Challenges Of Implementing Proprietary Foam Into Practice: It’s Kind of A Different Practice Model

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Varithena Proprietary Endovenous Microfoam (PEM)

- Microfoam generation mechanism
- Ultra-low-nitrogen gas
- Polidocanol liquid

PEM Indications
- Treatment of incompetence of the great saphenous vein (GSV)
- Treatment of accessory saphenous veins (AASV, PPSV)
- Treatment of visible varicosities that are tributaries of the GSV, AASV, or PPSV
- Not indicated for treatment of the small saphenous vein (SSV) or perforator veins as these veins were not included in the pivotal trials

Patient positioning for PEM

Endothermal Ablation-patient pathway
What makes the endothermal practice model easy?

- Predictable—we have been doing this for 15 years
- We know how to select patients/anatomy for technique
- Patient outcomes are well known in short and long term
- We know insurance requirements and can predict which payors will be problematic
- Staff familiar with procedure
- Disposables do not expire quickly

What makes the PEM model different/challenging?

- Unpredictable—new procedure
- How to select patients/anatomy for technique?
- Patient outcomes not established long term
- Insurance coverage is unpredictable, variable, regional
- Staff unfamiliar with procedure
- Drug expires in 30 days and is expensive

So why bother? What are the advantages?

- No tumescence needed
- Procedure almost painless (needle stick for access)
- Easy patient recovery
- Ability to treat tributary branches at same time as trunks
- No capital outlay for generator
- May be the best option for many patients

PEM works for straightforward cases, but is ideal for:

- Recurrent varicose veins after endothermal ablation or stripping:
  - Neovascularization
  - Segmental recanalization
  - Total recanalization with webs
- Patients with combination of pelvic source and truncal reflux
- Accessory saphenous veins with long tributary segments

Example—AASV reflux, multiple branches

PEM Pathway
Getting insurance approval
- Need same elements in LOMN as for endothermal ablation (impact on ADLs, etc)
- Explain why PEM is the best option for your patient
- Get help from the Varithena solutions center-start this process early
- Keep track of your approvals and reimbursements
- Not all policies will cover, but coverage is increasing

Billing
- Use unlisted CPT code (37799)
- Crosswalk to endothermal ablation (EVLT or RF)
- Use unlisted J-code for drug (if your practice buys drug)
  - or- patient prescription, drug obtained from Specialty Pharmacy

Patient Scheduling Considerations
- On the whole, faster than EVLT/RF
- Each can of Varithena contains enough foam to treat three patients
- Shelf life of can is one month once opened
- If purchasing cans yourself, need to take consider wasted foam-expensive, so schedule patients in batches of three if feasible, be careful when purging
- Remember the weekend when counting days until can expires

Summary
- Varithena can be performed without sedation and requires no tumescent anesthesia to treat the GSV, accessory branches, and tributaries
- Technique straightforward for physicians familiar with catheter-based skills and sclerotherapy
- Patient scheduling needs to take into account amount of drug in can and shelf life of product
- Product currently being used by multiple US physicians and company can provide resources for reimbursement issues