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Laser Treatment of Congenital Port Wine Stain (PWS), Hemangiomas, and Other External Vascular Malformations

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Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.

Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

EXCEPTION: Effective for policies issued on or after January 1, 2022, Illinois law (215 ILCS 5/356z.43, Public Act 102-0642) requires coverage for treatment to eliminate or provide maximum feasible treatment of nevus flammeus, also known as port-wine stains, including but not limited to, port-wine stains caused by Sturge-Weber syndrome. Treatment or maximum feasible treatment shall include early intervention treatment, including topical, intralesional, or systemic medical therapy and surgery, and laser treatments approved by the U.S. Food and Drug Administration in children aged 18 years and younger that are intended to prevent functional impairment related to vision function, oral function, inflammation, bleeding, infection, and other medical complications associated with port-wine stains. Coverage for treatment required **shall not** include treatment solely for cosmetic purposes.

This medical policy has become inactive as of the end date above. There is no current active version and is not to be used for current claims adjudication or business purposes.

See SUR716.001 Cosmetic and Reconstructive Procedures for dates of service 12/31/2025 and after.

Laser treatment of port wine stains, hemangiomas, and other external vascular malformations that are present from birth and have medical record documentation of progressive functional impairment **may be considered medically necessary.**

Laser treatment of acquired hemangiomas and other external vascular malformations that is performed primarily to alter or enhance appearance **is considered cosmetic.**

NOTE: Special Comment Regarding Cosmetic Service—Determination of benefit coverage for procedures considered to be cosmetic is based on how a member's benefit contract defines cosmetic services and their eligibility for benefit coverage. Coverage of laser treatment of port wine stains, hemangiomas, and other external vascular malformations will depend on benefit language related to definitions of medically necessary, reconstructive, and cosmetic services. Procedures are considered reconstructive when intended to address a significant variation from normal related to accidental injury, disease, trauma and treatment of a disease or congenital defect.

Treatment of port wine stains, hemangiomas, and other external vascular malformations with lasers in combination with photodynamic therapy or topical angiogenesis inhibitors **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Port Wine Stains

Port wine stains are the most common of the vascular malformations, affecting approximately 3 in 1000 children. (1) They usually occur on the face and neck, but can be located elsewhere on the body, such as the trunk or limbs. Port wine stains 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. 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 pulsed dye lasers (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. 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 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.

Hemangiomas

Hemangiomas are abnormally dense collections of benign, dilated, small blood vessels occurring in 10-12% of all children by one year of age, may occur in the skin or internal organs, and may be present anywhere on the body. However, they have the most psycho-social impact when they appear on the face or head. The classically recognized hemangioma is a visible red skin lesion that may be superficial, called a capillary hemangioma, a skin lesion that goes deeper than a superficial lesion (cavernous hemangioma), or a mixture of both. These lesions are usually present at birth, although they may appear within a few months after birth, often beginning at a site that has appeared slightly dusky or colored differently than the surrounding tissue. Hemangiomas of the eyelid may interfere with the development of normal vision and must be treated in the first few months of life. On rare occasions, the size and location of hemangiomas may interfere with breathing, feeding, or other vital functions. Superficial hemangiomas may disappear completely over time without treatment.

Other Vascular Malformations

Stork bite is a common type of birthmark seen in newborns that is due to a dilation of blood vessels, and usually disappears by about 18 months, although stork bite on the back of the neck may not disappear. Angel's kisses are birthmarks usually seen on the forehead, eyelids, tip of nose, or upper lip, and usually disappear by two years of age. Stork bites and angel's kisses are harmless and require no treatment. However, these may be removed with a laser to improve the patient's appearance. (2)

Telangiectasia are small, dilated, superficial blood vessels near the surface of the skin. These can be treated with laser or sclerotherapy; treatment is usually cosmetic.

Cherry angiomas are benign skin growths of unknown cause that vary in size, usually develop on the trunk, and are more common after age 30. They are also called senile angioma. Cherry

angiomas generally do not need to be treated, but they may be removed by cautery, cryotherapy, laser, or surgery. (3)

Regulatory Status

Multiple 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. Refer to <<https://www.accessdata.fda.gov>> for a complete list of U.S. FDA approved devices.

Rationale

This policy has been updated regularly with searches of scientific literature. The following is a summary of the key literature through April 3, 2024.

Laser Monotherapy Treatment

In 2011, a Cochrane review of trials on light or laser sources for treating port wine stains (PWS) was published by Faurschou et al. (1) 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 (e.g., split-side) design, and none included a sham treatment or no treatment group. Interventions in all 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 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 PWS. Representative RCTs included in the Cochrane review and published more recently that evaluated laser treatment of PWS are described next.

In 2009, Faurschou et al. in Denmark published a study with 20 patients with PWS. (2) PWS 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' post treatment 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 PWS, and the other 14 had received previous laser treatment. (3) PWS 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-naïve 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. (4) The study included 31 patients with PWS. Two areas of 2 cm were selected in each patient's PWS. 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%).

In 2015, Shen et al. performed a meta-analysis in order to review the therapeutic efficacy and safety of PDL in the treatment of infantile hemangiomas (IH). (5) Thirteen articles with 1529 hemangiomas were included. The meta-analysis demonstrated an overall resolution rate of 89.1% with 6.28% incidence of adverse effect. The reviewers concluded that PDL may be an effective modality to decrease the proliferative phase and accelerate rates of involution and resolution with few adverse events.

Chinnadurai et al. (2016) systematically reviewed studies of laser treatment of IH. (6) Twenty-nine studies addressing lasers were identified: 4 RCTs, 8 retrospective cohort studies, and 17 case series. Studies of laser treatment of IH primarily addressed different laser modalities compared with observation or other laser modalities. PDL was the most commonly studied laser type, but multiple variations in treatment protocols did not allow for demonstration of superiority of a single method. Most studies reported a high success rate with longer pulse PDL compared to observation in managing the size of IH, although the magnitude of effect differed

substantially. Studies generally found PDL more effective than other types of lasers for cutaneous lesions. When first introduced as a primary treatment for IH, various laser modalities generally offered superior outcomes compared with steroid therapy and observation. In the era of β -blocker therapy, laser treatment may retain an important role in the treatment of residual and refractory lesions.

A Comparative Effectiveness Review on the diagnosis and management of IH was performed by Chinnadurai et al. in 2016 for the Agency for HealthCare Research and Quality (AHRQ). (7) Limited research is available to guide decision-making about the use of laser modalities as the initial intervention. Historically, lasers provided a fair benefit in primary management of IH, which was comparable in many cases series to steroid treatment, and generally was superior to observation. The advent of propranolol has largely relegated laser treatment to secondary management. There is little comparative data between lasers and β -blockers, however the success rates for complete or near complete resolution in historical laser studies are notably lower than those in more recent propranolol studies. Under current treatment paradigms, PDL with epidermal cooling is most often used for residual cutaneous changes after the completion of the proliferative growth phase and with incomplete resolution after pharmacologic management, while Nd:YAG laser is most often used intralesionally for medically refractory lesions. A variety of other lasers are used for intralesional treatment or resection, though no conclusions can be drawn regarding the superiority of any of these modalities over any others.

In a systematic review and network meta-analysis, Fei et al. (2020) reviewed the efficacy and adverse effects of different therapies to address IH. (8) A total of 30 RCTs with more than 20 different therapeutic regimens were identified. Reviewers found that treatment combined propranolol orally with laser could improve the curative effect versus monotherapy. Laser with topical β blockers showed more efficiency than others whether in children under 6 months or not. The long-pulsed dye laser might be the best laser therapy, and when used with propranolol had the lowest incidence of adverse reactions, such as ulcer, color sink and color reduction. The authors concluded that a combination of β blockers and laser might be the first-line treatment of IHs, and a longer pulsed dye laser is preferred. Further well-designed RCTs are needed to confirm these findings.

Whether IHs need to be treated and which treatment should be preferred is still controversial. In 2020, Yang et al. aimed to compare and rank the treatments and identify the optimal treatment for IHs. (9) Twenty studies were deemed eligible, including 1149 participants and eight interventions. For efficacy, oral propranolol and topical propranolol/timolol were better than observation/placebo (OR 95% CrI: 17.05, 4.02-94.94; 9.72, 1.91-59.08). For safety, topical propranolol/timolol was significantly better tolerated than oral propranolol (0.05, 0.001-0.66). Cluster analysis demonstrated oral propranolol was the most effective treatment for IHs, while topical propranolol/timolol showed high efficacy and the highest safety. Laser, intralesional propranolol or glucocorticoid, oral glucocorticoid, or captopril had significantly lower priority than oral propranolol or topical propranolol/timolol considering both efficacy and safety. The quality of evidence was rated as moderate or low in most comparisons. This network meta-

analysis found topical beta-blockers had the potential to be the most preferable and beneficial option for IHs in consideration of both efficacy and safety.

Laser Combination Treatment (With Photodynamic Therapy or Topical Angiogenesis Inhibitors)

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 PWS no more than 100 cm². (11) 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. (12) 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).

Greveling et al. (2017) conducted a prospective, intra-patient, randomized controlled trial evaluating the efficacy of adjuvant use of commercially available topical rapamycin after PDL treatment in patients with PWS. (13) Four treatment areas of 1 cm² were created in each PWS. PDL-only treatment was compared to the following three treatments: PDL + rapamycin, PDL + Erbium YAG laser ablation of the stratum corneum + rapamycin, and rapamycin monotherapy. Researchers also compared PDL + Erbium YAG + rapamycin with PDL + rapamycin. The primary endpoint was the percentage clearance assessed colorimetrically at 6 months follow-up. Secondary outcomes were photographic evaluation by an expert panel, patient satisfaction, treatment related pain, and safety. Fourteen patients completed the treatment protocol. The highest percentage clearance was achieved with PDL-only treatment (mean [SD] 16% [34]), but there were no statistically significant differences between

treatments. The best photographic evaluation and highest patient satisfaction were also achieved with PDL-only treatment, but only the difference between PDL-only and rapamycin monotherapy was statistically significant. The treatment related pain was well tolerated. Application-site pruritus was a frequent occurring adverse event. Allergic contact dermatitis to rapamycin occurred in one patient. There were no serious adverse events. The authors concluded that topical application of the commercially available solution of rapamycin (Rapamune 0.1%) as an adjuvant to PDL treatment does not appear to improve PWS blanching.

In 2017, Doh et al. evaluated the effect of combined use of 1% topical rapamycin with PDL compared to PDL alone in cutaneous capillary malformations (CM) of trunk or extremities and tried to identify the optimal duration of topical rapamycin application. (14) Three adjacent areas of cutaneous CM that had never been treated before were selected in each patient and underwent the following regimens: A) PDL + vehicle for 8 weeks post-PDL; B) PDL + topical rapamycin for 1-week post-PDL and C) PDL + topical rapamycin for 8 weeks post-PDL. Each test site was treated by PDL for two sessions with 8 weeks interval. Only one of six patients showed clinical improvement with combined rapamycin treatment. Overall, there was no statistically significant difference in erythema and blanching rate among PDL alone and combined rapamycin regimens.

In a 2018 article, Lipner (15) reviewed the literature on use of topical therapies with PDL for the treatment of PWS. Topical agents identified in the clinical trials included timolol, imiquimod, and rapamycin. Topical timolol with PDL failed to show improved efficacy compared with PDL alone. Two clinical trials using imiquimod and PDL showed enhanced blanching of PWS compared with controls. Rapamycin and PDL were more effective than controls for facial PWS, but not for nonfacial PWS. The reviewer concluded that topical imiquimod and rapamycin have shown some efficacy in treating PWS with PDL, but to date there is no topical adjuvant to PDL that reliably improves results for PWS.

UpToDate

In 2023, UpToDate (17) published an article on laser and light therapy for cutaneous vascular lesions. Combined modality lasers, photodynamic therapy, and PDL plus topical agents with antiangiogenic properties were mentioned as emerging therapies that may have benefit in the treatment of PWS. However, further studies were deemed necessary to explore the efficacy and safety of these therapies in PWS.

Summary of Evidence

Studies have generally found that laser treatment can be effective at treating port wine stains, hemangiomas, and other external vascular malformations. The preponderance of evidence is on the pulsed dye laser; there is insufficient evidence that one type of laser is more effective than another. There is insufficient evidence that adding topical angiogenesis inhibitors to laser therapy results in better outcomes than lasers alone. Thus, laser treatment may be considered medically necessary in certain situations for patients with port wine stains, hemangiomas, and other external vascular malformations; however, combination treatment is considered experimental, investigational and/or unproven.

Practice Guidelines and Position Statements

American Academy of Pediatrics

In 2019, the American Academy of Pediatrics (AAP) issued a clinical practice guideline on the management of infantile hemangiomas. (18) The guidelines recommend early consultation (by 1 month of age) for lesions that are potentially high risk due to:

- Potential for disfigurement;
- Life-threatening complications;
- Functional impairment;
- Ulceration; and/or
- Underlying abnormalities.

Oral propranolol is identified as the treatment of choice for problematic infantile hemangiomas that require systemic therapy, while surgery and/or laser treatment are thought to be most useful for the treatment of residual skin changes after involution.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	17106, 17107, 17108
HCPSC Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <<http://www.cms.hhs.gov>>.

Policy History/Revision	
Date	Description of Change
12/31/2025	Document became inactive.
06/15/2024	Document updated with literature review. Coverage unchanged. Added references 1-3 and 18; others updated.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. The following references were added/updated: 8, 9, and 15.
05/15/2021	Reviewed. No changes.
04/01/2020	Document updated with literature review. Coverage unchanged. The following references were added: 12-14.
04/18/2018	Document updated with literature review. Coverage unchanged. References 5-7 and 10-12 added.
03/15/2016	Reviewed. No changes.
02/15/2015	Document updated with literature review. Coverage unchanged.
04/01/2011	Document updated with literature review. The following was added: treatment of port wine stain, hemangiomas, and other external vascular malformations with lasers in combination with photodynamic therapy or topical angiogenesis inhibitors is considered experimental, investigational and unproven. The title changed from Laser Treatment of Congenital Port Wine Stain (PWS), Hemangiomas, and External Vascular Malformations.
06/15/2008	Policy reviewed without literature review; new review date only. This policy is no longer scheduled for routine literature review and update.
05/15/2007	Revised/updated entire document
01/01/2005	Revised/updated entire document
11/01/2000	Revised/updated entire document
09/01/1999	Revised/updated entire document
05/01/1996	Revised/updated entire document
07/01/1994	Revised/updated entire document