

Final Comments and Response

LCD Database ID Number

L31615

LCD Title

Radiofrequency Treatment for Urinary Incontinence

Contractor's Determination Number

GU-021

Comment:

Comment from a Carrier Advisory Committee Member representing Urology. Renessa and similar devices have been approved by the FDA regarding safety. However, in the medical literature there is still insufficient data regarding efficacy and long term durability. After discussing this with some of the experts in the field of urinary incontinence, I feel the procedures are not being used very much around the country. Patient and physician preferences are subjective and will most likely be a factor in the future use of these devices. One might consider this as an option but not a standard intervention at this time.

Response:

Thank you for your comments. Please note that this device is not FDA approved. It only has FDA 510k, not FDA approval. It is equivalent to something else that is already on the market.

Comment

Comment was received from the National Association for Continence (NAFC) urging payer coverage for the transurethral remodeling procedure (Renessa) as a non-surgical option for female patients diagnosed with stress urinary incontinence (SUI). It was felt that this negative policy will prevent access to this minimally invasive treatment by Medicare-aged women. The commenter stated she failed to comprehend the basis and justification for the coverage decision, as results of even the latest study continue to show Renessa is effective, safe (i.e., free of adverse events being reported in any trials to date), and with outcomes that are sustained over time, to the extent patients have been tracked. NAFC works with physicians and other expert providers in the field to provide unbiased education and information to consumers about SUI.

Response

No additional literature was submitted for review. No change in the LCD will be made at this time.

Comment

A presentation was made at the Draft Local Coverage Decision Open meeting on January 6, 2011 by the Medical Director and VP Medical Affairs of Novasys Medical.

Response

No additional literature was submitted for review. No change in the LCD will be made at this time.

Comment

In the draft LCD, WPS includes the following statement:

April 28, 2010, the FDA issued a "RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I" for the Renessa RF System, model PR0918 [Recall # Z-1404-2010 (all lots)]. "Because of complaints received by the firm, the instructions for use were revised to emphasize potential side effects."

It is important to point out that this issue was not an actual recall of product or technology. Instead, Novasys updated the Physician IFU (Instructions For Use) document (supplied with every Probe) to reinforce language that one of the potential side effects of the Renessa System is worsening of incontinence following treatment (note: this language has always been listed in the IFU). Other IFU changes emphasized appropriate patient selection and the use of light traction on the Probe during treatment. This action involved labeling only, no actual products (Probes or Generators) were involved.

Response

Thank you for your comments. The statement includes "the instructions for use were revised to emphasize potential side effects." No change in the LCD will be made at this time.