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## zanubrutinib 80 mg hard capsules (Brukinsa®)

BeiGene UK Ltd

08 September 2023

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

**zanubrutinib (Brukinsa®)** is accepted for restricted use within NHSScotland.

**Indication under review:** as monotherapy for the treatment of adult patients with chronic lymphocytic leukaemia (CLL)

**SMC restriction:** For adults with CLL in whom chemo-immunotherapy is unsuitable.

Zanubrutinib offers an additional treatment choice in the therapeutic class of Bruton tyrosine kinase inhibitor in this setting.

Another medicine within this therapeutic class has been accepted via the end-of-life and 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.

**Chair**  
**Scottish Medicines Consortium**

**Advice context:**

*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.*

*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 25 May 2023.*