Healthcare Improvement Scotland | SMC Advice on new medicines

Advice document
SMC2946

seladelpar capsules (Livdelzi®)

Gilead Sciences Ltd

07 August 2026

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

seladelpar (Livdelzi®) is accepted for use within NHSScotland.

Indication under review: for the treatment of primary biliary cholangitis (PBC), including pruritus, in adults in combination with ursodeoxycholic acid (UDCA) who have an inadequate response to UDCA alone, or as monotherapy in those unable to tolerate UDCA.

Seladelpar offers an additional treatment choice in the therapeutic class of peroxisome proliferator-activated receptor (PPAR) agonists.

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

Chair
Scottish Medicines Consortium

1. Clinical Context

1.1. Medicine background

Seladelpar is a potent and selective peroxisome proliferator-activated receptor (PPAR) delta agonist. PPAR delta is a nuclear receptor expressed in the liver and other tissues. Activation of PPAR delta reduces bile acid synthesis in the liver, thereby lowering systemic bile acid levels. Additionally, seladelpar has been associated with decreased levels of interleukin-31 (IL-31), which may contribute to a reduction in pruritus.[1]

The recommended dose of seladelpar is 10 mg orally once daily with or without food.[1] Refer to the Summary of Product Characteristics (SPC) for further information.

1.2. Relevant comparator(s)

Elafibranor is a dual PPAR alpha and delta agonist within the same therapeutic class as seladelpar.

Elafibranor (SMC2714) has been accepted for use in NHSScotland for the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid in adults with an inadequate response to ursodeoxycholic acid or as monotherapy in adults unable to tolerate ursodeoxycholic acid.[2]

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

The evidence to support the use of seladelpar for this indication comes from an international, randomised, double-blind, placebo-controlled, phase III study. The study included adult patients ≥18 to ≤75 years of age with a diagnosis of PBC meeting at least two of the following diagnostic criteria: elevated ALP levels for ≥6 months; positive AMA titres >1:40; liver biopsy consistent with PBC. At month 12, a significantly greater proportion of patients in the seladelpar group (n=128) achieved a composite biochemical response and alkaline phosphatase (ALP) normalisation than the placebo group (n=65). In addition, patients with moderate to severe pruritus had significant improvements in pruritus with seladelpar from baseline to month 6 as assessed by the pruritus numerical rating scale (NRS) score.[3]

There is no direct evidence comparing seladelpar with the relevant comparator, elafibranor. The submitting company presented the results of an anchored matching-adjusted indirect comparison versus elafibranor using data from RESPONSE[3] and ELATIVE[4]. Notwithstanding the limitations of the indirect comparison, the results suggested that seladelpar is likely to have comparable efficacy to elafibranor.

3. Patient and Carer Involvement

SMC engaged with relevant Patient Group Partners inviting them to provide additional insights into the potential impact of this medicine on patients and carers. Information provided by the charity The PBC Foundation UK, as part of a previous full submission, was considered as part of the assessment process.

4. Company Estimate of Uptake and Budget Impact

4.1. Company's number of patients assumed to receive treatment*

SMC is unable to publish the estimated patient numbers as the company considered that these were commercial in confidence.

4.2. Budget impact assumption

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

References

1. Electronic Medicines Compendium (EMC). Gilead Sciences Ltd. Livdelzi 10 mg capsules Summary of product characteristics 2025 [updated 7 Feb 2025. Available from: https://www.medicines.org.uk/emc/product/100486/smpc.
2. Electronic Medicines Compendium (EMC). Ipsen Ltd. Elafibranor 80 mg film-coated tablets (Iqirvo®). Summary of product characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/ Last updated 08 October 2024.
3. Hirschfield GM, Bowlus CL, Mayo MJ, Kremer AE, Vierling JM, Kowdley KV, et al. A Phase 3 Trial of Seladelpar in Primary Biliary Cholangitis. N Engl J Med. 2024;390(9):783–94.
4. Kowdley KV, Bowlus CL, Levy C, Akarca US, Alvares-da-Silva MR, Andreone P, et al. Efficacy and Safety of Elafibranor in Primary Biliary Cholangitis. N Engl J Med. 2024;390(9):795–805.

This assessment is based on data submitted by the applicant company up to and including 03 August 2026.

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC includes Scottish national contract prices in its decision-making. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document.

Patient Access Schemes (PAS): A PAS 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. The Patient Access Scheme Assessment Group (PASAG), established under the auspices of Public Services Delivery Scotland, reviews and advises NHS Scotland on the feasibility and acceptability on implementing proposed schemes. PASAG operates separately from SMC to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a PAS that has been considered acceptable for implementation by PASAG, a set of guidance notes on the operation of the scheme will be circulated to health boards' Area Drugs and Therapeutics Committees 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.