

IMPORTANT SAFETY INFORMATION ABOUT PHOTOFRIN® (PORFIMER SODIUM) FOR INJECTION

Photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) is a two-stage process requiring administration of both drug and light in a properly equipped facility. Refer to the OPTIGUIDE™ instructions for use for complete instructions concerning the fiber optic diffuser.

PHOTOFRIN is contraindicated in patients with porphyria. PDT is contraindicated in patients with an existing tracheoesophageal or bronchoesophageal fistula and patients with tumors eroding into a major blood vessel. PDT is not suitable for emergency treatment of patients with severe acute respiratory distress caused by an obstructing endobronchial lesion because 40 to 50 hours are required between injection with PHOTOFRIN and laser light treatment. PDT is not suitable for patients with esophageal or gastric varices, or patients with esophageal ulcers >1 cm in diameter.

Tracheoesophageal or bronchoesophageal fistula can occur if esophageal tumor is eroding into trachea or bronchial tree. Gastrointestinal perforation can occur. There is a high risk of bleeding in patients with esophageal varices and for fatal massive hemoptysis with endobronchial tumors that are: large, centrally located; cavitating; extensive, extrinsic to the bronchus. After treatment of high-grade dysplasia (HGD) in Barrett's esophagus (BE), monitor endoscopic biopsy every three months, until four consecutive negative evaluations for HGD have been recorded. Photosensitivity can be expected; ocular sensitivity is possible. Allow 2-4 weeks between PDT and subsequent radiotherapy. Substernal chest pain may occur after treatment. Treatment-induced inflammation can cause airway obstruction. Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Esophageal stenosis occurs frequently after treatment of HGD in BE. Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity (possibly more than 90 days). Thromboembolic events can occur following photodynamic therapy with PHOTOFRIN.

References:

1. Diagnosis and procedure codes: abbreviated and full code titles. Version 31 abbreviated and full code titles – effective October 1, 2013. CMS website. http://www.cms.gov/ICD9ProviderDiagnosticCodes/06_codes.asp#TopOfPage. Accessed February 24, 2014.
2. 2014 ICD-10-CM and GEMs: code tables and index, Neoplasm table. CMS website <http://www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-CM-and-GEMs.html>. Accessed February 24, 2014.
3. HCPCS code sets. 2014 alpha-numeric HCPCS file. CMS website. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS.html>. Accessed February 24, 2014.
4. 2014 ICD-10-PCS and GEMs: code tables and index, PCS 2014. CMS website <http://www.cms.gov/Medicare/Coding/ICD10/2014-ICD-10-PCS.html>. Accessed February 24, 2014.
5. Current Procedural Terminology 2014. Current Procedural Terminology (CPT®) ©2013 American Medical Association. All Rights Reserved.
6. Hospital outpatient PPS – addendum A and addendum B updates. October 2016 addendum A and B. CMS website. <http://www.cms.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage>.
7. Ambulatory surgical center (ASC) payment – addenda updates. October 2016 ASC approved HCPCS code and payment rates. CMS website. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html. Accessed October 4, 2016.
8. 2016 Physician Fee schedule. CMS website. <http://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx>. Accessed October 4, 2016.

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MOST COMMON ADVERSE REACTIONS reported during clinical trials are:

Esophageal Cancer: Anemia, pleural effusion, pyrexia, constipation, nausea, chest pain, pain, abdominal pain, dyspnea, photosensitivity reaction, pneumonia, vomiting, insomnia, back pain, pharyngitis.

Obstructing Endobronchial Cancer: Dyspnea, photosensitivity reaction, hemoptysis, pyrexia, cough, pneumonia.

Superficial Endobronchial Tumors: Exudate, photosensitivity reaction, bronchial obstruction, edema, bronchostenosis.

High-Grade Dysplasia in Barrett's Esophagus: Photosensitivity reaction, esophageal stenosis, vomiting, chest pain, nausea, pyrexia, constipation, dysphagia, abdominal pain, pleural effusion, dehydration.

Inform patients to report adverse reactions. All patients who receive PHOTOFRIN will be photosensitive for at least 30 days and should be warned about this and counselled to take appropriate precautions. Laser treatment should not be given if an overdose of PHOTOFRIN is administered.

FOR MORE INFORMATION ABOUT PHOTOFRIN visit www.Photofrin.com or call Concordia Laboratories Inc. at 1-877-370-1142.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see full prescribing information for PHOTOFRIN.

Guide to PHOTOFRIN® (porfimer sodium) / PDT Reimbursement

Diagnosis Coding

INDICATIONS AND USAGE

Esophageal Cancer

PHOTOFRIN® (porfimer sodium) is indicated for the palliation of patients with completely obstructing esophageal cancer, or of patients with partially obstructing esophageal cancer who, in the opinion of their physician, cannot be satisfactorily treated with Nd:YAG laser therapy.

Endobronchial Cancer

PHOTOFRIN is indicated for the treatment of microinvasive endobronchial non-small cell lung cancer (NSCLC) in patients for whom surgery and radiotherapy are not indicated. PHOTOFRIN is indicated for the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial NSCLC.

High-Grade Dysplasia in Barrett's Esophagus

PHOTOFRIN is indicated for the ablation of high-grade dysplasia in Barrett's esophagus patients who do not undergo esophagectomy.

	ICD-9-CM and Description ¹		ICD-10-CM and Description ²	
Malignant neoplasm of esophagus	150.0	Malignant neoplasm of cervical esophagus	C15.3	Malignant neoplasm of upper third of esophagus
	150.1	Malignant neoplasm of thoracic esophagus	C15.4	Malignant neoplasm of middle third of esophagus
	150.2	Malignant neoplasm of abdominal esophagus	C15.5	Malignant neoplasm of lower third of esophagus
	150.3	Malignant neoplasm of upper third of esophagus	C15.3	Malignant neoplasm of upper third of esophagus
	150.4	Malignant neoplasm of middle third of esophagus	C15.4	Malignant neoplasm of middle third of esophagus
	150.5	Malignant neoplasm of lower third of esophagus	C15.5	Malignant neoplasm of lower third of esophagus
	150.8	Malignant neoplasm of other specified part of esophagus	C15.8	Malignant neoplasm of overlapping sites of esophagus
Malignant neoplasm of bronchus and lung	150.9	Malignant neoplasm of esophagus, unspecified	C15.9	Malignant neoplasm of esophagus, unspecified
	162.2	Malignant neoplasm of main bronchus	C34.00	Malignant neoplasm of unspecified main bronchus
			C34.01	Malignant neoplasm of right main bronchus
			C34.02	Malignant neoplasm of left main bronchus
	162.3	Malignant neoplasm of upper lobe, bronchus or lung	C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
			C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
			C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
	162.4	Malignant neoplasm of middle lobe, bronchus or lung	C34.2	Malignant neoplasm of middle lobe, bronchus or lung
	162.5	Malignant neoplasm of lower lobe, bronchus or lung	C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
			C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
			C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
162.8	Malignant neoplasm of other parts of bronchus or lung	C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and lung	
		C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung	
		C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung	

Malignant neoplasm of bronchus and lung, Continued	162.9	Malignant neoplasm of Bronchus and lung, unspecified	C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
			C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
			C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
High-Grade Dysplasia in Barrett's Esophagus	530.85	Barrett's esophagus	K22.711	Barrett's esophagus with high-grade dysplasia

Drug Coding

	HCPCS Code and Description ³	Physician rate*	OPPS rate* ASC rate*
PHOTOFRIN® (porfimer sodium)	J9600 Porfimer sodium, 75 mg	N/A	\$20,910.92 \$20,910.92

*Q4 2016 rate from Physician ASP Pricing File, OPPS Addendum B (SI =K, APC 0856), and ASC Addendum (SI =K2).

Q4 2016 Procedure Coding

DOSAGE AND ADMINISTRATION

Photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) is a 2-stage process requiring administration of both drug and light. The first stage of PDT is the intravenous injection of PHOTOFRIN at 2 mg/kg. PHOTOFRIN should be administered as a single slow intravenous injection over 3 to 5 minutes at 2 mg/kg of body weight. Illumination with laser light 40-50 hours following injection with PHOTOFRIN constitutes the second stage of therapy. A second laser light application may be given 96-120 hours after injection.

	ICD-9-CM and Description ¹	ICD-10-PCS and Description ⁴
Endoscopy	32.01 Endoscopic excision or destruction of lesion or tissue of the bronchus	0B538ZZ Destruction of right main bronchus, via natural or artificial opening endoscopic
		0B548ZZ Destruction of right upper lobe bronchus, via natural or artificial opening endoscopic
		0B558ZZ Destruction of right middle lobe bronchus, via natural or artificial opening endoscopic
		0B568ZZ Destruction of right lower lobe bronchus, via natural or artificial opening endoscopic
		0B578ZZ Destruction of left main bronchus, via natural or artificial opening endoscopic
		0B588ZZ Destruction of left upper lobe bronchus, via natural or artificial opening endoscopic
		0B598ZZ Destruction of lingula bronchus, via natural or artificial opening endoscopic
		0B5B8ZZ Destruction of left lower lobe bronchus, via natural or artificial opening endoscopic
		32.28 Endoscopic excision or destruction of lesion or tissue of the lung
	0B5D8ZZ Destruction of right middle lung lobe, via natural or artificial opening endoscopic	
	0B5F8ZZ Destruction of right lower lung lobe, via natural or artificial opening endoscopic	
	0B5G8ZZ Destruction of left upper lung lobe, via natural or artificial opening endoscopic	
	0B5H8ZZ Destruction of lung lingula, via natural or artificial opening endoscopic	
	0B5J8ZZ Destruction of left lower lung lobe, via natural or artificial opening endoscopic	
	0B5K8ZZ Destruction of right lung, via natural or artificial opening endoscopic	
	0B5L8ZZ Destruction of left lung, via natural or artificial opening endoscopic	
	0B5M8ZZ Destruction of bilateral lungs, via natural or artificial opening endoscopic	

Endoscopy, Continued	42.33 Endoscopic excision or destruction of lesion or tissue of esophagus	0D518ZZ	Destruction of upper esophagus, via natural or artificial opening endoscopic
		0D528ZZ	Destruction of middle esophagus, via natural or artificial opening endoscopic
		0D538ZZ	Destruction of lower esophagus, via natural or artificial opening endoscopic
		0D548ZZ	Destruction of esophagogastric junction, via natural or artificial opening endoscopic
		0D558ZZ	Destruction of esophagus, via natural or artificial opening endoscopic

	CPT Code and Description ⁵	APC and Description Status Ind.*	OPPS rate ^{6*}	ASC rate ^{7*}	Physician rate ^{8*} In-office In-facility
Injection	96409 Chemotherapy administration; intravenous, push technique, single or initial substance/drug	0439 Level VI Drug Administration SI = S	\$173.18	N/A	\$111.71 \$111.71
Endoscopy	43229 (New code effective 01/01/2014; Replaces 43228) 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)	0422 Level III Upper GI Procedures SI = T	\$1980.43	1107.43	\$733.99 \$213.04
	31641 Bronchoscopy (rigid or flexible); with destruction of tumor or relief of stenosis by any method other than excision (eg, laser therapy, cryotherapy)	0415 Level II Endoscopy Lower Airway SI = T	\$1991.92	\$1,113.86	\$266.74 \$266.74
Photodynamic Therapy	96570 (Use 96570-52 for therapy lasting less than 23 min. Use 96570 for therapy lasting 23-37 min.) 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 gastrointestinal tract)	N N/A	N/A	N/A	\$59.08 \$59.08
	96571 (Use 96571 in addition to 96570 for therapy lasting 38-52 min.) 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 gastrointestinal tract)	N N/A	N/A	N/A	\$27.57 \$27.57

* Q4 2015 rate from ASC Addendum AA, OPPS Addendum B, and MPFS.

* Status Indicator from Addendum D1: S = Procedure or Service, Not Discounted When Multiple;

T = Procedure or Service, Multiple Reduction Applies; N = Items and Services Packaged into APC Rates.