SAMPLE #1: REQUEST FOR PRIOR AUTHORIZATION

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

RE: [Patient Name]
[Patient Address]
[Insurance Plan Name]
[Policy Number/Group ID]

To Whom It May Concern:

I am requesting Prior Authorization to treat my patient, [Patient Name], with Photodynamic Therapy (PDT) using LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% (HCPCS J7308) followed by BLU-U® blue light exposure [select appropriate CPT® code] for treatment of actinic keratoses (ICD-10 L57.0).

LEVULAN KERASTICK as a topical photosensitizing agent followed by BLU-U blue light exposure is an FDA approved treatment for minimally to moderately thick actinic keratoses of the face, scalp, or upper extremities. This process results in the destruction of target lesions. Multiple clinical studies have shown that PDT ultimately results in marked reduction of actinic keratoses. It is my professional opinion this procedure is medically indicated and necessary for my patient because [insert clinical rationale]. Therefore, insurance coverage should be provided.

I would anticipate [insert treatment plan] for optimal results. The codes for the photodynamic destruction of actinic keratoses are L57.0 (ICD-10), [insert appropriate CPT code] (CPT), and J7308 (HCPCS). This procedure is for treatment of [insert lesion description and body site]. Again, we are requesting prior authorization by the plan for this therapy.

Thank you for consideration of this request. Please contact our office with any additional questions or concerns.

Sincerely,

[Physician Signature]

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA

SAMPLE #2: REQUEST FOR CHANGE IN CONTRACTED REIMBURSEMENT RATE

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

[Date]
[Insurance Company Name]
[Insurance Company Address]

Dear Carrier:

Our practice offers Photodynamic Therapy (PDT) with LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% followed by BLU-U® blue light exposure to patients with minimally to moderately thick actinic keratoses (AKs) of the face, scalp, or upper extremities. It is our opinion that PDT provides our patients a safe, effective, and convenient method for treating AKs.

Other treatments for AKs include ablative/destructive therapies such as curettage and cryosurgery or topical therapies such as various fluorouracil formulations (Efudex®, Carac®), imiquimod (Zyclara®), ingenol mebutate (Picato®), and diclofenac (Solaraze®). For patients with multiple AK lesions, which is often the case, topical therapies are most commonly used. LEVULAN KERASTICK as a topical photosensitizing agent followed by BLU-U blue light exposure is an FDA approved treatment for minimally to moderately thick actinic keratoses of the face or scalp. We believe that PDT is a cost effective treatment for multiple AKs. In addition, PDT is an in-office therapy which may enhance patient compliance unlike alternative topical treatments which require application for several weeks. It should also be noted that there is a published analysis concluding that PDT is a very cost-effective treatment of multiple AKs.[1]

This procedure is reported using a HCPCS code and the most applicable CPT® code, as follows:

- HCPCS J7308 — LEVULAN KERASTICK
- CPT 96567 or 96573 — Photodynamic Light Therapy

Medicare currently reimburses our practice:

$_____ for J7308

$_____ for 96567

$_____ for 96573

Our LEVULAN KERASTICK cost is $_____ per stick (requires a patient prescription and can only be used for a single application).

Based upon our current contract with [Commercial Payer], we are being reimbursed:

$_____ for J7308

$_____ for 96567

$_____ for 96573

Despite PDT being a highly beneficial treatment for our patients, at our current contracted rate this therapy is cost prohibitive to our practice when provided to patients covered under this plan.

We respectfully request that you make appropriate adjustments to our contracted rates for J7308 and CPT code(s) [insert CPT codes].

Sincerely,

[Contact Name]
[Practice Name]
[Practice Address]
[Phone/Email]

[1] Gold MH. Pharmacoeconomic analysis of the treatment of multiple actinic keratoses. J Drugs Dermatol. 2008;7(1):23-25

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA

SAMPLE #3: REQUEST FOR REVIEW OF A DENIED CLAIM

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

[Date]
[Insurance Company Name]
[Insurance Company Address]

Dear Carrier:

We are in receipt of a claim denial from [Plan Name] for [Patient Name]. We are requesting a review of this claim denial based upon additional information and documentation provided herein.

The procedure reported on the claim was for Photodynamic Therapy (PDT) utilizing a photosensitizing agent; LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%. The physician applies LEVULAN KERASTICK directly onto the patient's minimally to moderately thick actinic keratoses lesions of the face, scalp, or upper extremities. After the recommended incubation period, the lesions are illuminated by a photodynamic therapy light source. The light exposure causes a cytotoxic reaction with the topical agent that was applied to the lesions, killing the diseased cells.

The claim for services for this patient includes the LEVULAN KERASTICK code (HCPCS code J7308) with procedure code [insert CPT® code] for the BLU-U® blue light photodynamic therapy session. The CPT code is reported per exposure session per day, not for each lesion treated. Medicare and commercial insurers pay separately for the cost of the drug as well as the related procedure when medically necessary.

This treatment is medically indicated for this patient and as such, we ask that the plan reconsider appropriate payment for this procedure.

Should you have questions regarding this procedure or the claim submitted by our office, contact us. Thank you for your prompt attention to this urgent matter. We look forward to a favorable review of this request.

Sincerely,

[Physician Signature]
[Name/Title]
[Address]
[Phone/Email]

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA

SAMPLE #4: REQUEST FOR REVIEW OF A DENIED CLAIM — UPPER EXTREMITIES

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

[Date]
[Insurance Company Name]
[Insurance Company Address]

Dear Carrier:

We are in receipt of a claim denial from [Plan Name] for [Patient Name]. We are requesting a review of this claim denial based upon additional information and documentation provided herein which supports appropriate, on label use of the treatment provided to this patient. Specifically, this is in reference to a newly approved FDA clinical indication for LEVULAN® KERASTICK® to treat upper extremities, effective as of [FDA approval date].

The procedure reported on the claim was for Photodynamic Therapy (PDT) utilizing a photosensitizing agent; LEVULAN KERASTICK (aminolevulinic acid HCl) for topical solution, 20%. The physician applies LEVULAN KERASTICK directly onto the patient's minimally to moderately thick actinic keratoses lesions of the face, scalp, or upper extremities. After the incubation period, lesions are illuminated by a photodynamic therapy light source. The light exposure causes a cytotoxic reaction with the topical agent that was applied to the lesions, killing the diseased cells.

The claim for services for this patient includes the LEVULAN KERASTICK code (HCPCS code J7308) with procedure code [insert CPT® code] for the BLU-U® blue light photodynamic therapy session.

This treatment is medically indicated for this patient and as such, we ask that the plan allow appropriate coverage and payment for ***on label*** use of this procedure.

Please refer to attached LEVULAN KERASTICK Package Insert under "INDICATIONS AND USAGE" section to support the FDA approved indication for treatment of upper extremities, which would include [area treated] for this patient.

Should you have questions regarding this procedure or the claim submitted by our office, please contact us. Thank you for your prompt attention to this urgent matter. We look forward to a favorable review of this request.

Sincerely,

[Physician Signature]
[Name/Title]
[Address]
[Phone/Email]

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA

SAMPLE #5: REQUEST OF APPEAL CPT UPDATES

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

[Date]
[Insurance Company Name]
[Insurance Company Address]

Dear Carrier:

We are in receipt of a claim denial from [PLAN NAME] for patient [PATIENT NAME]. We are requesting a review of this claim denial based upon additional information provided as part of this letter and attached supporting documentation.

The procedure reported on the claim was for photodynamic therapy (PDT) utilizing a photosensitizing agent; LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%. LEVULAN KERASTICK is applied directly onto the patient's lesions to treat premalignant cells, such as non-hyperkeratotic minimally to moderately thick actinic keratoses of the face, scalp, or upper extremities. The lesions are irradiated by photodynamic therapy illumination light source. The light exposure causes a cytotoxic reaction with the topical agent that was applied to the lesions, killing the target cells.

The claim for services for this patient included LEVULAN KERASTICK (HCPCS code J7308) with procedure code [insert CPT® code]. Recently the American Medical Association (AMA) assigned two additional CPT codes for Photodynamic therapy. Effective January 1, 2018 the Center for Medicare & Medicaid Services (CMS) added these new codes to its fee schedule to allow for appropriate reimbursement relative to the clinical designation, time and resources required to perform this treatment. Please see attached clinical notes which support the criteria for CPT code [insert CPT code] considering [insert provider and rationale].

This treatment is medically indicated care for this patient and as such, we ask that the plan reconsider the appropriate payment for this procedure.

Should you have questions regarding this procedure or the claim submitted by our center, please feel free to contact us. Thank you for your prompt attention to this urgent matter. We look forward to a favorable review of this request.

Sincerely,

[Physician Signature]
[Name/Title]
[Address]
[Phone/Email]

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA

SAMPLE #6: LETTER OF MEDICAL NECESSITY

[Physician Name]
[Physician Address]
[Phone Number/Fax Number]

[Date]
[Insurance Company Name]
[Insurance Company Address
[Insurance Company City, State, Zip Code]

Patient: [Patient Name]
Member #: [Patient Member #]
Group #: [Patient Group #]
DOB: [Patient Date of Birth]

RE: Medical Necessity for Photodynamic Therapy with LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20%

Dear Carrier:

The patient listed above has a long standing history of significant precancerous damage resulting in actinic keratoses (ICD-10 L57.0). Due to the large number of actinic keratoses, the patient remains at an elevated risk for the development of squamas cell carcinoma and other skin cancers. During the patient's last office visit, I recommended photodynamic therapy (PDT) for treatment of the numerous actinic keratoses.

PDT is an FDA-approved treatment for actinic keratoses using Levulan Kerastick (HCPCS J7308) as a topical photosensitizing agent followed by BLU-U® blue light exposure [insert CPT® code]. This process results in the destruction of visible or Grade 1/2 actinic keratoses or non-hyperkeratotic lesions. Multiple clinical studies have shown that PDT ultimately results in marked reduction of actinic keratoses. Due to the severity of the patient's actinic keratoses, I believe this medical procedure is medically indicated and necessary and insurance coverage should be provided.

I would anticipate one to two treatments will be medically necessary over an 8-week period for optimal results. The diagnostic and procedural codes for the photodynamic destruction of actinic keratoses are L57.0 (ICD-10), [insert CPT code] (CPT's), and J7308 (HCPCS) respectively. This is for treatment of non-hyperkeratotic lesions of the [body site].

We are requesting prior authorization by the plan for this procedure. Thank you for consideration of this request. Please feel free to contact my office with any additional questions or concerns.

Sincerely,

[Physician Signature]
[Name/Title]
[Address]
[Phone/Email]

LEVULAN® KERASTICK® (aminolevulinic acid HCl) for topical solution, 20% + BLU-U® Blue Light Photodynamic Therapy Illuminator Model 4170

The sample letter above is provided as an example only.

DUSA® a SUN PHARMA company | SUN PHARMA