CLINICAL GUIDELINE

Dupilumab for Moderate to Severe Atopic Dermatitis (Eczema)

A guideline is intended to assist healthcare professionals in the choice of disease-specific treatments.

Clinical judgement should be exercised on the applicability of any guideline, influenced by individual patient characteristics. Clinicians should be mindful of the potential for harmful polypharmacy and increased susceptibility to adverse drug reactions in patients with multiple morbidities or frailty.

If, after discussion with the patient or carer, there are good reasons for not following a guideline, it is good practice to record these and communicate them to others involved in the care of the patient.

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Important Note:

The online version of this document is the only version that is maintained.
Any printed copies should therefore be viewed as 'Uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

NHS GGC Dupilumab Protocol for Moderate-to-Severe Atopic Dermatitis (Eczema)

Dupilumab Indication:

Dupilumab is a recombinant human IgG4 monoclonal antibody which inhibits the signaling of the interleukin cytokines, IL-4 & IL-13. It is licensed for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy.

Evidence for dupilumab use in atopic dermatitis comes from the randomized, double-blind, placebo controlled phase III studies; CHRONOS[1], SOLO 1[2], SOLO 2[2] and CAFÉ[3]. Eligible patients had baseline Investigator's Global Assesment (IGA)≥3 or eczema area severity index (EASI) score ≥16 (20 in CAFÉ). Main outcome measures were a reduction in IGA from baseline of ≥2 points and 75% improvement in EASI from baseline at 16 weeks.

Scottish Medicines Consortium (SMC) Advice:

Following SMC review, dupilumab has been accepted for resticted use in Scotland for the treatment of moderate-to-severe atopic dermatitis in patients older than 12 years who are candidates for systemic therapy who have had inadequate response to existing systemic immunosuppressants e.g. cyclosporin, or in whom such treatment is considered unsuitable[4].

NHS GGC eligibility criteria

For NHS GGC the decision to initiate dupilumab therapy for moderate-to-severe atopic dermatitis is restricted to a Consultant or Associate Specialist Dermatologist in adult patients who have failed or have a contra-indication to at least two of the standard systemic treatments normally used; cyclosporin, methotrexate, UVB.

Patient Assessment prior to starting dupilumab

Document the following:

- Age of onset of eczema
- Previous treatments including duration, disease control, adverse effects and reason for discontinuation.
- Co-morbidities (atopic and other)
- History of skin infection esp. HSV/ Eczema herpeticum
- History of dry eyes
- Concomitant medication
- Contraception status (females)

Pre-screening/ baseline

- Check U&Es, LFTs, FBC, Hepatitis B, Hepatitis C, HIV and Varicella serology – if a positive BBV result is recorded this should be discussed with Infectious Diseases; is negative Varicella serology is recorded prophylactic Varicella immunisation should be considered.

- Record if current infection
- Record the following disease severity scores at baseline:

  Eczema area severity index (EASI)
  Dermatology Life Quality Index (DLQI)/ CDLQI if < 16yrs)
  Patient Orientated Eczema Measure (POEM)

Prescription

Prescribe dupilumab, initiated via Homecare prescription completion. Homecare supply includes nurse demonstration for drug administration at home. A centralized database of patients will be kept to allow uploading of details to the A-STAR registry.

Please inform the patient's GP that this medicine is being prescribed by Acute and supplied to the patient via home delivery services. Within General Practice it is beneficial for patient and prescriber safety to ensure that a patient's medicine record includes medicines that may be prescribed and supplied outwith the GP practice.

Drug Preparation

- Pre-filled pen of dupilumab 300mg in 2ml

Dosage and Administration

Adults
Initial dose: 600 mg of Dupilumab (two 300mg injections) to be administered by subcutaneous injection
Maintenance dose: 300mg of Dupilumab every other week to be administered by subcutaneous injection
Adolescents (12 to 17 years of age)
Body weight <60kg
Initial dose: 400mg (two 200mg injections) of Dupilumab to be administered by subcutaneous injection
Maintenance dose: 200mg of Dupilumab every other week to be administered by subcutaneous injection
Body weight ≥ 60kg
Initial dose: 600mg of Dupilumab (two 300mg injections) to be administered by subcutaneous injection
Maintenance dose: 300mg of Dupilumab every other week to be administered by subcutaneous injection

Contraindications

Hypersensitivity to the active substance or to any of the excipients.

Side effects of treatment

Common side effects include injection site reactions, headache, conjunctivitis (both infective & allergic), and blepharitis.

Adjuvant prescribing

All patients to be encouraged to use prophylactic eye lubricants – Hyloforte eye drops 4 times per day prophylactically for 2 weeks before starting Dupilumab

Patient monitoring whilst receiving dupilumab

Monitoring will be the responsibility of the dermatology service. Patients should be reviewed at the following time points:

8 weeks

Adverse effects – (if eye symptoms are present (redness, burning, itch) increase Hyloforte drop use to 8 times per day and if symptoms are significant consider referral by Dermatologist to Acute Referral Centre for Ophthalmology **)**

Check U and E, LFT, FBC

16 weeks

- Adverse effects – especially eye side effects – if eye symptoms are present (redness, burning, itch) increase Hyloforte drop use to 8 times per day and if symptoms are significant consider referral to Acute Referral Centre for Ophthalmology

- EASI and POEM
- DLQI
- Check UE, LFT and FBC

Dupilumab to continue if EASI score has reduced by at least 50% from baseline and DLQI improved by 4 points.

Monitoring of Dupilumab Treatment Response

6 monthly thereafter –

- Adverse effects
- EASI
- DLQI
- Check U&Es, LFTs & FBC

Dupilumab to continue if EASI and DLQI scores remain improved from baseline (at least 50% improvement as above)

5. References

1. Blauvelt A, de Bruin-Weller M, Gooderham M, Cather JC, Weisman J, Pariser D*, et al.* Long-term management of moderate-to-severe atopic dermatitis with dupilumab and concomitant topical corticosteroids (LIBERTY AD CHRONOS): a 1-year, randomised, double-blinded, placebo-controlled, phase 3 trial. Lancet. 2017;389(10086):2287-303.

2. Simpson EL, Bieber T, Guttman-Yassky E, Beck LA, Blauvelt A, Cork MJ*, et al.* Two Phase 3 Trials of Dupilumab versus Placebo in Atopic Dermatitis. N Engl J Med. 2016;375(24):2335-48.

3. de Bruin-Weller M, Thaçi D, Smith CH, Reich K, Cork M, Radin A*, et al.* Dupilumab with concomitant topical corticosteroids in adult patients with atopic dermatitis who are not adequately controlled with or are intolerant to ciclosporin A, or when this treatment is medically inadvisable: a placebo-controlled, randomized phase 3 clinical trial (LIBERTY AD CAFÉ). Br J Dermatol. 2017.

4. Scottish Medicines Consortium (SMC) (2015). Omalizumab 150mg solution for injection (Xolair®) SMC No. (1017/14). Glasgow: SMC. [Online] https://www.scottishmedicines.org.uk/media/3751/dupilumab-dupixent-final-august-2018-for-website.pdf [Accessed 03/10/18]

This protocol does not represent a summary of all available literature and prescribing information.

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