Ablation Procedures for Peripheral Neuromas

Summary
Morton neuroma is a common and painful compression neuropathy of the dorsal foot. Historically, Morton neuroma has been treated with conservative measures (pads, orthotics, drugs) or surgical approaches. Minimally invasive procedures that include radiofrequency ablation (RFA) or cryoablation have been investigated as an alternative to open surgery. RFA uses heat delivered by a probe to denature proteins and destroy cells within a lesion. Cryoablation uses a coolant to chill a cryoprobe, which freezes and ablates a lesion on direct contact. These ablation methods have been used to treat other peripheral neuromas.

FDA REGULATORY STATUS
Although radiofrequency ablation probes and generators and cryoablation equipment have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process, none appear to be specifically indicated for treatment for Morton neuroma or any other specific peripheral neuroma.

POLICY STATEMENT
Minimally invasive ablation procedures, radiofrequency ablation, and cryoablation, are considered investigational for treatment of peripheral neuromas.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE
Summary of Evidence
For individuals who have Morton neuroma who receive radiofrequency ablation (RFA), the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Three case series have reported outcomes of RFA to treat Morton neuroma. The body of evidence is highly heterogeneous in terms of RFA protocols, prior conservative management, patient characteristics, follow-up durations, outcome measures, and reporting of outcomes. The available evidence is also limited by variable proportions of patients requiring surgery after RFA. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have Morton neuroma who receive cryoablation, the evidence includes case series. Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. Only 1 retrospective case series on the use of cryoablation to treat peripheral nerve pain was identified in the
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literature review. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have peripheral neuroma(s) other than Morton neuroma who receive ablation, the evidence is very limited (no published literature was identified). Relevant outcomes are symptoms, functional outcomes, and treatment-related morbidity. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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## POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Added policy statement indicating all other indications not described are investigational. References 15-16, 22-23, 32, 42-43, 48 and 51 added. References 4-6 and 49-51 updated.</td>
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<tr>
<td>June 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Added policy statement indicating all other indications not described are investigational. References 15-16, 22-23, 32, 42-43, 48 and 51 added. References 4-6 and 49-51 updated.</td>
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<tr>
<td>December 2016</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2016; references 12-13, 47, and 49 added.</td>
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Signature on File

_Deborah M. Smith, MD, MPH_