

MEDICAL POLICY



SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE	EFFECTIVE DATE: 11/19/99 REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18
POLICY NUMBER: 8.01.06 CATEGORY: Technology Assessment	PAGE: 1 OF: 9
<ul style="list-style-type: none">• <i>If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</i>• <i>If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.</i>• <i>If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</i>	

POLICY STATEMENT:

- I. Based upon our criteria and assessment of peer-reviewed literature, photodynamic therapy with Photofrin® has been medically proven to be effective and therefore, **medically appropriate** for the following indications:
 - A. the treatment of early stage non-small-cell lung cancer in patients who are ineligible for surgery and radiation therapy, or
 - B. reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial lesions; or
 - C. palliative treatment of obstructing esophageal cancer, or
 - D. the treatment of Barrett's high-grade dysplasia in patients who:
 1. are considered at high risk for adverse outcomes (morbidity and mortality) during prophylactic esophagectomy surgery; and
 2. decide on this treatment method, based on shared decision-making with their physician and understanding the actual risks and benefits of various treatment options. A consensus regarding the optimal management of Barrett's high-grade dysplasia does not currently exist. Some suggest patients with HGD should undergo prophylactic esophagectomy (due to the number of concomitant adenocarcinomas missed) but esophagectomy is associated with significant mortality (3-12%) and morbidity (30-50%). For some patients, the risks of surgery may outweigh the potential benefits and PDT treatment with endoscopic surveillance may be the preferred strategy.
- II. Based upon our criteria and assessment of peer-reviewed literature, photodynamic therapy has not been proven to be medically effective and therefore, is considered **investigational** in the treatment of other types of malignancies, including but not limited to: colon, rectal, pancreas, hepatobiliary, prostate, bladder, brain, skin, head and neck cancers, and Barrett's esophagus (other than high grade dysplasia as stated above).
- III. PDT with porfimer sodium is **contraindicated** in patients:
 - A. with known bone marrow suppression;
 - B. with porphyria or in patients with known allergies to porphyrins;
 - C. with existing tracheoesophageal or bronchoesophageal fistula; or
 - D. with tumors eroding into a major vessel.

Refer to Medical Policy #8.01.01 regarding Extracorporeal Photochemotherapy/Photopheresis.

Refer to Corporate Medical Policy #8.01.11 regarding Photodynamic Therapy for Subfoveal Choroidal Neovascularization.

Refer to Corporate Medical Policy #8.01.16 regarding Light and Laser Therapies for Dermatological Conditions.

Refer to Medical Policy # 11.01.01 regarding Clinical Trials.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE POLICY NUMBER: 8.01.06 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 2 OF: 9
---	--

POLICY GUIDELINES:

- I. A second laser treatment (with NO additional Photofrin) can be given 96-120 hours after the first injection, preceded by debridement (via endoscopy) 2 days after the initial light application.
- II. Patients may receive a second course of PDT (with Photofrin) a minimum of 30 days after the initial therapy. Up to 3 courses of PDT (every 30 days) can be given.
- III. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
- IV. As pathologists do not always agree about differentiating between low and high-grade dysplasia and between high-grade dysplasia and carcinoma in situ, many times high-grade Barrett's dysplasia is confirmed by 2 pathologists with expertise in gastrointestinal pathology.

DESCRIPTION:

Photodynamic therapy (PDT) is a cancer treatment method using intravenous injection of a photosensitizing agent (porfimer sodium, Photofrin®) and exposure of tumor cells to a laser light source to cause cellular damage. The clearance of porfimer sodium occurs over a period of time (40-72 hours) in normal tissue, however tumor cells retain porfimer for a longer period. Treatment of the tumor is the result of selective retention of porfimer and selective delivery of light.

Photodynamic therapy with Photofrin® is a two-stage process. The first stage is the intravenous injection of Photofrin®. Illumination with 630-nm wavelength laser light constitutes the second stage of therapy. The laser treatment induces a photochemical, not a thermal, effect. The photochemical reaction results in the release of toxic, singlet oxygen that causes tumor necrosis.

Photodynamic therapy should not be confused with extracorporeal photopheresis, which is the treatment of certain skin malignancies through the use of ultraviolet light irradiation of the patient's blood.

RATIONALE:

Photofrin® (porfimer sodium) is the only FDA approved photosensitizing agent with specific indications for use. Published studies have shown that PDT with Photofrin® improves the quality of life (e.g. relief of dysphagia, improvement in dyspnea) and relieves obstruction by reducing tumor mass for those patients with obstructing tumors of the esophagus or endobronchial tree. For those patients with microinvasive NSCLC, not amenable to surgery or radiation, which were treated with PDT, reported tumor response rates (50-84%) and disease-free survival rates (2.7-4.1 years) are favorable. Studies investigating the Nd: YAG laser and PDT found comparable survival rates, found that PDT was technically easier to perform, more comfortable for patients, and caused fewer side effects (e.g. perforation).

A recent interim analysis of porfimer PDT for high-grade dysplasia in Barrett's esophagus demonstrated that patients receiving PDT/medication had an 80% chance of being cancer free, compared to a 50% chance of being cancer free for patients receiving medication only. The effectiveness of photofrin PDT in reducing the long-term risk of esophageal cancer has not been demonstrated. PDT does not completely eliminate Barrett's esophagus (with or without low/high-grade dysplasia), thus these patients still require intensive endoscopic surveillance and close follow-up.

Although photodynamic therapy (using porfimer sodium or other photosensitizing agents) has been used in treatment of other cancers, all are either in Phase I or Phase II studies and have not yet been proven outside an investigational setting.

SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE POLICY NUMBER: 8.01.06 CATEGORY: Technology Assessment	EFFECTIVE DATE: 11/19/99 REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18 PAGE: 3 OF: 9
---	--

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT: 96570 Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drugs(s); first 30 minutes (to be used in addition to endoscopy/bronchoscopy codes)

 96571 each additional 15 minutes

Copyright © 2018 American Medical Association, Chicago, IL

HCPCS: J9600 Drug; porfimer sodium, 75 mg

ICD10: C15.3-C15.9 Malignant neoplasm esophagus (code range)
 C34.00-C34.92 Malignant neoplasm bronchus and lung (code range)
 C78.00-C78.02 Secondary malignant neoplasm of lung (code range)
 C78.80-C78.89 Secondary malignant neoplasm of other and unspecified digestive organs (code range)
 D00.1 Carcinoma in situ of esophagus
 D02.20-D02.22 Carcinoma in situ of bronchus and lung (code range)
 K22.70-K22.719 Barrett's esophagus (code range)

REFERENCES:

*Ackroyd R, et al. Eradication of dysplastic Barrett's oesophagus using photodynamic therapy: long -term follow-up. Endosc 2003 Jun;53(6):496-501.

*Ackroyd R, et al. Photodynamic therapy for dysplastic Barrett's oesophageus: a prospective, double blind, randomized, placebo controlled trial. Gut 2000 Nov;47(5):612-7.

Ahn PH, et al. Toxicities and early outcomes in a phase I trial of photodynamic therapy for premalignant and early stage head and neck tumors. Oral Oncol 2016 April;55:37-42.

Akopov A, et al. Preoperative endobronchial photodynamic therapy improves resectability in initially irresectable (inoperable) locally advanced non small cell lung cancer. Photodiagnosis Photodyn Ther 2014 Sep;11(3):259-64.

*Aljiffry M, et al. Evidenced-based approach to cholangiocarcinoma: a systematic review of the current literature. J Am Coll Surg 2009 Jan;208(1):134-47.

*Allison R, et al. Photodynamic therapy for chest wall progression from breast carcinoma is an underutilized treatment modality. Cancer 2001 Jan;91(1):1-8.

Allum WH, et al. Guidelines for the management of oesophageal and gastric cancer. Gut 2011 Nov;60(11):1449-72.

*American Society for Gastrointestinal Endoscopy. Technology status evaluation report. Photodynamic therapy for gastrointestinal disease. Gastrointest Endosc 2006;63(7):927-32.

*American Gastroenterological Association medical position statement on the management of Barrett's esophagus. Gastroenterol 2011 Mar;140(3):1084-91.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 4 OF: 9</p>
--	---

Azzouri AR, et al. **TOOKAD[®]** Soluble vascular-targeted photodynamic (VTP) therapy: determination of optimal treatment conditions and assessment of effects in patients with localized prostate cancer. BJU Int 2013 Oct;112(6):766-74.

Bader MJ, et al. Photodynamic therapy of bladder cancer- a phase I study using hexaminolevulinate (HAL). Urol Oncol 2013 Oct;31(7):1178-83.

Bahng S, et al. Photodynamic therapy for bile duct invasion of hepatocellular carcinoma. Photochem Photobiol Sci 2013 Mar;12(3):439-45.

*Barnett AA, et al. A randomized, double-blind, placebo- controlled trial of photodynamic therapy using 5-aminolaevulinic acid for the treatment of cervical intraepithelial neoplasia. Int J Cancer 2003 Mar 1;103(6):829-32.

Barret E, et al. Morbidity of focal therapy in the treatment of localized prostate cancer. Eur Urol 2013 Apr;63(4):618-22.

*Bauer TW, et al. Preliminary report of photodynamic therapy for intraperitoneal sarcomatosis. Ann Surg Oncol 2001 Apr;8(3):254-9.

*Bennett C, et al. Surgery versus radical endotherapies for early cancer and high grade dysplasia in Barrett's oesophagus. Cochrane Database Syst Rev 2010 May 12;(5):CD007334.

*Biel MA. Photodynamic therapy for early oral and laryngeal cancers. Photochem Photobiol 2007 Sep-Oct;83(5):1063-8.

BlueCross BlueShield Association. Oncologic applications of photodynamic therapy, including Barrett's esophagus. Medical Policy Reference Manual Policy #8.01.06. 2017 Aug 10.

*Buttar NS, et al. Combined endoscopic mucosal resection and photodynamic therapy for esophageal neoplasia with Barrett's esophagus. Gastrointest Endosc 2001 Dec;54(6):682-8.

Cai XJ, et al. Photodynamic therapy for intractable bronchial lung cancer. Photodiagnosis Photodyn Ther 2013 Dec;10(4):672-6.

Cheon YK, et al. Long term outcome of photodynamic therapy compared with biliary stenting alone in patients with advanced hilar cholangiocarcinoma. HPB (Oxford) 2012 Mar;14(3):185-93.

Choi MC, et al. Fertility preservation by photodynamic therapy combined with conization in young patients with early stage cervical cancer: a pilot study. Photodiagnosis Photodyn Ther 2014 Sep;11(3):420-5.

*Cooper MP, et al. Meta-tetra (hydro-xylphenyl) chlorin photodynamic therapy in early-stage squamous cell carcinoma of the head and neck. Arch Otolaryngol Head Neck Surg 2003 Jul;129(7):709-11.

*Cooper MP, et al. Photodynamic therapy in the treatment of multiple primary tumours in the head and neck, located to the oral cavity and oropharynx. Clin Otolaryngol 2007 Jun;32(3):185-9.

*Corti L, 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 2007 Jun;39(5):394-402.

*Cuenca RE, et al. Breast cancer with chest wall progression: treatment with photodynamic therapy. Ann Surg Oncol 2004 Mar;11(3):322-7.

Dai Y, et al. Interventions for dysphagia in oesophageal cancer. Cochrane Database Syst Rev. 2014 Oct 30;10:CD005048.

De Visscher SA, et al. mTHPC mediated photodynamic therapy (PDT) of squamous cell carcinoma in the head and neck: a systematic review. Oral Oncol 2013 Mar;49(3):192-210.

Dunn JM, et al. A randomized controlled trial of ALA vs. Photofrin photodynamic therapy for high-grade dysplasia arising in Barrett's oesophagus. Lasers Med Sci 2013 May;28(3):707-15.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 5 OF: 9</p>
--	---

- *Fayter D, et al. 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 2010 Jul;14(37):1-288.
- *Fernando HC, et al. The Society of Thoracic Surgeons practice guideline series: guidelines for the management of Barrett's esophagus with high-grade dysplasia. Ann Thorac Surg 2009 Jun;87(6):1993-2002.
- Filonenko F, et al. Own experience in treatment of patients with penile cancer using photodynamic therapy. Biomed Res Int 2015:245080.
- *Foroulis CN, et al. Photodynamic therapy (PDT) in Barrett's esophagus with dysplasia or early cancer. Eur J Cardiothor Surg 2006 Jan;29(1):30-4.
- *Friedberg JS, et al. Phase II trial of pleural photodynamic therapy and surgery for patients with non-small cell lung cancer with pleural spread. J Clin Oncol 2004 Jun 1;22(11):2192-201.
- *Gao F, et al. Systematic review: photodynamic therapy for unresectable cholangiocarcinoma. J Hepatobiliary Pancreat Surg 2009 May 20 [Epub ahead of print].
- Godoy H, et al. Photodynamic therapy effectively palliates gynecologic malignancies. Eur J Gynaecol Oncol 2013;34(4):300-2.
- Gondivkar SM, et al. Photodynamic treatment outcomes of potentially-malignant lesions and malignancies of the head and neck region: A systematic review. J Investig Clin Dent 2017 May 8. [Epub ahead of print].
- Gray J, et al. Long term efficacy of photodynamic therapy (PDT) as an ablative therapy of high grade dysplasia in Barrett's oesophagus. Photodiagnosis Photodyn Ther 2013 Dec;10(4):561-5.
- *Harewood GC, et al. Pilot study to assess patient outcomes following endoscopic application of photodynamic therapy for advanced cholangiocarcinoma. J Gastroenterol Hepatol 2005 Mar;20(3):415-20.
- Hauge T, et al. Randomised controlled trial of temoporfin photodynamic therapy plus chemotherapy in nonresectable biliary carcinoma--PCS Nordic study. Photodiagnosis Photodyn Ther. 2016 Mar;13:330-3.
- *Hendren SK, et al. Phase II trial of debulking surgery and photodynamic therapy for disseminated intraperitoneal tumors. Ann Surg Oncol 2001 Jan-Feb;8(1):65-71.
- Hillemanns P, et al. A randomized study of hexaminolevulinat photodynamic therapy in patients with cervical intraepithelial neoplasia. Am J Obstet Gynecol 2015 Apr;212(4):465.e1-7.
- Hong MJ, et al. Long-term outcome of photodynamic therapy with systemic chemotherapy compared to photodynamic therapy alone in patients with advanced hilar cholangiocarcinoma. Gut Liver 2014 May;8(3):318-23.
- Huggett MT, et al. Phase I/II study of verteporfin photodynamic therapy in locally advanced pancreatic cancer. Br J Cancer 2014 Apr 2;110(7):1698-704.
- *Hur C, et al. Cost-effectiveness of photodynamic therapy for treatment of Barrett's esophagus with high-grade dysplasia. Dig Dis Sci 2003 Jul;48(7):1273-83.
- *Institute for Clinical Systems Improvement. Technology assessment # 39. Photodynamic therapy for head and neck, tracheobronchial, and esophageal cancer. 2002 Oct [http://www.icsi.org/technology_assessment_reports_-_active/ta_photodynamic_therapy_for_head_and_neck__tracheobronchial__and_esophageal_cancer.html] assessed 1/16/18.
- *Johnston MH. Technology insight: ablative techniques for Barrett's esophagus- current and emerging trends. Nat Clin Pract Gastroenterol Hepatol 2005 Jul;2(7):323-30.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 6 OF: 9</p>
--	---

- *Kahaleh M, et al. Unresectable cholangiocarcinoma: comparison of survival in biliary stenting alone versus stenting with photodynamic therapy. Clin Gastroenterol Hepatol 2008 Mar;6(3):290-7.
- Karakullukcu B, et al. A matched cohort comparison of mTHPC-mediated photodynamic therapy and trans-oral surgery of early stage oral cavity squamous cell cancer. Eur Arch Otorhinolaryngol 2013 Mar;270(3):1093-7.
- *Kelty CJ, et al. Endoscopic ablation of Barrett's oesophagus: a randomized-controlled trial of photodynamic therapy vs argon plasma coagulation. Aliment Pharmacol Ther 2004 Dec;20(11-12):1289-96.
- Kidane B, et al. Photodynamic therapy in non-gastrointestinal thoracic malignancies. Int J Mol Sci 2016 Jan 21;17(1).
- Kniebuhlar G, et al. Photodynamic therapy for cholangiocarcinoma using low dose mTHPC (Foscan®). Photodiagnosis Photodyn Ther 2013 Sep;10(3):220-8.
- *Lee TY, et al. Photodynamic therapy prolongs metal stent patency in patients with unresectable hilar cholangiocarcinoma. World J Gastroenterol 2012 Oct 21;18(39):5589-94.
- Lee JY, et al. Efficacy and safety of photodynamic therapy for recurrent, high grade nonmuscle invasive bladder cancer refractory or intolerant to bacilli Calmette-Guerin immunotherapy. J Urol 2013 Oct;190(4):1192-9.
- *Li LB, et al. Retrospective study of photodynamic therapy vs photodynamic therapy combined with chemotherapy and chemotherapy alone on advanced esophageal cancer. Photodiagnosis Photodyn Ther 2010 Sep;7(3):139-43.
- *Li YM, et al. A systematic review and meta-analysis of the treatment for Barrett's esophagus. Dig Dis Sci 2008 Nov;53(11):2837-46.
- *Lindenmann J, et al. Individualized, multimodal palliative treatment of inoperable esophageal cancer: clinical impact of photodynamic therapy resulting in prolonged survival. Lasers Surg Med 2012 Mar;44(3):189-98.
- Lindenmann J, et al. Multimodal therapy of malignant pleural mesothelioma: is the replacement of radical surgery imminent? Interact Cardiovasc Thorac Surg 2013 Mar;16(3):237-43.
- *Loewen G, et al. Endobronchial photodynamic therapy for lung cancer. Lasers Surg Med 2006 Jun;38(5):364-70.
- Lu Y, et al. Efficacy and safety of photodynamic therapy for unresectable cholangiocarcinoma: A met-analysis. Clin Res Hepatol Gastroenterol 2015 Dec;39(6):718-724.
- *Mackenzie GD, et al. Optimal conditions for successful ablation of high-grade dysplasia in Barrett's oesophagus using aminolaevulinic acid photodynamic therapy. Lasers Med Sci 2009 Sep;24(5):729-34.
- *Magro CM, et al. The application of photodynamic therapy in the treatment of metastatic endobronchial disease. Lasers Surg Med 2006 Jun;38(5):376-83.
- *March Rde W, et al. Comprehensive review of the diagnosis and treatment of biliary tract cancer 2012. Part II: multidisciplinary management. J Surg Oncol 2012 Sep 1;106(3):339-45.
- Matsubara T, et al. Can a less radical surgery using photodynamic therapy with acridine orange be equal to a wide-margin resection? Clin Orthop Relat Res 2013 Mar;471(3):792-802.
- *Maunoury V, et al. Photodynamic therapy for early oesophageal cancer. Dig Liver Dis 2005 Jul;37(7):491-5.
- *May A, et al. Local endoscopic therapy for intraepithelial high-grade neoplasia and early adenocarcinoma in Barrett's oesophagus: acute-phase and intermediate results of a new treatment approach. Eur J Gastroenterol Hepatol 2002 Oct; 14(10):1049-51.
- *McCann P, et al. The safety and effectiveness of endoscopic and non-endoscopic approaches to the management of early esophageal cancer: a systematic review. Cancer Treat Rev 2011 Feb;37(1):11-62.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 7 OF: 9</p>
--	---

*Moghissi K, et al. Photodynamic therapy (PDT) in early lung cancer: a treatment option for patients ineligible for surgical resection. Thorax 2007 May;62(5):391-5.

Moole H, et al. Success of photodynamic therapy in palliating patients with unresectable cholangiocarcinoma: A systematic review and meta-analysis. World J Gastroenterol 2017 Feb 21;23(7):1276-1288.

Moore CM, et al. determination of optimal drug dose and light dose index to achieve minimally invasive focal ablation of localized prostate cancer using WST11-vascular targeted Photodynamic (VTP) therapy. BJU Int 2014 May 19 [Epub ahead of print].

Morrison SA, et al. Efficacy and safety of continuous low-irradiance photodynamic therapy in the treatment of chest wall progression of breast cancer. J Surg Res 2014 Dec;192(2):235-41.

Muragaki Y, et al. Phase II clinical study on intraoperative photodynamic therapy with talaporfin sodium and semiconductor laser in patients with malignant brain tumors. J Neurosurg 2013 Oct;119(4):845-52.

*National Institute for Health and Clinical Excellence. Interstitial photodynamic therapy for malignant parotid tumours. 2008 Apr [www.nice.org] accessed 1/16/18.

*National Institute for Health and Clinical Excellence (NICE). Photodynamic therapy for Barrett's oesophagus. IPG 350. 2010 Jun [www.nice.org] accessed 1/16/18.

*National Institute for Health and Clinical Excellence (NICE). Clinical guideline 106. Ablative therapy for the treatment of Barrett's oesophagus. 2010 Aug [www.nice.org] accessed 1/16/18.

*National Institute for Health and Clinical Excellence (NICE). Photodynamic therapy for brain tumours. IPG 290. 2010 Jun [www.nice.org] accessed 1/16/18.

Nava HR, et al. Photodynamic therapy (PDT) using HPPH for the treatment of precancerous lesions associated with Barrett's esophagus. Lasers Surg Med 2011 Sep;43(7):705-12.

*Nomura T, et al. Focal therapy in the management of prostate cancer: an emerging approach for localized prostate cancer. Adv Urol 2012;2012:391437.

*Ortner ME, et al. Successful photodynamic therapy for unresectable cholangiocarcinoma. Gastroenterol 2003 Nov;125(5):1355-63.

*Overholt BF, et al. Photodynamic therapy for Barrett's esophagus with dysplasia and/or early stage carcinoma: long term results. Gastrointest Endosc 2003 Aug;58(2):183-8.

*Overholt BF, et al. Photodynamic therapy for Barrett's esophagus: follow-up in 100 patients. Gastrointest Endosc 1999 Jan;49(1):1-7.

*Overholt BF, et al. Photodynamic therapy with porfimer sodium for ablation of high-grade dysplasia in Barrett's esophagus: international, partially blinded, randomized phase III trial. Gastrointest Endosc 2005 Oct;62(4):488-98.

*Overholt BF, et al. Five-year efficacy and safety of photodynamic therapy with Photofrin in Barrett's high-grade dysplasia. Gastrointest Endosc 2007;66(3):460-8.

*Panjehpour M, et al. Optimization of light dosimetry for photodynamic therapy of Barrett's esophagus: efficacy vs incidence of stricture after treatment. Gastrointest Endosc 2005 Jan;61(1):13-8.

*Panjehpour M, et al. Porfimer sodium photodynamic therapy for management of Barrett's esophagus with high-grade dysplasia. Lasers Surg Med 2006 Jun;38(5):390-5.

Park do H, et al. randomized phase II trial of photodynamic therapy plus oral fluoropyrimidine, S-1, versus photodynamic therapy alone for unresectable hilar cholangiocarcinoma. Eur J Cancer 2014 May;50(7):1259-68.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 8 OF: 9</p>
--	---

Park YK, et al. Clinical efficacy of photodynamic therapy. Obstet Gynecol Sci 2016 Nov;59(6):479-488.

*Pereira SP, et al. Safety and long term efficacy of porfimer sodium photodynamic therapy in locally advanced biliary tract carcinoma. Photodiagnosis Photodyn Ther 2012 Dec;9(4):287-92.

*Prasad GA, et al. Factors associated with increased survival after photodynamic therapy for cholangiocarcinoma. Clin Gastroenterol Hepatol 2007 Jun;5(6):743-8.

*Nanashima A, et al. Adjuvant photodynamic therapy for bile duct carcinoma after surgery: a preliminary study. J Gastroenterol 2004 Nov;39(11):1095-101.

*Rees JR, et al. Treatment for Barrett's oesophagus. Cochrane Database Syst Rev. 2010 Jan 20;(1):CD004060.

*Ross P Jr, et al. Incorporation of photodynamic therapy as an induction modality in non-small cell lung cancer. Lasers Surg Med 2006 Dec;38(10):881-9.

Rigual NR, et al. Adjuvant intraoperative photodynamic therapy in head and neck cancer. JAMA Otolaryngol Head Neck Surg 2013 Jul;139(7):706-11.

*Rupinski M, 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 2011 Sep;106(9):1612-20.

*Schweitzer VG, et al. PHOTOFRIN-mediated photodynamic therapy for treatment of early stage (Tis-T2N0M0) SqCCa of oral cavity and oropharynx. Lasers Surg Med 2010 Jan;42(1):1-8.

*Shim CS, 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 2005 May;37(5):425-33.

*Soergel P, et al. Photodynamic therapy of cervical intraepithelial neoplasia 1-3 and human papilloma virus (HMV) infection with methylaminolevulinic acid and hexaminolevulinic acid- a double-blind, dose-finding study. Lasers Surg Med 2012 Aug;44(6):468-74.

*Spechler SJ, et al. American Gastroenterological Association technical review on the management of Barrett's esophagus. Gastroenterol 2011 Mar;140(3):e18-52.

*Tanaka T, et al. Photodynamic therapy for large superficial squamous cell carcinoma of the esophagus. Gastrointest Endosc 2011 Jan;73(1):1-6.

Tao XH, et al. Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia: a systematic review. Photodiagnosis Photodyn Ther 2014 Jun;11(2):104-12.

*Tokar, JL, et al. Endoscopic therapy of dysplasia and early-stage cancers of the esophagus. Semin Radiat Oncol 2006;17:10-21.

*Tomizawa Y, et al. Photodynamic therapy for unresectable cholangiocarcinoma. Dig Dis Sci 2012 Feb;57(2):274-83.

Toratani S, et al. Photodynamic therapy using photofrin and excimer dye laser treatment for superficial oral squamous cell carcinomas with long-term follow up. Photodiagnosis Photodyn Ther 2016 June;14:104-110.

*Usuda J, et al. Photodynamic therapy for lung cancers based on novel photodynamic diagnosis using talaporfin sodium (NPe6) and autofluorescence bronchoscopy. Lung Cancer 2007 Dec;58(3):317-23.

*Van Duijnhoven FH, et al. Photodynamic therapy with 5, 10, 15, 20-tetrakis (m-hydroxy-phenyl) bacteriochlorin for colorectal liver metastases is safe and feasible: results from a phase I study. Ann Surg Oncol 2005 Oct;12(10):808-16.

Vohra F, et al. Efficacy of photodynamic therapy in the management of oral premalignant lesions. A systematic review. Photodiagnosis Photodyn Ther 2015 Mar;12(1):150-9.

<p>SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE</p> <p>POLICY NUMBER: 8.01.06</p> <p>CATEGORY: Technology Assessment</p>	<p>EFFECTIVE DATE: 11/19/99</p> <p>REVISED DATE: 12/20/01, 01/16/03, 01/15/04, 10/20/04, 08/18/05, 06/15/06, 05/17/07, 05/14/08, 06/18/09, 05/27/10, 04/21/11, 04/19/12, 03/21/13, 02/20/14, 02/19/15, 02/18/16, 02/16/17, 02/15/18</p> <p>PAGE: 9 OF: 9</p>
--	---

- *Webber J, et al. Photodynamic therapy for carcinoma in situ of the anus. Arch Surg 2004 Mar;139(3):259-61.
- Welbourn H, et al. Can photodynamic therapy be the preferred treatment option for anal intraepithelial neoplasia? Initial results of a pilot study. Photodiagnosis Photodyn Ther 2014 Mar;11(1):20-21.
- Wentrup R, et al. Photodynamic therapy plus chemotherapy compared with photodynamic therapy alone in hilar nonresectable cholangiocarcinoma. Gut Liver 2016 May 23;10(3):470-475.
- *Wiedmann M, et al. Photodynamic therapy in patients with non-resectable hilar cholangiocarcinoma: 5-year follow-up of a prospective phase II study. Gastrointest Endosc 2004 Jul;60(1):68-75.
- *Wildeman MA, et al. Photodynamic therapy in the therapy for recurrent/persistent nasopharyngeal cancer. Head Neck Oncol 2009 Dec 17;1:40.
- *Witzigmann H, et al. Surgical and palliative management and outcome in 184 patients with hilar cholangiocarcinoma: palliative photodynamic therapy plus stenting is comparable to R1/R2 resection. Ann Surg 2006 Aug;244(2):230-9.
- *Wolfsen HC, et al. Photodynamic therapy for dysplastic Barrett esophagus and early esophageal adenocarcinoma. Mayo Clin Proc 2002;77:1176-81.
- *Wolfsen HC. Uses of photodynamic therapy in premalignant and malignant lesions of the gastrointestinal tract beyond the esophagus. J Clin Gastroenterol 2005 Sep;39(8):653-4.
- *Yamaguchi S, et al. Photodynamic therapy for cervical intraepithelial neoplasia. Oncol 2005;69(2):110-16.
- Yang J, et al. Treatment of unresectable extrahepatic cholangiocarcinoma using hematoporphyrin photodynamic therapy: A prospective study. Photodiagnosis Photodyn Ther 2016 Dec;16:110-118.
- *Yano T, et al. Long-term results of salvage photodynamic therapy for patients with local failure after chemoradiotherapy for esophageal squamous cell carcinoma. Endoscopy 2011 Aug;43(8):657-63.
- *Yano T, et al. Photodynamic therapy as salvage treatment for local failure after chemoradiotherapy in patients with esophageal squamous cell carcinoma: a phase II study. Int J Cancer 2012 Sep 1;131(5):1228-34.
- *Yano T, et al. Phase I study of photodynamic therapy using talaporfin sodium and diode laser for local failure after chemoradiotherapy for esophageal cancer. Radiat Oncol 2012 Jul 23;7:113.
- *Zoepl T, et al. Palliation of nonresectable bile duct cancer: improved survival after photodynamic therapy. Am J Gastroenterol 2005 Nov;100(11):2426-30.

*key articles

KEY WORDS:

Photofrin®, Porfimer sodium.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, Photodynamic therapy for malignant conditions is not specifically addressed in National or Regional Medicare coverage determinations or policies.