

EFFECTIVE DATE: 11 | 20 | 2007

POLICY LAST UPDATED: 03 | 08 | 2016

OVERVIEW

Photodynamic therapy (PDT) refers to light activation of a photosensitizer to generate highly reactive intermediaries, which ultimately cause tissue injury and necrosis. Photosensitizing agents, administered orally or intravenously, have been used in nondermatologic applications and are being proposed for use with dermatologic conditions such as actinic keratoses and nonmelanoma skin cancers.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

BlueCHiP for Medicare

Photodynamic therapy is medically necessary as a treatment for the destruction of actinic keratoses without restrictions based on lesion or patient characteristics.

Commercial Products

Photodynamic therapy is medically necessary as a treatment of nonhyperkeratotic actinic keratoses of the face and scalp, superficial basal cell skin cancer only when surgery and radiation are contraindicated, and for the treatment of Bowen disease (squamous cell carcinoma in situ) only when surgery and radiation are contraindicated.

Photodynamic therapy is not medically necessary for other dermatologic applications, including but not limited to, acne vulgaris, nonsuperficial basal cell carcinomas, hidradenitis suppurativa and mycoses, or as a technique of skin rejuvenation, hair removal, or other cosmetic indications as there is insufficient peer-reviewed scientific literature that demonstrates the procedure/service is effective.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Member Certificate/Subscriber Agreement for applicable medically/not medically necessary coverage/benefits.

BACKGROUND

Photodynamic therapy refers to light activation of a photosensitizing agent light to produce photochemical effects in the target area. The evidence to date suggests that the net health outcome is better with surgery than with PDT for treating basal cell carcinoma (BCC). For superficial BCC, the evidence is sufficient to conclude that PDT has a similar efficacy to cryotherapy and better cosmetic outcomes. In addition, there is evidence from randomized controlled trials that PDT is an effective treatment for selected patients with actinic keratoses of the face and scalp compared to placebo or cryotherapy. There is insufficient evidence that PDT improves the net health outcome for nodular BCC and other dermatological conditions compared to accepted treatments. Thus, PDT may be considered medically necessary for treating selected patients with actinic keratoses, superficial BCC, and Bowen disease, but is considered not medically necessary for all other dermatologic indications.

Surgery or radiation is the preferred treatment for superficial basal cell cancer and Bowen disease. If PDT is selected for these indications because of contraindications to surgery or radiation, patients and physicians need to be aware that it may have a lower cure rate in comparison with surgery or radiation. Photodynamic therapy typically involves two office visits: one to apply the topical aminolevulinic acid (ALA), and a second visit to expose the patient to blue light. The second physician office visit, performed solely to administer blue light, should not warrant a separate Evaluation and Management CPT code. Photodynamic protocols typically involve two treatments spaced a week apart; more than one treatment series may be required.

CODING

BlueCHiP for Medicare

The following codes are considered medically necessary when filed with the diagnosis code listed below:

96567

J7308 Aminolevulinic hydrochloric acid for topical administration, 20%, single unit dosage form (354 mg)

J7309 Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 gram

ICD-10 L57.0

ICD-9 702.0

Commercial Products

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ICD-10 Ranges L57.0, C44.0-C44.9, D04.0-D04.9

ICD-9 Ranges 702.0, 173.0-173.9, 232.0-232.9

RELATED POLICIES

Not applicable

PUBLISHED

Provider Update, May 2016

Provider Update, May 2015

Provider Update, July 2008

Policy Update, February 2008

Policy Update, September 2002

REFERENCES

1. Pariser DM, Lowe NJ, Stewart DM et al. **Photodynamic therapy** with topical methyl aminolevulinate for actinic keratosis: results of a prospective randomized multicenter trial. *J Am Acad Dermatol* 2003;48(2):227-32.
2. Hauschild A, Stockfleth E, Popp G et al. Optimization of **photodynamic therapy** with a novel self-adhesive 5-aminolaevulinic acid patch: results of two randomized controlled phase III studies. *Br J Dermatol* 2009; 160(5):1066-74.
3. Morton C, Campbell S, Gupta G et al. Intraindividual, right-left comparison of topical methylaminolaevulinate-**photodynamic therapy** and cryotherapy in subjects with actinic keratoses: a multicentre, randomized controlled study. *Br J Dermatol* 2006; 155(5):1029-36.

4. Szeimies RM, Stockfleth E, Popp G et al. Long-term follow-up of **photodynamic therapy** with a self-adhesive 5-aminolaevulinic acid patch: 12 months data. *Br J Dermatol* 2010; 162(2):410-4.
5. Serra-Guillen C, Nagore E, Hueso L et al. A randomized pilot comparative study of topical methyl aminolevulinate **photodynamic therapy** versus imiquimod 5% versus sequential application of both therapies in immunocompetent patients with actinic keratosis: clinical and histologic outcomes. *J Am Acad Dermatol* 2012; 66(4):e131-7
6. Scola N, Terras S, Georgas D et al. A randomized, half-side comparative study of aminolaevulinate **photodynamic therapy** vs. CO(2) laser ablation in immunocompetent patients with multiple actinic keratoses. *Br J Dermatol* 2012; 167(6):1366-73
7. Bath-Hextall F, Leonardi-Bee J, Somchand N et al. Interventions for preventing non-melanoma skin cancers in high-risk groups. *Cochrane Database Syst Rev* 2007; (4):CD005414.
8. Roozeboom MH, Arits AH, Nelemans PJ et al. Overall treatment success after treatment of primary superficial basal cell carcinoma: a systematic review and meta-analysis of randomized and nonrandomized trials. *Br J Dermatol* 2012; 167(4):733-56.
9. Szeimies RM, Ibbotson S, Murrell DF et al. A clinical study comparing methyl aminolevulinate **photodynamic therapy** and surgery in small superficial basal cell carcinoma (8-20 mm), with a 12-month follow-up. *J Eur Acad Dermatol Venereol* 2008; 22(11):1302-11.
10. Basset-Seguín N, Ibbotson SH, Emtestam L et al. Topical methyl aminolaevulinate **photodynamic therapy** versus cryotherapy for superficial basal cell carcinoma: a 5 year randomized trial. *Eur J Dermatol* 2008; 18(5):547-53.
11. Foley P, Freeman M, Menter A et al. **Photodynamic therapy** with methyl aminolevulinate for primary nodular basal cell carcinoma: results of two randomized studies. *Int J Dermatol* 2009; 48(11):1236-45..
12. Mosterd K, Thissen MR, Nelemans P et al. Fractionated 5-aminolaevulinic acid-**photodynamic therapy** vs. surgical excision in the treatment of nodular basal cell carcinoma: results of a randomized controlled trial. *Br J Dermatol* 2008; 159(4):864-70.
13. Roozeboom MH, Aardoom MA, Nelemans PJ et al. Fractionated 5-aminolevulinic acid **photodynamic therapy** after partial debulking versus surgical excision for nodular basal cell carcinoma: a randomized controlled trial with at least 5-year follow-up. *J Am Acad Dermatol* 2013; 69(2):280-7.
14. Rhodes LE, de Rie M, Enstrom Y et al. **Photodynamic therapy** using topical methyl aminolevulinate vs surgery for nodular basal cell carcinoma: results of a multicenter randomized prospective trial. *Arch Dermatol* 2004; 140(1):17-23.
15. Rhodes LE, de Rie MA, Leifsdottir R et al. Five-year follow-up of a randomized, prospective trial of topical methyl aminolevulinate **photodynamic therapy** vs surgery for nodular basal cell carcinoma. *Arch Dermatol* 2007; 143(9):1131-6.
16. Lindberg-Larsen R, Solvsten H, Kragballe K. Evaluation of recurrence after **photodynamic therapy** with topical methylaminolaevulinate for 157 basal cell carcinomas in 90 patients. *Acta Derm Venereol* 2012; 92(2):144-7
17. Bath-Hextall FJ, Matin RN, Wilkinson D et al. Interventions for cutaneous Bowen's disease. *Cochrane Database Syst Rev* 2013; 6:CD007281.

18. Morton C, Horn M, Leman J et al. Comparison of topical methyl aminolevulinic acid **photodynamic therapy** with cryotherapy or Fluorouracil for treatment of squamous cell carcinoma in situ: Results of a multicenter randomized trial. *Arch Dermatol* 2006; 142(6):729-35
19. Salim A, Leman JA, McColl JH et al. Randomized comparison of **photodynamic therapy** with topical 5-fluorouracil in Bowen's disease. *Br J Dermatol* 2003; 148(3):539-43.
20. Lansbury L, Bath-Hextall F, Perkins W et al. Interventions for non-metastatic squamous cell carcinoma of the skin: systematic review and pooled analysis of observational studies. *BMJ* 2013; 347:f6153.
21. Orringer JS, Sachs DL, Bailey E et al. **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; 9(1):28-34.
22. Shaaban D, Abdel-Samad Z, El-Khalawany M. **Photodynamic therapy** with intralesional 5-aminolevulinic acid and intense pulsed light versus intense pulsed light alone in the treatment of acne vulgaris: a comparative study. *Dermatol Ther* 2012; 25(1):86-91
23. Mei X, Shi W, Piao Y. Effectiveness of **photodynamic therapy** with topical 5-aminolevulinic acid and intense pulsed light in Chinese acne vulgaris patients. *Photodermatol Photoimmunol Photomed* 2013; 29(2):90-6.
24. Wiegell SR, Wulf HC. **Photodynamic therapy** of acne vulgaris using methyl aminolevulinic acid: a blinded, randomized, controlled trial. *Br J Dermatol* 2006; 154(5):969-76.
25. Gold M, Bridges TM, Bradshaw VL et al. ALA-PDT and blue light **therapy** for hidradenitis suppurativa. *J Drugs Dermatol* 2004; 3(1 Suppl):S32-5.
26. Schweiger ES, Riddle CC, Aires DJ. Treatment of hidradenitis suppurativa by **photodynamic therapy** with aminolevulinic acid: preliminary results. *J Drugs Dermatol* 2011; 10(4):381-6
27. Calzavara-Pinton PG, Venturini M, Capezzeri R et al. **Photodynamic therapy** of interdigital mycoses of the feet with topical application of 5-aminolevulinic acid. *Photodermatol Photoimmunol Photomed* 2004; 20(3):144-7.
28. Xiao Q, Li Q, Yuan KH et al. **Photodynamic therapy** of port-wine stains: long-term efficacy and complication in Chinese patients. *J Dermatol* 2011; 38(12):1146-52.
29. National Comprehensive Cancer Network Practice Guidelines in Oncology Version 2. 2013. Basal cell and squamous cell skin cancers. Available online at:
http://www.nccn.org/professionals/physician_gls/pdf/nmsc.pdf
. Last accessed December, 2013.
30. Morton CA, McKenna KE, Rhodes LE et al. Guidelines for topical **photodynamic therapy**: update. *Br J Dermatol* 2008; 159(6):1245-66.
31. Braathen LR, Szeimies RM, Basset-Seguín N et al. Guidelines on the use of **photodynamic therapy** for nonmelanoma skin cancer: an international consensus. International Society for **Photodynamic Therapy** in Dermatology, 2005. *J Am Acad Dermatol* 2007; 56(1):125-43.

32. Centers for Medicare and Medicaid Services. National Coverage Determination (NCD) for Treatment of Actinic Keratosis (250.4). Available online at: www.cms.gov. Last accessed December, 2013
33. Zloty D, Guenther LC, Sapijaszko M, et al. Non-melanoma skin cancer in Canada. Chapter 4: Management of basal cell carcinoma. J Cutan Med Surg. May-Jun 2015;19(3):239-248. PMID 25986316
34. Poulin Y, Lynde CW, Barber K, et al. Non-melanoma skin cancer in Canada. Chapter 3: Management of actinic keratoses. J Cutan Med Surg. May-Jun 2015;19(3):227-238. PMID 25926621

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