Shared Care Protocol
Topical Tacrolimus (Protopic)

1. Medicine name:

Topical tacrolimus (Protopic ointment) 0.03% and 0.1%

2. Licensed indication(s):

Treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or who are intolerant of conventional therapies such as topical corticosteroids (0.03 and 0.1%)

Treatment of moderate to severe atopic dermatitis in children (2 years of age and above) who fail to respond adequately to conventional therapies such as topical corticosteroids (0.03% only)

3. Scottish Medicines Consortium advice:

Recommended for restricted use within NHS Scotland. Use should be initiated and supervised by dermatologists within secondary care who have experience of treating atopic dermatitis using immunomodulatory therapy. A register of recipients should be established and maintained. (September 2002)

4.* Prescriber details:

Prescription should be initiated and supervised by Dermatologists within secondary care (consultant or specialist registrar). May be prescribed by General Practitioners in primary care after initiation of treatment by dermatologist.

Consultant Responsibilities
Confirm diagnosis and severity of atopic dermatitis
Verify prior conventional therapy unsuccessful
Ask GP to prescribe initial 3-6 week supply of topical tacrolimus
Review response to treatment - within 3 weeks children age 2-16, 6 weeks adults
Ask GP to continue prescribing if initial therapeutic response favourable
Outline written instructions for GP
Ensure inclusion in departmental register
Discuss potential risk of malignancy with patient and/or parents prior to initiation of therapy
Regular patient review - at least annual

GP Responsibilities
Prescription of tacrolimus as recommended by dermatologist
Review response to ongoing treatment as per written instructions from hospital
Stop treatment when skin clears, or if adverse events
Refer back to secondary care if not responding to recommended treatment

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5.* Criteria for patient selection:

Conventional treatment with topical emollient / steroid regimens will continue to be the mainstay of treatment for patients with atopic dermatitis (eczema). Use of topical tacrolimus may however be considered as an alternative to systemic therapy (as is the case with phototherapy) in the following situations:

Body eczema - when requiring continuous use of potent topical steroid

Facial eczema – when requiring continuous use of moderate strength topical steroid

6. Administration details:

Apply thinly to affected areas of the skin only

Each affected region of the skin should be treated with topical tacrolimus until clearance occurs and then treatment should be discontinued. Generally, improvement is seen within one week of starting treatment. If no signs of improvement are seen after two weeks of treatment, the diagnosis of atopic eczema should be re-evaluated and / or further treatment options considered

Topical tacrolimus can be used for short term and intermittent treatment, but continuous long-term treatment should be avoided

Age < 2 years – not recommended

Age 2-16 years – 0.03% ointment once daily for up to three weeks until clear. Twice daily use may occasionally be required as determined by a dermatologist

Age > 16 years - 0.1% ointment twice daily until clear. If symptoms recur, restart 0.1% twice daily. An attempt should be made to reduce the frequency of application to once daily and to use the lower strength 0.03% ointment if clinical condition allows

Do not use under occlusion, especially wet-wrap bandaging

Avoid contact with eyes and mucous membranes

Do not use topical corticosteroids concurrently on areas being treated, although these may be used as a 'rescue' treatment for flares of eczema

7. <u>Contra-indications:</u>

Hypersensitivity to macrolides (eg erythromycin) in general, to tacrolimus or to any of the excipients (White soft paraffin, Liquid paraffin, Propylene carbonate, White beeswax, Hard paraffin

Avoid in genetic epidermal barrier defects, eg Netherton's syndrome (because of increased absorption)

Do not use in pregnancy or if breast-feeding

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	Cautions: **Do not use in immunocompromised patients or those on immunosuppressive therapy** **Do not apply to malignant or potentially malignant skin conditions, eg cutaneous T cell lymphoma** **Do not use when undergoing photo(chem)therapy, or for 2 months after. Advise about sun protection and sun bed avoidance (additional immunosuppression)** **Clear any overt secondary infection prior to use, particularly herpes simplex** **Vaccinations should be administered pre-treatment, or 14 days (28 days for live vaccines) after treatment ceases** **Use with caution in patients taking drugs that inhibit CYP 3A4 enzyme (eg erythromycin, itraconazole, diltiazem) and in those with hepatic dysfunction**
8.	**Side-effects** **Burning sensation, pruritus, erythema, sensation of warmth and tingling are common** **Facial flushing after consumption of an alcoholic beverage** **Increased risk of folliculitis, acne and herpes viral infections** **Lymphadenopathy – monitor to ensure that resolves. Investigate / stop tacrolimus if persists.**
9.	**Contact points** **Dr G Lowe Consultant Dermatologist Ninewells Hospital 01382 633901** **Dr S Lewis-Jones Consultant Dermatologist Ninewells Hospital 01382 633901** **Ms A Coulson Principal Clinical Pharmacist Specialist Services 01382 660111 Bleep 4861** **Ms K Stephen Senior Charge Nurse Dermatology Ninewells Hospital 01382 633901**
10.	**Review date: December 2007**

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