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Medicare

Comments and Responses Regarding Draft Local Coverage Determination: Non-Covered Services

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft update of the Non-Covered Services LCD. The official notice period for the final LCD begins on October 2, 2014, and the final determination will become effective on November 16, 2014.

Prostatic Urethral Lift (PUL)

Comment: Comments were received from several individuals as well as from Neotract, the UroLift device manufacturer. In addition, two presentations were made about the use of the device at the June 2014 Open Meeting. The comments generally disagreed with the LCD determination.

Response: The comments and presentations were reviewed in detail. There was no new relevant literature provided through the comment process. After consideration, the LCD determination was not changed. The available literature reports on a relatively small number of individuals for a relatively short duration of time (a few years follow-up). The condition treated by the UroLift device, Benign Prostatic Hypertrophy (BPH), is very common and persists for decades once it develops. In addition, there is a documented failure rate associated with the use of UroLift. While that rate appears to be similar to the failure/recurrence rate associated with trans-urethral prostatectomy (TURP), there is little reported experience in the published literature regarding repeated treatment of individuals with BPH with repeat UroLift or other modalities after use of UroLift. Accordingly, larger trials with longer term follow-up for safety and efficacy are required.

Vestibular Autorotation Testing (VAT)

Comment: One comment received agreed with the draft position and indicated that VAT was “not a mainstream diagnostic test.”

Response: We agree with this comment.

Comment: One comment received noted that, the “Literature does not support testing to be reliable in the home nor in the office.”

Response: We agree with this comment.