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 non-small cell lung cancer (NSCLC); 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.

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.
PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE

POLICY NUMBER: 8.01.06
CATEGORY: Technology Assessment

EFFECTIVE DATE: 10/18/01
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, 04/19/16

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.

CODES:

<table>
<thead>
<tr>
<th>Number</th>
<th>Description</th>
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<tbody>
<tr>
<td>96570</td>
<td>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)</td>
</tr>
</tbody>
</table>

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

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HCPCS: J9600 Drug; porfimer sodium, 75 mg

ICD9: 150.0-150.9 Malignant neoplasm of esophagus (code range)
162.2-162.9 Malignant neoplasm of trachea, bronchus and lung (code range)
197.0 Secondary malignant neoplasm of lung and bronchus system
197.8 Secondary malignant neoplasm of other digestive organs and spleen (includes esophagus)
230.1 Carcinoma in situ of esophagus
231.2 Carcinoma in situ of bronchus and lung
530.85 Barrett’s esophagus

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:


SUBJECT: PHOTODYNAMIC THERAPY FOR MALIGNANT DISEASE

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*key articles

KEY WORDS:
Photofrin®, Porfimer sodium.

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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.

Proprietary Information of YourCare Health Plan