

**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

**ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 08/16/22
CURRENT EFFECTIVE DATE: 09/19/22
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:**

NEXT ANNUAL REVIEW DATE: 3RD QTR 2023

ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Photodynamic therapy (PDT); also called phototherapy, photoradiotherapy, photosensitizing therapy, or photochemotherapy, is an ablative treatment that uses a photosensitizing agent to expose tumor cells to a light source of a specific wavelength for the purpose of damaging the cells. After administration of the photosensitizing agent, the target tissue is exposed to light using a variety of laser techniques. For example, a laser fiber may be placed through the channel of the endoscope, or a specialized modified diffuser may be placed via fluoroscopic guidance. Treatment for tumor cells occurs through selective retention of the photosensitizing agent and the selective delivery of light.

Photodynamic therapy (PDT) has been investigated for use in a wide variety of tumors, including esophageal, lung, cholangiocarcinoma, prostate, bladder, breast, brain (administered intraoperatively), skin, and head and neck cancers, as well as Barrett esophagus. The photosensitizing agent porfimer sodium (Photofrin®; Pinnacle Biologics) was approved by the U.S. Food and Drug Administration (FDA).

Criteria:

- One or more courses of photodynamic therapy are considered **medically necessary** with documentation of **ANY** of the following oncologic applications:
 1. Palliative treatment of obstructing esophageal cancer
 2. Palliative treatment of obstructing endobronchial lesions
 3. Treatment of early-stage non-small-cell lung cancer in patients who are ineligible for surgery and radiotherapy
 4. Treatment of high-grade dysplasia in Barrett esophagus
 5. Palliative treatment of unresectable cholangiocarcinoma when used with stenting.
- Photodynamic therapy for all other oncologic indications not previously listed or if above criteria not met is considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement outside the investigational setting.

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Criteria: (cont.)

These indications include, *but are not limited to*:

- Barrett esophagus without associated high-grade dysplasia
- Other malignancies

Resources:

Literature reviewed 08/16/22. We do not include marketing materials, poster boards and non-published literature in our review.

1. Ahn PH, Quon H, O'Malley BW, et al. Toxicities and early outcomes in a phase 1 trial of photodynamic therapy for premalignant and early stage head and neck tumors. *Oral Oncol.* Apr 2016;55:37-42. doi:10.1016/j.oraloncology.2016.01.013
2. Akopov A, Rusanov A, Gerasin A, Kazakov N, Urtenova M, Chistyakov I. Preoperative endobronchial photodynamic therapy improves resectability in initially irresectable (inoperable) locally advanced non small cell lung cancer. *Photodiagnosis Photodyn Ther.* Sep 2014;11(3):259-64. doi:10.1016/j.pdpdt.2014.03.011
3. American Gastroenterological A, Spechler SJ, Sharma P, Souza RF, Inadomi JM, Shaheen NJ. American Gastroenterological Association medical position statement on the management of Barrett's esophagus. *Gastroenterology.* Mar 2011;140(3):1084-91. doi:10.1053/j.gastro.2011.01.030
4. Aziz F, Telara S, Moseley H, Goodman C, Manthri P, Eljamel MS. Photodynamic therapy adjuvant to surgery in metastatic carcinoma in brain. *Photodiagnosis Photodyn Ther.* Sep-Dec 2009;6(3-4):227-30. doi:10.1016/j.pdpdt.2009.09.003
5. Bader MJ, Stepp H, Beyer W, et al. Photodynamic therapy of bladder cancer - a phase I study using hexaminolevulinate (HAL). *Urol Oncol.* Oct 2013;31(7):1178-83. doi:10.1016/j.urolonc.2012.02.007
6. Bahng S, Yoo BC, Paik SW, et al. Photodynamic therapy for bile duct invasion of hepatocellular carcinoma. *Photochem Photobiol Sci.* Mar 2013;12(3):439-45. doi:10.1039/c2pp25265a
7. Baron TH. Photodynamic therapy: standard of care for palliation of cholangiocarcinoma? *Clin Gastroenterol Hepatol.* Mar 2008;6(3):266-7. doi:10.1016/j.cgh.2008.01.015

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Resources: (cont.)

8. Berr F. Photodynamic therapy for cholangiocarcinoma. *Semin Liver Dis.* May 2004;24(2):177-87. doi:10.1055/s-2004-828894
9. Biel MA. Photodynamic therapy treatment of early oral and laryngeal cancers. *Photochem Photobiol.* Sep-Oct 2007;83(5):1063-8. doi:10.1111/j.1751-1097.2007.00153.x
10. Choi MC, Jung SG, Park H, Cho YH, Lee C, Kim SJ. Fertility preservation via photodynamic therapy in young patients with early-stage uterine endometrial cancer: a long-term follow-up study. *Int J Gynecol Cancer.* May 2013;23(4):698-704. doi:10.1097/IGC.0b013e31828b5ba2
11. Choi MC, Jung SG, Park H, et al. Fertility preservation by photodynamic therapy combined with conization in young patients with early stage cervical cancer: a pilot study. *Photodiagnosis Photodyn Ther.* Sep 2014;11(3):420-5. doi:10.1016/j.pdpdt.2014.06.001
12. Cortese DA, Edell ES, Kinsey JH. Photodynamic therapy for early stage squamous cell carcinoma of the lung. *Mayo Clin Proc.* Jul 1997;72(7):595-602. doi:10.1016/S0025-6196(11)63563-5
13. Corti L, Toniolo L, Boso C, et al. Long-term survival of patients treated with photodynamic therapy for carcinoma in situ and early non-small-cell lung carcinoma. *Lasers Surg Med.* Jun 2007;39(5):394-402. doi:10.1002/lsm.20513
14. Dai Y, Li C, Xie Y, et al. Interventions for dysphagia in oesophageal cancer. *Cochrane Database Syst Rev.* Oct 30 2014;(10):CD005048. doi:10.1002/14651858.CD005048.pub4
15. de Visscher SA, Dijkstra PU, Tan IB, Roodenburg JL, Witjes MJ. mTHPC mediated photodynamic therapy (PDT) of squamous cell carcinoma in the head and neck: a systematic review. *Oral Oncol.* Mar 2013;49(3):192-210. doi:10.1016/j.oraloncology.2012.09.011
16. Diaz-Jimenez JP, Martinez-Ballarin JE, Llunell A, Farrero E, Rodriguez A, Castro MJ. Efficacy and safety of photodynamic therapy versus Nd-YAG laser resection in NSCLC with airway obstruction. *Eur Respir J.* Oct 1999;14(4):800-5. doi:10.1034/j.1399-3003.1999.14d13.x
17. Dunn JM, Mackenzie GD, Banks MR, et al. A randomised controlled trial of ALA vs. Photofrin photodynamic therapy for high-grade dysplasia arising in Barrett's oesophagus. *Lasers Med Sci.* May 2013;28(3):707-15. doi:10.1007/s10103-012-1132-1
18. Durbec M, Cosmidis A, Fuchsmann C, Ramade A, Ceruse P. Efficacy and safety of photodynamic therapy with temoporphin in curative treatment of recurrent carcinoma of the oral cavity and oropharynx. *Eur Arch Otorhinolaryngol.* Mar 2013;270(4):1433-9. doi:10.1007/s00405-012-2083-7

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Resources: (cont.)

19. Endo C, Miyamoto A, Sakurada A, et al. Results of long-term follow-up of photodynamic therapy for roentgenographically occult bronchogenic squamous cell carcinoma. *Chest*. Aug 2009;136(2):369-375. doi:10.1378/chest.08-2237
20. Farlex Inc. FNCLCC. The Free Dictionary by Farlex. Accessed May 21, 2019. <https://acronyms.thefreedictionary.com/FNCLCC>
21. Fayter D, Corbett M, Heirs M, Fox D, Eastwood A. A systematic review of photodynamic therapy in the treatment of pre-cancerous skin conditions, Barrett's oesophagus and cancers of the biliary tract, brain, head and neck, lung, oesophagus and skin. *Health Technol Assess*. Jul 2010;14(37):1-288. doi:10.3310/hta14370
22. Friedberg JS, Simone CB, 2nd, Culligan MJ, et al. Extended Pleurectomy-Decortication-Based Treatment for Advanced Stage Epithelial Mesothelioma Yielding a Median Survival of Nearly Three Years. *Ann Thorac Surg*. Mar 2017;103(3):912-919. doi:10.1016/j.athoracsur.2016.08.071
23. Furukawa K, Kato H, Konaka C, Okunaka T, Usuda J, Ebihara Y. Locally recurrent central-type early stage lung cancer < 1.0 cm in diameter after complete remission by photodynamic therapy. *Chest*. Nov 2005;128(5):3269-75. doi:10.1378/chest.128.5.3269
24. Gao F, Bai Y, Ma SR, Liu F, Li ZS. Systematic review: photodynamic therapy for unresectable cholangiocarcinoma. *J Hepatobiliary Pancreat Sci*. Mar 2010;17(2):125-31. doi:10.1007/s00534-009-0109-3
25. Godoy H, Vaddadi P, Cooper M, Frederick PJ, Odunsi K, Lele S. Photodynamic therapy effectively palliates gynecologic malignancies. *Eur J Gynaecol Oncol*. 2013;34(4):300-2.
26. Gondivkar SM, Gadbail AR, Choudhary MG, Vedpathak PR, Likhithkar MS. Photodynamic treatment outcomes of potentially-malignant lesions and malignancies of the head and neck region: A systematic review. *J Investig Clin Dent*. Feb 2018;9(1)doi:10.1111/jicd.12270
27. Harewood GC, Baron TH, Rumalla A, et al. Pilot study to assess patient outcomes following endoscopic application of photodynamic therapy for advanced cholangiocarcinoma. *J Gastroenterol Hepatol*. Mar 2005;20(3):415-20. doi:10.1111/j.1440-1746.2005.03582.x
28. Hauge T, Hauge PW, Warloe T, et al. Randomised controlled trial of temoporfin photodynamic therapy plus chemotherapy in nonresectable biliary carcinoma--PCS Nordic study. *Photodiagnosis Photodyn Ther*. Mar 2016;13:330-333. doi:10.1016/j.pdpdt.2015.09.004

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Resources: (cont.)

29. Heier SK, Rothman KA, Heier LM, Rosenthal WS. Photodynamic therapy for obstructing esophageal cancer: light dosimetry and randomized comparison with Nd:YAG laser therapy. *Gastroenterology*. Jul 1995;109(1):63-72. doi:10.1016/0016-5085(95)90269-4
30. Hillemanns P, Garcia F, Petry KU, et al. A randomized study of hexaminolevulinate photodynamic therapy in patients with cervical intraepithelial neoplasia 1/2. *Am J Obstet Gynecol*. Apr 2015;212(4):465 e1-7. doi:10.1016/j.ajog.2014.10.1107
31. Huggett MT, Jermyn M, Gillams A, et al. Phase I/II study of verteporfin photodynamic therapy in locally advanced pancreatic cancer. *Br J Cancer*. Apr 2 2014;110(7):1698-704. doi:10.1038/bjc.2014.95
32. Istomin YP, Lapzevich TP, Chalau VN, Shliakhtsin SV, Trukhachova TV. Photodynamic therapy of cervical intraepithelial neoplasia grades II and III with Photolon. *Photodiagnosis Photodyn Ther*. Sep 2010;7(3):144-51. doi:10.1016/j.pdpdt.2010.06.005
33. Karakullukcu B, Stoker SD, Wildeman AP, Copper MP, Wildeman MA, Tan IB. A matched cohort comparison of mTHPC-mediated photodynamic therapy and trans-oral surgery of early stage oral cavity squamous cell cancer. *Eur Arch Otorhinolaryngol*. Mar 2013;270(3):1093-7. doi:10.1007/s00405-012-2104-6
34. Kato H, Okunaka T, Shimatani H. Photodynamic therapy for early stage bronchogenic carcinoma. *J Clin Laser Med Surg*. Oct 1996;14(5):235-8. doi:10.1089/clm.1996.14.235
35. Kohoutova D, Haidry R, Banks M, et al. Long-term outcomes of the randomized controlled trial comparing 5-aminolaevulinic acid and Photofrin photodynamic therapy for Barrett's oesophagus related neoplasia. *Scand J Gastroenterol*. May 2018;53(5):527-532. doi:10.1080/00365521.2017.1403646
36. Konda VJ, Waxman I. Endotherapy for Barrett's esophagus. *Am J Gastroenterol*. Jun 2012;107(6):827-33. doi:10.1038/ajg.2012.70
37. Lambert A, Nees L, Nuyts S, et al. Photodynamic Therapy as an Alternative Therapeutic Tool in Functionally Inoperable Oral and Oropharyngeal Carcinoma: A Single Tertiary Center Retrospective Cohort Analysis. *Front Oncol*. 2021;11:626394. doi:10.3389/fonc.2021.626394
38. Lee JY, Diaz RR, Cho KS, et al. Efficacy and safety of photodynamic therapy for recurrent, high grade nonmuscle invasive bladder cancer refractory or intolerant to bacille Calmette-Guerin immunotherapy. *J Urol*. Oct 2013;190(4):1192-9. doi:10.1016/j.juro.2013.04.077

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Resources: (cont.)

39. Li LB, Xie JM, Zhang XN, et al. Retrospective study of photodynamic therapy vs photodynamic therapy combined with chemotherapy and chemotherapy alone on advanced esophageal cancer. *Photodiagnosis Photodyn Ther*. Sep 2010;7(3):139-43. doi:10.1016/j.pdpdt.2010.06.002
40. Lightdale CJ, Heier SK, Marcon NE, et al. Photodynamic therapy with porfimer sodium versus thermal ablation therapy with Nd:YAG laser for palliation of esophageal cancer: a multicenter randomized trial. *Gastrointest Endosc*. Dec 1995;42(6):507-12. doi:10.1016/s0016-5107(95)70002-1
41. Lindenmann J, Matzi V, Neuboeck N, et al. Multimodal therapy of malignant pleural mesothelioma: is the replacement of radical surgery imminent? *Interact Cardiovasc Thorac Surg*. Mar 2013;16(3):237-43. doi:10.1093/icvts/ivs465
42. Lu Y, Liu L, Wu JC, Bie LK, Gong B. Efficacy and safety of photodynamic therapy for unresectable cholangiocarcinoma: A meta-analysis. *Clin Res Hepatol Gastroenterol*. Dec 2015;39(6):718-24. doi:10.1016/j.clinre.2014.10.015
43. Matsubara T, Kusuzaki K, Matsumine A, Nakamura T, Sudo A. Can a less radical surgery using photodynamic therapy with acridine orange be equal to a wide-margin resection? *Clin Orthop Relat Res*. Mar 2013;471(3):792-802. doi:10.1007/s11999-012-2616-9
44. Matzi V, Maier A, Woltsche M, Smolle-Juttner FM. Polyhematoporphyrin-mediated photodynamic therapy and decortication in palliation of malignant pleural mesothelioma: a clinical pilot study. *Interact Cardiovasc Thorac Surg*. Mar 2004;3(1):52-6. doi:10.1016/S1569-9293(03)00213-5
45. McCann P, Stafinski T, Wong C, Menon D. The safety and effectiveness of endoscopic and non-endoscopic approaches to the management of early esophageal cancer: a systematic review. *Cancer Treat Rev*. Feb 2011;37(1):11-62. doi:10.1016/j.ctrv.2010.04.006
46. Moghissi K, Dixon K, Thorpe JA, Stringer M, Oxtoby C. Photodynamic therapy (PDT) in early central lung cancer: a treatment option for patients ineligible for surgical resection. *Thorax*. May 2007;62(5):391-5. doi:10.1136/thx.2006.061143
47. Muragaki Y, Akimoto J, Maruyama T, et al. Phase II clinical study on intraoperative photodynamic therapy with talaporfin sodium and semiconductor laser in patients with malignant brain tumors. *J Neurosurg*. Oct 2013;119(4):845-52. doi:10.3171/2013.7.JNS13415
48. Nakamura T, Kusuzaki K, Matsubara T, et al. Long-term clinical outcome in patients with high-grade soft tissue sarcoma who were treated with surgical adjuvant therapy using acridine orange after intra-lesional or marginal resection. *Photodiagnosis Photodyn Ther*. Sep 2018;23:165-170. doi:10.1016/j.pdpdt.2018.06.001

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Resources: (cont.)

49. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Esophageal and esophagogastric junction cancer. Version 2.2021. Accessed May 27, 2021. https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
50. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary cancers. Version 2.2021. Accessed May 27, 2021. https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf
51. National Comprehensive Cancer Network (NCCN). NCCN Clinical Practice Guidelines in Oncology: Non-small cell lung cancer. Version 4.2021. Accessed May 27, 2021. https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
52. National Institute for Health and Care Excellence. Interstitial photodynamic therapy for malignant parotid tumours [IPG259]. Accessed May 26, 2021. <http://www.nice.org.uk/nicemedia/pdf/IPG259Guidance.pdf>
53. National Institute for Health and Care Excellence. Photodynamic therapy for Barrett's oesophagus [IPG350]. Accessed May 27, 2021. <http://www.nice.org.uk/guidance/ipg350>
54. National Institute for Health and Care Excellence. Photodynamic therapy for brain tumours [IPG290]. Accessed May 30, 2021. <http://www.nice.org.uk/nicemedia/pdf/IPG290Guidance.pdf>
55. National Institute for Health and Care Excellence. Photodynamic therapy for advanced bronchial carcinoma [IPG87]. Accessed May 27, 2021. <http://guidance.nice.org.uk/IPG87/Guidance/pdf/English>
56. National Institute for Health and Care Excellence. Photodynamic therapy for bile duct cancer [IPG134]. Accessed May 27, 2021. <http://www.nice.org.uk/guidance/IPG134/Guidance/pdf>
57. National Institute for Health and Care Excellence. Photodynamic therapy for localised inoperable endobronchial cancer [IPG137]. Accessed May 27, 2021. <http://www.nice.org.uk/guidance/ipg137>
58. Ortnier ME, Caca K, Berr F, et al. Successful photodynamic therapy for nonresectable cholangiocarcinoma: a randomized prospective study. *Gastroenterology*. Nov 2003;125(5):1355-63. doi:10.1016/j.gastro.2003.07.015
59. Overholt BF, Wang KK, Burdick JS, et al. Five-year efficacy and safety of photodynamic therapy with Photofrin in Barrett's high-grade dysplasia. *Gastrointest Endosc*. Sep 2007;66(3):460-8. doi:10.1016/j.gie.2006.12.037

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ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS (cont.)

Resources: (cont.)

60. Pereira S. Photodynamic therapy for pancreatic and biliary tract cancer: the United Kingdom experience. *J Natl Compr Canc Netw*. Oct 1 2012;10 Suppl 2:S48-51. doi:10.6004/jnccn.2012.0175
61. Pereira SP, Aithal GP, Ragunath K, Devlin J, Owen F, Meadows H. Safety and long term efficacy of porfimer sodium photodynamic therapy in locally advanced biliary tract carcinoma. *Photodiagnosis Photodyn Ther*. Dec 2012;9(4):287-92. doi:10.1016/j.pdpdt.2012.03.005
62. Pinnacle Biologics. Photofrin (porfimer sodium) Injection [prescribing information]. U.S. Food and Drug Administration. Accessed June 7, 2018. http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/020451s020lbl.pdf
63. Rigual NR, Shafirstein G, Frustino J, et al. Adjuvant intraoperative photodynamic therapy in head and neck cancer. *JAMA Otolaryngol Head Neck Surg*. Jul 2013;139(7):706-11. doi:10.1001/jamaoto.2013.3387
64. Rigual NR, Thankappan K, Cooper M, et al. Photodynamic therapy for head and neck dysplasia and cancer. *Arch Otolaryngol Head Neck Surg*. Aug 2009;135(8):784-8. doi:10.1001/archoto.2009.98
65. Rupinski M, Zagorowicz E, Regula J, et al. Randomized comparison of three palliative regimens including brachytherapy, photodynamic therapy, and APC in patients with malignant dysphagia (CONSORT 1a) (Revised II). *Am J Gastroenterol*. Sep 2011;106(9):1612-20. doi:10.1038/ajg.2011.178
66. Schweitzer VG, Somers ML. PHOTOFRIN-mediated photodynamic therapy for treatment of early stage (Tis-T2N0M0) SqCCa of oral cavity and oropharynx. *Lasers Surg Med*. Jan 2010;42(1):1-8. doi:10.1002/lsm.20881
67. Shaheen NJ, Falk GW, Iyer PG, Gerson LB, American College of G. ACG Clinical Guideline: Diagnosis and Management of Barrett's Esophagus. *Am J Gastroenterol*. Jan 2016;111(1):30-50; quiz 51. doi:10.1038/ajg.2015.322
68. Shim CS, Cheon YK, Cha SW, et al. Prospective study of the effectiveness of percutaneous transhepatic photodynamic therapy for advanced bile duct cancer and the role of intraductal ultrasonography in response assessment. *Endoscopy*. May 2005;37(5):425-33. doi:10.1055/s-2005-861294
69. Silbergleit AK, Somers ML, Schweitzer VG, Gardner GM, Peterson E. Vocal fold vibration after photofrin-mediated photodynamic therapy for treatment of early-stage laryngeal malignancies. *J Voice*. Nov 2013;27(6):762-4. doi:10.1016/j.jvoice.2013.07.010

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Resources: (cont.)

70. Soergel P, Dahl GF, Onsrud M, Hillemanns P. Photodynamic therapy of cervical intraepithelial neoplasia 1-3 and human papilloma virus (HPV) infection with methylaminolevulinate and hexaminolevulinate--a double-blind, dose-finding study. *Lasers Surg Med*. Aug 2012;44(6):468-74. doi:10.1002/lsm.22041
71. Tao XH, Guan Y, Shao D, et al. Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia: a systemic review. *Photodiagnosis Photodyn Ther*. Jun 2014;11(2):104-12. doi:10.1016/j.pdpdt.2014.02.012
72. Tomizawa Y, Tian J. Photodynamic therapy for unresectable cholangiocarcinoma. *Dig Dis Sci*. Feb 2012;57(2):274-83. doi:10.1007/s10620-011-1957-7
73. Vohra F, Al-Kheraif AA, Qadri T, et al. Efficacy of photodynamic therapy in the management of oral premalignant lesions. A systematic review. *Photodiagnosis Photodyn Ther*. Mar 2015;12(1):150-9. doi:10.1016/j.pdpdt.2014.10.001
74. Wildeman MA, Fles R, Herdini C, et al. Primary treatment results of Nasopharyngeal Carcinoma (NPC) in Yogyakarta, Indonesia. *PLoS One*. 2013;8(5):e63706. doi:10.1371/journal.pone.0063706
75. Wildeman MA, Nyst HJ, Karakullukcu B, Tan BI. Photodynamic therapy in the therapy for recurrent/persistent nasopharyngeal cancer. *Head Neck Oncol*. Dec 17 2009;1:40. doi:10.1186/1758-3284-1-40
76. Winters U, Daayana S, Lear JT, et al. Clinical and immunologic results of a phase II trial of sequential imiquimod and photodynamic therapy for vulval intraepithelial neoplasia. *Clin Cancer Res*. Aug 15 2008;14(16):5292-9. doi:10.1158/1078-0432.CCR-07-4760
77. Wisnivesky JP, Yung RC, Mathur PN, Zulueta JJ. Diagnosis and treatment of bronchial intraepithelial neoplasia and early lung cancer of the central airways: Diagnosis and management of lung cancer, 3rd ed: American College of Chest Physicians evidence-based clinical practice guidelines. *Chest*. May 2013;143(5 Suppl):e263S-e277S. doi:10.1378/chest.12-2358
78. Zhang R, Wang L. Photodynamic therapy for treatment of usual-type vulvar intraepithelial neoplasia: a case report and literature review. *J Int Med Res*. Aug 2019;47(8):4019-4026. doi:10.1177/0300060519862940
79. Zhang W, Zhang A, Sun W, Yue Y, Li H. Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia and human papilloma virus infection: A systematic review and meta-analysis of randomized clinical trials. *Medicine (Baltimore)*. May 2018;97(21):e10864. doi:10.1097/MD.00000000000010864



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**EVIDENCE-BASED CRITERIA
SECTION: MEDICINE**

ORIGINAL EFFECTIVE DATE: 09/19/22
LAST REVIEW DATE: 08/16/22
CURRENT EFFECTIVE DATE: 09/19/22
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

NEXT ANNUAL REVIEW DATE: 3RD QTR 2023

ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS (cont.)

Resources: (cont.)

80. Zoepf T, Jakobs R, Arnold JC, Apel D, Riemann JF. Palliation of nonresectable bile duct cancer: improved survival after photodynamic therapy. *Am J Gastroenterol*. Nov 2005;100(11):2426-30. doi:10.1111/j.1572-0241.2005.00318.x

Coding:

CPT: 96570, 96571, 31641, 43229
HCPCS: J9600

History:

Date:

Activity:

Medical Policy Panel

08/16/22

Approved guideline (Effective 09/19/22)

Policy Revisions:

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ONCOLOGIC APPLICATIONS OF PHOTODYNAMIC THERAPY, INCLUDING BARRETT ESOPHAGUS (cont.)

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If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

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Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



NEXT ANNUAL REVIEW DATE: 3RD QTR 2023