December 18, 2020

Andrew Conn
Chief Operating Officer
National Government Services
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Dear Mr. Conn:

The undersigned organizations are jointly writing to express our disappointment with the NGS decision to move forward with LCD 38573, which provides payment coverage for only one of the currently approved percutaneous fistula procedures. We continue to appreciate the vigilance and candor that NGS has expressed in their release of LCD 38573, however, we are dissatisfied with the decision to not provide payment coverage for G2171. The overwhelming input of several specialty societies remains that both innovative technologies are safe and effective, a position that is also supported by major kidney patient organizations. With this decision, physicians and patients will not have all the options that CMS has approved to create an arteriovenous fistula as they develop an End Stage Kidney Disease Life Plan.

We want to respectfully share our concerns about how the NGS rationale and conclusion deviated from medical society physician experts who, we believe, should be your primary source for information in coverage determination.

First, NGS has assigned superior outcomes to the Ellipsys device. Our input continues to be that Ellipsys and WavelinQ have equivalent safety and efficacy. Indeed, in the single head to head comparison study that is cited in the LCD, the only statistically significant difference between the two procedures is the intra-procedural time it requires to create the fistula.

Second, the finalized LCD indicates that WavelinQ does not have enough study patients from which to draw conclusions supporting coverage. Our interpretation and input are that both have adequate data as new technologies to warrant payment coverage. The combined two studies used by the FDA to approve the 6 French and modified 4 French WavelinQ device have 92 patients which is very similar to the Ellipsys pivotal trial of 107 patients. We believe that there is no reason to limit payment consideration to just the 32 patients in the 4 French EASE trial.

Third, the NGS guidance requiring 2-year patency data for the WavelinQ device appears to be arbitrary. While the Ellipsys device has a 2-year retrospective chart review describing patency, we maintain that a single year of follow-up is more than adequate to assess the scientifically valid concerns – namely technical success, safety, maturation, and successful use. Good quality longer term data based on a larger patient base will be helpful in further comparison of both techniques for percutaneous fistula placement to each other as well as the open surgical techniques. As G codes created partially in response to national access to care concerns, neither device has the quality of longer-term robust data that is desired for CPT inclusion at this time; however G code non-coverage decisions should not hinge on this information and certainly should not favor one procedure over the other

While we respect the effort NGS put into authoring this LCD and commend you for developing a payment coverage policy for this important additional path for patients to get an optimal dialysis fistula, we remain disappointed with the decision to move forward with LCD 38573 providing payment coverage for only one of the percutaneous fistula procedures. Because of the potentially profound impact on both patients and their physicians, the undersigned organizations urge NGS to reassess this decision and modify the LCD to cover payment for both techniques prior to its implementation.

Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

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