



## **Treatment Protocols\***

#### **Document Control Sheet**

#### **Key Information**

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#### **Revision History**

| Version | Date      | Summary of Changes   |
|---------|-----------|--|
| V5      | 3/11/2022 | 1) Treatment Protocol No 15:   |
|         |           | <ul> <li>Third paragraph, advice around glasses removed and<br/>link to Photonet guidance document around 'Protective<br/>eyewear' inserted.</li> </ul>  |
|         |           | <ul> <li>Two bullet points specifying brand of MPDs removed</li> <li>2) New protocol 'Guidance for MED testing using handheld MED device' added as Treatment Protocol 15b</li> <li>3) Protocol No 18 added: 'Psoralen dosing for oral PUVA treatment'</li> <li>4) Formatting changes inline with NHS Scotland</li> <li>5) Accessibility check</li> </ul> |
|         |           | To note: Protocol15b and 18 (now added to this Treatment Protocols document) were stand-alone documents. These would be removed from the website and QPulse.   |
| V4      |           | Protocol No 17 rewritten   |
| V3      |           | Minor changes  |
| V2      |           | Addition of clinical guideline disclaimer  |
| V1      |           | New Guideline  |

#### Photonet National Managed Clinical Network Treatment Protocols\*

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### Photonet National Managed Clinical Network **Treatment Protocols**\*

\*This guideline is not intended to be construed or to serve as a standard of care. Standards of care are determined based on all clinical data available for an individual case and are subject to change as scientific knowledge and technology advance and patterns of care evolve. Adherence to guideline recommendations will not ensure a successful outcome in every case, nor should they be construed as including all proper methods of care or excluding other acceptable methods of care aimed at the same results. The ultimate judgement must be made by the appropriate healthcare professional(s) responsible for clinical decisions regarding a particular clinical procedure or treatment plan. This judgement should only be arrived at following discussion of the options with the patient, covering the diagnostic and treatment choices available. It is advised, however, that significant departures from the national guideline or any local guidelines derived from it should be fully documented in the patient's case notes at the time the relevant decision is taken (this disclaimer applies to all protocols listed above)

### TREATMENT PROTOCOL No. 1 MED BASED UVB PHOTOTHERAPY (TL-01)

- 1. Determine MED (minimal erythema dose) with readings at 24 hours, +/- 6 hours. If patient's back is too extensively involved (active/flared) to perform MED selected starting dose (as recommended by senior nurse or doctor or if none available *0.025* J/cm<sup>2</sup>) should be given to a small test area, such as one forearm, for first treatment.
- 2. Initial irradiation dose: **70%** of MED.
- 3. UVB treatment will usually be given three times weekly, usually with a minimum of 48 hours interval between treatments. Phototherapist must document administered dose of UVB in J/cm² and exposure time. Reason for non-administration of treatment should also be documented in treatment notes. Face shield should be worn unless otherwise indicated.
- 4. **Increment Regimen**: Increments will be given at each visit, based on a percentage of the previous dose and erythema response as follows:
- a) No erythema give 20% increments. Where patients attending twice weekly, 20% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 48 hours, repeat previous dose then 10% increments.
- c) <u>Grade Two</u> (moderate) well-defined erythema, possibly causing slight manageable discomfort. Postpone one treatment if not completely settled; if settled, repeat previous dose and thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well-defined symptomatic/painful erythema. No treatment and review by doctor when possible. When erythema has completely settled, treat with 50% of previous dose then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent /immediate review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- f) In patients with pigmented skin, erythema and oedema may not always be seen, the patient may complain of heat and skin tightness instead.
- g) If a patient develops facial erythema or unacceptable facial pigmentation, a face shield or sunscreen should be considered and if started used for each treatment thereafter.
- h) If a patient develops itch, encourage use of emollients. If persistent, review by doctor.
- i) If patient develops Polymorphic Light Eruption (PLE), encourage use of emollients and prescribed topical steroids or seek medical advice. Postpone treatment if troublesome and reduce to 10% increments. Consider checking ANA & ENA and seeking medical advice regarding possible biopsy if not definite straightforward PLE.
- 5. **If patient cancels/misses treatment** See missed treatment protocol.
- 6. **Discharge** See discharge protocol.

#### If the patient is receiving UVB for Desensitisation

- Treatment may be given three times weekly or daily
- Exposed sites only should be treated unless otherwise stated by the doctor
- Topical steroid should be applied immediately post treatment if prescribed
- Maximum 15 treatments

# TREATMENT PROTOCOL No. 2 PHOTOCHEMOTHERAPY (PUVA) WITH ORAL PSORALENS HIGH INCREMENT REGIMEN suitable for all conditions EXCEPT Atopic Eczema, PLE, Urticaria and patients taking oral Retinoids

Psoralen tablets to be taken two hours prior to treatment and protective glasses to be worn from the time of taking the tablets for the rest of the daylight hours that day (unless the referrer has requested longer). The average peak phototoxic response after 5-MOP is around 3 hours whereas with 8-MOP it is at 2 hours. For safety reasons (to avoid some patients being treated 2 hours and some 3 hours after taking oral psoralen risking errors) most centres, for consistency, treat 2 hours after any oral psoralen.

- Determine MPD (minimum phototoxic dose) with readings at 96 hours, +/- 6 hours. If patient's back is too extensively involved (active/flared) to perform MPD, starting dose according to doctor's or senior nurse's instructions. Usually, if MPD test not possible the first treatment should be to a test area, such as forearm. If no phototoxic response (no MPD detectable) see relevant local policy, but MPD testing after a higher oral psoralen dose will usually be required.
- 2. Initial irradiation dose: 70% of MPD
- 3. PUVA treatment will be given twice weekly, usually with a minimum of 72 hours interval between treatments, unless patient is attending once weekly.
  - Phototherapist must document administered dose of UVA in J/cm<sup>2</sup>, exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes.
  - Face shield should be worn unless otherwise indicated.
- 4. **Increment Regimen**: increments will be given at each visit based on a percentage of the previous dose and erythema response.
- a) No erythema give 40% increment. Where patient is attending once weekly, 20% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and settles within 72 hours. Repeat previous dose and thereafter reduce to 20% increments, reducing further to 10% increments if necessary.
- c) <u>Grade Two</u> (moderate) well defined erythema, possibly causing slight manageable discomfort. Postpone one treatment and repeat previous dose at the next visit, thereafter reducing to 20% increments, reducing further to 10% if necessary.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and review by doctor where possible. When erythema completely settled, treat with 50% of previous dose then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- f) In patients with pigmented skin, erythema and oedema may not always be seen, but they may complain of heat and skin tightness instead.
- g) If a patient develops nausea, consider changing to 5-MOP tablets or 8-MOP bath/soaks, following discussion with medical staff. If changing psoralen or route of psoralen consider reviewing local protocols.

# TREATMENT PROTOCOL No. 2 – CONTINUED PHOTOCHEMOTHERAPY (PUVA) WITH ORAL PSORALENS HIGH INCREMENT REGIMEN suitable for all conditions EXCEPT Atopic Eczema, PLE, Urticaria and patients taking oral Retinoids

- h) If a patient develops facial erythema or unacceptable facial pigmentation, a face shield or sunscreen should be considered and if started used for each treatment thereafter.
- i) If patient develops itch, encourage use of prescribed topical steroids and emollients. If persistent, review by doctor.
- j) PUVA pain no treatment and review by doctor.
- k) If patient develops Polymorphic Light Eruption (PLE), encourage use of emollients and prescribed topical steroids or seek medical advice. If troublesome, postpone treatment and then repeat previous dose at next visit. Reduce to 10% increments. Consider checking ANA & ENA and seeking medical advice regarding possible biopsy if not definite straightforward PLE.
- 5. **If patient cancels/misses treatments** See missed treatment protocol.
- 6. **Discharge** See discharge protocol.

# TREATMENT PROTOCOL NO. 3 PHOTOCHEMOTHERAPHY (PUVA) WITH ORAL PSORALENS LOW INCREMENT REGIMEN

suitable for patients with Atopic Eczema, Urticaria, PLE or on oral Retinoids

Psoralen tablets to be taken two hours prior to treatment and protective glasses to be worn from the time of taking the tablets for the rest of the daylight hours that day (unless the referrer has requested longer). The average peak phototoxic response after 5-MOP is around 3 hours whereas with 8-MOP it is at 2 hours. For safety reasons (to avoid some patients being treated 2 hours and some 3 hours after taking oral psoralen risking errors) most centres, for consistency, treat 2 hours after any oral psoralen.

- Determine MPD (minimum phototoxic dose) with readings at 96 hours, +/- 6 hours If patient's back is too extensively involved (active/flared) to perform MPD, starting dose according to doctor's or senior nurse's instructions. Usually, if MPD test not possible the first treatment should be to a test area, such as forearm. If no phototoxic response (no MPD detectable) see relevant local policy, but MPD testing after a higher oral psoralen dose will usually be required.
- 2. Initial irradiation dose: 70% of MPD
- 3. PUVA treatment will be given twice weekly, usually with a minimum of 72 hours interval between treatments, unless patient is attending once weekly. Phototherapist must document administered dose of UVA in J/cm², exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes. Face shield should be worn unless otherwise indicated.
- 4. **Increment Regimen**: Increments will be given at each visit based on a percentage of previous dose and erythema response.
- a) No erythema give 20% increments. Where patients attending once weekly, 10% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 72 hours. Repeat previous dose then give 10% increments.
- c) <u>Grade Two</u> (moderate) well defined erythema causing mild but manageable discomfort. Postpone one treatment and then repeat previous dose at next visit; thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and review by doctor where possible. When erythema has completely settled, treat with 50% of previous dose then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- 5. If attending for Desensitisation -

Exposed sites only should be treated unless otherwise stated by the doctor

Topical steroid should be applied immediately post treatment if prescribed, patients should be treated twice weekly for 5 weeks.

- 6. **If patient cancels/misses treatment** See missed treatment protocol
- 7. **Discharge** See discharge protocol

### TREATMENT PROTOCOL No. 4 UVB PHOTOTHERAPY HAND and FOOT (TL-01)

**HANDS** Palms and backs of hands can be treated together or separately. Fingers

should be spread in the centre of the unit. Cuffs should also be used to

protect the untreated areas.

**FEET** Can be treated at the same time as hands or separately. Feet should be in

the centre of the unit.

Treatment is usually given three times a week unless patients prefer twice-weekly treatment. Phototherapist must document administered dose of UVB in mJ/cm², exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes documented.

- 1. **Starting Dose**: No MED is required. Give 0.39J cm<sup>2</sup> as a starting dose unless otherwise decided by doctor.
- 2. **Increment Regimen** increments will be given at each visit based on a percentage of the previous dose and erythema response.
- a) No erythema give 20% increments. Where patients attending twice weekly, 20% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 48 hours. Repeat previous dose then give 10% increments.
- c) <u>Grade Two</u> (moderate) well-defined erythema causing mild but manageable discomfort. Postpone one treatment if necessary and then repeat previous dose, thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and review by doctor where possible. When erythema has completely settled, treat with 50% of previous dose then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- f) In patients with pigmented skin, erythema and oedema may not be seen, but the patient may complain of heat and skin tightness.
- g) If patient develops itch, encourage use of prescribed topical steroids and emollients. If persistent, review by doctor.
- 3. **If patient cancels/misses treatment** See missed treatment protocol.
- 4. **Discharge** See discharge protocol.

### TREATMENT PROTOCOL No. 5 LOCALISED TOPICAL SOAKS (TOPICAL SOAKS /GEL/PAINT)

**For Topical Soaks**, the patient is required to soak using 8-MOP solution for 15 minutes, then wait for a further 30 minutes prior to treatment. If treating legs only, UVA treatment given immediately after soak.

**For Gel**, apply directly to the skin and the patient is required to wait in the department for a further 15 minutes prior to treatment.

PUVA treatment will usually be given twice weekly, with a minimum of 72-hour intervals between treatment, unless patient is attending once weekly.

Phototherapist must document administered dose of UVA in J/cm<sup>2</sup> and exposure time. Reason for non-administration of treatment should also be documented in treatment notes.

#### **TOPICAL SOAKS**

FEET Concentration - 0.75 ml 8-MOP 1.2% solution in 3 litres of water.

Concentration - 0.75 ml of 8-MOP 1.2% solution in 3 litres of water

Concentration - 9 ml of 8-MOP 1.2% solution in 45 litres of water

#### **GEL**

0.005% 8-Methoxypsoralen solution in aqueous gel. Apply a thin layer over the affected areas, care must be taken to avoid applying to surrounding unaffected areas.

#### **PAINT**

0.15% 8-methoxypsoralen solution in a solvent base. Apply sparingly, taking care to avoid unaffected areas. Not to be applied to delicate areas e.g. eyelids, genitalia.

- 1. **Starting Dose** If treating legs only, carry out MPD as for bath PUVA and follow Protocol 7 increment regime.
  - **Topical Soaks** Hands and Feet give 0.3 J/cm² as a starting dose unless otherwise decided by doctor. No MPD is usually required.
  - **Emulsion/Gel/Paint** Give 0.1 J/cm<sup>2</sup> as a starting dose unless otherwise decided by doctor. No MPD is usually required.
- 2. **Increment Regimen** increments will be given at each visit based on a percentage of the previous dose and erythema response.
- a) No erythema give 20% increments. Where patients attend once weekly, 10% increments are given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 72 hours. Repeat previous dose then give 10% increments.
- c) <u>Grade Two</u> (moderate) well defined erythema causing mild but manageable discomfort. Postpone one treatment if necessary and then repeat previous dose; thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and to be reviewed by doctor. When erythema has completely settled, treat with 50% of previous dose, then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).

### TREATMENT PROTOCOL No. 5 – CONTINUED LOCALISED TOPICAL SOAKS (TOPICAL SOAKS /GEL/PAINT)

- f) In patients with pigmented skin, erythema and oedema may not be seen, but the patient may complain of heat and skin tightness.
- g) If patient develops itch, encourage use of prescribed topical steroid and emollients. If persistent, review by doctor.
- h) PUVA pain no treatment and review by doctor.
- 3. **If patient cancels/misses treatment** See missed treatment protocol.
- 4. **Discharge** See discharge protocol

### TREATMENT PROTOCOL No. 6 HAND AND FOOT PUVA WITH ORAL PSORALENS

Psoralen tablets to be taken two hours prior to treatment and protective glasses to be worn for 24 hours during daylight hours following ingestion of psoralen.

PUVA treatment will be given twice weekly, usually with a minimum of 72 hours interval between treatments, unless patient is attending once weekly.

Phototherapist must document administered dose of UVA in J/cm<sup>2</sup>, exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes.

- 1. **Starting Dose** No MPD is usually required to determine start dose (some centres perform MPD as a bioassay to determine that sufficient psoralen is in the skin). Give 0.5 J/cm<sup>2</sup> as a starting dose unless otherwise decided by doctor.
- 2. **Increment Regimen**: increments will be given at each visit based on a percentage of the previous dose and erythema response.
- a) No erythema give 40% increments. Where patients attending once weekly, 20% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 72 hours. Repeat previous dose then continue with 20% increments, reducing to 10% if necessary
- c) <u>Grade Two</u> (moderate) well defined erythema causing mild but manageable discomfort. Postpone one treatment if necessary and then repeat previous dose, thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and reviewed by doctor. When erythema completely settled, treat with 50% of previous dose then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- f) In patients with pigmented skin, erythema and oedema may not always be seen, but the patient may complain of heat and skin tightness instead.
- g) If patient develops itch, encourage use of prescribed topical steroids and emollients. Seek medical advice.
- h) <u>PUVA pain</u> no treatment, encourage use of emollients and review by doctor.
- 3. **If patient cancels/misses treatment** See missed treatment protocol.
- 4. **Discharge** See discharge protocol

#### TREATMENT PROTOCOL No. 7 8-METHOXYPSORALEN BATH PUVA

Prior to MPD or treatment, the patient is required to soak in a bath of 8-MOP solution for 15 minutes. Concentration - 30 ml of 1.2% 8-MOP solution to 150 litres of water.

- 1. Determine MPD (minimum phototoxic dose) with readings at 96 hours
- 2. Initial irradiation dose: 40% of MPD
  - If patient's back is too extensively involved (active/flared) or MPDs are not performed in your unit, starting dose according to doctor's instructions.
- 3. UVA treatment will usually be given twice weekly, with a minimum of 72 hours interval between treatments, unless patients attending once weekly. Phototherapist must document administered dose of UVA in J/cm², exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes.
- 4. **Increment Regimen** increments will be given at each visit based on a percentage of the previous dose and erythema response.
- a) No erythema give 20% increments. Where patients attending once weekly, 10% increments to be given unless otherwise indicated by medical staff.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 72 hours. Repeat previous dose and thereafter reduce to 10% increments.
- c) <u>Grade Two</u> (moderate) well defined erythema, possibly causing slight manageable discomfort. Postpone one treatment and repeat previous dose at next visit, thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) symptomatic/painful erythema. No treatment and reviewed by doctor where possible. When erythema completely settled, treat with 50% of dose then 10% increments thereafter (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor. (All such events should be reported to Photonet, to be included in the national risk register).
- f) In patients with pigmented skin, erythema or oedema may not be seen, but the patient may complain of heat and skin tightness instead.
- g) If a patient develops facial erythema or unacceptable facial pigmentation, a face shield or sunscreen should be considered and if started used for each treatment thereafter.
- h) If patient develops itch, encourage use of prescribed topical steroids and emollients. Seek medical advice.
- 5. **If patient cancels/misses treatments** See missed treatment protocol
- 6. **Discharge** See discharge protocol

### TREATMENT PROTOCOL No. 8 PHOTOTHERAPY UVA (Broadband without Psoralen)

- Determine MED (minimal erythema dose) with readings at 24 hours. If patient's back is too extensively involved (active/flared) to perform MED or your unit does not do MEDs, starting dose according to skin type (using local skin type protocol, if available) or doctor's instructions.
- 2 Initial irradiation dose: 70% of MED.
- 3 Treatment to be given three times weekly, with a minimum of 48-hour interval between each treatment
- 4 Phototherapist must document administered dose of UVA in J/cm², exposure time and erythema grade. Reason for non-administration of treatment should also be documented in treatment notes.
- 5 **Increment Regimen**: Increments will be given at each visit based on a percentage of the previous dose and erythema response
- a) No erythema give 20% increments. Where patients attending twice weekly, 20% increments to be given.
- b) <u>Grade One</u> (mild) barely perceptible and resolves within 48 hours, repeat previous dose then reduce to 10% increments.
- c) <u>Grade Two</u> (moderate) well defined erythema, possibly causing slight but manageable discomfort. Postpone one treatment if not completely settled; if settled, repeat previous dose, thereafter reducing to 10% increments.
- d) <u>Grade Three</u> (severe) well defined symptomatic/painful erythema. No treatment and review by doctor. When erythema has completely settled, treat with 50% of previous dose, then 10% increments (If cause(s) determined to be one(s) others could learn from this should be reported to Photonet, to be included in the national risk register).
- e) <u>Grade Four</u> (very severe) painful erythema usually with bullae. No treatment and urgent review by doctor (All such events should be reported to Photonet, to be included in the national risk register).
- f) If a patient develops facial erythema or unacceptable facial pigmentation, a face shield or sunscreen should be used for each treatment.
- g) If patient develops itch, encourage use of emollients. If persistent, seek medical advice.
- h) In patients with pigmented skin, erythema and oedema may not be seen, but they may complain of heat and skin tightness instead.
- i) If patient develops polymorphic light eruption (PLE), encourage use of emollients and prescribed topical steroids or seek medical advice. If troublesome, postpone treatment, treat with previous dose and reduce to 10% increments.
- 6 If patient cancels/misses treatment See Missed treatment protocol
- 7 **Discharge** see discharge protocol

#### If the patient is receiving UVA for Desensitisation

- Exposed sites only should be treated unless otherwise stated by the doctor
- Topical steroid should be applied immediately post treatment if prescribed
- Maximum 15 treatments
- 10% increments

#### TREATMENT PROTOCOL No. 9 DISCHARGE

Treatment usually continues until the patient is clear, condition is no longer improving, has 4 treatments at MRA (minimal residual activity) or is stopped on medical advice

A letter is sent to the patient's GP on completion of treatment.

The following is only a guide to follow-up care and if in doubt discuss with medical staff

- 1. Patients completing treatment having incurred no problems – discharge to GP
- 2. Patients who have failed to attend – discharge to GP If patient has had problems, discuss with referring doctor
- 3. Patients who are known to flare quickly when treatment is completed should be given an open appointment or an appointment at their referring clinic
- 4. Timely follow up should be arranged with referrer/ medical staff for patients who are taking acitretin (Neotigason) or isotretinoin (Roaccutane). They should have fasting bloods taken at GP surgery prior to attending clinic NB: Ensure the patient has enough tablets to last until next clinic appointment, as these are only available in hospital pharmacy
- 5. Patients attending for desensitisation could be given an appointment for early the following year.

#### TREATMENT PROTOCOL No. 10 **MISSED TREATMENTS**

Ensure treatments have not been cancelled or missed due to erythema, if so follow appropriate protocol increment regimen.

One treatment cancelled/missed -UVB - Continue previous increments.

PUVA - Repeat previous dose then

continue previous increments.

Two treatments cancelled/missed -Repeat previous dose.

Three treatments cancelled/missed -Treat at penultimate dose.

Four to six treatments cancelled/missed -Give 50% of last treatment dose.

DNA for more than two weeks -Discharge to GP or review by medical

Staff

More than three weeks missed due to -

holiday or sickness

Repeat MED/MPD or consult starting

dose

### TREATMENT PROTOCOL No. 11 MAXIMUM DOSE

Patients receiving phototherapy are treated on an incremental regimen up to a maximum dose.

The maximum dose is based on patient comfort and safety.

As a guide, stand-up cubicle treatment times are generally limited to about 15 minutes.

(This equates to approximately 2.4J/ cm² in a UVB cabinet and about 15 J/cm² in a PUVA cabinet).

Sit-down treatment, such as hands and feet, can be longer, up to 30 minutes.

### TREATMENT PROTOCOL No. 12 ADVICE AND TREATMENT OF ERYTHEMA POST-UVB PHOTOTHERAPY

If symptomatic erythema i.e. painful or burning discomfort, cooling emollients should be encouraged and use of a moderately potent topical steroid, e.g. Clobetasone Butyrate 0.05% ("Eumovate")/Betamethasone Valerate 0.025% ("Betnovate 1:4) can be applied twice daily for up to 5 days.

If severe discomfort, a more potent topical steroid cream should be applied in addition to soothing, cooling emollients. Regular paracetamol can be recommended for any systemic symptoms such as shivering.

Patients who have developed severe erythema should be asked to attend the department the following morning, Monday to Friday, for review by medical staff if symptoms/signs not settling.

Out of hours – patients should be given advice on local procedures (such as contacting the dermatology ward if there is 24 hour dermatology on call or other arrangements if dermatology medical staff are not available).

### TREATMENT PROTOCOL No. 13 HOME UVB PHOTOTHERAPY

- 1. Determine MED (minimal erythemal dose) with readings at 24 hours.
- 2. Initial irradiation dose: 70% of MED. If the patient's back is too extensively involved to perform the MED test, the starting dose should be according to the clinician's instructions. Frequently if an MED cannot be done the first treatment is to a small area.
- 3. UVB treatment will be given thrice weekly, with 48-hour minimum interval between treatments (Monday, Wednesday and Friday). The patient will have successfully completed the training programme, which includes three supervised treatments in the Photobiology Unit. Repeat treatment courses = repeat training:
  - 2 day training (including MED reading, and 1 supervised treatment)
- 4. Each patient will be contacted on a fortnightly basis by the Home Phototherapy nurse, and reviewed by a clinician midway through their treatment course (after approximately 12 treatments). Further hospital assessments may be required. Each patient will be assessed by a clinician at the end of his or her treatment course.
- 5. Exposure time, non-administration of UVB and adverse effects (including erythema grade) will be documented by the patient on the Treatment Recording Sheet.
- 6. The patient will follow the Treatment Guidelines Protocol for each treatment.
- 7. If a patient misses/cancels treatment(s), they should be advised of the following:
  - 1-2 treatments: repeat previous treatment time
  - 3 treatments: administer penultimate treatment time
  - 4-5 treatments: administer 60% of the previous treatment time (as decided by the nurse)
  - 2-3 weeks: administer 50% of the previous treatment time (as decided by the nurse)
  - More than 3 weeks: to be decided by clinician
- 8. Only nursing staff trained to operate the Home Phototherapy Equipment should administer treatment during the training period.

# TREATMENT PROTOCOL No. 14 UVB (TL-01) PSORACOMB (FOR SCALP (localised) – TREATMENT)

- 1. Determine the MED (Minimal Erythemal Dose), on mid-upper back, with readings at 24 hours.
- 2. Initial irradiation dose = 70% of MED. If the patient's back is too extensively involved to perform the MED, the starting dose should be according to the clinician's instructions.
- 3. Each patient will undergo a 2-day training programme, which includes 1 supervised treatment using the Psoracomb. A second person may be required to administer treatment to the patient at home. If so, they will attend the department for training with the patient on Day 2 of the programme. The training programme will be extended if the Psoracomb user does not demonstrate an understanding of the treatment guidelines protocol and/or competence in administering treatment.
- 4. The training programme will be repeated for further treatment courses. If someone is to be administering treatment to the patient at home, they will attend with the patient on Day 2 of the training programme.
- 5. Treatment will be administered on alternate days, commencing on Treatment Scale 'A' (20% increments), reducing to Treatment Scale 'B' (10% increments) following erythema.
- 6. Each patient will be contacted on a weekly basis by their Nurse, and reviewed by a clinician every 4 weeks during the treatment course.
- 7. The patient will maintain their treatment recording sheet, documenting each treatment time, missed treatments and any adverse effects.
- 8. ADVERSE EFFECTS
- a) **Grade 1 erythema (mild)** barely perceptible and resolves within 48 hours. Repeat previous dose and reduce to 10% increments.
- b) **Grade 2 erythema (moderate)** well defined erythema causing slight manageable discomfort. Postpone one treatment if not completely settled. If settled, repeat previous dose on next treatment day. Reduce to 10% increments thereafter.
- c) **Grade 3 erythema (severe)** well defined symptomatic/painful erythema. No treatment and review by clinician.
- d) **Grade 4 erythema (very severe)** painful erythema, usually with bullae. No treatment and review by clinician.
- e) Phototherapy for the scalp erythema and oedema may not always be seen because of the patient's hair. They may complain of heat and skin tightness instead.
- f) If the patient develops itch, encourage use of emollients. Patient to be reviewed by clinician if itch persists.

#### 9. MISSED TREATMENTS

If patient cancels or misses:

- 1 or 2 treatments repeat previous dose.
- 3 treatments administer penultimate dose.
- 4 or 5 treatments administer 60% of the last treatment dose.
- 2 or 3 weeks administer 50% of the last treatment dose.
- If more than 3 weeks of treatment is missed, the patient must be reviewed by a clinician, otherwise they will be discharged to their GP or given a review appointment for Dermatology clinic.

\*A copy of the Treatment Time Scales (including treatment times and corresponding doses are filed in each patients' photobiology notes). The Treatment Time Scale sheet given to the patient does not include corresponding doses.

### TREATMENT PROTOCOL No. 15a PROTOCOL TO ESTABLISH MED/ MPD

(Minimum Erythema Dose (MED) & Minimum Phototoxic Dose (MPD)

It is desirable that all patients referred for Phototherapy or Photochemotherapy should have an MED or MPD test performed. This establishes an appropriate starting dose for each individual and identifies any possible abnormal response to light. MPD testing for oral PUVA also ensures that sufficient psoralen has reached the skin to cause a reaction.

Before proceeding, the nurse/ technician performing the MED/ MPD test should check that a referral form has been completed by a clinician and that the patient has consented.

Before MPD testing, it should be ensured that the patient has taken the Psoralen tablets 2 hours previously (or had his/ her Psoralen bath) and if required, has had their sunglasses checked as suitable for PUVA (see <a href="Photonet Guidance">Photonet Guidance</a> document "Protective Eyewear for oral PUVA photochemotherapy").

The MED/ MPD is normally carried out on the back avoiding the paravertebral groove and in an area with little or no background activity and where the back is as straight as possible. This is to ensure even distribution of light during the test itself. If the back area is not suitable, perhaps due to background activity, it may be carried out on the upper buttock area or on the inner arm area.

Apart from the test sites, ensure all other areas are covered and the material used is thick enough to stop any UV transmission. Although the patient will not be facing the UV source, they should still wear protective goggles. The technician/ nurse performing the test must also be adequately protected by wearing protective goggles, sun barrier or long sleeves and whenever possible, standing outwith the angle of irradiance.

MED/ MPD testing can be carried out in a number of ways and using different equipment such as:

- Bank of TL01 or UVA lamps using plastic templates
- Handheld MED Tester

In all these techniques, the skin is exposed to a number of incremental doses of either UVB or UVA radiation using the same type of lamp as for treatment. MED and MPD doses are calculated according to skin type and the times for the selected doses are tabled on a spreadsheet. Outputs are measured regularly and times adjusted accordingly.

After the test has been completed, a tracing of the sites on a polythene map, including any moles or spots as 'landmarks', should be performed. This enables accurate recording of results.

An MED is judged to be the lowest dose to produce just perceptible erythema at 24 hours after testing and an MPD is judged to be the lowest dose to produce perceptible erythema 96 hours after testing. Readings should be performed by experienced staff preferably with access to a wall mounted spotlight and good ambient light levels to ensure readings are carried out effectively.

### TREATMENT PROTOCOL No. 15b GUIDANCE FOR MED TESTING USING HANDHELD MED DEVICE

TL01 MED testing is carried out before a patient starts a course of Phototherapy and is used for the purpose of:

- Establishing a safe and accurate starting dose for treatment.
- Ensuring that the patient has no underlying photosensitivity condition.

The back is usually used for MED testing, avoiding the spine, however if this area is too active, then the inner arm may be used. If the inner arms are not suitable, any other area that is clear of disease may be used. An exception would be a patient with Vitiligo where an area of depigmented skin should be used for MED testing, if possible. If the patient has a tan, then the MED test should be carried out on untanned skin and in the case of fake tanning, the MED test should be delayed until 3 days after application.

#### **Procedure:**

- 1. Appropriate PPE should be worn when using the MED tester if recommended by your local Medical Physics department
- 2. The MED tester should be warmed up prior to testing. The length of time for the warm-up will have been defined by your local Medical Physics department.
- 3. During this warm up period, after checking the name and date of birth, explain the procedure to the patient and decide on the area to be tested.
- 4. After the warm up, place the unit on the area for testing and start the timer for the prescribed length of time on the dosimetry sheet depending upon skin type. Advise the patient that the unit will feel quite warm against the skin initially and hold firmly in place ensuring that all the test apertures are in contact with the skin. The unit can be held upright or horizontally.
- 5. On completion, switch off the unit.
- 6. Mark the outline of the area tested with a skin marker pen, indicating on the skin the position of the highest dose given (i.e. the aperture that is 'open' with no grid over it).
- 7. Using clear polythene, trace the area tested onto this using the spine as a guide and other moles/ freckles to use as landmarks.
- 8. Label the polythene map with the patient details, date and area tested.
- 9. Check the test area after 5 minutes to check for any evidence of immediate abnormal responses.
- 10. The area may still be red from the heat component that has been induced from the unit, however urticarial responses will become evident at this point if present. A clinician should be informed if this is the case.
- 11. The MED tester should be cleaned according to local recommendations and be wiped dry using a paper towel.
- 12. The unit must also have a cool down period and then a further warm up before further testing on another patient can be carried out. This cool down and warm up period will be defined by your local Medical Physics department.

### TREATMENT PROTOCOL No. 15b (Continued) GUIDANCE FOR MED TESTING USING HANDHELD MED DEVICE

- 13. The MED is judged to be the lowest dose to produce just perceptible erythema 24hours (+/- 6hrs) after testing. Readings should be performed by experienced staff preferably with access to a wall mounted tungsten lamp and good ambient light levels to ensure the readings are carried out effectively.
- 14. A clinician should be informed if there is erythema evident at all 10 apertures or if there were any <u>abnormal</u> early (5 minutes) responses.

### TREATMENT PROTOCOL No. 16 TRANSFERRING A PATIENT TO ANOTHER PHOTOTHERAPY UNIT

Although there is good agreement across Scottish Phototherapy Units in relation to UV metering, it is still possible to have a variation of up to ~ 20% in meter readings. Also, the transfer of a patient between units may result in treatments being missed.

On transfer, any previous difficulties with erythema following treatment should be communicated to the new unit (by phototherapy staff) to ensure additional caution is exercised in deciding the dose on transfer. If there have been no such side effects, the following regime is suggested:

#### **Transfer Outwith Health Board**

| On transfer/no missed treatment/ 1 treatment missed | Treat at 20% less than last dose          |
|---|---|
| 2 treatments missed                                 | Treat at 40% less than last dose          |
| 3 treatments missed                                 | Treat at 50% less than last dose          |
| 4 treatments missed                                 | Treat at 60% less than last dose          |
| More than 4 treatments missed                       | Repeat MED/MPD or review by Medical staff |

#### **Transfer Within Health Board**

Transfer of patients between units within regions where the same meter is used or where local variation is known may allow lower reductions to be made than suggested above.

### TREATMENT PROTOCOL No. 17 SKIN CANCER SURVEILLANCE

- Once yearly obtain from Photosys a list of patients considered to be at increased risk
  of skin cancer as a result of phototherapy or PUVA. Currently, Photonet advises
  offering yearly follow-up of all who have had > 500 cumulative UVB treatments or >
  200 PUVA treatments. The Photonet Network office will provide this.
- 2. There is a facility in Photosys to "tag" individual patients who are considered at risk even if they do not fit the minimum Photonet criteria for follow-up. These patients will be included in the list provided by the Photonet office.
- 3. There is a facility in Photosys to note withdrawal from annual skin surveillance at either patient or clinician request. These patients will be removed from the list provided by the Photonet office.
- 4. Individual centres may decide to set more rigorous follow up standards for themselves: for example, a centre might, in the absence of long term (> 25 years) follow up data for this treatment, decide to offer follow up to all who have received > 300 NB-UVB treatments.
- 5. Send a letter to all patients offering a screening appointment (except when they have previously explicitly declined all future offers of follow up on the list).
- 6. Each centre will have its own arrangements for follow-up clinics. Some will add patients at the end of existing clinics; others will arrange 1 or 2 "extra" clinics to accommodate these patients.
- 7. Follow up assessment should include whole body skin examinations. However, the major purpose is to educate patients, and their GPs, that they are considered at probable (or, at least, possible) increased risk of skin cancer development as a result of their treatment. Patients should know that all skin cancers are curable if diagnosed early and that this is the reason for alerting them to the need to seek advice early if they are unsure about any skin lesions.
- 8. Each centre will ensure Photosys is updated to capture that patients have been offered annual skin review.
- 9. The phototherapy centre where last treatments were performed holds responsibility for following up with the patient. If the patient has moved out-of-area, it is suggested that the treatment centre write to both the patient and their new local Dermatology department highlighting the need for skin cancer review. If the new Dermatology department agree to take over responsibility for yearly skin cancer review the patient's treatment centre should be changed on Photosys.

#### APPENDIX TO TREATMENT PROTOCOL No. 17 SUGGESTED ACTION LEVEL CUMULATIVE LIFETIME NUMBER OF NARROW-BAND UVB EXPOSURES

The term "ceiling dose/exposure" is often used but perhaps, wrongly, implies that this is an absolute maximum number of exposures, hence the choice of phrase "action level" here. This is to imply a number of exposures at which careful consideration should always be given as to whether or not further treatments should be given but not an absolute limit.

Guidance on such an action level is difficult to issue in the absence of adequate human data about the carcinogenic risk of narrow-band UVB. Two studies, one of very small numbers of patients,<sup>1</sup> and the other of greater numbers (but of patients who had received only small to moderate numbers of treatments and limited follow-up),<sup>2,3</sup> have not detected any definite increased risk of skin cancer likely to be attributable to narrow-band UVB. Few studies addressing the issue of possible carcinogenicity of broad-band UVB have been conducted but the overall impression has been that any increased risk of skin cancer is low.<sup>4</sup> This was borne out by a recent study of risk of non-melanoma skin cancer attributable to UVB (predominantly broad-band) in the North American PUVA follow-up study cohort.<sup>5</sup> The adjusted (taking into account known risk factors including PUVA exposure) incidence rate ratio for squamous cell carcinoma for >300 vs. <300 UVB treatments was estimated at only 1.37 (95% CI 1.03 to 1.83). Whether or not the risk with narrow-band UVB is lower or higher than with broad-band UVB is not known.

It has been estimated, based on the *assumption* that NB-UVB is as carcinogenic as sunlight, that 1000 treatments, with one treatment course a year, to whole-body (face unshielded during treatment) would lead to a lifetime relative risk of non-melanoma skin cancer of 2.6 The letter in which these estimates were presented considered that a "risk-taker" would accept a relative risk of 2 (i.e. an increase in lifetime risk to 2 in 100 vs. 1 in 100; ISD Scotland National Statistics give prevalence of non-melanoma skin cancers as 0.9%). Recent British Photodermatology Group guidelines using the same estimates suggested that 450 treatments might be a reasonable ceiling dose for whole-body treatment (with the corresponding number for treatments with face-shielded of >1000 treatments)<sup>6</sup> based on the assumption of an "average" attitude to risk. Such an average attitude to risk was conservatively taken as acceptance of a relative risk no higher than 1.5 (i.e. accepting an increase in chance of getting a non-melanoma skin cancer from 2 in 200 to 3 in 200).

On the basis of this limited evidence **500 treatments** would seem to be an appropriate, cautious, action level cumulative number of exposures. This is **not** a lifetime **limit** but a guide as to the cumulative exposure after which particularly careful consideration should be given to the possible risks of NB-UVB versus the risks of alternatives.

#### References

- 1 Weischer M, Blum A, Eberhard F et al. No evidence for increased skin cancer risk in psoriasis patients treated with broadband or narrowband UVB phototherapy: a first retrospective study. *Acta Derm Venereol* 2004; **84**: 370-4.
- 2 Man I, Crombie IK, Dawe RS et al. The photocarcinogenic risk of narrowband UVB (TL-01) phototherapy: early follow-up data. *Br J Dermatol* 2005; **152**: 755-7.
- 3 Hearn RM, Kerr AC, Rahim KF et al. Incidence of skin cancers in 3867 patients treated with narrow-band ultraviolet B phototherapy. *Br J Dermatol 2008;* **159**: 931-5
- 4 Studniberg HM, Weller P. PUVA, UVB, psoriasis, and nonmelanoma skin cancer. *J Am Acad Dermatol* 1993; **29**: 1013-22.
- 5 Lim JL, Stern RS. High levels of ultraviolet B exposure increase the risk of non-melanoma skin cancer in psoralen and ultraviolet A-treated patients. *J Invest Dermatol* 2005; **124**: 505-13.
- 6 Diffey BL. Factors affecting the choice of a ceiling on the number of exposures with TL01 ultraviolet B phototherapy. *Br J Dermatol* 2003; **149**: 428-30.
- 7 Ibbotson SH, Bilsland D, Cox NH et al. An update and guidance on narrowband ultraviolet B phototherapy: a British Photodermatology Group Workshop Report. *Br J Dermatol* 2004; **151**: 283-97.

### TREATMENT PROTOCOL No. 18 GUIDANCE ON PSORALEN DOSING FOR ORAL PUVA TREATMENT

There are two main methods that an individual phototherapy unit may wish to use for determining the dose of psoralen to be given to a patient undergoing oral PUVA (whole body or localised area) treatment for the first time. If a patient has received PUVA before then, unless there has been a major change in body weight, or addition of an enzyme inducing drug, that usually requires an increase in psoralen dose, that patient should be prescribed the same dose as for the last course.

The first method is to use solely the weight of the patient as follows:

- 0.6 mg/Kg body weight for 8-MOP
- or 1.2 mg/Kg for 5-MOP

The second method is to use the estimated body surface area (BSA) as follows:

- 25mg per estimated m<sup>2</sup> body surface area for 8-MOP [1]
- or 50mg per m<sup>2</sup> body surface area for 5-MOP.

This requires a patient to have their weight and height recorded prior to a treatment course being commenced. For more practical use in the clinical setting, Table 1 (following page) is based on the BSA method, and expressed as the dose of 8-MOP to be given for any patient between a weight of 40-137 Kg and height between 108-200 cm. This table assumes 8-MOP is only available as 10 mg tablets.

The decision on which dosing method (weight or BSA) to use is at the discretion of an individual treatment centre and is likely to be influenced by various factors. The more important point of practice is to **consistently use the same method for calculating the psoralen dose for a given patient**, such as when switching from using 8-MOP to 5-MOP (or vice versa). Failure to do so could lead to an unnecessary phototoxic response.

Performing a Minimal Phototoxic Dose (MPD) test prior to initiation of the treatment course in patients will help inform if enough psoralen (8-MOP or 5-MOP) is reaching the skin to cause a therapeutically beneficial phototoxic response. This is irrespective of whether a weight-based or BSA-based approach to calculate psoralen dose is used. Again, the decision on whether to routinely perform MPD test doses is at the discretion of an individual treatment centre and is likely to be influenced by the resources available.

### TREATMENT PROTOCOL No. 18 (Continued) GUIDANCE ON PSORALEN DOSING FOR ORAL PUVA TREATMENT

Table 1. The dose (mg) of 8-MOP based on Height (cm) and Weight (Kg) – taken from Sakuntabhai *et al.* 

|             |        | Height (cm) |      |      |      |      |      |      |      |
|-------------|--------|-------------|------|------|------|------|------|------|------|
|             |        | 108-        | 117- | 126- | 136- | 147- | 159- | 171- | 185- |
|             |        | 116         | 125  | 135  | 146  | 158  | 170  | 184  | 200  |
|             | 40-43  | 30          | 30   | 30   | 30   | 30   | 30   | 40   | 40   |
|             | 44-47  | 30          | 30   | 30   | 30   | 30   | 40   | 40   | 40   |
| Weight (Kg) | 48-52  | 30          | 30   | 30   | 30   | 40   | 40   | 40   | 40   |
|             | 53-57  | 30          | 30   | 30   | 40   | 40   | 40   | 40   | 50   |
|             | 58-63  | 30          | 30   | 30   | 40   | 40   | 40   | 40   | 50   |
|             | 64-70  | 30          | 30   | 40   | 40   | 40   | 40   | 50   | 50   |
|             | 71-77  | 30          | 40   | 40   | 40   | 40   | 40   | 50   | 50   |
|             | 78-85  | 30          | 40   | 40   | 40   | 40   | 50   | 50   | 50   |
|             | 86-93  | 40          | 40   | 40   | 40   | 50   | 50   | 50   | 60   |
|             | 94-103 | 40          | 40   | 40   | 40   | 50   | 50   | 50   | 60   |
|             | 104-   | 40          | 40   | 40   | 50   | 50   | 50   | 60   | 60   |
|             | 113    |             |      |      |      |      |      |      |      |
|             | 114-   | 40          | 40   | 50   | 50   | 50   | 50   | 60   | 60   |
|             | 124    |             |      |      |      |      |      |      |      |
|             | 125-   | 40          | 50   | 50   | 50   | 50   | 60   | 60   | 70   |
|             | 137    |             |      |      |      |      |      |      |      |

#### Reference:

1. Sakuntabhai, A., B.L. Diffey, and P.M. Farr, *Calculation of 8-methoxypsoralen dose according to body surface area in PUVA treatment.* Br J Dermatol, 1995. **133**(6): p. 919-23.