



## **ParaStep**

### **Medicare to Pay for FES Walking System**

As of April 1, 2003, Medicare will pay for the Parastep system, a \$13,000 functional electrical stimulation (FES) device that allows paraplegics to walk. The government will also cover the required training of at least 32 sessions of physical therapy necessary to use the device safely and effectively.

Parastep is a computerized “neuroprosthesis” system. Users hold on to a front-wheeled walker fitted with a keypad wired to a microprocessor worn on the belt. Surface electrodes are placed on the quadriceps, the gluteal muscles and the peroneal nerve. The user initiates stepping by firing muscles in the proper sequence. Stimulation of the quadriceps causes a contraction that results in knee extension, enabling the user to stand. Stimulation of leg nerves initiates a contraction to flex the hip, knee, and ankle; this lifts the foot off the floor as quadriceps stimulation then cycles on to extend the knee for taking a step.

The Parastep has been in use for 20 years and obtained FDA approval in 1994. Over the years, only about 550 walking devices have been sold by Sigmedics, the manufacturer. Getting the device paid for has been a major drawback. Private insurance sometimes covered Parastep, but the Medicare decision is the first ever government reimbursement coverage for any FES device. “We are delighted,” says Sigmedics founder and CEO Frank Zeiss. “We’re kind of surprised ourselves, not that we did not believe in the value of our device but because of the generally tight posture regarding FES. We’re happy to see they’ve come to their senses about the value of this.”

Medicare’s coverage of Parastep will be limited. Paraplegics must have intact muscle and peripheral nerves in the legs, and joint stability for weight bearing. Another important qualification is high motivation. Parastep “walking” takes practice.

Medicare’s decision has been well received by the paralysis community. “We support any and all efforts to maximize function and to prevent secondary conditions related to paralysis,” says National Spinal Cord Injury Association

Executive Director Marcie Roth. “While the Parastep may benefit only a segment of the community we are happy to see Medicare’s decision to pay for it and hope this will open the door for coverage of all adaptive equipment and products. Investment in maximizing the health and quality of life for people with disabilities is not only good for those individuals, but sound public policy as well.”

Meanwhile, manufacturers of FES ergometry “bikes” are still hoping to get Medicare coverage. With a large body of medical literature in support of the benefits—and with a much larger population of potential users—FES bike makers are currently lobbying Medicare for coverage. So far, the bikes have been considered exercise, which is not covered by Medicare. Parastep was successful in their bid because they convinced Medicare of the “medical need” for standing and walking.

Both FES bike companies, Electrologic (StimMaster) and Therapeutic Alliances, Inc. (Regys), report brisk sales since last fall in the wake of Christopher Reeve’s report of functional gain that his doctor says is related to his use of FES ergometry. Still, a favorable nod from Medicare would significantly expand the market.

The companies are likewise focusing on medical benefits, saying “ergometer” instead of bike and “long-term rehab” or “increased cardiovascular function” instead of aerobic workout.

Steve Petrofsky, head of Electrologic, thinks the Medicare decision on FES walking could help the field. “The government never has paid for prevention,” he says. “But the benefits of FES are clear in terms of preventing secondary conditions, including spasticity, and reducing pressure sores.”

James Shorey, CEO of Therapeutic Alliances, which has management links to Sigmedics, says there is no reason Medicare should not cover the Regys. “We’re hoping to use the same mechanism Parastep used to get coverage.”

Two other FES products, a hand-grasp system for quadriplegics called Freehand and an FES bladder control called Vocare, received FDA clearance and were aggressively marketed in the United States. While both products were technically successful, neither was covered by Medicare and the manufacturer (NeuroCare) stopped selling them last year.

Parastep will be available at specified clinics and rehabilitation centers. Contact Sigmedics for a list of places. Telephone 937-439-9131 or visit the Internet site <http://www.sigmedics.com>

Source: <http://www.paralysis.org>

For more on FES ergometry, see <http://electrologic.com> or <http://www.musclepower.com>

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