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### **First Coast Medicare to Provide Case By Case Reimbursement for the *Renessa*® Treatment for Incontinence in Women**

NEWARK, CALIF., June 24, 2009 – Novasys Medical, Inc., a developer of innovative therapies in women’s health, announced today that as of July 1, 2009, First Coast Service Options, Inc. (“First Coast”), a large regional Medicare carrier serving over 3 million beneficiaries in Florida, Puerto Rico and the U.S. Virgin Islands, has removed the non-surgical *Renessa*® treatment for women with stress urinary incontinence (SUI) from its noncovered services list and will be looking at claims for the *Renessa* procedure on an individual case by case basis.

On its Web site, First Coast states, “in order to provide an option for those physicians who are appropriately trained in treating women with stress urinary incontinence (SUI) and who are appropriately trained in performing the *Renessa* procedure, we will be removing *Renessa* from our noncovered LCD and we will be looking at claims for the *Renessa* procedure on an individual case by case basis.” First Coast goes on to state that it “expects that providers submitting claims for *Renessa* are providing the services within the FDA approved guidelines and in accordance with the indications supported by peer-reviewed literature which limits its use to moderate to severe stress urinary incontinence (SUI) in females.” [http://medicare.fcso.com/Coverage\\_News/151387.asp](http://medicare.fcso.com/Coverage_News/151387.asp)

“We are very pleased with First Coast’s decision,” said Debra Reisenhel, Novasys Medical President and Chief Executive Officer, “as it enables access to this safe and effective treatment option for Medicare beneficiaries in Florida with moderate to severe SUI.” First Coast joins Noridian Medicare, a large regional carrier administering benefits in nine states, in providing reimbursement for the *Renessa* procedure. Other private insurers, including AvMed and HealthFirst in Florida and Aetna US Healthcare nationwide, also cover this safe and effective non-surgical treatment for women who suffer from the debilitating effects of SUI.

#### **Female Stress Urinary Incontinence**

SUI is the involuntary leakage of urine associated with laughing, coughing, sneezing and recreational activities. The condition is caused by a variety of factors, most commonly childbirth, and often restricts the social, professional, and personal lives of a significant number of women. With currently available surgical and non-surgical SUI therapies, many patients and physicians have concerns about safety, recovery, compliance, and/or effectiveness.

The FDA-cleared *Renessa* System includes a small probe which a physician passes through the natural opening of the urethra (transurethral). The probe heats multiple small treatment sites in the submucosa of the bladder neck and upper urethra, denaturing the patient’s own collagen in the tissue, thereby reducing or eliminating leaks. The *Renessa* treatment can be performed in the convenience of a physician's office using local anesthesia. There are no incisions, bandages or dressings required. Recovery is rapid and comfortable, with minimal post-procedure limitations. The *Renessa* treatment

offers an option for women who have tried conservative therapies such as Kegel exercises or biofeedback without success, but who cannot have or do not desire an invasive surgical procedure. To date, over 350 urologists, urogynecologists and gynecologists in 40 states have been trained and have performed the Renessa procedure in over 2500 patients.

### **About Novasys Medical**

Novasys Medical, Inc. is a privately held, venture-backed company which develops innovative therapies in women's health. The company's initial focus is the development and commercialization of the Renessa System, a proprietary, non-surgical approach to the treatment of female stress urinary incontinence (SUI).

For more information, please visit [www.novasysmedical.com](http://www.novasysmedical.com) or call (510) 226-4060.

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