**Clinical Study Protocol**

A Single-Center, Open-Label Study to Evaluate Tralokinumab in Atopic Dermatitis Subjects Who Experienced Inadequate Response on Dupilumab

**Testing Facility**

Eczema Treatment Center of New Jersey
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**Study Sponsor and Principal Investigator**

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**Institutional Review Board**

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**PROTOCOL SYNOPSIS:**

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|---|---|
| **Study Title** | A Single-Center, Open-Label Study to Evaluate Tralokinumab in Atopic Dermatitis Subjects Who Experienced Inadequate Response on Dupilumab |
| **Sponsors** | Jerry Bagel, MD |
| **Study Objectives** | **Primary Objective:** To assess efficacy of tralokinumab in subjects who had an inadequate response to dupilumab<br>**Secondary Objective:** To assess safety and patient satisfaction of tralokinumab in subjects who had an inadequate response to dupilumab |
| **Study Design** | 24-week study of 20 atopic dermatitis patients who have been treated with dupilumab will receive Tralokinumab 600mg at week 0 followed by 300mg Q2W for 24 weeks.<br>Baseline characteristics for Dupilumab treatment will be captured including IGA, BSA, prior and concomitant therapy as well as Baseline characteristics at tralokinumab initiation.<br>Atopic Dermatitis will be confirmed at screening using the Hanifin and Rajka (1980) diagnostic criteria for AD.<br>A target lesion representative of subject's disease will be selected by the investigator at baseline and photographed throughout the study. |
| **Study Centers** | Eczema Treatment Center of New Jersey<br>59 One Mile Road, East Windsor, NJ 08520 |
| **Study Population** | Adult male and female subjects with moderate-to-severe atopic dermatitis |
| **Main Inclusion Criteria** | Subjects must meet the following criteria to be enrolled in this study:<br>1. Male or female adult ≥ 18 years of age;<br>2. All participants must have prior treatment with dupilumab for atopic dermatitis meeting one of the following conditions:<br>● Participants who stopped dupilumab treatment due to non-response, partial response, loss of efficacy must have been previously treated with dupilumab for at least 12 weeks.<br>● Participants who stopped dupilumab treatment due to intolerance or AEs to the drug may enter the study with no required prior length of dupilumab treatment. AE's must be resolved prior to 1st tralokinumab dose.<br>3. Females of childbearing potential (FCBP) must have a negative urine pregnancy test at Baseline. FCBP who engage in activity in which conception is possible must use one of the approved contraceptive options: hormonal contraception; intrauterine device (IUD); tubal ligation; or partner's vasectomy; Male or female condom diaphragm with spermicide, cervical cap with spermicide, or contraceptive sponge with spermicide. |

| | |
|---|---|
| | 4. Subject is a candidate for systemic therapy.<br>5.Subject must be in general good health as judged by the Investigator, based on medical history, physical examination.<br>6.Able and willing to give written informed consent prior to performance of any study-related procedures. |
| **Main Exclusion Criteria** | Subjects who meet any of the following criteria will be excluded from participation in this study:<br>1. Subjects with previous exposure to tralokinumab.<br>2. Known or suspected hypersensitivity to tralokinumab or any of its excipients.<br>3. Women of childbearing potential who are pregnant, intend to become pregnant, or are lactating.<br>4. Use of tanning beds or phototherapy within 4 weeks of baseline<br>5. Use of systemic therapies (systemic steroids, cyclosporine, oral JAK inhibitors etc.) for atopic dermatitis within 4 weeks<br>6. Patient non-compliant with Dupixent dosing based on investigator discretion.<br>7. Any clinically significant (as determined by the investigator) cardiac, endocrinologic, pulmonary, neurologic, psychiatric, hepatic, renal, hematologic, immunologic disease, or other major disease that is uncontrolled. |
| **Study Visits** | Screening<br>Week 0<br>Week 4<br>Week 8<br>Week 12<br>Week 16<br>Week 20<br>Week 24 |
| **Study Endpoints** | **Primary Endpoints:**<br>Proportion of subjects achieving IGA 0 or 1 at week 16<br>**Secondary Endpoints:**<br>Proportion of subjects achieving IGA 0 or 1 at weeks 20, 24<br>Proportion of patients achieving 50% reduction in BSA at weeks 12, 16, 20 and 24<br>IGA, BSA, Pruritis NRS and DLQI improvement at weeks 0, 4, 8, 12, 16, 20 and 24<br>Adverse Events/Serious Adverse Events (SAE's) |

## 2 ETHICS AND REGULATORY OBLIGATIONS

### 2.1 Institutional Review Board (IRB)

Written IRB approval of this protocol must be obtained before the study is initiated. Compliance with Title 21 of the US Code of Federal Regulations (CFR), Part 56, is required in order to protect the rights and welfare of human subjects involved in this study.

### 2.2 Ethical Conduct of the Study

The study will be conducted in accordance with the ethical principles that have their origins in the Declaration of Helsinki and its amendments. In addition, the study will be performed in compliance with Good Clinical Practices (GCP), including the archiving of essential documents.

### 2.3 Subject Information and Consent

The Informed Consent Form will be reviewed and approved by the IRB. The purpose, duration and possible risks and benefits will be explained to each potential subject. Consent in writing must be obtained from the subject before enrollment into the study. Consents will be signed and dated as required by Title 21 of CFR, Part 50. The consent will also comply with the requirements of the Health Insurance Portability and Accountability Act (HIPAA). The original, signed Informed Consent Form will be retained by the Investigator. A signed copy of the Informed Consent Form will be given to the subject. Each subject will be assigned a subject number that will be used in lieu of the subject's name on further research documentation.

## 3 INTRODUCTION

### 3.1 Overview of Atopic Dermatitis

Atopic Dermatitis (AD) or eczema is a common chronic inflammatory skin disease with a prevalence of 2-10% in adults.[1] AD is often associated with other atopic disorders, such as rhinitis and asthma.[2] Atopic Dermatitis is characterized by chronic, relapsing skin inflammation, a disturbance of epidermal-barrier function that culminates in dry skin, and IgE-mediated sensitization to food and environmental allergens.[3] Immunologically, AD is characterized by excessive T-cell activation. T helper type 2 (Th2) cells produce interleukin (IL)-4, IL-5 and IL-13; and activate eosinophils, basophils and mast cells, as well as immunoglobulin E (IgE)-producing B cells, which are involved in allergic reactions.[4]

### 3.2 Rationale for Treating Atopic Dermatitis with Tralokinumab

Tralokinumab, a fully human monoclonal antibody, specifically neutralizes interleukin-13, a key cytokine driving peripheral inflammation in atopic dermatitis (AD). In phase II studies, tralokinumab combined with topical corticosteroids provided early and sustained improvements in AD signs and symptoms. In two 52-week, randomized, double-blind, placebo-controlled, phase III trials, ECZTRA 1 and ECZTRA 2, adults with moderate-to-severe AD were randomized (3 : 1) to subcutaneous tralokinumab 300 mg every 2 weeks (Q2W) or placebo. Tralokinumab monotherapy was superior to placebo at 16 weeks of treatment and was well tolerated up to 52 weeks of treatment.[5] Dupilumab, a parenterally administered inhibitor of IL-4 and IL-13, is the first biologic drug approved for use in adults with moderate-to-severe atopic dermatitis. While Phase III trials showed improvement in AD symptoms and itch for patients with atopic dermatitis, many patients fail to achieve and/or maintain satisfactory efficacy, have an intolerance to dupilumab treatment or are unable to continue treatment related to insurance coverage. This study aims to explore the effectiveness and safety of tralokinumab (ADBRY) in patients previously exposed to dupilumab for atopic dermatitis.

## 4. STUDY OBJECTIVE

To explore the effectiveness and safety of tralokinumab in subjects who have previously used dupilumab for the treatment of moderate-to-severe atopic dermatitis

## 5. INVESTIGATIONAL PLAN

### 5.1 Overall Study Design and Plan

20 adult subjects with moderate-to-severe atopic with previous exposure to dupilumab will receive tralokinumab loading dose of 600mg (4 150mg syringes) at week 0 followed by tralokinumab 300mg (2 150mg syringes) Q2W for 24 weeks.

### 5.2 Study Population Criteria

Males and females ≥ 18 years of age with moderate-to-severe atopic dermatitis.

#### 5.2.1 Inclusion Criteria

Patients who meet all of the following criteria will be enrolled in the study:

1. Male or female adults ≥ 18 years of age.

2. All participants must have prior treatment with dupilumab for atopic dermatitis meeting one of the following conditions:

● Participants who stopped dupilumab treatment due to non-response, partial response, loss of efficacy must have been previously treated with dupilumab for at least 12 weeks.
● Participants who stopped dupilumab treatment due to intolerance or AEs to the drug may enter the study with no required prior length of dupilumab treatment. AE's must be resolved prior to 1st tralokinumab dose.

3. Females of childbearing potential (FCBP) must have a negative urine pregnancy test at Baseline. FCBP who engage in activity in which conception is possible must use one of the approved contraceptive options: hormonal contraception; intrauterine device (IUD); tubal ligation; or partner's vasectomy; Male or female condom diaphragm with spermicide, cervical cap with spermicide, or contraceptive sponge with spermicide.

4. Subject is a candidate for systemic therapy.

5. Subject must be in general good health as judged by the Investigator, based on medical history, physical examination.

6. Able and willing to give written informed consent prior to performance of any study-related procedures.

### 5.2.2 Exclusion Criteria

Patients will NOT be enrolled in this study if they meet any of the following criteria:

1. Subjects with previous exposure to tralokinumab
2. Subjects with known or suspected hypersensitivity to tralokinumab or any of its excipients.
3. Women of childbearing potential who are pregnant, intend to become pregnant, or are lactating.
4. Use of tanning beds or phototherapy within 4 weeks of baseline
5. Use of systemic therapies (systemic steroids, cyclosporine, oral JAK inhibitors etc.) for atopic dermatitis within 4 weeks
6. Patient non-compliant with Dupixent dosing based on investigator discretion.
7. Subjects who have received live vaccine within 4-weeks prior to Baseline or who intend to receive live vaccine during the study.
8. Active or acute infection requiring systemic antibiotics within 2 weeks of baseline visit.

9. Use of any investigational drug within 8 weeks prior to Baseline or within 5 pharmacokinetic/pharmacodynamic half-lives, if known (whichever is longer).
10. Any clinically significant (as determined by the investigator) cardiac, endocrinologic, pulmonary, neurologic, psychiatric, hepatic, renal, hematologic, immunologic disease, or other major disease that is uncontrolled.

## 5.3 Source of Subjects and Recruitment Methods

The Investigator will manage the recruitment of subjects upon approval of the study by the Institutional Review Board. Subjects may be recruited from internal patient lists and outside IRB approved advertisements.

## 5.4 Subject Enrollment and Treatment Assignment

20 subjects of either gender with moderate-to severe atopic dermatitis will be enrolled to receive open-label tralokinumab

## 5.5 STUDY TREATMENT

### 5.5.1 Tralokinumb (ADBRY)

#### 5.5.1.1 Tralokinumab Description

Tralokinumab ADBRY is an interleukin-13 antagonist indicated for the treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequate controlled with topical prescription therapies or when those therapies are not advisable. ADBRY can be used with or without topical corticosteroids.

#### 5.5.1.2 Tralokinumab Dosing Schedule

For the initial 600 mg dose, administer each of the four ADBRY 150 mg injections at different injection sites within the same body area. For the subsequent 300 mg doses, administer the two ADBRY 150 mg injections at different injection sites within the same body area.. Acceptable injection sites are thighs, abdomen >2 inches from the naval, or the upper arm (administered by medical staff or a caregiver). Subjects may come to the site for site staff to administer IP if they choose not to self-inject.

#### 5.5.1.3 Tralokinumab Dosage Adjustments

If an adverse event that is thought to be related to tralokinumab and is not alleviated by symptomatic intervention, tralokinumab may be temporarily or permanently discontinued. If an adverse event causes the delay of administering tralokinumab, the dose may be

administered once the event has resolved or is stable in the opinion of the investigator. If an Q2W week dose is missed, the patient should administer the injection within 7 days from the missed dose and then resume the patient's original schedule. If the missed dose is not administered within 7 days, instruct the patient to wait until the next dose on the original schedule. Subjects who permanently discontinue tralokinumab under this protocol should receive standard care of atopic dermatitis treatment as prescribed by their physician.

### 5.5.2 Non-Investigational Medicinal Products

Starting from the screening visit, participants will be instructed to use a topical emollient (moisturizer) daily.

### 5.5.3 Permitted Concomitant Therapy

Subjects may continue prescribed topical therapies throughout the trial which will be documented by site staff. Appropriate interventions (e.g., prescribed medications) may be performed as the investigator deems necessary to treat concomitant illnesses and/or safeguard the subjects' wellbeing. No investigational product or device may be used during the study.

## 5.6 Study Procedures

### 5.6.1 Informed Consent

This Study will be conducted in compliance with CFR Title 21, Part 50 (Informed Consent of Human Subjects). Informed consent will be obtained from each subject in writing before participation in the Study. A signed copy of the Informed Consent Form will be provided to each subject. A provision to obtain a signed authorization to provide protected health information to the study sponsor, internal quality assurance agencies, health insurance agencies, and other parties as specified in the Federal Health Insurance Portability and Accountability Act (HIPAA) privacy regulation will be included in the Informed Consent Document. HIPAA authorization is voluntary. However, since the use and release of health information is critical to the conduct of the study, subjects who do not provide authorization to use and disclose their health information will not be enrolled into the study. Subjects who withdraw their authorization to use and release health information during study participation will be formally discontinued from the study. The investigator may use and release at any time all the information collected prior to a subject's withdrawal of the authorization to all authorized parties to satisfy scientific, regulatory, and financial concerns.

### 5.6.2 Inclusion and Exclusion Criteria

Subjects' eligibility to participate in the study will be determined according to the Inclusion and Exclusion Criteria during the screening period (0 – 30 days prior to the first dose of the study drug). Subjects who ultimately do not satisfy the eligibility criteria except changing treatments and undergoing a washout period, will not be enrolled into the study. Investigator will confirm any adverse events experienced on dupilumab treatment will be fully resolved prior to initiating tralokinumab. Subjects who need to meet eligibility requirements will be asked to make the necessary changes. Subjects who agree and comply will be re-evaluated prior to initiation dosing.

### 5.6.3 Demographics and Medical History

The following information will be obtained for each subject during screening: date of birth, sex, race/ ethnic origin, medical and surgical history, year of diagnosis of atopic dermatitis, current atopic dermatitis treatments, and other previous atopic dermatitis treatments within the last 6 months. All current therapies for other medical conditions will be documented. Medical history will be reviewed and updated at the Baseline Visit to ensure that the patient remains eligible to participate in the study.

### 5.6.4 Pregnancy Test

Urine Pregnancy testing will be conducted in all female subjects, except those without childbearing potential (e.g., one-year post-menopause, post-hysterectomy, post-bilateral oophorectomy, etc.) at Screening Visit & Week 0, prior to the first dose of tralokinumab. Subjects with a positive pregnancy test will not be eligible to participate or to continue to receive study treatment.

### 5.6.5 Physical Examination

A physical examination, including vital signs measurements (blood pressure, pulse and temperature), will be performed at each study visit. Any clinically significant abnormalities discovered during physical examinations after the Screening visit should be documented and evaluated as potential adverse events.

### 5.6.6 Investigator's Global Assessment (IGA)

IGA will be determined for all subjects throughout the study. The Investigator's Global Assessment of atopic dermatitis is scored on a 5-point scale (0-4), evaluating global erythema, induration and scaling. *See Appendix A*

### 5.6.8 Body Surface Area (BSA)

BSA will be determined for all subjects throughout the study. The subjects palm will be selected for the measuring unit of body surface area. The physician will equate the number of palms affected by atopic dermatitis to derive the BSA total.

### 5.6.9 Photography

A target region/lesion representative of subject's disease will be selected by the investigator at baseline and photographed at weeks 0, 4, 8 ,12 ,16, 20 & 24.

### 5.6.10 Patient Reported Outcomes

#### *5.6.10.1* Dermatology Life Quality Index (DLQI)

Subjects will complete the Dermatology Life Quality Index (DLQI) at weeks 0, 4, 8, 12, 16, 20 and 24. *See Appendix B*

#### 5.6.10.2 Pruritis Numerical Rating Scale (Pruritis NRS)

Subjects will complete a pruritis numerical rating scale to assess patient itch intensity over the previous 24 hours. Patients will be asked On a scale of 0 to 10, how would you rate your itch overall (on average) during the previous 24 hours? Where 0=no itch and 10=worst imaginable itch. *See Appendix C*

### 5.6.11 Early Discontinuation Procedures

Subjects will be prematurely discontinued from the study under the following conditions:

1. Subject requests to withdraw from the study.
2. Subject is noncompliant with protocol schedule, restrictions, and/or requirements.
3. Subject experiences an adverse event that makes it difficult or intolerable for the subject to continue treatment, or increases risk to the subject, or interferes with the investigator's ability to clinically evaluate the progress of the subject's treatment.
4. Subject begins an unapproved concomitant therapy for atopic dermatitis or another medical condition that may increase risk to the subject if continuing study treatment.
5. Subject cannot be reached / lost to follow-up.
6. The study investigator suspends or terminates the study.
7. Other unanticipated reason.

Any subject who prematurely discontinues the study should complete the week 24 (End of Study) assessments. Any subject who withdraws consent to participate in the study will be removed from further treatment and/or study observation immediately upon the date of request.

# 6 Adverse Events

## 6.1 Adverse Events (AEs)

An adverse event (AE) is any untoward occurrence in a subject, whether or not related to the product. An AE does not necessarily have to have a causal relationship with the study treatment. AEs include events not present at baseline and events that worsened if present at baseline. Hospitalizations for pre-treatment conditions (e.g., elective cosmetic procedures) or surgeries that were planned prior to entry into the study are not considered adverse events. Adverse events, regardless of causality, will be captured from the signing of the Informed Consent Form and for the duration of the subject's participation. Events will be captured as observations from investigator or events reported by subjects from the signing of the informed consent form.

## 6.2 Serious Adverse Events (SAEs)

A **serious adverse event** (SAE) is any untoward medical occurrence that meets one or more of the following criteria according to federal regulations:

a. results in death;
b. is life-threatening (the subject was at risk of death at the time of the event. It does not refer to an event, which hypothetically might have caused death if it were more severe);
c. results in persistent or significant disability or incapacity;
d. requires inpatient hospitalization or prolongation of existing hospitalization;
e. is a congenital anomaly or birth defect;
f. is considered an important medical event (may not be immediately life-threatening or result in death or hospitalization but may jeopardize the subject or may require intervention to prevent one of the outcomes listed in the definition above).

### 6.2.1 SAE Reporting

An **Adverse Event or Suspected Adverse Reaction** is considered ''serious'' if, in the view of either the investigator or sponsor, it results in any of the following outcomes:

- Death;

- A life-threatening adverse event; (Note: the term “life-threatening” as used here refers to an event in which the patient was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe);
- In-patient hospitalization or prolongation of existing hospitalization;
- A persistent or significant disability/incapacity (substantial disruption of the ability to conduct normal life functions);
- A congenital anomaly/birth defect;
- Any “other” important medical event.

Important medical events that may not result in death, be life-threatening or require hospitalization may be considered Serious Adverse Events when, based on appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.

Adverse events will be reported as per local guidelines.

### 6.3 Pregnancy Reporting

The investigator will follow the pregnancy and outcome. Any information gained will be documented in the subject source documents and reported as per local guidelines. Female subjects who become pregnant will be discontinued from study treatment.

## 7 INVESTIGATIONAL PRODUCT HANDLING

### 7.1 Investigational Product Receipt

At study initiation and as needed thereafter, tralokinumab will be shipped to a responsible person at the investigator's institution, who will check the amount and condition of the drug, and maintain a record of this information.

### 7.2 Investigational Product Storage

#### 7.2.1 Tralokinumab Storage

Tralokinumab will be stored between 2-8 degrees Celsius. The study site will monitor and record daily temperatures during business days. At the study site, all IP will be stored in a locked, safe area to prevent unauthorized access.

## 8 RECORD RETENTION

The investigator must retain these documents according to local laws or requirements. Essential documents include, but are not limited to, the following:

- Signed informed consent documents for all subjects;
- Subject screening and enrollment log;
- Record of all communications between the Investigator and the IRB/EC
- List of Sub-investigators and other appropriately qualified persons to whom the Investigator has delegated significant study-related duties, together with their roles in the study, curriculum vitae, and their signatures;
- Copies of CRFs (if paper) and of documentation of corrections for all subjects;
- IP accountability records;
- All other source documents (subject records, hospital records, laboratory records, etc);
- Essential Documents for the Conduct of a Clinical Trial.

### 8.1 Study Monitoring

The investigator will self-monitor all study records for accuracy, completeness, and compliance with the protocol and GCPs and federal regulations. Study site facilities and study records will be made available to regulatory authorities' inspectors if an inspection takes place.

### 8.2 Statistics

It is desired to have approximately n=20 subjects at randomization. Analysis will performed by the Investigator for IGA, BSA, DLQI, Pruritis NRS. The Investigator will also analyze AE's and SAE's.

**Primary Endpoints:**

Proportion of subjects achieving an IGA score of 0 or 1 at week 16

**Secondary Endpoints:**

Proportion of subjects achieving IGA 0 or 1 at weeks 4, 8, 12, 20, 24

Proportion of patients achieving 50% reduction in BSA at weeks 12, 16, 20 and 24

IGA, BSA, Pruritis NRS and DLQI improvement at weeks 0, 4, 8, 12, 16, 20 and AE's/SAE's

#### 8.2.1 Additional Statistical Considerations

Additional statistical procedures may be detailed in and performed according to a separate statistical plan at the discretion of sponsor-investigator.

## Schedule of Assessments

| Procedure | Screening | BASELINE | Week4 | Week 8 | Week 12 | Week 16 | Week 20 | Week 24 |
|---|---|---|---|---|---|---|---|---|
| **Informed Consent** | X | | | | | | | |
| **Demographics/Medical History** | X | X | | | | | | |
| **Inclusion/Exclusion** | X | X | | | | | | |
| **Physical Exam** | X | X | | X | X | X | X | X |
| **Concomitant Medications** | X | X | X | X | X | X | X | X |
| **Adverse Events** | X | X | X | X | X | X | X | X |
| **Urine Pregnancy Test** | X | X | | | | | | |
| **BSA** | X | X | | X | X | X | X | X |
| **IGA** | X | X | | X | X | X | X | X |
| **Itch NRS** | | X | X | X | X | X | X | X |
| **DLQI** | | X | | X | X | X | X | X |
| **Vital Signs** | X | X | | X | X | X | X | X |
| **Photography** | | X | | X | X | X | X | X |
| **IP Dispensing and Accountability** | | X | X | X | X | X | X | X |

## 9 REFERENCES

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# 10. APPENDICES

## Appendix A

Investigator's Global Assessment

**Validated Investigator Global Assessment scale for Atopic Dermatitis**

**vIGA-AD™**

***Instructions:***

*The IGA score is selected using the descriptors below that best describe the overall appearance of the lesions at a given time point. It is not necessary that all characteristics under Morphological Description be present.*

| Score | Morphological Description |
|---|---|
| **0 – Clear** | No inflammatory signs of atopic dermatitis (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present. |
| **1 – Almost clear** | Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting. |
| **2 – Mild** | Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting. |
| **3 – Moderate** | Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present. |
| **4 – Severe** | Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present. |

***Notes:***

*1. In indeterminate cases, please use extent to differentiate between scores.*

*For example:*

- *Patient with marked erythema (deep or bright red), marked papulation and/or marked lichenification that is limited in extent, will be considered "3 – Moderate".*

*2. Excoriations should not be considered when assessing disease severity.*

## Appendix B
## DLQI

**DERMATOLOGY LIFE QUALITY INDEX**

**DLQI**

Hospital No: Date:
Name: Score:
Address: Diagnosis:

**The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick ☑ one box for each question.**

| | | | | |
|---|---|---|---|---|
| **1.** | Over the last week, how **itchy**, **sore**, **painful** or **stinging** has your skin been? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | |
| **2.** | Over the last week, how **embarrassed** or **self conscious** have you been because of your skin? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | |
| **3.** | Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden**? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **4.** | Over the last week, how much has your skin influenced the **clothes** you wear? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **5.** | Over the last week, how much has your skin affected any **social** or **leisure** activities? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **6.** | Over the last week, how much has your skin made it difficult for you to do any **sport**? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **7.** | Over the last week, has your skin prevented you from **working** or **studying**? | Yes<br>No | ❒<br>❒ | Not relevant ❒ |
| | If "No", over the last week how much has | A lot | ❒ | |

| | | | | |
|---|---|---|---|---|
| | your skin been a problem at **work** or **studying**? | A little<br>Not at all | ❒<br>❒ | |
| **8.** | Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives**? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **9.** | Over the last week, how much has your skin caused any **sexual difficulties**? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |
| **10.** | Over the last week, how much of a problem has the **treatment** for your skin been, for example by making your home messy, or by taking up time? | Very much<br>A lot<br>A little<br>Not at all | ❒<br>❒<br>❒<br>❒ | Not relevant ❒ |

**Please check you have answered EVERY question. Thank you.**

**Appendix C**
**Pruritis Numeric Rating Scale**

# PRURITIS NUMERIC RATING SCALE

On a scale of 0 to 10, how would you rate your itch overall (on average) during the previous 24 hours?

Circle One

0 1 2 3 4 5 6 7 8 9 10

0= No Itch 10= Worst itch imaginable