HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Infrared Therapy

Policy MP-028

Origination Date: 09/27/2023

Reviewed/Revised Date: 09/18/2024

Next Review Date: 09/18/2025

Current Effective Date: 09/18/2024

Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained.
4. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Infrared light therapy is the use of infrared lamps, heating pads or hot water bottles to relieve pain, stiffness, muscle spasm and increase circulation to a particular area of the body.

Treatment with monochromatic near-infrared photo energy (MIRE™) or low-level infrared therapy delivered by the Anodyne Infrared Therapy System (FDA approved in 1994) is a type of low-energy laser that uses light in the infrared spectrum. MIRE has been studied as a supplement to standard care for many indications, such as hemorrhoids, neuropathy, healing wound, lymphedema, miscellaneous musculoskeletal conditions, etc. Anodyne therapy is thought to benefit patients by improving circulation and promoting local healing. The goal of this treatment is to reduce or reverse nerve damage and relieve symptoms such as pain and loss of sensation. Treatment with the Anodyne Therapy Professional System Model 480 is administered by a physician, physical therapist, occupational therapist, or chiropractor in a physician's office or other outpatient setting, while the Anodyne Therapy Home System can be used at home by patients who have been trained in its use.

Infrared coagulation is one of the several non-surgical outpatient therapies in treating hemorrhoids. Infrared coagulation involves the direct application of infrared light waves to the hemorrhoidal tissues. Patients with grade I or II bleeding internal hemorrhoids are candidates for this procedure. Infrared light waves are converted into heat, which results in protein necrosis within the hemorrhoid.

Policy Statement and Criteria

1. Commercial Plans/CHIP

U of U Health Plans considers infrared coagulation, cautery or radiofrequency treatment medically necessary for members with grade I or grade II internal hemorrhoids that are painful or persistently bleeding and have not responded to or not a candidate for rubber band ligation.

U of U Health Plans does not cover infrared therapy treatment with monochromatic infrared energy (MIRE™) delivered by the Anodyne Therapy System or any other system as it is considered experimental and investigational for all indications. Including but not limited to, diabetic or nondiabetic peripheral neuropathy, non-healing wounds, or hemorrhoids.

2. Medicaid Plans

Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at: https://medicaid.utah.gov/utah-medicaid-official-publications/ or the Utah Medicaid code Look-Up tool

CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.

Clinical Rationale

Hemorrhoids

In 2021 UpToDate revised their review on home and office treatment of symptomatic hemorrhoids. Office-based procedures commonly include rubber band ligation, sclerotherapy, infrared coagulation of internal hemorrhoids, and excision of thrombosed external hemorrhoids. The authors concluded that the first line of treatment should be lifestyle modifications and conservative treatment. If patients are refectory to these treatments and have a grade I, II or III hemorrhoids consideration of one of the following should be considered, rubber band ligation, sclerotherapy and infrared coagulation. For healthy patients rubber band ligation is recommended, as this is more effective and requires fewer treatment sessions. Compared with rubber band ligation, infrared coagulation has fewer complications and causes less discomfort immediately after the procedure. However, it is associated with more recurrences.

Osteoarthritis

A subsequent randomized, double-blind, placebo-controlled study in 2012, Hsieh et al. examined the short-term therapeutic effects of monochromatic infrared energy (MIRE) on participants with knee osteoarthritis (OA). MIRE is commonly used in therapy for patients with peripheral neuropathies. However, research has not focused intensively on the therapeutic effects of MIRE in patients with knee OA. Seventy three participants were evaluated with knee OA. Participants received six 40-minute

sessions of active or placebo MIRE treatment (890-nm wavelength; power, 6.24 W; energy density, 2.08 J/cm2/min; total energy, 83.2 J/cm2) over the knee joints for 2 weeks. International Classification of Functioning, Disability and Health-related outcomes were collected weekly over 4 weeks using the Knee injury and Osteoarthritis Outcome Score (KIOOS), Lysholm Knee Scale (LKS), Hospital Anxiety and Depression Scale (HADS), Multidimensional Fatigue Inventory (MFI), Chronic Pain Grade (CPG) questionnaire, World Health Organization (WHO) Quality of Life-brief version, and OA Quality of Life (QOL) Questionnaire. Data were analyzed by repeated-measures analysis of variance. The study found no statistically significant differences for the interaction of group by time for KIOOS, including pain, other symptoms, function in daily living, function in sport and recreation, and knee-related QOL. Scores on the LKS, HADS, MFI, CPG questionnaire, WHO QOL-brief version, and OA QOL Questionnaire also showed no significant differences between the two groups at any of the 4 follow-up assessments. The authors concluded that short-term MIRE therapy provided no beneficial effects to body functions, activities, participation, or QOL in patients with knee OA.

Chronic Non-Healing Wounds

Several meta-analyses have investigated the evidence supporting the use of low-level (cold) lasers, including low-level infrared lasers, for treatment of chronic non-healing wounds. These meta-analyses are unanimous in concluding that there is insufficient evidence to support low-level laser in the treatment of chronic venous ulcers or other chronic non-healing wounds.

Pressure Ulcers

In 2014, the National Pressure Ulcer Advisory Panel (NPUAP) in conjunction with the European Pressure Ulcer Advisory Panel (EPUAP) and Pan Pacific Pressure Injury Alliance (PPPIA) developed clinical practice guidelines in the prevention and treatment of pressure ulcers. The guideline reviewed infrared therapy and here were the conclusions “Due to current insufficiency of evidence to support or refute the use of infrared therapy in the treatment of pressure ulcers, infrared therapy is not recommended for routine use at this time. While studies and systematic reviews have been done on infrared therapy with and without heat; overall, findings are mixed. Studies were unclear regarding concurrent management strategies (e.g., the type of support surfaces used and what comprised standard wound care) and sample sizes were small”. For laser therapy the guideline stated the following “Due to current insufficiency of evidence to support or refute the use of laser therapy in the treatment of pressure ulcers, laser therapy is not recommended for routine use at this time. (Strength of Evidence = C; Strength of Recommendation = No specific recommendation) They also cited that Woodruff et al. (2004) performed a meta-analysis of 24 animal and clinical studies on the effectiveness of laser (including infrared-based units) on wound healing in a variety of ulcers on both animals and humans. They concluded that laser therapy studies had numerous methodological limitations”.

Peripheral Neuropathy

A systematic review in 2008 by Li et al examined all clinical studies, including retrospective and prospective experimental studies and case series, evaluating the Anodyne MIRE system for the treatment of diabetic peripheral neuropathy. Ten studies were identified, including 4 retrospective chart reviews, 5 studies with an experimental research design, and 2 studies that used a prospective randomized, placebo controlled design. Six of the 10 studies had a sample size of 50 subjects or less. The authors found that studies suggested the Anodyne MIRE system had efficacy for improving lower extremity sensation, balance, gait, and decreasing fall risk. However, poor study designs, small sample sizes, limited information regarding treatment volume or intensity, concomitant use of conventional physical therapy modalities, and a lack of long-term follow-up decreased the validity of most of the

studies. Therefore, further more robust well-designed placebo-controlled RCTs are recommended to determine the effectiveness of the Anodyne MIRE system for treating patients with diabetic peripheral neuropathy.

A 2011 systematic review (Ites et al) analyzed the use of physical therapy interventions along with monochromatic infrared energy (MIRE) therapy, for balance dysfunction in patients with diabetic peripheral neuropathy (DPN). Upon thorough review of outcome measures, statistical significance, and clinical relevance, lower extremity strengthening exercises was given a fair recommendation for clinical use in treating balance dysfunction in patients with DPN. All others had insufficient evidence to either support or refute their effect on balance in this population. MIRE being one of several interventions evaluated, demonstrated insufficient evidence to be recommended as a treatment for balance dysfunction.

A 2006 preliminary, multicenter study assessed the effect of monochromatic infrared photo energy (MIRE™) combined with physical therapy in reducing pain, improving sensation, and increasing balance in patients with peripheral neuropathy (Volkert et al.). A total of 272 patients, average age 69 years, were documented before and after receiving treatments at eight physical therapy clinics, which included pain [VAS scale], diminished foot sensation [Semmes Weinstein Monofilament 5.07], and balance deficits [Tinetti Assessment Tool]. The study found that neuropathic pain, diminished foot sensation, and balance impairments at baseline were present in 93% of patients. After an average of 18 treatments, neuropathic pain decreased by 38%, lower extremity sensory impairment improved by 77%, and balance deficits decreased by 73% [$P \leq 0.006$ for all results]. The authors concluded when compared with the literature, preliminary findings suggest that MIRE™ plus manual physical therapy improves pain, balance, and sensation symptoms in patients with peripheral neuropathy, at least temporarily. However, it was felt further more robust studies are needed to validate these findings.

A 2008 double-blind, sham-controlled, randomized study, (Lavery et al) evaluated the effectiveness of Anodyne monochromatic infrared energy (MIRE) in-home treatments over a 90-day period to improve peripheral sensation and self-reported QOL in individuals with diabetes. A total of 69 individuals with diabetes and a vibration perception threshold (VPT) between 20 and 45 were randomly assigned to 2 treatment groups: active or sham treatment. Sixty patients (120 limbs) completed the study. Anodyne units were used at home every day for 40 minutes for 90 days. Nerve conduction velocities, VPT, Semmes-Weinstein monofilaments (SWM) (4-, 10-, 26-, and 60-g monofilaments), the Michigan Neuropathy Screening Instrument (MNSI), a 10-cm visual analog pain scale, and a neuropathy-specific QOL instrument were measured. A nested repeated-measures multiple ANOVA design was employed. Two sites (great toe and 5th metatarsal) were tested on both the left and right feet of each patient, so two feet were nested within each patient and two sites were nested within each foot. To analyze the ordinal SWM scores, a non-parametric factorial analysis for longitudinal data was used. The authors found no significant differences in measures for QOL, MNSI, VPT, SWM, or nerve conduction velocities in active or sham treatment groups ($p > 0.05$). In conclusion, the study demonstrated that the Anodyne MIRE therapy was no more effective than sham therapy in the treatment of sensory neuropathy in individuals with diabetes.

In another 2008 controlled, double-blind, randomized clinical study, Franzen-Korzendorfer et al investigated the effect of MIRE on transcutaneous oxygen measurements and protective sensation in patients with diabetes and a loss of protective sensation. A total of 18 adults (12 men, 6 women; mean age of 65 +/-13 years, range of 39 to 86 years) with diabetes and loss of protective sensation were recruited using convenience sampling methods. All patients served as their own control. Pre- and post-treatment tests assessed sensation, pain, and transcutaneous oxygen measurements on 2 sites/foot.

Patients underwent a series of 30-min MIRE treatments (1 foot active treatment, 1 foot sham). MIRE was delivered at the manufacturer pre-set level of energy of 1.5 J/cm(2)/min at a wavelength of 890 nm; sham units delivered no energy. Scores were analyzed using paired t-tests and Pearson's correlation coefficient. The study found no significant differences were observed between active and sham treatments for transcutaneous oxygen values, pain, or sensation. Both active and sham MIRE-treated feet had significantly improved sensation when compared to pretest baseline scores ($p < 0.05$). No statistical relationship was found between transcutaneous oxygen and sensation. In conclusion, this small study did not demonstrate any effects of MIRE treatment on transcutaneous oxygen measurements, pain, or sensation in adults with diabetes and loss of protective sensation. Therefore, further research using larger sample sizes are needed to determine the effects of MIRE for these conditions.

Hayes conducted a research brief in 2023 on the topic of monochromatic infrared energy (MIRE) for the treatment of neuropathic pain. The review found adequate published peer-reviewed literature to evaluate the evidence related to MIRE therapy for treatment of neuropathic pain. There was limited evidence that MIRE results in short-term improvement of tactile sensitivity, which is probably not sustained over time and also suggested that MIRE does not provide relief for neuropathic pain. Being the quality of evidence is low, further studies are needed to change the estimated effect. Conclusions about safety and effectiveness cannot be made within this report because a full-text review of the evidence is required first.

CMS has issued a National Coverage Determination stating that it does not cover the use of infrared and/or near-infrared light and/or heat, including monochromatic infrared energy (MIRE) for treatment, including the symptoms such as pain arising from these conditions, of diabetic and/or nondiabetic peripheral neuropathy. Coverage is also denied for wounds and/or ulcers of the skin and/or subcutaneous tissues. There is insufficient evidence in peer reviewed literature to support the safety and clinical effectiveness of MIRE™ treatment.

Applicable Coding

CPT Codes

Possibly covered

46930 Destruction of internal hemorrhoid(s) by thermal energy (eg, infrared coagulation, cautery, radiofrequency)

Not covered

97026 Application of a modality to 1 or more areas; infrared

HCPCS Codes

Not covered

A4639 Replacement pad for infrared heating pad system, each

E0221 Infrared heating pad system

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