

Request for Proposal – PICO US Reimbursement study

Summary

Smith & Nephew is interested in receiving proposals for investigating clinical outcomes of treatment with a PICO device (single-use negative pressure wound therapy) in patients with lower extremity chronic wounds, primarily diabetic foot ulcers.

Products

PICO 1.6, PICO 7, PICO 14

Topics of Interest

We are interested in comparison of the clinical outcomes in patients receiving PICO treatment compared to those receiving standard of care (without negative pressure wound therapy) for diabetic ulcers (lower extremity). The inclusion of venous leg ulcers as a second patient group would also be of interest.

Patients must have the device applied in a clinical setting (physician office or hospital outpatient department). Datapoints and outcomes of interest include time to complete wound closure, wound measurements over time, out of pocket treatment cost (by devices/treatments used) and total treatment cost (determined by time spent by healthcare professionals in addition to the treatment cost). A minimum follow-up period of 3 months is required, and 6 months would be desirable. The study should be powered to be able to reach conclusions by wound type rather than a heterogenous population.

The scope of this RFP is limited to clinical research and does not include in vitro laboratory-based research. Applications for funding will only be considered in which all products/devices are used in accordance with standard surgical techniques, as well as the cleared Indications for Use.

Regional considerations

For commercial reasons we are only interested in applications from the US at this time.

Proposal and budget forms can be found here (www.smith-nephew.com/education/iis/) along with Guidance on the submission process