MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Photodynamic Therapy for Malignant Disease**
Policy Number	**8.01.06**
Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program(DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the peer-reviewed literature, photodynamic therapy (PDT) with Photofrin has been medically proven to be effective and, therefore, is considered **medically appropriate** for the following indications:

A. treatment of early-stage non-small-cell lung cancer (NSCLC) in patients who are ineligible for surgery and radiation therapy;
B. reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial lesions;
C. palliative treatment of obstructing esophageal cancer,
D. treatment of Barrett's high-grade dysplasia (HGD) 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 that 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 the peer-reviewed literature, the following have been medically proven to be effective and, therefore, are considered **medically appropriate:**

A. PDT with 5-aminolevulinic acid (5-ALA) topical preparations for the treatment of:
   1. superficial basal cell skin cancer, only when surgery and/or radiation is contraindicated; or
   2. Bowen's disease (squamous cell carcinoma in situ), only when surgery and/or radiation is contraindicated.

III. Based upon our criteria and the lack of peer-reviewed literature, PDT 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, head and neck cancers, and Barrett's esophagus (other than HGD, as stated above).

IV. PDT with porfimer sodium is **contraindicated** in patients with any of the following:
- A. known bone marrow suppression
- B. porphyria or known allergies to porphyrins
- C. existing tracheoesophageal or broncho esophageal fistula; or
- D. tumors eroding into a major vessel

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

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

Refer to Corporate Medical Policy #8.01.21 Light and Laser Therapies for Dermatological Conditions.

Refer to Corporate Medical Policy #7.01.01 Focal Therapies for Prostate Cancer Treatment

Refer to Corporate Medical Policy # 11.01.10 Clinical Trials.

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

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) 48 hours 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 three courses of PDT (every 30 days) can be given.

III. As pathologists do not always agree on differentiating between low- and high-grade dysplasia and between high-grade dysplasia and carcinoma in situ, in many cases, high-grade Barrett's dysplasia is confirmed by two pathologists with expertise in gastrointestinal pathology.

DESCRIPTION

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.

PDT 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.

PDT 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 photosensitizing agent with specific indications for use that has been approved by the U.S. Food and Drug Administration (FDA). 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, who 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 that survival rates were comparable, and that PDT was technically easier to perform, more comfortable for patients, and caused fewer side effects (e.g., perforation).

An interim analysis of porfimer PDT for high-grade dysplasia in Barrett's oesophagus demonstrated that patients receiving PDT and 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- or high-grade dysplasia); thus, these patients still require intensive endoscopic surveillance and close follow-up.

The 2017 National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology stated that, in patients with low-risk, superficial, basal cell cancer or low-risk squamous cell carcinoma in situ (Bowen's disease), where surgery or radiation is contraindicated or impractical, topical therapies such as 5-fluorourcil, imiquimod, photodynamic therapy (e.g., aminolevulinic acid [ALA], porfimer sodium), or vigorous cryotherapy may be considered, even though the cure rate may be lower.

Although PDT (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.

CODES

- *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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
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

HCPCS Codes

Code	Description
J9600	Drug; porfimer sodium, 75 mg

ICD10 Codes

Code	Description
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)

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*Key Article

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.