

August 21, 2006

To Whom It May Concern:

On behalf of 90 home care agencies that are members of the Home Care Association of Colorado, we request that CMS please reconsider the current opinion to render a Medicare Non-Coverage Determination for Infrared Therapy Devices (ITDs) as an effective treatment.

Patients treated in the home care environment for functional limitations associated with peripheral neuropathy will lose initial gains without access to the ITD system in the home or re-treatment on an outpatient basis. Loss of coverage for home treatment will have adverse clinical results for home care patients who can often not pay for access. CMS has made its position clear in regards to the desire to measure performance of home care agencies. Why then would the regulatory body responsible for developing measures to promote an improvement in patient outcomes be the responsible party to deny the health care industry tools to promote improved patient outcomes? Not to mention the need to improve the quality of life for the beneficiaries, which is what we are in the health care business to do.

Please take a moment to review the following comments in support of Medicare coverage for Infrared Therapy Devices as a viable treatment modality. The Colorado Home Care industry provides more than 3 million home care visits to some 60,000 patients per year. The industry has embraced ITDs commonly known as Anodyne Therapy since 2001 with more than 29 Colorado home care agencies using Anodyne Therapy. Physical Therapists practicing in the home care environment are most aware of the devastating consequences of peripheral neuropathy as it relates to foot wounds, amputations, pain interfering with the activities of daily living and high fall risk among the elderly.

Summary:

- Peripheral neuropathy (nerve damage resulting in pain and/or sensory loss) undermines quality of life and heightens the risk of falls, amputations, and other complications for millions of Medicare beneficiaries.
- The annual cost of diabetic peripheral neuropathy (DPN) and its complications exceeds \$10.9 billion, accounting for up to 27% of the direct medical costs of diabetes.
- Treatment options for peripheral neuropathy have historically been limited or non-existent.
- ITDs are widely accepted as clinically effective for the treatment of peripheral neuropathy.
- Access to these devices for patients with peripheral neuropathy is vital to preventing costly complications and curtailing the increase in Medicare expenditures for this condition.
- One single amputation costs approximately \$40,000 in Medicare expenditures on average

Thank you for your consideration and we again request that CMS reconsider the current opinion to render a Medicare Non-Coverage Determination for Infrared Therapy Devices (ITDs) as an effective treatment.

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