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Advice document
SMC2744

bevacizumab gamma (Lytenava®)

Outlook Therapeutics Limited

7 February *(Issued 6 June 2025)*

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

bevacizumab gamma (Lytenava®) is accepted for use within NHSScotland.

Indication under review: in adults for treatment of neovascular (wet) age-related macular degeneration (nAMD).

Bevacizumab gamma offers an additional treatment choice in the therapeutic class of vascular endothelial growth factor inhibitors.

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

1. Clinical Context

1.1. Medicine background

Bevacizumab gamma is a recombinant humanised IgG1 monoclonal antibody that binds to human vascular endothelial growth factor (VEGF). It is administered by intravitreal injection for the treatment of neovascular (wet) age-related macular degeneration (nAMD). Refer to the Summary of Product Characteristics for dosing information[1].

1.2. Relevant comparator(s)

Other VEGF inhibitors that have been accepted for use by SMC for the treatment of nAMD include ranibizumab (Lucentis®) (SMC advice was superseded by NICE multiple technology appraisal TA155), aflibercept (Eylea®) (857/13), brolucizumab (Beovu®) (SMC2272) and faricimab (Vabysmo®) (SMC2512).

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

Bevacizumab gamma was compared with ranibizumab in the NORSE TWO study[2], a phase III, multi-centre, double-masked study in patients aged ≥50 years with active primary subfoveal choroidal neovascularisation lesions secondary to AMD in the study eye (n=228). Patients had best corrected visual acuity (BCVA) of 20/50 to 20/320 Snellen equivalent at baseline. Patients were randomised equally to receive intravitreal injection of bevacizumab gamma 1.25mg every month for up to 12 months or ranibizumab 0.5mg every month for three months (on days 0, 30 and 60) followed by two additional injections 90 days apart (on days 150 and 240). Bevacizumab gamma was significantly superior to ranibizumab for the primary outcome of proportion of patients who gained 15 or more letters in BCVA from baseline to 11 months (42% [45/108] for bevacizumab gamma versus 23% [24/104] for ranibizumab). Bevacizumab gamma was administered monthly for 12 months, whereas ranibizumab was administered less frequently. In total, 11 injections in the bevacizumab gamma group were compared with 5 injections in the ranibizumab group for the assessment of efficacy.

The submitting company presented the results from a network meta-analysis (NMA) comparing bevacizumab gamma with the relevant comparators, aflibercept, faricimab and ranibizumab. The network included 21 studies that reported the proportion of patients gaining at least 15 letters in BCVA at 12 months in the base case. The results of the NMA supported the conclusion of similar efficacy of bevacizumab gamma to relevant comparators in the treatment of nAMD.

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment*

The company estimated that there would be approximately 5,000 patients eligible for treatment with bevacizumab gamma each year, with an uptake rate for bevacizumab gamma estimated at 5% in year 1 and 25% in year 5.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Outlook Therapeutics Ltd, Summary of Product Characteristics, Lytenava 25 mg/mL solution for injection, accessed 05/11/24.
2. European Medicines Agency (EMA) European Public Assessment Report Lytenava EMA/146883/2024.

This assessment is based on data submitted by the applicant company up to and including 24 March 2025.

Medicine prices are those available at the time the papers were issued to SMC 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 Detailed Advice Document. 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 is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

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.