6 December 2019

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

**ADVICE:** following an abbreviated submission

**Dupilumab (Dupixent®)** is accepted for restricted use within NHSScotland.

**Indication under review:** the treatment of moderate-to-severe atopic dermatitis in adolescents (≥12 to <18 years) who are candidates for systemic therapy.

**SMC restriction:** patients who have had an inadequate response to existing systemic immunosuppressants such as ciclosporin, or in whom such treatment is considered unsuitable.

SMC has previously accepted dupilumab for restricted use under the orphan medicine process for the treatment of moderate-to-severe atopic dermatitis in adult patients who are candidates for systemic therapy (SMC2011). This advice takes account of views from a Patient and Clinician Engagement (PACE) meeting.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/list price that is equivalent or lower.

Patient access schemes: A patient access scheme is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. A Patient Access Scheme Assessment Group (PASAG), established under the auspices of NHS National Services Scotland reviews and advises NHSScotland on the feasibility of proposed schemes for implementation. The PASAG
operates separately from SMC in order to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHSScotland on the basis of a patient access scheme that has been considered feasible by PASAG, a set of guidance notes on the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS Boards prior to publication of SMC advice.

This assessment is based on data submitted by the applicant company up to and including 4 September 2019.

Chairman
Scottish Medicines Consortium