

Case Study: Transurethral Needle Ablation

The case of transurethral needle ablation (TUNA), an innovative non-surgical treatment for benign prostatic hyperplasia (BPH), illustrates both the importance of the local coverage process and the significant challenges that manufacturers can encounter in obtaining local coverage.

TUNA was developed by VidaMed, Inc., a start-up medical technology company based in Fremont, California, as an alternative to more invasive treatments for BPH. BPH is a non-cancerous enlargement of the prostate that causes a range of health problems and primarily affects elderly men.

FDA approved the TUNA device in October 1996. It took VidaMed 15 months, until January 1998, to obtain a procedure code from the American Medical Association.

Assignment of a unique procedure code for TUNA raised the profile of the procedure with local Medicare contractors (carriers). As a result, many of the carriers who had been reimbursing the technology using a “miscellaneous” code issued non-coverage policies.

It took VidaMed two years of working through multiple carriers’ local coverage processes, which often were non-transparent and unpredictable, to secure broader coverage of TUNA. By February 2000, 47 states had established positive coverage policies for the procedure.

The length of time it took VidaMed to obtain local coverage was due in part to the local contractors’ demands for data beyond that required by FDA for premarket clearance. Carriers typically did not accept the data from VidaMed’s premarket submission, instead demanding evidence from published medical literature.

The lack of both a clear process for obtaining local coverage and mechanisms for formal communication between medical technology companies and Medicare contractors further complicated VidaMed’s efforts. The unpredictable, closed nature of the local process, and VidaMed’s relative inexperience with complex reimbursement requirements as a start-up company, combined to create miscommunication that further delayed local coverage.

Medicare contractors’ local advisory committees do not include manufacturers as members, and frequently committee meetings are not open to the public. Further, carriers typically do not inform manufacturers of pending or finalized coverage and non-coverage decisions.

Finally, the Carrier Medical Directors who make local coverage decisions have many competing responsibilities. In the case of TUNA, this resulted in delays in local coverage decisions and heightened the company’s uncertainty as to the status of its product.

Vidamed’s difficulties highlight the need for an open review process and predictable timeframes for coverage at the local carrier level.