, 2010. Available at http://www.dansdata.com/danletters189b.htm. Accessed June 22, 2011.

two models. The 300 Model has a single output of 7.83 hertz (Hz), or 7.83 on/off pulse signals per second, which corresponds with a peak among a set (also known as Schumann resonances) in the extremely low frequency portion of the Earth's electromagnetic spectrum which ranges from 3 to 69 Hz.[14] The other ReBuilder model is the 2407 Deluxe Model with three outputs, including 7.83 Hz, standard TENS, and electrical muscle stimulation.

Food and Drug Administration (FDA). ReBuilder is an FDA class II, neurologic therapeutic medical device that first received FDA 510(k) approval[15] in 1987 for marketing as a TENS unit for pain relief. In 1989, the FDA cleared ReBuilder for additional indications.[16] These two 510(k) approvals were granted to MicroMed, Incorporated, the previous name of ReBuilder Medical, Incorporated.[17] The FDA has approved numerous TENS devices for pain relief via its 510(k) process under the same product code as ReBuilder.[18]

Indications. ReBuilder is FDA-approved for the symptomatic relief of chronic intractable pain, post-traumatic and post-surgical pain relief, relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle reeducation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, and maintaining or increasing range of motion.[19] The FDA has written warning letters to the manufacturer of ReBuilder against marketing the device for any off-label indications, including peripheral neuropathy.

Contraindications. The manufacturer states that ReBuilder is contraindicated for patients with pacemakers and suggests that pregnant women and children not use the device. ReBuilder should not be applied transcerebrally, at or near the neck and the mouth, or in the vicinity of swollen, infected, or inflamed areas.

Adverse events. Although ReBuilder is advertised as not having any side effects, its website warns that the long term effects of chronic electrical stimulation are unknown. In its medical device safety database, the FDA lists three adverse events[20,21,22] for ReBuilder with patients complaining of pain, muscle spasms, cramps, and other symptoms; this database also lists more than 400 adverse events related to various other TENS devices.[23] Defects in ReBuilder's signal generator components have been reported, but whether such defects led to any adverse events is unknown.[24]

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[14] Wikipedia, the free encyclopedia. Schumann resonances. Last modified June 16, 2011. Available at http://en.wikipedia.org/wiki/Schumann_resonances. Accessed June 30, 2011.
[15] FDA's 510(k) Premarket Notification Database. ReBuilder. 510(k) Number K874085. Last updated June 6, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm [Enter 510(k) Number K874085]. Accessed June 21, 2011.
[16] FDA's 510(k) Premarket Notification Database. ReBuilder Bucket System. 510(k) Number K882980. Last updated June 6, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm [Enter 510(k) Number K882980]. Accessed June 21, 2011.
[17] ReBuilder Medical, Incorporated, website. About us. Available at http://www.rebuildermedical.com/about_us.php. Accessed June 21, 2011.
[18] FDA's 510(k) Premarket Notification Database. Last updated June 6, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm [Enter product code "GZJ"]. Accessed June 21, 2011.
[19] Ulatowski, Timothy A. (Director, Office of Compliance, Center for Devices and Radiological Health, Food and Drug Administration, U.S. Department of Health and Human Services, Silver Spring, MD). Letter to: David B. Phillips, PhD. (Chief Executive Officer, ReBuilder Medical Technologies, Incorporated, Charlestown, WV). July 16, 2008. Available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2008/ucm1048206.htm. Accessed June 22, 2011.
[20] FDA's Manufacturer and User Facility Device Experience (MAUDE) Adverse Event Report Database. ReBuilder Medical Technology Inc ReBuilder None. Event date May 10, 2008. Last updated May 31, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1071090. Accessed June 21, 2011.
[21] FDA's Manufacturer and User Facility Device Experience (MAUDE) Adverse Event Report Database. ReBuilder Medical Inc. ReBuilder 3000. Event date May 27, 2008. Last updated May 31, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1125964. Accessed June 21, 2011.
[22] FDA's Manufacturer and User Facility Device Experience (MAUDE) Adverse Event Report Database. ReBuilder Medical Technologies, Inc. The ReBuilder TENS Unit. Event date January 1, 2009. Last updated May 31, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/Detail.CFM?MDRFOI__ID=1291403. Accessed June 21, 2011.
[23] FDA's Manufacturer and User Facility Device Experience (MAUDE) Adverse Event Report Database. Last updated May 31, 2011. Available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm [Enter search term "GZJ" and select "ALL YEARS"]. Accessed June 22, 2011.
[24] Bonnin, Evelyn. (District Director, Food and Drug Administration, U.S. Department of Health and Human Services, Baltimore, MD). Letter to: David B. Phillips, PhD. (Chief Executive Officer, ReBuilder Medical Technologies, Incorporated, Charles Town, WV). March 8, 2011. Available at http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm248520.htm. Accessed June 22, 2011.

Clinical trials. The U.S. National Institutes of Health's ClinicalTrials.gov website does not list trials on ReBuilder for any indication.[25] The manufacturer claims that studies are currently underway but gave no specifics.[26]

Scientific Evidence

Search strategy and results

- **Original studies**
  - **MEDLINE-indexed.** A MEDLINE search was conducted on June 22, 2011, limited to articles that contain the following search terms:

    ReBuilder* OR MicroMed OR "Micro Med" OR (Phillips AND (transcutaneous electrical nerve stimulat* OR TENS))

    A study was included for review if it involved at least one patient who received ReBuilder treatment for any indication.

    No study was found that met these criteria.

  - **Non-MEDLINE-indexed.** ReBuilder Medical, Incorporated, was contacted on June 23, 2011 for studies on ReBuilder for any indication.

    The manufacturer identified no published or unpublished studies of ReBuilder.[26]

- **Technology assessments.** The databases of the following organizations were searched on June 22, 2011 for reports on ReBuilder for any indication or TENS for peripheral neuropathy published within the last three years: the Advisory Board Company; the Agency for Healthcare Research and Quality; Blue Cross and Blue Shield Association's Technology Evaluation Center; the California Technology Assessment Forum; the Canadian Agency for Drugs and Technologies in Health; the Cochrane Database of Systematic Reviews; the ECRI Institute; Hayes, Inc.; the Institute for Clinical Systems Improvement; Kaiser Permanente's Interregional New Technologies Committee; and the United Kingdom's National Institute for Health and Clinical Excellence.

  No assessments of ReBuilder for any indication or TENS for peripheral neuropathy were found.

Summary. No original studies or technology assessments evaluated ReBuilder for any indication. Therefore, no conclusions can be made with regard to the safety and efficacy of ReBuilder for peripheral neuropathy.

[25] ClinicalTrials.gov. [Enter search term "ReBuilder."] National Institutes of Health. U.S. Department of Health and Human Services. Available at http://clinicaltrials.gov/. Accessed June 23, 2011.
[26] Lumpp, Nancy. (Sales Representative and Secretary [of David Phillips, PhD, Inventor and Chief Executive Officer], ReBuilder Medical, Incorporated, Charles Town, WV), [(304) 725-2202, extension 117]. Telephone conversations with: TPMG New Medical Technology (Oakland, CA). June 23, 2011.

Positions of Professional Societies

Professional organizations in neurology, neuromuscular and electrodiagnostic medicine, physical medicine and rehabilitation, and physical therapy are silent on ReBuilder for any indication.

- On ReBuilder for any indication, the following organizations are silent:
  - American Academy of Neurology (AAN)
  - American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM)
  - American Academy of Physical Medicine and Rehabilitation (AAPM&R)
  - American Physical Therapy Association (APTA)
  - National Institute of Neurological Disorders and Stroke (NINDS)

- On TENS for pain from diabetic neuropathy, the AAN, AANEM, and AAPM&R issued a joint statement[27] in 2011 concluding that electrical stimulation is probably effective in lessening the pain of painful diabetic neuropathy and improving quality of life, although the mechanism of action is unknown. This conclusion was primarily based on one randomized controlled trial,[28] involving 50 patients who received three weeks of percutaneous electrical nerve stimulation, a TENS variation that uses acupuncture-like needles. APTA and NINDS[29] are silent on TENS for peripheral neuropathy.

Positions of Payers

- **Centers for Medicare and Medicaid Services (CMS).** CMS has issued no national coverage determination (NCD) or local coverage determination (LCD) on ReBuilder for any indication. CMS has issued an NCD[30] and an LCD for California[31] on TENS that cover chronic intractable pain[30,31] or acute postoperative pain,[31] but do not address peripheral neuropathy as an indication.

- **Private national health insurers.** Aetna, Blue Cross and Blue Shield Regence, Cigna HealthCare, Humana, and United Healthcare have no coverage positions on ReBuilder for any indication nor do they identify peripheral neuropathy as an indication in their TENS policies.[32,33,34,35,36]

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[27] Bril V, England J, Franklin GM, Backonja M, Cohen J, Del Toro D, et al. Evidence-based guideline: Treatment of painful diabetic neuropathy: Report of the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation. Neurology. 2011 May 17;76(20):1758-65. Epub 2011 Apr 11. Cited in PubMed; PMID: 21482920. Available at http://www.neurology.org/content/76/20/1758.full.pdf. Accessed June 23, 2011.

[28] Hamza MA, White PF, Craig WF, Ghoname ES, Ahmed HE, Proctor TJ, et al. Percutaneous electrical nerve stimulation: a novel analgesic therapy for diabetic neuropathic pain. Diabetes Care. 2000 Mar;23(3):365-70. Cited in PubMed; PMID: 10868867.

[29] National Institute of Neurological Disorders and Stroke. Pain: Hope Through Research. Last updated June 15, 2011. Available at http://www.ninds.nih.gov/disorders/chronic_pain/detail_chronic_pain.htm. Accessed June 23, 2011.

[30] Medicare Coverage Database. National Coverage Determination (NCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (280.13). Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Effective August 7, 1995. Available at http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=273. Accessed June 23, 2011.

[31] Medicare Coverage Database. Local Coverage Determination (LCD) for Transcutaneous Electrical Nerve Stimulators (TENS) (L11495). Noridian Administrative Services. Revision effective January 1, 2011. Available at http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=11495. Accessed June 23, 2011.

[32] Aetna. Clinical Policy Bulletin: Electrical Stimulation for Pain. Number 0011. Last reviewed January 11, 2011. Available at http://www.aetna.com/cpb/medical/data/1_99/0011.html. Accessed June 23, 2011.

[33] Blue Cross and Blue Shield Regence. Medical Policy: Electrical Stimulation Devices for Home Use. Number 11. Effective November 1, 2010. Available at http://blue.regence.com/trgmedpol/dme/dme11.html. Accessed June 23, 2011.

[34] Cigna HealthCare. Medical Coverage Policy: Electrical Stimulators. Number 0160. Effective October 15, 2010. Available at http://www.cigna.com/customer_care/healthcare_professional/coverage_positions/medical/mm_0160_coveragepositioncriteria_electrical_stimulators.pdf. Accessed June 23, 2011.

[35] Humana. Medical Coverage Policy: Electrical Stimulators for Pain and Nausea/Vomiting. Number CPD-0412-004. Revised December 2, 2010. Available at http://dctm.humana.com/Mentor/Web/v.aspx?chronicleID=0900092980aacb9f. Accessed June 23, 2011.

[36] United Healthcare. Coverage Summary: Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid. Number D-SHO-002A. Revised February 21, 2010. Available at https://www.unitedhealthcareonline.com/ccmcontent/ProviderII/UHC/en-US/Assets/ProviderStaticFiles/ProviderStaticFilesPdf/Tools%20and%20Resources/Policies%20and%20Protocols/UnitedHealthcare%20Medicare%20Coverage/DME_Grid_SH_Ovations.pdf. Accessed June 23, 2011.