Berkshire West Integrated Care System
Representing
Berkshire West Clinical Commisioning Group
Royal Berkshire NHS Foundation Trust
Berkshire Healthcare NHS Foundation Trust
Berkshire West Primary Care Alliance

Prescribing Guidelines

Prescribing arrangement for the management of patients transferring from ***Secondary Care to Primary Care***

Topical tacrolimus (Protopic) for the treatment of moderate to severe atopic dermatitis in adults not responding to conventional therapies

APC PG 031

For the latest information on interactions and adverse effects, always consult the latest version of the Summary of Product Characteristics (SPC), which can be found at: http://www.medicines.org.uk/

Approval and Authorisation

Approved by	Job Title	Date
BW Area Prescribing Committee	A Penn, Chair	January 2017
GP Medicines Optimisation Committee	W Beecham, Chair	January 2017
RBH Drugs and Therapeutics Committee	S Hussain, Chair	April 2017

Change History

Version	Date	Author	Reason
v.1.0	January 2017	A Scott	New Document
v.1.0	October 2017	n/a	Update to APC category

This prescribing guideline remains open to review considering any new evidence.

This guideline should only be viewed online and will no longer be valid if printed off or saved locally

Author	Amaka Scott	Date of production:	November 2016
Job Title	Lead Interface Pharmacist	Review Date	April 2016
Protocol Lead	Dr Mehra, RBFT	Version	v.1.0

Introduction

Topical tacrolimus is licensed for the 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% strengths)

It is also licensed for the 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% strength only)

Use should be initiated and supervised by dermatologists within secondary care who have experience of treating atopic dermatitis using immunomodulatory therapy

Principles of shared care

This shared care agreement outlines suggested ways in which the responsibilities for managing the prescribing of topical tacrolimus can be shared between the consultant and general practitioner (GP). GPs are invited to participate. If the GP is not confident to undertake these roles, then he or she is under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed condition remains with the consultant. If the consultant asks the GP to prescribe this drug, the GP must reply to this request as soon as practicable confirming whether or not they are happy to do so.

Sharing of care assumes communication between the consultant, GP and patient. The intention to share care should be explained to the patient by the doctor initiating treatment. It is important that patients are consulted about treatment and are in agreement with it.

Shared Care is only appropriate if it provides the optimum solution for the patient.

The doctor who prescribes the medication legally assumes clinical responsibility for the drug and the consequences of its use**.**

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 in writing to continue prescribing if initial therapeutic response favourable. Recommended drug and dosage must be stated. 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

CONSULTANT Responsibilities
General Practitioner 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

Patient's role (or that of carer)
Adhere to treatment as advised by the specialist. Report any adverse events to the doctor who last administered their injection.

SUPPORTING INFORMATION

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

Administration

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

Contraindications
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)

Cautions
Do not apply to malignant or potentially malignant skin conditions, eg cutaneous T cell lympho
Do not use when undergoing photo(chem)therapy, or for 2 months after. Advise about sur (additional immunosuppression)

Clear any overt secondary infection prior to use, particularly herpes simplex
treatment ceases
Use with caution in patients taking drugs that inhibit CYP 3A4 enzyme (eg erythromycin, itrac
hepatic dysfunction

Pregnancy and breastfeeding
Do not use in pregnancy or if breast-feeding

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

Contact Information

Royal Berkshire Foundation Trust Hospital, 0118 322511	
Lead Consultant	
Lead Nurse	
Medicines Information	