

Subject: Phototherapy and Laser Therapy for Acne Vulgaris		Original Effective Date: 11/20/08
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: <http://www.cms.hhs.gov/center/coverage.asp>.

FDA INDICATIONS

A number of different phototherapy devices specifically indicated for the treatment of mild to moderate inflammatory acne vulgaris have been approved by the FDA, including devices that deliver blue, green, and yellow light phototherapy; photothermolysis devices; intense pulsed dye lasers; and near-infrared lasers.¹⁶

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS does not have a national coverage determination (NCD) or Local Coverage Determination (LCD) regarding phototherapy, photochemotherapy, or light therapies for acne vulgaris.¹⁷

INITIAL COVERAGE CRITERIA

Phototherapy, photodynamic therapy, laser therapy, pulsed dye laser therapy (585nm) photothermolysis, UV and PUVA phototherapy are considered investigational and unproven as scientific research data is insufficient for the treatment of acne vulgaris.

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

Phototherapy, photodynamic therapy, laser therapy, pulsed dye laser therapy (585nm) photothermolysis, UV and PUVA phototherapy are considered investigational and unproven as scientific research data is insufficient for the treatment of acne vulgaris.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Phototherapy- is defined as exposure to nonionizing radiation for therapeutic benefit.¹ Various types are included in this definition including visible light, photodynamic therapy, photothermolysis, and laser therapy. Visible light phototherapy uses ultraviolet-free light within the visible spectrum, such as blue and red visible light with wavelength spans of 415 to 660 nm. Photodynamic therapy uses visible light with a topical application of a photosensitizer, such as a 5-aminolevulinic acid (ALA). Photothermolysis uses both light and heat energy with broadband intense pulsed light. Lasers are near-infrared with 1320 to 1540nm wavelengths.

Acne vulgaris- Acne vulgaris is a common skin disorder that peaks in incidence around the time of puberty.² When the opening or pore becomes blocked by other cells; this prevents sebum from being released. When sebum and other skin cells are trapped, it allows bacteria to grow inside the pore. This bacterium then attracts white blood cells which cause the entire pore to become inflamed. When the hair follicle ruptures, it spills its contents of sebum, cells, bacteria, onto the nearby skin which results in the production of proinflammatory mediators that are largely responsible for the appearance of the inflammatory lesions of acne vulgaris: papules, pustules, and nodules. Scarring or hyperpigmentation may occur.²

GENERAL INFORMATION

Summary of Medical Evidence

Medical Evidence for Phototherapy and Light Therapies for Acne Vulgaris

Phototherapy treatment options for acne vulgaris are also considered experimental and investigational due to the limited number of studies and small sample sizes (10 to 107 patients) with limited follow-up (4 to 20 weeks).⁵⁻¹⁰ The quality of evidence is weak. Studies performed have variable selection criteria, limited comparisons to conventional therapies, treatment protocol differences making it difficult to evaluate treatment effect. Long term safety and efficacy has not been established.¹¹

Systematic Review

A systematic review by Ingram and colleagues (2010) summarized clinical findings from RCTs (n=62 studies), systematic reviews (n=3) and a single guideline on the management of acne vulgaris. The review indicated that “PDT, phototherapy and laser therapy cannot be recommended universally for acne until minimal post-inflammatory pigmentation and longer-term benefit can be shown.”²³

Hamilton et al. (2009) conducted a systematic review of randomized controlled trials of light and laser therapies for acne vulgaris. The review included 25 RCTs (n=694), 13 of light therapy and 12 of light therapy with light-activated topical cream (i.e., PDT). The trials were generally small with very short follow-up times. The review found limited or no benefit for light therapies alone. Study results could not be used in a meta-analysis because

of the different wavelengths of light used across trials. Results of PDT trials were found to be more consistent and some short-term benefit was demonstrated in a meta-analysis of 3/12 trials. Overall, trials were limited by small sample sizes and short follow-up periods. There was a lack of studies comparing PDT with conventional treatment. Side effects of pain, erythema, and folliculitis followed by desquamation were reported.²⁴

Riddle et al (2009) reviewed the results of clinical trials and case series examining PDT in the treatment of acne vulgaris. The authors found 21 clinical trials and case series of various designs. Eight studies employed a split-face design comparing photosensitizer to placebo, no treatment or another photosensitizer. Two trials used three test spots and one control spot per patient. Three studies utilized control subjects receiving no photosensitizer with or without light therapy. All 21 studies reported a reduction in inflammatory lesions and/or a significant improvement in acne. The light sources utilized included blue light, pulsed-dye laser (PDL), intense pulsed light (IPL) and red light. Studies comparing the use of PDT to light therapy alone demonstrated greater improvement in treatment groups pretreated with a photosensitizer. All studies reported reduction in inflammatory lesions or significant improvement in acne. Several studies confirm a light source combined with photosensitizer is superior to light alone. Adverse reactions including photosensitivity, pustular eruptions, and crusting varied among photosensitizers and light sources. The review concludes that PDT appears to be a useful therapeutic option for acne patients who are recalcitrant to standard treatments and poor candidates for systemic retinoids. Further studies are still needed before a consensus protocol can be established. Additional investigations are needed to establish optimal incubation time, activating light source and frequency of treatment.²⁵

A systematic review was conducted by Haerdersdal et al. (2008a) on photodynamic therapy, lasers and light sources. The authors indicate that the analysis included weak studies that most likely would have been eliminated by other reviewers and would have reduced the number to insignificant levels. The quality of the studies are described as “suboptimal methodological quality as the randomization method was mentioned in only 6 of 16 RCTs, only one trial described adequate allocation concealment, and most studies had many losses to follow-up with no intention-to-treat analyses.” Studies were also described as lacking long-term follow-up. The authors also conclude “the fact that several well-established drugs are available for the treatment of acne requires that new treatment modalities are profoundly examined before being included among first line treatments as well as their efficacies have to be documented similar to existing standard treatments.”¹²

Pulsed Dye Lasers (PDL)

A single-blinded randomized controlled trial (RCT) [n=80] by Karsai et al. (2010) compared the use of a proven topical treatment alone versus this treatment in combination with PDL. No substantial benefit of adjuvant PDL was found.¹⁸

Leheta (2009) performed an RCT (n=45) that compared outcomes for three groups of patients whose acne vulgaris was treated with PDL, topical preparations or chemical peeling. In the short term a significant improvement of lesions within each group was reported, but there was no significant difference found between

the three protocols after the treatment period. Remission in the follow-up period was found to be higher in the PDL group.¹⁹

An RCT (n=45) by Sami et al. (2008) evaluated the effectiveness PDL, intense IPL and LED phototherapy and reported a $\geq 90\%$ reduction in acne lesions treated with the PDL, 41.7% reduction in cases of IPL and 35.3% reduction for LED cases at one-month follow-up.²⁰

Haerdersdal et al. (2008b) found a significantly greater reduction in inflammatory lesions on MAL-LPDL-treated skin versus LPDL-treated skin at four weeks ($p=0.003$) and 12 weeks ($p=0.004$) with up to 80% reduction in inflammatory lesions.²¹

Photodynamic Therapy

Orringer et al (2010) conducted a randomized, controlled, split-face, single-blind clinical trial of 44 patients with facial acne to examine the efficacy of PDT using 5-aminolevulinic acid (ALA) and pulsed dye laser therapy. Patients were randomized to receive three pulsed dye laser treatments to one side of the face after a 60-90 min ALA application time, while the contralateral side remained untreated and served as a control. Serial blinded lesion counts and global acne severity ratings were performed. Thirty percent of patients were deemed responders to this treatment with respect to improvement in their inflammatory lesion counts, while only 7% of patients responded in terms of noninflammatory lesion counts.²²

Three earlier randomized control trials evaluating the efficacy of ALA and MAL-PDT were conducted. Two MAL-PDT treatments for facial acne showed a 68% reduction versus 0% reduction ($p=0.005$) in facial acne in the untreated control and 54% versus 20% in the placebo-PDT ($p=0.0006$) following 12 weeks. Efficacy and pain scores from one ALA-PDT and MAL-PDT treatment were similar (59% reduction of moderate to severe pain, and reduction of inflammatory lesion; $p=ns$). Erythema, epithelial exfoliation, and oustular eruptions were more severe in ALA than MAL treated sides. The study limitations included short term follow-up.¹³⁻¹⁵

Hayes, Cochrane, UpToDate

A Hayes Directory report was developed evaluating the safety and effectiveness of Phototherapy for Acne Vulgaris.¹¹ The report indicates that there is evidence that some types of phototherapy, including blue light, red light (or a combination of the 2), pulsed dye laser (PDL), and laser light, can reduce the severity of mild to moderate facial acne, at least in the short term. However, the majority of patients in the reviewed studies did not experience complete improvement in acne lesions, and the durability of the effect remains unclear due to a lack of long-term follow-up data from well-designed and adequately sized randomized controlled trials (RCTs). The evidence regarding the use of selective photothermolysis was very limited, and no studies were found for ultraviolet (UV) and psoralen plus ultraviolet A (PUVA) phototherapy. No serious complications were reported with any of these phototherapy modalities, although there is some concern about long-term effects of exposure, including increased risk of skin cancer. Studies comparing phototherapy with other treatments for acne were lacking. Additional well-designed, longer-term RCTs are required to adequately evaluate the safety and efficacy

of phototherapy, laser, PDT, UV, and PUVA, and to compare these techniques with other medical therapies for acne vulgaris.

UpToDate

In a report entitled Light-based, adjunctive, and other therapies for acne vulgaris, the section on light/laser therapy indicates that clinician-administered light sources are used for the treatment of acne but well-designed clinical trials supporting the benefit of these treatments are limited.⁴

Professional Organizations

The American Academy of Dermatology developed guidelines of care for acne vulgaris management in 2007. These guidelines were archived in 2012 and new guidelines are under development.³

CODING INFORMATION: THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS A COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

CPT	Description
96567	Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least four to eight hours of care under direct supervision of the physician (includes application of medication and dressings)

HCPCS	Description
E0691	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection; treatment area 2 sq. ft. or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection, 4 ft. panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection, 6 ft. panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft. cabinet, includes bulbs/lamps, timer, and eye

	protection
S8948	Application of a modality (requiring constant provider attendance) to one or more areas; low-level laser; each 15 minutes

ICD-9	Description
706.1	Other acne; vulgaris

ICD-10	Description
L70.0	Acne vulgaris

RESOURCE REFERENCES

1. American Academy of Dermatology. Dermatology from A to Z. Accessed at: <http://www.aad.org>
2. American Academy of Dermatology. Acne Vulgaris, Folliculitis, and Acne Rosacea. Accessed at: <http://www.aad.org>
3. Strauss J, Krowchuk DP, Leyden J. et al. Guidelines of care for acne vulgaris management. American Academy of Dermatology February, 2007. Archived 2012. Journal of American Academy of Dermatology April, 2007;56(4):651-663. Accessed at: <http://www.aad.org/education/clinical-guidelines>
4. UpToDate [website]: Dover J, Batra P. Light-based, adjunctive, and other therapies for acne vulgaris. March 2014.
5. Na J, Suh SH. Red light phototherapy alone is effective for acne vulgaris: randomized, single blind clinical trial. Dermatology Surg, 2007 Oct;33(10):1228-33.
6. Taub AF. A comparison of intense pulsed light, combination radiofrequency and intense pulsed light, and blue light in photodynamic therapy for acne vulgaris. J Drugs Dermatology Oct 2007;6(10):1010-6.
7. Lee SY, You CE, Park MY. Blue and red light combination LED phototherapy for acne vulgaris in patients with skin phototype IV. Lasers Surg Med. 2007 Feb;39(2):180-8.
8. Noborio R, Nishida E, Kurokawa M, Morita A. A new targeted blue light phototherapy for the treatment of acne. Photodermatology Photoimmunol Photomed. Feb, 2007;23(1):32-4.
9. Rojanamatin J, Choawawanich P. Treatment of inflammatory facial acne vulgaris with intense pulsed light and short contact of topical 5-aminolevulinic acid: a pilot study. Dermatology Durg Aug, 2006;32(8):991-6.
10. Goldberg DJ, Russell BA. Combination blue (415 nm) and red (633nm) LED phototherapy in the treatment of mild to severe acne vulgaris. J Cosmet Laser Therapy Jun 2006;8(2):71-5.
11. Hayes, Inc. Directory Report. Phototherapy for acne vulgaris. Lansdale, PA: Hayes, Inc.; January 2013
12. Haedersdal M, Togsverd-Bo K, Wulf HC. Evidence-based review of lasers, light sources and photodynamic therapy in the treatment of acne vulgaris. 2008. J Euro Acad of Dermatol Venereol, 22:267-278.
13. Horfelt C, Funk J, Frohm-Nilsson M et al. Topical methyl aminolevulinate therapy for the treatment of facial acne vulgaris: results of a randomized controlled study. British Journal Dermatology 2006;155:608-613.
14. Wiegell SR, Wul HC. Photodynamic therapy of acne vulgaris using methyl aminolevulinic: a blinded randomized controlled trial. British Journal Dermatology 2006;154:969-976.

15. Wiegell SR, Wul HC. Photodynamic therapy of acne vulgaris using 5-aminolevulinic acid versus methyl aminolevulinic. *Journal of Academy Dermatology* 2006;54:647-651.
16. Food and Drug Administration (FDA) [website]. Center for Devices and Radiological Health (CDRH). Accessed at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>
17. Centers for Medicare & Medicaid Services. National Coverage Determinations (NCDs). Accessed at: http://www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd
- 10/26/11 – New evidence review was conducted by the MCG Committee. The document was approved without revision.

2014 Evidence Review

18. Karsai S, Schmitt L, Raulin C. The pulsed-dye laser as an adjuvant treatment modality in acne vulgaris: a randomized controlled single-blinded trial. *Br J Dermatol*. 2010 Aug;163(2):395-401. Epub 2010 Apr 15.
19. Leheta TM. Role of the 585-nm pulsed dye laser in the treatment of acne in comparison with other topical therapeutic modalities. *J Cosmet Laser Ther*. 2009 Jun;11(2):118-24.
20. Sami NA, Attia AT, Badawi AM. Phototherapy in the treatment of acne vulgaris. *J Drugs Dermatol*. 2008 Jul;7(7):627-32.
21. Haedersdal M, Togsverd-Bo K, Wiegell SR, Wulf HC. Long-pulsed dye laser versus long-pulsed dye laser-assisted photodynamic therapy for acne vulgaris: A randomized controlled trial. *J Am Acad Dermatol*. 2008b Mar;58(3):387-94.
22. Orringer JS, Sachs DL, Bailey E, Kang S, Hamilton T, Voorhees JJ. Photodynamic therapy for acne vulgaris: a randomized, controlled, split-face clinical trial of topical aminolevulinic acid and pulsed dye laser therapy. *J Cosmet Dermatol*. 2010 Mar;9(1):28-34.
23. Ingram JR, Grindlay DJ, Williams HC. Management of acne vulgaris: an evidence-based update. *Clin Exp Dermatol*. 2010 Jun;35(4):351-4.
24. Hamilton FL, Car J, Lyons C, Car M, Layton A, Majeed A. Laser and other light therapies for the treatment of acne vulgaris: systematic review. *Br J Dermatol*. 2009 Jun;160(6):1273-85. Epub 2009 Feb 23.
25. Riddle CC, Terrell SN, Menser MB et al. A review of photodynamic therapy (PDT) for the treatment of acne vulgaris. *J Drugs Dermatol*. 2009 Nov;8(11):1010-9.
Evidence not cited in this MCG:
26. Erceg A, de Jong EM et al. The efficacy of pulsed dye laser treatment for inflammatory skin diseases: a systematic review. *J Am Acad Dermatol*. 2013 Oct;69(4):609-615.e8.
27. Babilas P, Schreml S et al. Intense pulsed light (IPL): a review. *Lasers Surg Med*. 2010 Feb;42(2):93-104.
28. Advanced Medical Review (AMR): Policy reviewed by a practicing physician board certified in Dermatology. April 24, 2014.