

Photodynamic Therapy with Porfimer Sodium

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Approved By:	Highmark Health Options – Market Leadership
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Products:	Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 4

Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary photodynamic therapy with porfimer sodium.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children (DHCP) and Diamond State Health Plan Plus members.

Photodynamic Therapy (PDT) – An ablative treatment for cancer which uses a combination of a photoactive drug and light from a laser to destroy cancer cells while eliminating damage to surrounding healthy tissue. PDT is also called phototherapy, photoradiation therapy, photosensitizing therapy, or photochemotherapy.

PROCEDURES

A prior authorization is not required.

One (1) or more courses of PDT may be considered medically necessary for the following oncological applications:

- Palliative treatment of obstructing esophageal cancer; or
- Palliative treatment of partially obstructing esophageal cancer in individuals who cannot be satisfactorily treated with neodymium-doped yttrium aluminum garnet (Nd:YAG) laser therapy; or
- Reduction of obstruction and palliative treatment of partially or completely obstructing endobronchial lesions; or
- Treatment of early-stage non-small-cell lung cancer in individuals who are ineligible for surgery and radiotherapy; or
- Treatment of high-grade dysplasia in Barrett esophagus; or
- Palliative treatment of unresectable cholangiocarcinoma when used with stenting.

Endoscopic debridement of the necrotic tumor site may be considered medically necessary approximately two to three (2-3) days after the initial PDT.

Subsequent PDT courses may be considered medically necessary for a minimum of one (1) month after the initial therapy. This sequence may be repeated two to three (2-3) times depending on the individual's response to treatment.

PDT with porfimer sodium not meeting the criteria as indicated in this policy is considered experimental/investigational and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

POST-PAYMENT AUDIT STATEMENT

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

PLACE OF SERVICE: INPATIENT/OUTPATIENT

Experimental/investigational (E/I) services are not covered regardless of place of service.

Photodynamic therapy with porfimer sodium is typically an outpatient procedure which is only eligible for coverage as an inpatient procedure in special circumstances, including, but not limited to, the presence of a co-morbid condition that would require monitoring in a more controlled environment such as the inpatient setting.

CODING REQUIREMENTS

CPT code	Description
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy).
43229	Esophagoscopy, flexible, transoral; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).
96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug.
96411	Chemotherapy administration; intravenous, push technique, each additional substance/drug (list separately in addition to code for primary procedure).
96570	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); first 30 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus).
96571	Photodynamic therapy by endoscopic application of light to ablate abnormal tissue via activation of photosensitive drug(s); each additional 15 minutes (list separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus).

COVERED DIAGNOSIS CODES FOR PROCEDURE CODES: 43229, 96570, AND 96571

Codes						
C15.3	C15.4	C15.5	C15.8	C15.9	C22.1	C34.2
C34.00	C34.01	C34.02	C34.10	C34.11	C34.12	C34.30
C34.31	C34.32	C34.80	C34.81	C34.82	C34.90	C34.91
C34.92	C78.00	C78.01	C78.02	C78.80	C78.89	D00.1
D02.20	D02.21	D02.22	K22.70	K22.711		

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

SUMMARY OF LITERATURE
National Comprehensive Cancer Network – 2021

Esophageal and Esophageal Junction Cancers the NCCN guidelines (v.4.2021) for esophageal cancer state that radiofrequency ablation has become the preferred treatment while PDT is an alternative strategy for patients who have Barrett esophagus with HGD. The guidelines also state that PDT can effectively treat esophageal obstruction but "is less commonly performed due to photosensitivity and costs" compared with radiotherapy and brachytherapy.

Hepatobiliary Cancers

The NCCN (v.5.2021) guidelines on hepatobiliary cancers describe PDT as a relatively new therapy for local treatment of unresectable cholangiocarcinoma, stating that the combination of PDT and biliary stenting "was reported to be associated with prolonged overall survival in patients with unresectable cholangiocarcinoma based on 2 small randomized clinical trials.

Non-Small-Cell Lung Cancer

The NCCN guidelines (v.6.2021) on non-small-cell lung cancer state that PDT is a treatment option for patients with locoregional recurrence of non-small-cell lung cancer with an endobronchial obstruction or severe hemoptysis.

Reference

U.S. National Institutes of Health. ClinicalTrials.gov. Safety and efficacy of photodynamic therapy for bile duct invasion of hepatocellular carcinoma.

Zhang W, Zhang A, Sun W, et al. Efficacy and safety of photodynamic therapy for cervical intraepithelial neoplasia and human papilloma virus infection: A systematic review and metaanalysis of randomized clinical trials. *Medicine (Baltimore)*. 2018;97(21): e10864.

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*. 2017;103(3):912-919.

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*. 2018;53(5):527-532.

Gondivkar SM, Gadbail AR, Choudhary MG, Vedpathak PR, Likhitkar MS. Photodynamic treatment outcomes of potentially malignant lesions and malignancies of the head and neck region: A systematic review. *J Investig Clin Dent*. 2018;9(1).

National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Esophageal and esophagogastric junction cancers. Version 4.2021.

National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Hepatobiliary cancers. Version 5.2021.

National Comprehensive Cancer Network (NCCN). NCCN clinical practice guidelines in oncology: Non-small cell lung cancer. Version 6.2021.

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 metaanalysis of randomized clinical trials. *Medicine (Baltimore)*. 2018;97(21): e10864.

Zhang R, Wang L. Photodynamic therapy for treatment of usual-type vulvar intraepithelial neoplasia: A case report and literature review. *J Int Med Res*. 2019;47(8):4019-4026.

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.

Nakamura T, Kusuzaki K, Matsubara T, et al. Long-term clinical outcome in patients with highgrade soft tissue sarcoma who were treated with surgical adjuvant therapy using acridine orange after intra-lesional or marginal resection. *Photodiagnosis Photodyn Ther*. 2018; 23:165-170.

Nwogu C, Kloc A, Attwood K et al. Porfimer Sodium versus PS785 for Photodynamic Therapy (PDT) of lung cancer xenografts in mice. *J Surg Res*. 2021; 263:245-250.

Lu J, Roy B, Anderson M, et al. Verteporfin- and sodium porfimer-mediated photodynamic therapy enhances pancreatic cancer cell death without activating stromal cells in the microenvironment. *J Biomed Opt*. 2019;24(11):1-11.

Inoue T, Ishihara R. Photodynamic therapy for esophageal cancer. *Clin Endosc*. 2021;54(4):494-498.

Pereira SP, Jitlal M, Duggan M, et al. PHOTOSTENT-02: porfimer sodium photodynamic therapy plus, stenting versus stenting alone in patients with locally advanced or metastatic biliary tract cancer. *ESMO Open*. 2018;3(5): e000379.

POLICY UPDATE HISTORY

12/21/2021	Approved in Medical Policy Committee
01/2022	Approved in QI/UM
12/28/2022	Annual review; approved in Medical Policy Committee
01/03/2023	Approved in QI/UM