Reimbursement Guide

Photofrin®

(parfimer sodium) for Injection
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Please see full Prescribing Information on PHOTOFRIN® (porfimer sodium) for Injection inside back pocket.

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PHOTOFRIN® Reimbursement Hotline 1-888-PDT-1411

Revised February 2003
This guide was developed to help you receive optimal reimbursement for PHOTOFRIN® (porfimer sodium) for Injection as part of the entire course of photodynamic therapy (PDT). It provides coverage, coding, and reimbursement information on PHOTOFRIN®. This guide focuses on Medicare policies because many patients receiving PHOTOFRIN® for the treatment of the approved indications are likely to be Medicare beneficiaries. In addition, other insurers often use Medicare as the standard when setting their own policies.

To assist you in preparing claims for PHOTOFRIN® and PDT, this Reimbursement Guide contains the following:

- a general overview of third-party payors’ coverage and reimbursement for PHOTOFRIN®
- the proper coding to use on claim forms, including coding for the diagnosis, administration of PHOTOFRIN®, and PDT
- sample claim forms that illustrate the key components in completing a claim for PHOTOFRIN®
- information on what to include in a letter of medical necessity (LMN) should a payor require it
- a sample LMN
- advice on appealing a denied or underpaid claim

These materials are provided for your guidance only. For more information about coverage and reimbursement, call the PHOTOFRIN® Reimbursement Hotline. Reimbursement specialists are available between 8 AM and 5 PM, Central Time, Monday through Friday, to assist patients, physicians and billing departments with any reimbursement questions.
As with most medical technologies, there is no national Medicare coverage policy for PDT with PHOTOFRIN®. In the absence of a national policy, local Medicare carriers and fiscal intermediaries (FIs) have the discretion to make coverage decisions for PDT with PHOTOFRIN®. In general, Medicare covers physician-administered drugs and services that are medically necessary and accepted by the medical community as appropriate standards of care. For information about current policies, or assistance in researching specific Medicare policies, please call the PHOTOFRIN® Reimbursement Hotline.

PHOTOFRIN® – Coding for Drug
The Health Care Financing Administration (HCFA) Common Procedure Coding System (HCPCS) is used by Medicare, most private insurers, and many Medicaid plans to identify drugs and other therapies on claim forms. HCFA assigned a unique HCPCS code to facilitate billing for PHOTOFRIN®, effective January 1, 1998. The HCPCS code for PHOTOFRIN® is:

J9600- PHOTOFRIN® (porfimer sodium) for Injection, per 75 mg

Medicare reimbursement for PHOTOFRIN® and its administration depends on the setting of care in which the drug is administered to the patient. The details of Medicare reimbursement for each setting are discussed below.

PHOTOFRIN® – Coding for Administration
Hospital Inpatient Setting
When PHOTOFRIN® is administered to a hospital inpatient, the hospital does not receive separate reimbursement for the cost of the drug and its administration. Instead, Medicare’s payment for the drug and its administration is included in an all-inclusive prospective payment to the hospital known as a diagnosis related group (DRG), which includes all facility services associated with the patient’s hospital stay. The DRG also includes related services provided in the hospital outpatient setting within the 72 hours prior to admission. DRG reimbursement amounts vary after factoring in region-specific wage indices, geographic and cost-of-living adjustment values, and additional adjustments for the hospital (e.g., disproportionate share, indirect medical education).

However, physician services provided in any setting are reimbursed separately by Medicare according to a national fee schedule known as the Resource-Based Relative Value Scale (RBRVS). Please refer to Exhibits 1-3 for possible codes for services associated with the administration of PHOTOFRIN®, including diagnosis codes, in the hospital inpatient setting.
PHOTOFRIN® – Coding for Administration (cont.)

Hospital Outpatient Setting

Medicare typically covers medically necessary hospital outpatient services. Coverage decisions are determined by information provided on the UB-92 (HCFA-1450) claim form, including diagnosis codes, procedure codes, and supply codes. A sample UB-92 form appears later in this Reimbursement Guide.

Effective August 1, 2000, Medicare reimburses for hospital outpatient care based on the Outpatient Prospective Payment System (OPPS). Under this payment methodology, services and some drugs and devices are assigned to payment categories called Ambulatory Payment Classifications (APCs). Services in each APC are similar clinically and in terms of the resources required.

Payment for APC categories are predetermined and adjusted for geographic variations in labor costs. Exhibits 1-3 list possible codes for the services associated with PHOTOFRIN®, including diagnosis codes, in the hospital outpatient setting. Coding for chemotherapeutic drugs administered in the outpatient setting requires both the revenue code, 636 (Pharmacy IV), and the HCPCS code, in this instance, J9600, (PHOTOFRIN® [porfimer sodium] for Injection, per 75mg). Exhibit 4 is a sample UB-92 claim form for hospital outpatient services.

Reimbursement for most drugs is bundled into the payment amount for the procedure during which the drug was used. However, PHOTOFRIN® has qualified for pass-through status under the OPPS, meaning separate reimbursement is available for this product. Pass-through status is intended to be temporary and lasts for a period of two to three years.

Physician’s Office

When PHOTOFRIN® is administered in a physician’s office, Medicare sets its allowable at 95% of the drug’s average wholesale price (AWP). Please contact your local insurance provider or the PHOTOFRIN® Reimbursement Hotline to determine your provider’s allowable for PHOTOFRIN®.

Medicare reimburses participating physicians (those who accept assignment) 80% of the allowable. Participating physicians should bill patients or a secondary insurer for the approved copayment (the remaining 20% of the allowable). Participating physicians cannot charge patients more than Medicare’s allowable for PHOTOFRIN®. Nonparticipating physicians (those who do not accept assignment) can charge patients up to, but not more than, 115% of Medicare’s allowable for PHOTOFRIN®.

Physicians may also bill the Medicare program for their professional services rendered in administering the drug. Medicare reimburses for a physician’s professional services according to the RBRVS fee schedule. Please refer to Exhibit 1 for possible codes for PHOTOFRIN® and its administration in the physician’s office and Exhibit 3 for diagnosis codes. (Exhibit 5 details the use of these codes on a sample HCFA-1500 form.)
Endoscopy or Bronchoscopy and Photodynamic Therapy (PDT)
Effective January 1, 2000, a new photodynamic therapy subsection added to CPT describes the ablation of abnormal tissue via activation of photosensitive drugs. The two new codes in this section are add-on codes to be used in conjunction with the code for the endoscopy or bronchoscopy. Please refer to “Coding for PDT” on page 5 for more information about the codes for PDT.

Medicare reimbursement for facility services associated with the endoscopy or bronchoscopy procedure and PDT also varies by setting of care, as indicated below. (Please refer to Exhibit 2 for possible procedure codes.)

Hospital Inpatient Setting
Facility services are included in the DRG payment. DRG reimbursement amounts vary after factoring in region-specific wage indices, geographic and cost-of-living adjustment values, and additional adjustments for the hospital (e.g., disproportionate share, indirect medical education).

However, physician services are reimbursed separately by Medicare according to the RBRVS national fee schedule. Please refer to Exhibit 2 for possible codes for services associated with photodynamic therapy.

Hospital Outpatient Setting
Facility services are included in the APC payments. APC payments are predetermined and adjusted for geographic variations in labor costs. Physician services are reimbursed separately by Medicare according to the RBRVS national fee schedule.

Services provided in Ambulatory Surgical Centers (ASCs) are also reimbursed based on a prospective system, with procedures reimbursed at a predetermined standard amount. The implementation of the proposed new ASC reimbursement system has been delayed. The PHOTOFRIN® Reimbursement Hotline will have additional information once the proposed rule is finalized.

Physician’s Services
Medicare reimburses physicians separately for performing the endoscopy or bronchoscopy and PDT procedures, according to the RBRVS fee schedule. Medicare’s allowable for performing these procedures varies by geographic location. Please call the PHOTOFRIN® Reimbursement Hotline to learn about your provider’s allowable for each procedure.
Coding for Endoscopy

There are two possible CPT procedure codes for endoscopy:

- 43228 - Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure) with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique

- 43258 - Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure) with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique

The major distinction between the two codes is how far down the gastrointestinal tract the endoscope passes and whether retrograde visualization and administration of PDT are needed to ablate lesions of the gastroesophageal (GE) junction. If the endoscope does not traverse the GE junction, CPT code 43228 should be used to describe the procedure. If the endoscope does traverse the GE junction and retrograde visualization and administration of PDT are needed for ablation of lesions of the GE junction, CPT code 43258 should be used.

For procedures performed in an ambulatory surgery center (ASC), 43228 is categorized as a Group 2 service and 43258 as a Group 3 service.

In addition to the CPT procedure code(s), indicate the ICD-9-CM procedure code in Field 80 for the principal procedure code:

- 42.33 - Endoscopic excision or destruction of lesion or tissue of esophagus

CPT five-digit codes, nomenclature, and other data are copyright 1999 American Medical Association (AMA). All Rights Reserved. No fee schedules, basic unit, relative values or related listings are included in CPT. The AMA assumes no liability for the data contained herein.
Coding for Bronchoscopy
There is one possible CPT procedure code for bronchoscopy:

- 31641 - Bronchoscopy; diagnostic, (flexible or rigid), with or without cell washing with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser)

For procedures performed in an ASC, 31641 is categorized as a Group 2 service.

In addition to facility service codes, use one of the following ICD-9-CM procedure codes in Field 80 for the principal procedure code:

- 32.01 - Endoscopic excision or destruction of lesion or tissue of the bronchus
- 32.28 - Endoscopic excision or destruction of lesion or tissue of the lung

Coding for PDT
There are two CPT add-on codes to describe the ablation of abnormal tissue via activation of photosensitive drugs, which are to be used in conjunction with the CPT codes for endoscopy and bronchoscopy:

- 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 - Each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of the lung and esophagus)

Add-on codes describe additional intra-service work associated with the primary service or procedure, and must never be reported as stand-alone codes. All add-on CPT codes are exempt from the multiple procedure modifier -51. Please see CPT 2000, Surgery Guidelines and Photodynamic Therapy subsection for more information.

Please refer to Exhibit 2 for a summary of coding for procedures. Hospitals also use revenue codes, developed by the American Hospital Association, to bill for services, drugs, and supplies furnished to hospital inpatients and outpatients. For additional information about coverage, coding and claim information for specific payors, please call the PHOTOFRIN® Reimbursement Hotline.
Coverage and Reimbursement by Other Insurers

Medicaid
Each Medicaid agency determines its own coverage and payment policies. Prior authorization may be required. The PHOTOFRIN® Reimbursement Hotline can verify each agency’s policy and assist providers with additional research if necessary.

Medicaid programs usually reimburse for hospital inpatient services on a per diem or DRG basis. Payment for hospital outpatient services is based on one of the following methods: state-specific fee schedules, preset outpatient visit rates, or a percentage of charges.

Medicaid pays for injections received in the physician’s office according to fee schedules. However, methods of paying for PHOTOFRIN® vary. In some states, Medicaid reimburses physicians for PHOTOFRIN® on the basis of average wholesale price (AWP) or invoice price. In other states, Medicaid may require that physicians order PHOTOFRIN® through a Medicaid participating pharmacy, and Medicaid reimburses the pharmacy on the basis of average wholesale price.

Many states have enrolled some of their Medicaid beneficiaries in managed care plans. Typically, guidelines for coverage and reimbursement for a Medicaid patient are the same as for a privately insured patient in the same plan. Payment for services provided to these beneficiaries is determined by each managed care plan according to the provisions of their contract with state Medicaid programs. Call the PHOTOFRIN® Reimbursement Hotline to obtain more information about a patient’s specific policy benefits.
Private Payors

Private insurers’ coverage policies for PHOTOFRIN® and PDT vary. However, unlike Medicare, private insurers often have a prior authorization process in place for procedures and/or drugs. In some cases, prior authorization of drugs may be required before coverage is allowed. Payors may request a letter of medical necessity (LMN). A sample LMN is included as Exhibit 6. If the physician determines that PDT with PHOTOFRIN® is medically necessary, the physician should contact the insurer to verify coverage requirements and request prior authorization if necessary.

If prior authorization is granted, providers should request a certification or authorization number to include on the claim for PHOTOFRIN® and PDT. This will signal the insurer that the services and supplies listed on the claim have already been approved. If you have a question on a specific patient’s coverage policy, please contact the PHOTOFRIN® Reimbursement Hotline.

Unlike Medicare, where reimbursement for supplies and services is standardized by setting of care, private insurers’ reimbursement for professional and facility services, as well as for drugs, varies from plan to plan. However, like Medicare, many private payors base reimbursement for PHOTOFRIN® on the drug’s AWP. Payors generally use AWP data from Medical Economics Data (Red Book), First Databank (Blue Book), or Medispan. You may provide these data to payors when submitting your claim to expedite the reimbursement process. Private insurers’ reimbursement rates typically depend on two things: the reimbursement arrangement outlined in the patient’s policy and any contractual arrangement between the physician and the insurer. You will need to contact the individual insurers to obtain their reimbursement rates for PHOTOFRIN® and the different components of PDT as rates may vary based on patients’ individual policies.

Most private payors follow the same coding conventions for professional services as Medicare. Please refer to Exhibits 1-3 for possible diagnosis and procedure codes, as well as the HCPCS code for PHOTOFRIN®, for use on your claim forms. However, individual payors may have specific coding requirements or restrictions. For example, some payors may require claims to include the National Drug Code (NDC) 0024-1550-01, rather than the HCPCS code for PHOTOFRIN®. If you need information about a patient-specific policy, please call the PHOTOFRIN® Reimbursement Hotline.
Claims Support

Some insurers may require an LMN to consider coverage of PDT with PHOTOFRIN®. The LMN, which includes specific details of a patient’s case history and clinical experience, demonstrates the medical necessity of PHOTOFRIN® for each individual patient and should be submitted with supporting documentation.* A sample LMN is included as Exhibit 6. If you need further information on an insurer’s coverage, reimbursement, or coding policies for PHOTOFRIN®, please contact the PHOTOFRIN® Reimbursement Hotline.

Claims Appeal

Claims may be denied or underpaid for a variety of reasons. The PHOTOFRIN® Reimbursement Hotline staff can assist you in your appeal by investigating the reason for a denied or underpaid claim. Typical reasons for denial include:

- Clerical errors such as misspellings or transposed numbers
- Questions about medical necessity
- Improper use of codes
- Incorrect procedure or product names
- Missing information

Medicare has a formal process that permits providers to appeal denied claims or inadequate reimbursement for drugs and/or services. If your claim for any element of PDT is denied, you will receive an Explanation of Benefits (EOB) from your local Medicare claims processor explaining the reasons for noncoverage. You may resubmit the claim, asking for a redetermination of coverage.

Resubmitted claims should fully document the medical necessity of PDT with PHOTOFRIN® for the patient in question, and include any supplemental information that may not have been included in the original claim.* A sample LMN is included as Exhibit 6. In addition, if the EOB requests additional coding or other information, you should fully comply with these requests. Axcan Scandipharm can provide information on favorable coverage policies for PHOTOFRIN® and PDT already established by Medicare, which you can include with any resubmitted claims.

Complete follow-through on the appeals process educates payors about the medical necessity of PDT with PHOTOFRIN® and contributes to the development of favorable coverage policies for this treatment. If you have received a denial or need further information on insurers’ coverage, reimbursement, or coding policies for PHOTOFRIN®, please contact the PHOTOFRIN® Reimbursement Hotline.

*Please note: Should a payor request the package insert and/or reprints of clinical articles, both are available through Axcan Scandipharm’s PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411.
### Exhibit 1

**Sample Claims Coding for Administration of PHOTOFRIN\(^\circledR\) (porfimer sodium) for Injection**

<table>
<thead>
<tr>
<th></th>
<th>Hospital Inpatient</th>
<th>Hospital Outpatient</th>
<th>Physician’s Office</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of Code</strong></td>
<td>Description</td>
<td><strong>Type of Code</strong></td>
<td>Description</td>
</tr>
<tr>
<td>Revenue code</td>
<td>Administration of PHOTOFRIN(^\circledR)</td>
<td>Revenue code</td>
<td>CPT code</td>
</tr>
<tr>
<td>280</td>
<td>General oncology</td>
<td>280 - General oncology</td>
<td>96408 - Chemotherapy administration intravenous; push technique</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCPCS code</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q0083 - Chemotherapy administration by other than infusion technique only (e.g., subcutaneous, intramuscular, push), per visit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Q0084 - Chemotherapy administration by infusion technique only, per visit</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>ICD-9-CM procedure code</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>99.25 - Injection or infusion of cancer chemotherapeutic substance</td>
<td></td>
</tr>
<tr>
<td>Revenue code</td>
<td>260 - Pharmacy IV</td>
<td>636 - Pharmacy IV</td>
<td></td>
</tr>
<tr>
<td>HCPCS code</td>
<td>J9600 - PHOTOFRIN(^\circledR) (porfimer sodium) per 75 mg</td>
<td>HCPCS code</td>
<td>J9600 - PHOTOFRIN(^\circledR) (porfimer sodium) per 75 mg</td>
</tr>
</tbody>
</table>

*CPT five-digit codes, nomenclature, and other data are copyright 2001 American Medical Association (AMA). All Rights Reserved. No fee schedules, basic unit, relative values, or related listings are included in CPT.*

*These materials are provided for your guidance only. Please call the PHOTOFRIN\(^\circledR\) Reimbursement Hotline at 1-888-PDT-1411 to verify coding and claim information for specific payors.*
### Sample Claims Coding for Photodynamic Therapy (PDT)

#### Procedure Codes for Endoscopy

<table>
<thead>
<tr>
<th>Type of Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT code</td>
<td>43228 Esophagoscopy, rigid or flexible; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure) with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique</td>
</tr>
<tr>
<td></td>
<td>43258 Upper gastrointestinal endoscopy including esophagus, stomach, and either the duodenum and/or jejunum as appropriate; diagnostic, with or without collection of specimen(s) by brushing or washing (separate procedure) with ablation of tumor(s), polyp(s), or other lesion(s) not amenable to removal by hot biopsy forceps, bipolar cautery or snare technique</td>
</tr>
<tr>
<td>ICD-9-CM procedure code</td>
<td>42.33 Endoscopic excision or destruction of lesion or tissue of esophagus</td>
</tr>
</tbody>
</table>

#### Procedure Codes for Bronchoscopy

<table>
<thead>
<tr>
<th>Type of Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT code</td>
<td>31641 Bronchoscopy, (rigid or flexible); diagnostic, with or without cell washing (separate procedure) with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser)</td>
</tr>
<tr>
<td>ICD-9-CM procedure code</td>
<td>32.01 Endoscopic excision or destruction of lesion or tissue of the bronchus</td>
</tr>
<tr>
<td></td>
<td>32.28 Endoscopic excision or destruction of lesion or tissue of the lung</td>
</tr>
</tbody>
</table>

#### Add-on Procedure Codes* for Endoscopic Application of Light

<table>
<thead>
<tr>
<th>Type of Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT code</td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td>96571 Each additional 15 minutes (List separately in addition to code for endoscopy or bronchoscopy procedures of lung and esophagus)</td>
</tr>
</tbody>
</table>

Add-on codes describe additional intra-service work associated with the primary service or procedure, and must never be reported as stand-alone codes. All add-on codes found in CPT are exempt from the multiple procedure modifier -51. Please see CPT 2000, Surgery Guidelines section, for more information. CPT five-digit codes, nomenclature, and other data are copyright 1999 American Medical Association. All Rights Reserved. No fee schedules, basic unit, relative values, or related listings are included in CPT. The AMA assumes no liability for the data contained herein.

* These materials are provided for your guidance only. Please call the PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411 to verify coding and claim information for specific payors.
### Principal ICD-9-CM Diagnosis Codes (All Settings)

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>150</td>
<td>Malignant neoplasm of esophagus</td>
</tr>
<tr>
<td>150.0</td>
<td>Cervical esophagus</td>
</tr>
<tr>
<td>150.1</td>
<td>Thoracic esophagus</td>
</tr>
<tr>
<td>150.2</td>
<td>Abdominal esophagus</td>
</tr>
<tr>
<td>150.3</td>
<td>Upper third of esophagus</td>
</tr>
<tr>
<td>150.4</td>
<td>Middle third of esophagus</td>
</tr>
<tr>
<td>150.5</td>
<td>Lower third of esophagus</td>
</tr>
<tr>
<td>150.8</td>
<td>Other specified part of esophagus</td>
</tr>
<tr>
<td>150.9</td>
<td>Esophagus, unspecified</td>
</tr>
<tr>
<td>162</td>
<td>Malignant neoplasm of trachea, bronchus, and lung</td>
</tr>
<tr>
<td>162.2</td>
<td>Trachea (cartilage or mucosa of trachea)</td>
</tr>
<tr>
<td>162.3</td>
<td>Upper lobe, bronchus or lung</td>
</tr>
<tr>
<td>162.4</td>
<td>Middle lobe, bronchus or lung</td>
</tr>
<tr>
<td>162.5</td>
<td>Lower lobe, bronchus or lung</td>
</tr>
<tr>
<td>162.8</td>
<td>Malignant neoplasm of contiguous or overlapping sites of bronchus or lung whose point of origin cannot be determined</td>
</tr>
<tr>
<td>162.9</td>
<td>Bronchus and lung, unspecified</td>
</tr>
<tr>
<td>197.8</td>
<td>Secondary malignant neoplasm of respiratory and digestive systems, other digestive organs, and spleen</td>
</tr>
<tr>
<td>230.1</td>
<td>Carcinoma in situ of digestive organs, esophagus</td>
</tr>
</tbody>
</table>

Some payor policies specify diagnosis codes for which treatment with PHOTOFRIN® and PDT are covered. For information about specific payor policies, call the PHOTOFRIN® Reimbursement Hotline.
Sample UB-92 for Hospital Outpatient Services for Administration of PHOTOFRIN® (porfimer sodium) for Injection

Field 67:
Enter the appropriate ICD-9-CM diagnosis code (see Exhibit 3). Two examples include 150.3 for malignant neoplasm, esophagus, upper third, and 162.8 for malignant neoplasm, other parts of bronchus or lung. Please note some payor policies specify eligible diagnosis codes for treatment with Photofrin.

Field 68:
Enter ICD-9-CM procedure code and date of Photofrin administration.

Field 42:
Enter revenue code 260 for the Photofrin and 280 for the procedure.

Field 43:
Enter description of the product and the procedure.

Field 44:
Enter J9600-porfimer sodium, 75mg for the Photofrin and the appropriate code for its administration.

Field 46:
Enter the appropriate units of service. Enter 2 units for 150mg of Photofrin.

These materials are provided for your guidance only. Please call the PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411 to verify coding and claim information for specific payors.
Exhibit 5

Sample HCFA-1500 for Administration of PHOTOFRIN® (porfimer sodium) for Injection in Physician’s Office

Block 21: Enter the appropriate ICD-9-CM diagnosis code (see Exhibit 3). Two examples include 150.3 for malignant neoplasm, esophagus, upper third, and 162.8 for malignant neoplasm, other parts of bronchus or lung. Please note some payor policies specify eligible diagnosis codes for treatment with Photofrin.

Block 24, Column E: For each HCPCS or CPT code, insert the number corresponding to the appropriate diagnosis code entered in Block 21.

Block 24, Column G: Enter the appropriate units of service. Enter 2 units for 150 mg of Photofrin.

Block 24, Column D: Enter J9600-porfimer sodium, 75mg for the Photofrin and the appropriate code for its administration.

These materials are provided for your guidance only. Please call the PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411 to verify coding and claim information for specific payors.
Sample Prior Authorization Letter/Letter of Medical Necessity (LMN) for PHOTOFRIN® (porfirmer sodium) for Injection

[To be printed on physician’s letterhead]

[Date]

[Insurer’s Name]
[Street Address]
[City, State, Zip]
Re: [Patient’s Name]
[Patient ID]
[Patient Group #]
[Date of Birth]

Dear [Name of Medical Director]:

I am writing to provide documentation supporting the medical necessity of treating [patient’s name] with photodynamic therapy (PDT) using PHOTOFRIN® (porfirmer sodium) for Injection. PHOTOFRIN® was approved for marketing in the United States by the Food and Drug Administration in December 1995. PHOTOFRIN® is approved in the United States for treatment of esophageal and endobronchial cancer; specifically, for the following indications:

- the palliative treatment 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;

- the reduction of obstruction and palliation of symptoms in patients with completely or partially obstructing endobronchial non-small cell lung cancer (NSCLC); and

- the treatment of microinvasive endobronchial NSCLC in patients for whom surgery and radiotherapy are not indicated.

It is my clinical opinion that [patient’s name] falls into the [specify patient’s diagnosis] group. This letter provides information on PDT with PHOTOFRIN®, along with the patient’s medical history and diagnosis and my rationale for this course of treatment. I have also enclosed a package insert with clinical information to support the use of PDT with PHOTOFRIN® for [patient’s name].

These materials are provided for your guidance only. Please call the PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411 to verify coding and claim information for specific payors.

14 Revised February 2003
Sample Prior Authorization Letter/Letter of Medical Necessity (LMN) for PHOTOFRIN® (porfirmer sodium) for Injection

Product and Treatment Description
Each vial of PHOTOFRIN® (porfirmer sodium) for Injection contains 75 mg of porfirmer sodium as a sterile freeze-dried cake or powder. PDT with PHOTOFRIN® is a two-stage process requiring administration of both drug and light. The first stage of PDT is the intravenous injection of PHOTOFRIN® at 2 mg/kg. Illumination with laser light at [specify light dose] nm wavelength for [specify the number of hours] hours following injection with PHOTOFRIN® constitutes the second stage of PDT. [Provide further information on second laser light application and gentle debridement of residual tumor when applicable.]

Patient’s Diagnosis and History
The history and course of [patient’s diagnosis] for [patient’s name] is as follows: [Insert information concerning the date and method of diagnosis and patient’s complete history, including copies of test results. Include a complete summary of all previous treatment (including treatment response or failure) and documentation of clinical improvements and failures. Also summarize the patient’s clinical course since treatment with PHOTOFRIN® if already treated.]

Treatment Rationale
I recommend PDT and PHOTOFRIN® for [patient’s name] because [he/she] has been diagnosed with [patient’s diagnosis] since [date], and I believe that [he/she] can benefit substantially from the procedure. [Provide further information to support medical necessity, medical efficacy, and positive medical results and quality-of-life improvements resulting from PDT.]

Please feel free to contact me if any additional information is required to ensure the prompt approval of this procedure for [patient’s name].

Sincerely,

[Physician’s Name]

Enclosures

[Please note: To obtain Package insert and reprints of clinical articles contact the PHOTOFRIN® Reimbursement Hotline at 1-888-PDT-1411.]