

Guide to PHOTOFRIN® (porfimer sodium) / PDT Reimbursement

IMPORTANT WARNINGS AND PRECAUTIONS:

Gastroesophageal Fistula and Perforation: Do not initiate PHOTOFRIN with photodynamic therapy (PDT) in patients with esophageal tumors eroding into the trachea or bronchial tree or bronchial wall.

Pulmonary and Gastroesophageal Hemorrhage: Assess patients for tumors eroding into a pulmonary blood vessel and esophageal varices. Do not administer light directly to an area with esophageal varices.

High-Grade Dysplasia (HGD) in Barrett's Esophagus (BE): After treatment of HGD in BE, conduct endoscopic biopsy surveillance every 3 months, until 4 consecutive negative evaluations for HGD have been recorded.

Photosensitivity and Ocular Photosensitivity: Observe precautions to avoid exposure of skin and eyes to direct sunlight or bright indoor light for at least 30 days. Instruct patients when outdoors to wear dark sunglasses which have an average light transmittance of <4% for at least 30 days and until ocular sensitivity resolves.

Use Before or After Radiotherapy: Allow 2-4 weeks between PDT and subsequent radiotherapy.

Chest Pain: Substernal chest pain can occur.

Airway Obstruction and Respiratory Distress: Administer with caution to patients with tumors in locations where treatment-induced inflammation can obstruct the main airway. Monitor patients closely between the laser light therapy and the mandatory debridement bronchoscopy for any evidence of respiratory distress.

Esophageal Strictures: Esophageal strictures can occur.

Hepatic and Renal Impairment: Patients with hepatic or renal impairment may need longer precautionary measures for photosensitivity.

Thromboembolism: Thromboembolic events can occur.

Embryo-Fetal Toxicity: May cause embryo-fetal toxicity. Advise females of reproductive potential of the potential risk to a fetus and to use effective contraception.

Diagnosis Coding

ICD-9-CM and Description1	ICD-10-CM and Description2
Malignant neoplasm of esophagus	C15.3 Malignant neoplasm of upper third of esophagus
	C15.4 Malignant neoplasm of middle third of esophagus
	C15.5 Malignant neoplasm of lower third of esophagus
	C15.3 Malignant neoplasm of upper third of esophagus
	C15.4 Malignant neoplasm of middle third of esophagus
	C15.5 Malignant neoplasm of lower third of esophagus
	C15.8 Malignant neoplasm of overlapping sites of esophagus
	C15.9 Malignant neoplasm of esophagus, unspecified
	Malignant neoplasm of bronchus and lung
C34.01 Malignant neoplasm of right main bronchus	
C34.02 Malignant neoplasm of left main bronchus	
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	
C34.2 Malignant neoplasm of middle 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	
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	C34.90 Malignant neoplasm of unspecified part of unspecified bronchus or lung
	C34.91 Malignant neoplasm of unspecified part of right bronchus or lung
High-Grade Dysplasia in Barrett's Esophagus	C34.92 Malignant neoplasm of unspecified part of left bronchus or lung
	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	For latest rate please contact the local Sales Representative.	For latest rate please contact the local Sales Representative.

Procedure Coding

DOSAGE AND ADMINISTRATION

Photodynamic therapy (PDT) with PHOTOFRIN® (porfimer sodium) for injection 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.

Endoscopy

ICD-10-PCS and Description ⁴	
OB538ZZ	Destruction of right main bronchus, via natural or artificial opening endoscopic
OB548ZZ	Destruction of right upper lobe bronchus, via natural or artificial opening endoscopic
OB558ZZ	Destruction of right middle lobe bronchus, via natural or artificial opening endoscopic
OB568ZZ	Destruction of right lower lobe bronchus, via natural or artificial opening endoscopic
OB578ZZ	Destruction of left main bronchus, via natural or artificial opening endoscopic
OB588ZZ	Destruction of left upper lobe bronchus, via natural or artificial opening endoscopic
OB598ZZ	Destruction of lingula bronchus, via natural or artificial opening endoscopic
OB5B8ZZ	Destruction of left lower lobe bronchus, via natural or artificial opening endoscopic
OB5C8ZZ	Destruction of right upper lung lobe, via natural or artificial opening endoscopic
OB5D8ZZ	Destruction of right middle lung lobe, via natural or artificial opening endoscopic
OB5F8ZZ	Destruction of right lower lung lobe, via natural or artificial opening endoscopic
OB5G8ZZ	Destruction of left upper lung lobe, via natural or artificial opening endoscopic
OB5H8ZZ	Destruction of lung lingula, via natural or artificial opening endoscopic
OB5J8ZZ	Destruction of left lower lung lobe, via natural or artificial opening endoscopic
OB5K8ZZ	Destruction of right lung, via natural or artificial opening endoscopic
OB5L8ZZ	Destruction of left lung, via natural or artificial opening endoscopic
OB5M8ZZ	Destruction of bilateral lungs, via natural or artificial opening endoscopic

Endoscopy continued

ICD-10-PCS and Description⁴

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 Description⁵		APC and Description Status Ind.+	OPPS rate⁶	ASC rate⁷	Physician rate⁸ In-office In-facility
Injection	96409	Chemotherapy administration; intravenous, push technique, single or initial substance/drug	0439 Level VI Drug Administration SI=S	These rates vary by location and provider. - Cost of living - State of hospital - Population of area - Cost to run hospital		
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			
	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			
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			
	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			

+ 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.



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 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 patient 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 hemolysis 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. CMS website. <http://www.cms.gov/HospitalOutpatientPPS/AU/list.asp#TopOfPage>.
7. Ambulatory surgical center (ASC) payment – addenda updates. ASC approved HCPCS code and payment rates. CMS website. http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/11_Addenda_Updates.html.
8. Physician Fee schedule. CMS website. <http://www.cms.gov/apps/physician-fee-schedule/search/search-criteria.aspx>.
9. PHOTOFRIN®(porfimer sodium) for Injection [package insert]. Bannockburn, IL: Pinnacle Biologics, Inc.; December, 2019.)

*NOTE: Healthcare professionals/entities are solely responsible for accurately coding claims for such products and billing third-party payors (including Medicaid, Medicare, and other federal healthcare programs) for any products used with or provided to patients. The HCPCS codes set forth herein are for general reference only. Pinnacle Biologics, Inc./Concordia Laboratories Inc. does not provide any reimbursement advice. It is the responsibility of the healthcare professional or entity to ensure the accuracy of the information they submit to the government or any third party relating to the reimbursement of their costs for products or services they provide to their patients.

MOST COMMON ADVERSE REACTIONS (>10%) are:

Esophageal Cancer: Anemia, pleural effusion, pyrexia, constipation, nausea, chest 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.

Other Photosensitizing Agents: May increase the risk of photosensitivity reaction.

Lactation: Because of the potential for serious adverse reactions in the breastfed infant, advise patients that breastfeeding is not recommended during treatment with PHOTOFRIN and for 5 months after the last dose.

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 counseled to take appropriate precautions. Laser treatment should not be given if an overdose of PHOTOFRIN is administered.

FOR MORE INFORMATION ABOUT PHOTOFRIN REIMBURSEMENT QUESTIONS

visit www.photofrin.com (<https://www.photofrin.com/>) or call 1-224-795-8308.

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.



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