



May 16, 2008

Jerry Stringham
President
Medical Technology Partners, Inc.
9700 Great Seneca Highway
Rockville, MD 20850

Dear Mr. Stringham;

Thank you for asking the Society for Vascular Surgery to render an opinion regarding appropriate CPT coding for placement of the HeRO vascular access device. Your original request is included here as Appendix I, while the opinion rendered by the SVS Health Policy Committee is enclosed in Appendix II. If you have any questions, feel free to contact Ms. Pam Phillips at the SVS Washington office.

Yours truly,

A handwritten signature in black ink, appearing to read "R. Zwolak", is written over the typed name.

Robert Zwolak, M.D., Ph.D.
Chair, SVS Health Policy Committee

Appendix I: HeRO Catheter Coding Request

On April 1, 2008, Mr. Jerry Stringham sent the following request to the Health Policy Committee of the Society for Vascular Surgery:

We [Medical Technology Partners] are writing to request CPT® coding information for a new technology for hemodialysis access.

Background

Hemosphere, Inc. (formerly called GRAFTcath, Inc.) manufactures the HeRO™ (Hemodialysis Reliable Outflow) vascular access device, a new long-term peripheral vascular access solution for access-challenged hemodialysis patients. The HeRO device is intended for use in maintaining long-term vascular access for chronic hemodialysis patients who have exhausted peripheral venous access sites suitable for fistulas or grafts. The US Food and Drug Administration (FDA) cleared the HeRO device for marketing on January 30, 2008 via 510(k) clearance (K071778). The HeRO device gives patients who are ineligible for other long-term peripheral access (like a fistula or graft) a surgical option with a significantly lower bacteremia rate than a tunneled dialysis catheter (TDC), and adequacy of dialysis, patency, and intervention rates that are comparable to a conventional graft.

The typical patient is a 63-year-old male with end stage renal disease (ESRD), diabetes, coronary artery disease, hypertension, and two previous bacteremia events, as well as an exhaustive previous vascular access history, including multiple failed fistulas, grafts and TDCs. The patient will come to the surgeon needing a new long-term peripheral access or will be referred to the surgeon as a catheter-dependent patient who may be eligible for a HeRO device. Standard pre-operative diagnostics are performed by the surgeon and the patient is counseled as to the potential complications of the procedure and post-operative care.

Device Description

The HeRO device is a non-autogenous (i.e., synthetic) vascular access device composed of two components, a graft component and an outflow catheter component. During the surgical implant procedure, the outflow catheter is sized and attached to the graft.

Implant Procedure (see attached document for more information)

1. Catheter placement

The patient is prepped, draped, and given anesthesia for a standard operating room procedure under fluoroscopic guidance. Three incision sites are marked and the internal jugular vein (IJV) is located using ultrasound. Per standard technique, the HeRO outflow catheter is then percutaneously placed into the IJV using a guidewire and sheath following the Seldinger technique. Standard endovascular techniques are used to balloon venous stenoses as needed and to guide the outflow catheter past stenosed veins. Fluoroscopic guidance is used to guide outflow catheter placement into the proximal-to-mid right atrium so that the distal tip of the

HeRO outflow catheter resides in the right atrial-SVC junction when the patient is in the upright position (consistent with conventional central venous catheter placement).

2. Catheter to graft connection

An incision is made medial to the humeral head in the delta-pectoral groove for the HeRO connector. The proximal end of the HeRO outflow catheter is then tunneled from the IJV to the connector incision. A brachial artery incision is made. A graft tunnel is created between the brachial artery incision and the connector incision and the HeRO graft assembly is tunneled. The HeRO outflow catheter is cut to length and attached to the HeRO graft assembly and the connection is pulled into incision site from the graft.

3. Graft placement/graft anastomosis

Per standard graft placement technique, the surgeon cuts down and exposes the brachial artery. Next, the HeRO graft is cut to length and the brachial anastomosis is performed.

4. Image confirmation

Lastly, fluoroscopy is performed to verify proper outflow catheter tip placement and flow. The procedure is then completed and the patient is awoken if general anesthesia was used. Operative notes and dictation are recorded. The patient and family are counseled. The patient is typically sent home the same day or the next day.

Request

Considering the graft and catheter segments of the technology, our position is that there are two codes that should be reported together to fully report implantation of the catheter- and graft-related aspects of the HeRO device:

36830: Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (e.g., biological collagen, thermoplastic graft)

36558-51: Insertion of a tunneled central venous dialysis catheter

We would like the society's opinion and guidance on coding the HeRO device.

As a reference, we have enclosed a Device Dossier, which provides detailed information about the technology, clinical studies performed, literature, FDA status, a more detailed implant procedure description and other information.

Thank you for taking the time to help us assist your members in proper coding for placement of this important technology.

Enclosures:

HeRO Device Dossier
Power Point Presentation

PDF Cover Letter

Jerry Stringham
President
Medical Technology Partners, Inc.

Appendix II: SVS Coding Recommendations for HeRO vascular access device placement:

The SVS Health Policy Coding Subcommittee met by conference call on 5/7/08 to discuss this issue. The committee reviewed the HeRO catheter placement procedure and agreed in concept that the open surgical portion of HeRO catheter placement is identical to one aspect of CPT 36830 {Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (e.g., biological collagen, thermoplastic graft)}, while the catheter placement portion of HeRO placement is identical to CPT 36558 {Insertion of a tunneled central venous dialysis catheter}.

In terms of physician work, SVS believes that the open surgical aspects of HeRO system placement are equivalent to the arterial dissection and arterial anastomosis portions of 36830, but since 36830 also includes a venous dissection and a venous anastomosis, it would be inappropriate to report a full 36830 for HeRO. Therefore, SVS recommends that, on an interim basis, the arterial portion of HeRO could be reported by use of 36830-52, the -52 limited service modifier serving to identify that less than the full work of 36830 is being performed.

SVS believes there is work equivalence between the catheter portion of HeRO system placement and CPT 36558.

In conclusion, SVS recommends that the best interim coding strategy for placement of this FDA-510k-approved hemodialysis system is the combination of Category I CPT codes:

- 36830-52 to represent the open surgical portion of this procedure
- 36558-51 to represent the tunneled catheter portion of this procedure
- If ultrasound guidance is required for the tunneled catheter portion of the procedure, CPT 76937 would be additionally reported assuming all CPT requirements are met, including image documentation.
- If fluoroscopic guidance is required for the tunneled catheter portion of this procedure, CPT 77001 would be additionally reported assuming all CPT requirements are met, including image documentation.

Given the difficulty associated with assessment of the frequency with which venous angioplasty or other catheter based interventions would be required, compounded by issues of assessing physician work when multiple ancillary codes are reported, SVS is not prepared at this time to support simultaneous reporting of additional interventional codes (e.g. 35460, 35476, 37205-37208, 75978) during the HeRO procedure. As a permanent solution, SVS encourages the HeRO device vendor to accumulate, perform, or sponsor sufficient clinical outcomes research to allow this procedure to meet Category I CPT code application requirements.