Laser Treatment of Port Wine Stains
Corporate Medical Policy

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File code: UM.SURG.09
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Description/Summary

Port wine stains are common vascular malformations that start as pink macules and, if untreated, tend to become darker and thicker over time. They usually occur on the face and neck, but can be located elsewhere on the body. Treatment with lasers (including pulsed dye lasers [PDL], Alexandrite, Nd:YAG lasers, and intense pulsed light [IPL]) is proposed.

Policy

Coding Information
Click the links below for attachments, coding tables & instructions.
Attachment I- Code Table & Instructions

When a service may be considered medically necessary

Laser treatment may be medically necessary for port wines stains causing functional impairment. Functional impairment may include, but is not limited to:

1. Lesions located where there is potential compromise or actual compromise (see numbers 3 and 4 below) of vital structures (e.g. nose, eyes, ears, lips, tongue or larynx)

2. Lesions which are symptomatic (e.g. bleeding, painful, ulcerated, prior infection, or pedunculated and symptomatic)

3. Lesions which involve the eyelids or periorbital tissue and result in impaired vision or strabismus

4. Lesions which result in auditory impairment and secondary speech delay (lesions which are located on or around the ear)
5. Lesions which result in a risk of bleeding caused by bleb formation or incidental trauma

When a service is considered investigational

Treatment of port wine stains with lasers in combination with photodynamic therapy or topical angiogenesis inhibitors is considered investigational.

Policy Guidelines

Performance of a prior spot test is necessary to select suitable candidates for treatment and to determine the degree of scarring that may occur.

The size of the lesion may require more than 1 treatment.

Background

Port wine stains are the most common of the vascular malformations, affecting approximately 3 in 1000 children. They are composed of networks of ectatic vessels and primarily involve the papillary dermis. Unlike many other birthmarks, port wine stains do not resolve spontaneously. In contrast, they typically begin as pink macules and become redder and thicker over time due to decreased sympathetic innervation. The depth of the skin lesions ranges from about 1 to 5 mm. Port wine stains are generally located on the face and neck but can occur in other locations such as the trunk or limbs.

Before the availability of laser treatment in the 1980s, there were no effective therapies for port wine stains. A laser is a highly focused beam of light that is converted to heat when absorbed by pigmented skin lesions. Several types of lasers have been used to treat port wine stains. Currently, the most common in clinical practice is the PDL, which uses yellow light wavelengths (585-600 nm) that selectively target both oxyhemoglobin and deoxyhemoglobin. PDLs penetrate up to 2 mm in the skin. Newborns and young children, who have thinner skin, tend to respond well to this type of laser; the response in thicker and darker lesions may be lower. Other types of lasers with greater tissue penetration and weaker hemoglobin absorption are used for hypertrophic and resistant port wine stains. In particular, alternatives to the PDL are the long-pulsed 1064 nm Nd:YAG and 755 nm pulsed Alexandrite lasers. The 1064 nm Nd:YAG laser requires a substantial degree of skill to use to avoid scarring. Carbon dioxide and argon lasers are relatively nonselective; they were some of the first lasers used to treat port wine stains but were associated with an increased incidence of scarring and are not currently used frequently in clinical practice to treat port wine stains. IPL devices emit polychromatic high-intensity pulsed light. Pulse duration is in the millisecond range, and devices use an emission spectrum ranging from 500 to 1400 nm. Compared with other types of lasers, IPL devices include both the oxyhemoglobin selective wavelengths emitted by PDL systems and longer wavelengths that allow deeper penetration into the dermis.

Regulatory Status

Several laser systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for a variety of dermatologic indications, including treatment of port wine stains. Approved lasers for this indication include the
Candela® PDL system (Candela Corp., Wayland, MA), the Cynosure Photogenica® PDL (Cynosure Inc., Westford, MA), and the Cynosure Nd:YAG laser system. In addition, the Cynergy™ Multiplex Laser (Cynosure), a combined Nd:YAG and PDL was approved by FDA in 2005 for treatment of benign vascular and vascular dependent lesions, including port wine stains.

In 2003, the Lumenis® family of IPL systems was approved by FDA; indications for use include dermatologic applications. Subsequently, the NannoLight® IPL system (Global USA Distribution) was approved by FDA in 2008 and the Mediflash3 and Esterflash3 systems (Dermeo) were approved in 2010 for indications specifically including treatment of port wine stains.

Rationale/Scientific Background

The policy was created in 1996 and was on “no further review” status from 2003 to 2010, at which time it returned to active review and was updated with a search of the MEDLINE database. Most recently, the literature was reviewed through May 5, 2014. Following is a summary of the key literature to date on laser treatment of port wine stains.

Laser treatment monotherapy

In 2011, a Cochrane review of trials on light or laser sources for treating port wine stains was published by Faurusch et al. The review included randomized controlled trials (RCTs) comparing any laser or light source with any comparison intervention. Five RCTs with a total of 103 participants met inclusion criteria. The investigators reported that interventions and outcomes were too heterogenous for a meta-analysis of study findings. All studies used a within-participant (eg, split-side) design, and none included a sham treatment or no treatment group. Interventions in all of the trials were between 1 and 3 treatment sessions and all trials followed patients for less than 6 months’ follow-up. A primary efficacy outcome of the review was reduction in redness; investigators judged that a reduction of more than 20% would represent a clinically relevant effect. In all of the 5 trials, treatment with the pulsed dye laser (PDL) resulted in more than 25% reduction in redness in 50% to 100% of participants, depending on setting of the laser device. In addition, intense pulsed light (IPL) and the Nd:YAG laser also led to a reduction in redness in 1 trial each. The trials found that long-term adverse effects of laser and light treatment were rare; only 1 participant in 1 trial experienced scarring of the skin, and this person had a too-high dose of the Nd:YAG laser. The authors concluded that the evidence supports the use of the PDL as the treatment of choice for port-wine stains.

Representative RCTs included in the Cochrane review and published more recently that evaluated laser treatment of port wine stains are described next.

In 2009, Faurusch et al in Denmark published a study with 20 patients with port wine stains. Port wine stains were on the face (n=15), trunk (n=4), or extremities (n=1). Eight (40%) had previously untreated lesions, and the remainder were previously treated, but with types of lasers not under investigation in the study. Patients received 1 treatment with a PDL on a randomly selected side of the lesion (left/lower or right/upper) and IPL treatment on the other side. Blinded assessment 12 weeks’ posttreatment found a median of 65% percentage lightening on the PDL side and 30% on the IPL side (p<0.001). Fifteen (75%) of 20 patients
had more than 70% lightening with PDL treatment compared with 6 (30%) in the IPL group; this difference was also statistically significant (p=0.014).

A 2010 study in Germany by Babilas et al was a split-face comparison of PDL and IPL treatment in 25 patients; 11 (40%) had previously untreated port wine stains, and the other 14 had received previous laser treatment. Port wine stains were located in the face and neck region in 18 patients, the trunk in 3 patients, and the extremities in 4 patients. The previously untreated patients were treated with IPL, short-PDL (585 nm and 0.45-ms pulse duration), and long-PDL (584-600 nm and 1.5-ms pulse duration). Patients who previously failed either short- or long-PDLs did not receive that type of treatment. Blinded outcome assessment was done 6 weeks after treatment. In the treatment-naive group, assessors rated lightening as excellent (at least 75%) or good (51% to 75%) in at least 1 test spot in 7 of 11 (64%) patients after IPL treatment, 5 of 11 (45%) after long-PDL, and 1 of 11 (9%) after short-PDL (between group p value not reported). In the group that had been previously treated, lightening was rated as excellent or good in at least 1 test spot in 4 of 14 (29%) patients after IPL treatment, 1 of 14 (7%) after long-PDL treatment, and 0 (0%) after short-PDL treatment.

In 2012, Klein et al in Germany published findings of an RCT evaluating treatment with a diode laser augmented by the dye indocyanine green. The study included 31 patients with port wine stains. Two areas of 2.0-2 cm were selected in each patient’s port wine stain. The areas were randomly assigned to receive treatment with a PDL or with an indocyanine green-augmented diode laser (ICG + DL). The cosmetic appearance of the lesions was assessed using a 5-point Likert-type scale (0=no clearance to 4=excellent clearance). Three months after treatment, the mean investigator-rated clearance score (SD) was 0.89 (0.99) for lesions receiving PDL treatment and 1.30 (1.29) for lesions receiving ICG + DL treatment. The difference in scores between groups was not statistically significant, p=0.11. At 3 months, patients rated the clearance level as a mean (SD) of 0.89 (0.88) after PDL treatment and 1.71 (1.24) after ICG + DL (p=0.004). Two patients in the diode laser treatment group experienced adverse events. There was 1 case of site-specific pain during ICG + DL treatment (8 on a 10-point scale) and 1 case of an atrophic scar measuring 5 mm in diameter. Other adverse effects were burning (PDL: 58%; ICG + DL: 68%), edema (PDL: 3%; ICG + DL: 10%), and purpura (PDL: 71%; ICG + DL, 42%).

Combination treatment

Two RCTs on laser treatment in combination with topical angiogenesis inhibitors were identified, and these trials had mixed findings. A 2013 RCT by Passeron et al included 22 children between the ages of 6 months and 18 years who had facial port wine stains no more than 100cm². Patients were randomized to receive PDL alone or laser followed by topical timolol. All patients received 3 laser sessions, with a month between sessions. For patients in the combination treatment group, timolol gel was applied twice daily beginning on the day of the first laser treatment and continuing until 15 days after the third and final treatment. Blinded evaluation of patients occurred at baseline and 1 month after the third laser session. In an intention-to-treat analysis, there was no statistically significant difference between groups in the clinical success rate of the 2 treatments, as measured by an investigator global assessment variable. This variable ranged from -1 (worsening) to 4 (complete clearance). A score of 3 (marked improvement) or 4 (complete clearance) was given to 1 of 10 patients treated with laser and 2 of 12 patients treated with combination
therapy (p=1.0).

A 2012 study by Tremaine et al evaluated PDL treatment with and without the addition of imiquimod cream. The study included 24 subjects with port wine stains. All patients initially received 1 session of laser treatment. Five patients enrolled in the study twice, with a washout period of at least 4 weeks before re-enrollment. Patients were randomized to receive additional treatment with either 5% imiquimod cream or placebo cream, to be applied 3 times a week for 8 weeks, beginning the day following laser treatment. Chromameter measurements were taken at baseline and at 8 weeks after laser treatment. The primary outcomes were change in erythema (defined as red/green color saturation with values ranging from +60 green to -60 red) and overall change in 3 color dimensions (reflected light intensity, green/red color saturation, and blue/yellow color saturation). The mean change (SD) in erythema was 0.43 (1.63) for the laser plus placebo sites and 1.27 (1.76) for the laser plus imiquimod sites. The difference between groups was statistically significant (p=0.03) and favored combined treatment. Similarly, the mean change (SD) in overall color was 2.59 (1.54) for laser plus placebo and 4.08 (3.39) for laser plus imiquimod (p=0.04).

Summary

Studies have generally found that laser treatment can be effective at lightening port wine stains. The preponderance of evidence is on the pulsed dye laser; there is insufficient evidence from comparative studies that 1 type of laser results in more lightening than another. There is insufficient evidence that adding topical angiogenesis inhibitor to laser therapy results in better outcomes than lasers alone. There was 1 positive RCT and 1 negative RCT. No comparative studies were identified on lasers combined with any other treatments. Thus, laser treatment may be considered medically necessary in certain situations for patients with port wine stains and combination treatment is considered investigational.

Reference Resources

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update information

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<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tbody>
<tr>
<td>08/2016</td>
<td>New policy. Adoption of BCBSA MPRM# 7.01.40.</td>
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<tr>
<td>08/2017</td>
<td>Policy reviewed. Prior Approval requirement removed.</td>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors      Date Approved

Gabrielle Bercy-Roberson, MD, MPH, MBA
Senior Medical Director
Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA
Chief Medical Officer

Attachment I
Code Table & Instructions

The following codes will be considered as Medically Necessary when applicable criteria has been met.

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Brief Description</th>
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<td>CPT®</td>
<td>17106</td>
<td>Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq. cm</td>
</tr>
<tr>
<td>CPT®</td>
<td>17107</td>
<td>Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq. cm</td>
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<tr>
<td>CPT®</td>
<td>17108</td>
<td>Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq. cm</td>
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<td>ICD-10-CM</td>
<td>Q82.5</td>
<td>Congenital non-neoplastic nevus (includes port wine nevus)</td>
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