The Shrewsbury and Telford Hospital NHS
NHS Trust

Shropshire Clinical Commissioning Group

Telford and Wrekin Clinical Commissioning Group

Topical Tacrolimus or Pimecrolimus for the treatment of mild, moderate or severe atopic eczema. Effective Shared Care Agreement

A Copy of this page signed by all three parties should be retained in the patient's trust clinical notes.

Section 1: Shared Care arrangements and responsibilities

Section 1.1 Agreement to transfer of prescribing of tacrolimus or pimecrolimus to GP

Patient details

Name: _____

Address: _____

Date of Birth: _____

NHS number: _____

Contact details
Consultant:
Address:

Email:

Contact number:

GP

Address:

Email:

Contact number:

Patient

Name:

Contact number:

Agreement to shared care, to be signed by GP and Consultant before prescribing is transferred to GP

Consultant Signature: _____

Date: _____

GP Signature: _____

Date: _____

Patient Signature: _____

Date: _____

Section 1.2:

Shared Care Guideline

Indication

Tacrolimus:

Adults and adolescents (16 years of age and above)

Treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

Children (2 years of age and above)

Treatment of moderate to severe atopic dermatitis in children who failed to respond adequately to conventional therapies such as topical corticosteroids.

Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).

Pimecrolimus:

Treatment of patients aged 2 years and over with mild or moderate atopic dermatitis where treatment with topical corticosteroids is either inadvisable or not possible. This may include:

• Intolerance to topical corticosteroids

• Lack of effect of topical corticosteroids

• Use on the face and neck where prolonged intermittent treatment with topical corticosteroids may be inappropriate

Areas of responsibility for shared care

This shared care agreement outlines the ways in which the responsibilities for managing the prescribing of tacrolimus or pimecrolimus can be shared between the specialist 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's health remains with the specialist. **If a specialist asks the GP to prescribe, the GP should reply to this request as soon as practicable.**

Sharing of care assumes communication between the specialist, 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.

The prescriber of the medication legally assumes clinical responsibility for the drug and the consequences of its use.

Referral and initiation

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

- Tacrolimus or Pimecrolimus should be initiated by a relevant specialist within dermatology or GPwSI for use within its licensed indications and can be continued by a primary care prescriber in line with this shared care protocol.
- The specialist should initiate therapy in secondary care and request that the patient and their GP consent to shared care allowing the transfer of prescribing responsibility.

RESPONSIBILITIES AND ROLES

Specialist responsibilities
1. Discuss benefits and side effects of treatment with the patient
2. Ensure that the patient has given informed consent for this treatment
3. Review current medication for potential drug interactions
4. Prescribe initial tacrolimus or pimecrolimus treatment
5. Forward a copy of this guideline to GP with a request for sharing care and signed statement that, at initiation, counselling and discussion around shared care had taken place with the patient.
6. If the GP does not accept shared care the total clinical responsibility for the patient for the diagnosed condition remains with the specialist. Ensure appropriate follow-up in conjunction with the GP.
7. Advise GPs on when to stop treatment
8. Communicate promptly with the GP when treatment is changed or needs to be changed by the GP, and any results of monitoring undertaken
9. Ensure that procedures are in place for the rapid re-referral of the patient by the GP
10. Report adverse events to the MHRA.
11. Ensure that clear backup arrangements exist for GPs to obtain advice and support.

General Practitioner responsibilities
1. Reply to the request for shared care as soon as practicable.
2. Confirm that the specialist has discussed shared care arrangements with the patient.
3. Prescribe tacrolimus or pimecrolimus as recommended.
4. Check for possible drug interactions when prescribing new medication and avoid prescribing interacting drug
5. Report to and seek advice from the specialist on any aspect of patient care that is of concern and may affect treatment.
6. Refer patient to specialist if his or her condition deteriorates
7. Stop treatment on the advice of the specialist
8. Report adverse events to the specialist and MHRA

Patients / Carers role
1. To use tacrolimus or pimecrolimus as prescribed unless advised by GP or specialist
2. To attend schedules appointments with consultant and GP and for monitoring as detailed above.
3. Report to the specialist or GP if he/she does not have a clear understanding of the treatment.
4. Share any concerns in relation to treatment.
5. Patients should immediately report any adverse effects to the specialist or GP.

Section 2:

Supporting information

See Summary of Product Characteristics (SPC) tacrolimus (Protopic 01% or 0.03%) pimecrolimus (Elidel 10 mg/g cream) for full prescribing information
www.emc.medicines.org.uk

Licensed Indication

Tacrolimus

Adults and adolescents (16 years of age and above)

Treatment of moderate to severe atopic dermatitis in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

Children (2 years of age and above)

Treatment of moderate to severe atopic dermatitis in children who failed to respond adequately to conventional therapies such as topical corticosteroids.

Maintenance treatment

Treatment of moderate to severe atopic dermatitis for the prevention of flares and the prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to a maximum of 6 weeks treatment of twice daily tacrolimus ointment (lesions cleared, almost cleared or mildly affected).

Pimecrolimus

Treatment of patients aged 2 years and over with mild or moderate atopic dermatitis where treatment with topical corticosteroids is either inadvisable or not possible. This may include:

• Intolerance to topical corticosteroids

• Lack of effect of topical corticosteroids

• Use on the face and neck where prolonged intermittent treatment with topical corticosteroids may be inappropriate

Dosage and administration

Tacrolimus:

Protopic is available in two strengths, Protopic 0.03% and Protopic 0.1% ointment.

Adults and adolescents (16 years of age and above).Treatment should be started with Protopic 0.1% twice a day and treatment should be continued until clearance of the lesion. If symptoms recur, twice daily treatment with Protopic 0.1% should be restarted. An attempt should be made to reduce the frequency of application or to use the lower strength Protopic 0.03% ointment if the clinical condition allows.

Generally, improvement is seen within one week of starting treatment. If no signs of improvement are seen after two weeks of treatment, further treatment options should be considered.

Children (2 years of age and above) should use the lower strength Protopic 0.03% ointment.

Treatment should be started twice a day for up to three weeks. Afterwards the frequency of application should be reduced to once a day until clearance of the lesion (see section 4.4).

Protopic ointment should not be used in children aged below 2 years until further data are available.

Patients who are responding to up to 6 weeks treatment using tacrolimus ointment twice daily (lesions cleared, almost cleared or mildly affected) are suitable for maintenance treatment.

Adult patients should use Protopic 0.1% ointment.

Protopic ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas commonly affected by atopic dermatitis to prevent progression to flares. Between applications there should be 2–3 days without Protopic treatment.

After 12 months treatment, a review of the patient`s condition should be conducted by the physician and a decision taken whether to continue maintenance treatment in the absence of safety data for maintenance treatment beyond 12 months.

If signs of a flare reoccur, twice daily treatment should be re-initiated (see flare treatment section above).

Children (2 years of age and above) should use the lower strength Protopic 0.03% ointment.

Protopic ointment should be applied once a day twice weekly (e.g. Monday and Thursday) to areas commonly affected by atopic dermatitis to prevent progression to flares. Between applications there should be 2–3 days without Protopic treatment.

The review of the child`s condition after 12 months treatment should include suspension of treatment to assess the need to continue this regimen and to evaluate the course of the disease.

Protopic ointment should not be used in children aged below 2 years until further data are available.

Pimecrolimus

Children and adolescents (2-16 years)
Apply a thin layer to the affected skin twice daily and rub in gently and completely. Each affected region of the skin should be treated with pimecrolimus until clearance occurs and then treatment should be discontinued.
Pimecrolimus cream may be used on all skin areas, including the head and face, neck and intertriginous areas, except on mucous membranes.
Emollients can be applied immediately after using pimecrolimus cream.

Contraindications

Tacrolimus and Pimecrolimus cream are contraindicated in patients with a known hypersensitivity to the drug, other macrolactams or any of the excipients

Special Precautions

Tacrolimus

- Due to the theoretical risk of skin cancer exposure of the skin to sunlight should be minimised and the use of ultraviolet (UV) light from a solarium, therapy with UVB or UVA in combination with psoralens (PUVA) should be avoided during use of tacrolimus oint.
- Emollients should not be applied to the same area within 2 hours of applying tacrolimus oint. Before commencing treatment with topical tacrolimus, clinical infections at treatment sites should be cleared.
- Transplant patients receiving immunosuppressive regimens (e.g. systemic tacrolimus) are at increased risk for developing lymphoma; therefore patients who receive topical tacrolimus and who develop lymphadenopathy should be monitored to ensure that the lymphadenopathy resolves. In the absence of a clear aetiology for the lymphadenopathy or in the presence of acute infectious mononucleosis, discontinuation of Protopic should be considered.
- Tacrolimus ointment should be used with caution in patients with hepatic failure.
- Tacrolimus oint should not be used in patients with Netherton's Syndrome (rare epidermal barrier defect).

Pimecrolimus

Pimecrolimus cream should not be used in:

- congenital or acquired immunodeficiencies
- patients on therapies that cause immunosuppression.

- potentially malignant or pre-malignant skin lesions.
- acute cutaneous viral infections (herpes simplex, chicken pox).
- clinical infections at treatment sites
- patients with Netherton's syndrome
- patients requiring occlusive dressings.

- Patients with severe atopic dermatitis may have an increased risk of skin bacterial infections (impetigo) during treatment with pimecrolimus cream.
- Use of pimecrolimus cream may cause mild and transient reactions at the site of application, such as a feeling of warmth and/or burning sensation. If the application site reaction is severe, the risk-benefit of treatment should be re-evaluated.
- Care should be taken to avoid contact with eyes and mucous membranes. If accidentally applied to these areas, the cream should be thoroughly wiped off and/or rinsed off with water.
- Physicians should advise patients on appropriate sun protection measures, such as minimisation of the time in the sun, use of sunscreen product and covering the skin with appropriate.
- Pimecrolimus cream contains cetyl alcohol and stearyl alcohol which may cause local skin reactions. It also contains propylene glycol, which may cause skin irritation.
- Cases of malignancies, including cutaneous and other types of lymphoma, and skin cancers have been reported in patients using pimecrolimus cream. However, patients with atopic dermatitis treated with pimecrolimus cream have not been found to have significant systemic pimecrolimus levels.

Side effects

The most common adverse effects are application site burning, irritation, pruritus, erythema, skin infections and hyperparasthesia. Post marketing cases of malignancy, including cutaneous and other types of lymphoma and skin cancers have been reported in patients using tacrolimus and pimecrolimus cream.
The summary of product characteristics should be consulted for full information with respect to adverse effects and drug interactions.

Drug Interactions

Tacrolimus

Formal topical drug interaction studies with tacrolimus ointment have not been conducted. Tacrolimus is not metabolised in human skin, indicating that there is no potential for percutaneous interactions that could affect the metabolism of tacrolimus. There is no experience of concomitant use of systemic steroids or immunosuppressive agents.

Vaccinations – The SPC states "Because of the potential risk of vaccination failure, vaccination should be administered prior to commencement of treatment, or during a treatment-free interval with a period of 14 days between the last application of tacrolimus oint and the vaccination. In the case of live attenuated vaccination this period should be extended to 28 days or the use of alternative vaccines should be considered".

Pimecrolimus

Pimecrolimus is exclusively metabolised by CYP 450 3A4. Based on its minimal extent of absorption, interactions of pimecrolimus cream with systemically administered medicinal products are unlikely to occur.

The present data indicate that pimecrolimus cream can be used simultaneously with antibiotics, antihistamines and corticosteroids (oral/nasal/inhaled).

Based on the minimal extent of absorption, a potential systemic interaction with vaccination is unlikely to occur. However, this interaction has not been studied. Therefore, in patients with extensive disease, it is recommended to administer vaccinations during treatment-free intervals.

There is no experience with concomitant use of immunosuppressive therapies given for atopic eczema such as UVB, UVA, PUVA, azathioprine and cyclosporin A. Pimecrolimus cream has no photocarcinogenic potential in animals. However, since the relevance to man is unknown excessive exposure of the skin to ultraviolet light including light from a solarium, or therapy with PUVA, UVA or UVB should be avoided during treatment with pimecrolimus cream.