Healthcare Improvement Scotland | SMC Advice on new medicines

Product update
SMC2364

pertuzumab and trastuzumab 600mg/600mg and 1,200mg/600mg solution for injection (Phesgo®)

Roche Products Limited

In confidence

04 June 2021

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

ADVICE: following an abbreviated submission

pertuzumab/trastuzumab (Phesgo®) is accepted for restricted use within NHSScotland.

Indication under review:
Early breast cancer (EBC)
In combination with chemotherapy in:
• the neoadjuvant treatment of adult patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer at high risk of recurrence
• the adjuvant treatment of adult patients with HER2-positive early breast cancer at high risk of recurrence

Metastatic breast cancer (MBC)
In combination with docetaxel in adult patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.

SMC restriction:
Restricted to use in line with previous SMC advice for pertuzumab and trastuzumab (see SMC2284; SMC2120; SMC2119; SMC No. 928/13; SMC No. 278/06).

Pertuzumab/trastuzumab (Phesgo®) provides a combination injection for subcutaneous use. Pertuzumab has previously been accepted by SMC under the orphan medicine process.

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.

Advice must be treated in strict confidence until published on the SMC website on **Monday 12 July 2021.**

Chairman
Scottish Medicines Consortium

Medicine prices are those available at the time the papers were issued to the SMC executive for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Product Update. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

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.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

This assessment is based on data submitted by the applicant company up to and including 16 February 2021.