curative

Photosensitizing Topical Agents Medical Policy

Drug(s) Applied:	**Ameluz** (aminolevulinic acid hydrochloride 10% topical gel), **Levulan Kerastick** (aminolevulinic acid hydrochloride 20% solution)

Criteria:

Drug(s) Applied are considered medically necessary when the requested drug meets ALL the criteria below:

I. Initial Therapy Criteria

A. Nonhyperkeratotic actinic keratosis as indicated by chart notes within past 180 days

1. Clinical documentation confirms actinic keratosis based on one or more flat or minimally raised rough macules or thin papules **and**
2. ONE of the following:
   a) Patient has tried and failed to adequately respond to topical imiquimod or 5-fluorouracil (5-FU) after a full treatment course or patient has a severe intolerance or contraindication to both agents **or**
   b) Patient has tried and failed to adequately respond to cryosurgery or is not a candidate to receive cryosurgery **and**
3. If for Ameluz, BOTH of the following:
   a) Will be used in combination with red-light photodynamic therapy (PDT) **and**
   b) Application area does not exceed 60 square centimeters and a maximum of 6 grams at a time **or**
4. If for Levulan Kerastick, BOTH of the following:
   a) Will be used in combination with blue-light photodynamic therapy (PDT) **and**
   b) Multiple treatment regions (e.g., upper extremity lesions and face/scalp lesions) are not being treated simultaneously **and**
5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: For Ameluz, 3 months (1 treatment session); For Levulan Kerastick, 8 weeks (1 treatment session)

B. **Superficial basal cell carcinoma** as indicated by chart notes within past 180 days

1. Requested agent is Ameluz **and**
2. Clinical documentation confirms superficial basal cell carcinoma (sBCC) via biopsy **and**

3. Lesions lack any histological evidence of aggressive growth patterns (e.g., severe squamous metaplasia, infiltrative/desmoplastic features or basosquamous features) **and**
4. ONE of the following:
    a) Patient has had an inadequate response to surgery **or**
    b) Patient is not a candidate to receive surgery **and**
5. Patient has tried and failed to adequately respond to topical imiquimod or 5-fluorouracil (5-FU) after a full treatment course or patient has a severe intolerance or contraindication to both agents **and**
6. Will be used in combination with red-light photodynamic therapy (PDT) **and**
7. Application area does not exceed 60 square centimeters and a maximum of 6 grams at a time **and**
8. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 3 months (one PDT cycle consisting of two treatment sessions administered 1 to 2 weeks apart)

II. Continued Therapy Criteria

A. Nonhyperkeratotic actinic keratosis as indicated by chart notes within past 180 days

1. Patient meets the initial therapy criteria above **and**
2. Documented clinical benefit with the requested agent (i.e., less lesions) **and**
3. ONE of the following:
    a) At least 3 months has elapsed since the last Ameluz application **or**
    b) At least 8 weeks has elapsed since the last Levulan Kerastick application **and**
4. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: For Ameluz, 3 months (1 treatment session); For Levulan Kerastick, 8 weeks (1 treatment session)

Coverage for retreatment of the same actinic keratosis treatment site is limited to one renewal (2 total treatments).

B. Superficial basal cell carcinoma as indicated by chart notes within past 180 days

1. Requested agent is Ameluz **and**
2. Patient meets the initial therapy criteria above **and**
3. Documented clinical benefit with the requested agent (i.e., less lesions) **and**
4. At least 3 months has elapsed since the last Ameluz application **and**

5. Prescriber is a specialist or has consulted with a specialist in the area of the patient's diagnosis (e.g., dermatology)

Approval Duration: 3 months (one PDT cycle consisting of two treatment sessions administered 1 to 2 weeks apart)

Coverage is limited to a maximum of two PDT cycles (four total treatment sessions) per treated lesion.

Curative considers all other indications as experimental and investigational including but not limited to prevention of actinic keratoses.

If submitting for medical billing:
J7345, aminolevulinic acid hcl for topical administration 10% gel, (Ameluz), 1 unit = 10 mg
J7308, aminolevulinic acid hcl 20% (Levulan Kerastick), 1 unit = 354 mg