I. POLICY

Laser treatment of port wine stains in the presence of functional impairment related to the port wine stains may be considered medically necessary.

In the absence of functional impairment, laser treatment for port wine stains may be considered medically necessary when the lesions are located on the face or neck in infants and young children.

Treatment of port wine stains with lasers in combination with photodynamic therapy or topical angiogenesis inhibitors is considered investigational. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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 one treatment.

Cross-reference:
MP-1.004 Cosmetic and Reconstructive Surgery

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

BlueJourney HMO* BlueJourney PPO*
III. DESCRIPTION/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.

Prior to 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 pulsed dye laser (PDL) which uses yellow light wavelengths (585-600nm) that selectively target both oxyhemoglobin and deoxyhemoglobin. Pulsed dye lasers 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 pulsed-dye laser are the long-pulsed 1064 nm Nd: YAG and 755 nm pulsed Alexandrite lasers. The 1064 nm Nd: YAG laser requires a substantial amount of skill to use to avoid scarring. Carbon dioxide and argon lasers are relatively non-selective; 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. Intense pulsed light (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 1,400 nm. Compared to 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.

### IV. RATIONALE

#### Laser Treatment Monotherapy

In 2011, a Cochrane review of trials on light or laser sources for treating port wine stains was published by Faurschou and colleagues. (1) The review included randomized controlled trials (RCTs) comparing any laser or light source to any comparison intervention. Five RCTs with a total of 103 participants met inclusion criteria. The investigators reported that interventions and outcomes were too heterogeneous for a meta-analysis of study findings. All studies used a within-participant (e.g., split-side) design and none of them 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 50-100% 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 below:

In 2009, Faurschou and colleagues in Denmark published a study with 20 patients with port wine stains. (2) 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 one treatment with a PDL on a randomly selected side of the lesion (left/lower or right/upper) and intense pulsed light (IPL) treatment on the other side. Blinded assessment 12 weeks’ post-treatment found a median of 65% percentage lightening on the PDL side and 30% on the IPL side (p<0.0003). Fifteen (75%) of 20 patients had more than 70% lightening with PDL treatment compared to 6 (30%) in the IPL group; this difference was also statistically significant, p=0.014.
A 2010 study in Germany by Babilas and colleagues 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. (3) 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-millisecond pulse duration), and long-PDL (584-600 nm and 1.5-millisecond 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-naïve group, assessors rated lightening as excellent (at least 75%) or good (51-75%) in at least one 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 was not reported). In the group that had been previously treated, lightening was rated as excellent or good in at least one 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 and colleagues in Germany published findings of an RCT evaluating treatment with a diode laser augmented by the dye indocyanine green. (4) The study included 31 patients with port wine stains. Two areas of 2 by 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 with 0=no clearance to 4=excellent clearance. Three months after treatment, the mean investigator-rated clearance score was 0.89 (standard deviation [SD]: 0.99) for lesions receiving PDL treatment and 1.30 (SD: 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 of 0.89 (SD: 0.88) after PDL treatment and 1.71 (SD: 1.24) after ICG + DL, p=0.004. Two patients in the diode laser treatment group experienced adverse events. There was one 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 side effects were burning (PDL: 58%, ICG + DL: 68%), edema (PDL: 3%, ICG + DL: 10%) and purpura (PLD: 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 100 cm². (5) 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. (6) 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. Chromometer 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.

Practice Guidelines and Position Statements

None identified.

2017

Review of the literature revealed no new information that would alter the policy position.

V. DEFINITIONS
**BASIC ACTIVITIES OF DAILY LIVING** include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

**CONGENITAL** refers to something that is present at birth.

**FUNCTIONAL IMPAIRMENT** is a condition that describes a state where an individual is physically limited in the performance of basic daily activities.

**HEMANGIOMA** is a benign tumor of dilated blood vessels.

### VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

### VII. DISCLAIMER

*Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

*Note:* This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.
Covered when medically necessary:

<table>
<thead>
<tr>
<th>CPT Codes®</th>
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<tbody>
<tr>
<td>17106</td>
<td>17107</td>
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<table>
<thead>
<tr>
<th>ICD-10-CM Diagnosis Code*</th>
<th>Description</th>
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<tr>
<td>Q82.5</td>
<td>Congenital non-neoplastic nevus</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES


Other:
Taber’s Cyclopedic Medical Dictionary, 19th edition.

X. POLICY HISTORY
| CAC 02/28/06 | Consensus - Policy statement unchanged. References updated. |
| CAC 2/27/07 | |
| CAC 5/27/08 | CAC 11/30/10 Minor revision –Policy retitled Laser Treatment of Port Wine Stains. A medical necessity indication for treatment in the presence of functional impairment was added to the policy. The existing policy statement regarding treatment of infants and young children was revised. Treatment with lasers in combination with photodynamic therapy or topical angiogenesis inhibitors was added as investigational. |
| CAC 9/29/09 | CAC 4/24/12 Consensus review; references updated. In the third policy statement regarding treatment with lasers, “port wine stains” was added for clarification. |
| CAC 3/24/15 Consensus. No change to policy statements. References and rationale updated. Codes reviewed. |
| CAC 3/29/16 Consensus. No change to policy statements. References and rationale reviewed. Changed LCD number from L27527 to L34938 due to CMS update to ICD-10. Coding reviewed. |
| Admin update 1/1/17: Product variation section reformatted. | |