AMELUZ®
Coding Tipsheet

AMELUZ® & BF-RhodoLED®

Biofrontera
Experts in dermatology
This tipsheet is intended to provide your office with a high-level overview of coding best practices for reporting the use of AMELUZ® (aminolevulinic acid hydrochloride) gel, 10%, for topical use, to payers. Coding guidance varies by payer; contact the patient's health plan directly to verify coding requirements.
AMELUZ® was approved by the US Food & Drug Administration (FDA) on May 10, 2016, for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. AMELUZ® is applied topically by a healthcare provider and used in combination with photodynamic therapy utilizing a BF-RhodoLED® lamp.¹
Until it is assigned a product-specific HCPCS code, use of AMELUZ® may be reported using a miscellaneous (not otherwise classified) billing code such as:

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Definition</th>
<th>Applicable Site(s) of Care and Payer(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>J3490</td>
<td>Unclassified drug</td>
<td>• Physician office (all payers)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Hospital outpatient department (non-Medicare payers)</td>
</tr>
<tr>
<td>C9399</td>
<td>Unclassified drugs or biologics</td>
<td>• Hospital outpatient department (Medicare and some other payers)</td>
</tr>
</tbody>
</table>

See Important Safety Information on Page 6 and accompanying Prescribing Information
Other codes helpful in reporting the use of AMELUZ® and its associated procedures are as follows:

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Code</th>
<th>Code Definition</th>
<th>Site(s) of Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD-10-CM diagnosis code</td>
<td>L57.0</td>
<td>Actinic keratosis</td>
<td>· All sites of care</td>
</tr>
<tr>
<td>National Drug Code (NDC)</td>
<td>10-digit format: 70621-101-01</td>
<td>Per 2 g tube. Each gram of AMELUZ® gel, 10%, contains 100 mg of aminolevulinic acid hydrochloride (equivalent to 78 mg of aminolevulinic acid)</td>
<td>· All sites of care · Retail pharmacy claims · Some specialty pharmacy claims · Physician office and hospital outpatient department (Please note: some payers such as Medicaid require providers to report the 11-digit NDC on medical claims along with the appropriate HCPCS code)</td>
</tr>
<tr>
<td></td>
<td>11-digit format: 70621-0101-01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPT® code</td>
<td>96567</td>
<td>Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session</td>
<td>· Physician office · Hospital outpatient department</td>
</tr>
</tbody>
</table>

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Tips for Filing Claims with Miscellaneous Drug Codes

Payers are likely to require medical professionals to submit additional documentation for claims including a miscellaneous drug code to help determine what drug was administered and whether its use is consistent with the payer's clinical guidelines for coverage. Supporting documentation can be included in the claim or affixed to the claim itself.

Types of information a payer may request include:

- Brand and generic drug names
- 11-digit NDC
- Drug strength and dosage
- Route of administration
- Letter of medical necessity
- AMELUZ® Prescribing Information
- AMELUZ® FDA approval letter
- Copy of the invoice
- Chart notes

\[ \text{direct cost of actinic keratosis management} \]
\[ \$1.2 \text{ BILLION in the US} \]
IMPORTANT SAFETY INFORMATION

AMELUZ® gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED® lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

AMELUZ® should not be used by persons who have known hypersensitivity to porphyrins or any of the components of AMELUZ®, which includes soybean phosphatidylcholine. AMELUZ® should also not be used for patients who have porphyria or photodermatoses.

Eye exposure to the red light of the BF-RhodoLED® lamp during PDT must be prevented by protective eye equipment. Direct staring into the light source must be avoided. AMELUZ® has not been tested on patients with inherited or acquired coagulation disorders. Special care should be taken to avoid bleeding during lesion preparation in such patients. Any bleeding must be stopped before application of the gel. AMELUZ® should not be used on mucous membranes or in the eyes.

Local skin reactions at the application site were observed in about 99.5% of subjects treated with AMELUZ® and narrow spectrum lamps. The most frequent adverse reactions during and after PDT were application site erythema, pain/burning, irritation, edema, pruritus, exfoliation, scab, induration, and vesicles. Most adverse reactions occurred during illumination or shortly afterwards, were generally of mild or moderate intensity, and lasted for 1 to 4 days in most cases; in some cases, however, they persisted for 1 to 2 weeks or even longer. Severe pain/burning occurred in up to 30% of treatments.

AMELUZ® is a prescription drug for topical use. There have been no formal studies of the interaction of AMELUZ® with other drugs. It is possible that concomitant use of other known photosensitizing agents may enhance the phototoxic reaction to PDT. The application area should not exceed 20 cm² and no more than 2 grams of AMELUZ® (one tube) should be used at one time. AMELUZ® increases photosensitivity. Patients should avoid sunlight, prolonged or intense light (e.g., tanning beds, sun lamps) on lesions and surrounding skin treated with AMELUZ® for approximately 48 hours following treatment whether exposed to illumination or not.

Please read the US Full Prescribing Information for AMELUZ® and/or US User Manual of BF-RhodoLED® lamp.

You are encouraged to report side effects of AMELUZ®.

Please contact Biofrontera Inc. at 1-844-829-7434 or FDA at 1-800-332-1088 or www.fda.gov/medwatch.
References

2. Skin Cancer Foundation