



One Wales Medicines Assessment Group Recommendation

Trametinib (Mekinist®) film-coated tablets (OW30)

Date of advice: June 2025

Date of last review: September 2026

AWTTC reference number: OW30

Using the agreed starting and stopping criteria trametinib (Mekinist®) can be made available within NHS Wales for the treatment of recurrent low grade serous ovarian carcinoma (LGSOC) which has progressed following at least one previous platinum-based regimen.

The risks and benefits of the off-label use of trametinib (Mekinist®) for this indication should be clearly stated and discussed with the patient to allow informed consent.

Providers should consult the relevant guidelines on prescribing unlicensed medicines before any off-label medicines are prescribed.

There is a simple discount patient access scheme (PAS) for trametinib.

This recommendation has been endorsed by the All Wales Medicines Strategy Group (AWMSG) and ratified by Welsh Government.

This recommendation will be reviewed after 12 months or earlier if new evidence becomes available.

Clinician responsibility

Clinicians will be obliged to collect and monitor patient outcomes. Evidence of clinical outcomes will be taken into consideration when reviewing the One Wales Medicines Assessment Group decision.

Health board responsibility

Health boards will take responsibility for implementing One Wales Medicines Assessment Group decisions and ensuring that a process is in place for monitoring clinical outcomes

One Wales advice assists consistency of access across NHS Wales and will be disseminated to the service following ratification by Welsh Government.

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Starting and stopping criteria for the treatment of recurrent low grade serous ovarian carcinoma (LGSOC) which has progressed following at least 1 previous platinum-based regimen

These criteria are adapted from the NHS England Clinical Commissioning Policy 2253¹ in collaboration with oncologists in Wales.

Starting criteria:

Patients must satisfy all the following criteria. Treatment may be considered in adults (aged 18 years and above) who:

- have a confirmed diagnosis of LGSOC that is recurrent or progressed following treatment with at least one line of platinum-based chemotherapy
- have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 at the time of treatment initiation.
- have not had previous treatment with a MEK inhibitor

A full list of precautions is included in the Summary of Product Characteristics (SmPC)².

Trametinib should always be initiated by an experienced oncologist following a multidisciplinary team (MDT) discussion.

Patients who satisfy the eligibility criteria will be prescribed trametinib following consultation with the patient and/or carer after consideration of potential adverse effects, cautions, contraindications and an explanation of alternative treatment options. This consultation should be recorded in the patient's notes.

Trametinib should be used as monotherapy at a maximum recommended dose of 2 mg orally once daily², as part of a 28-day cycle. Dose reduction(s) may be required down to either 1.5 mg orally once daily or 1 mg orally once daily. This decision should be made following appropriate clinical assessment. Treatment is continued until disease progression or unacceptable toxicity occurs. Recommended modifications to manage adverse reactions are provided in the SmPC².

Monitoring:

- Full blood count
- Urea and electrolytes
- Liver function tests
- Blood pressure
- ECG
- ECHO
- Clinical evaluation of side effects, refer to SmPC

The above tests should be done at baseline. Repeat blood tests and urea and electrolytes prior to each cycle for 3 months then every 3 months thereafter. Repeat liver function tests prior to each cycle for 6 months, then every 3 months thereafter.

ECHO at baseline then at one month and then approximately every 3 months. Blood pressure before every cycle. Refer also to local protocols on scheduling tests.



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Whilst on treatment a computed tomography (CT) will be performed every 3 months, according to response to treatment.

If patients report new visual disturbances, such as diminished central vision, blurred vision or loss of vision at any time while on trametinib, a prompt ophthalmological assessment is recommended². Symptoms suggestive of interstitial lung disease should be promptly investigated and treatment permanently discontinued².

This list is not exhaustive. Any other monitoring should be in accordance with the SmPC for trametinib².

Stopping criteria:

- evidence of clinically significant disease progression or symptomatic deterioration as agreed in the MDT
- toxicity; dosing reduction may be considered, follow the guidance in the SmPC.
- patient request

Only one course of treatment may be issued in accordance with this advice. Requests for repeat courses should be explored through funding mechanisms such as the individual patient funding request process.

Other considerations:

- AWTTTC patient information leaflets on understanding unlicensed medicines in English and Welsh and an easy read format, these can be accessed [here](#).
- It is important that outcomes are collected for this patient cohort and the outcomes will be reviewed by the One Wales Medicines Assessment Group after 12 months.
- Clinicians may wish to use one of the [Cancer Research UK consent forms for SACT \(Systemic Anti-Cancer Therapy\)](#) to help ensure your patient is fully informed when consenting to SACT.
- The Strategic Clinical Network for Cancer standard is that all patients receiving SACT should be given the All Wales Cancer Treatment Alert Card with the treating team being responsible for ensuring that the details of which treatment type and name is clearly indicated on the card and the patient is given supporting information and explanations. Further information can be found here: [Systemic Anti-Cancer Therapies \(SACT\) - NHS Wales Executive](#)

References

1. NHS England. Clinical commissioning policy. Trametinib in recurrent or progressive low grade serous ovarian cancer (adults). Nov 2023. Available at: <https://www.england.nhs.uk/publication/clinical-commissioning-policy-trametinib-in-recurrent-or-progressive-low-grade-serous-ovarian-cancer/>. Accessed September 2026.
2. Novartis Pharmaceuticals UK Ltd. Mekinist®. 2 mg film-coated tablets. Summary of Product Characteristics. Jul 2023. Available at: <https://www.medicines.org.uk/emc/product/5072/smpc>. Accessed September 2026.



First review of One Wales decision – June 2026

Trametinib (Mekinist®) to treat recurrent low-grade serous ovarian carcinoma (LGSOC) that has progressed following at least one platinum-based regimen (OW30)

This report was prepared by the All Wales Therapeutics and Toxicology Centre in June 2026. It summarises new evidence available and patient outcome data collected since the One Wales decision in June 2025.

Background: Low-grade serous ovarian carcinoma (LGSOC) is a rare subtype of ovarian cancer that grows slowly and is more resistant to chemotherapy than other ovarian cancer types. LGSOC is characterised by a younger age at diagnosis, relative resistance to platinum-based chemotherapy, and extended overall survival compared with high-grade serous carcinoma. However, LGSOC is usually diagnosed in the advanced stages, relapse occurs in over 70% of patients, and response rates to salvage chemotherapy are low. After disease progression or recurrence, the treatment options include hormonal therapy (if not previously given) or further chemotherapy (options include paclitaxel alone or pegylated liposomal doxorubicin hydrochloride).

Guidelines ([ESMO](#) and [NCCN](#)) recommend considering trametinib to treat recurrent LGSOC. Trametinib use is routinely commissioned in the NHS in [England](#) and in [Scotland](#) to treat LGSOC. Clinicians in Wales considered there was an unmet need and identified a cohort of people with LGSOC that has progressed after at least one platinum-based regimen who could benefit from this treatment. Trametinib was assessed through the One Wales process and supported for use; this is the first review of that decision.

Current One Wales Decision: [Recommended](#) to treat LGSOC that has progressed following at least one platinum-based regimen.

Licence status: off-label use for this licensed medicine.

Guidelines: The National Institute for Health and Care Excellence (NICE) updated its guideline [CG122 Ovarian cancer: recognition and management](#) in April 2026 and includes trametinib in accordance with the NHS England commissioning advice.

Licensed alternative medicines or Health Technology Assessment (HTA) advice for alternative medicines: No new medicines or HTA advice reported for this indication.

Effectiveness: AWTTC conducted a literature search to identify new evidence published since the One Wales decision in June 2025. We excluded: any studies published before 2025; conference abstracts; case series and case reports; non-English papers. Our literature search identified one study that included some patients with LGSOC who received trametinib and further supports its use to treat LGSOC.

The IMPRESS-Norway study (NCT04817956) is an ongoing prospective, non-randomised clinical trial assessing approved cancer medicines used outside their licensed indications in people with advanced cancer whose tumours have specific genetic alterations identified by molecular profiling ([Slørdahl et al. 2026](#)). Reported results from a sub-study aimed to assess the efficacy of trametinib monotherapy across tumour types with alterations activating the MAPK signalling pathway. LGSOC was the second largest tumour type in the study, affecting 12 of the 65 patients treated with trametinib (2 mg once daily).

After 16 weeks of treatment, three of eight evaluable patients with LGSOC achieved a partial response, and five achieved stable disease. No complete responses were reported. LGSOC was the tumour type associated with the greatest observed clinical benefit in the study. No further outcomes, such as overall survival or progression-free survival, were reported specifically for the group of patients with LGSOC. The study authors state that a more detailed analysis of the LGSOC cohort will be reported separately.

Safety: Safety data were reported for all 65 patients who received trametinib in the sub-study of the IMPRESS-NORWAY trial; but safety outcomes were not reported specifically for the LGSOC subgroup. A total of 58 treatment-related adverse events (TRAEs) were reported, in 31 patients (48%); of which 38 (66%) were serious adverse reactions. In total, 14 patients (22%) discontinued trametinib because of TRAEs, including one patient with LGSOC whose treatment response was not evaluate.

The most frequently reported TRAEs were: rash; increased liver enzymes; and mucositis. Six suspected unexpected serious adverse reactions were reported: myocardial infarction, sepsis, stroke and thromboembolic event (all occurring in one patient), and two additional thromboembolic events in two other patients. Two treatment-related deaths occurred: one due to a thromboembolic event, and the other due to an intra-abdominal haemorrhage. These adverse events are known potential side effects of trametinib ([SmPC](#)).

No other relevant safety analyses were identified in the literature search.

Cost-effectiveness: No relevant cost-effectiveness analyses were identified in the repeat literature search.

Budget impact: Clinicians at Velindre Cancer Centre reported that since the OW recommendation in June 2025, [confidential information removed]. The number of patients treated from North Wales has not been provided but even when taking this into account, it is expected that the overall number of patients treated in Wales is significantly less than the original predicted value of 13 per year.

Impact on health and social care services: Minimal.

Patient outcome data: Clinicians reported data for the [confidential information removed].

Evaluation of evidence

No significant new evidence has been published which challenges the current One Wales advice. Since the One Wales decision, [confidential information removed] with LGSOC have received trametinib, which is less than the predicted 13 patients each year. [Confidential information removed]. Although patient numbers are too small to draw any firm conclusions on efficacy, the response rate is in line with that reported in the GOG 281/LOGS pivotal study as detailed in the original assessment report. AWTTC recommends continuing access in Wales to trametinib for the treatment of recurrent low-grade serous ovarian carcinoma (LGSOC) that has progressed following at least one platinum-based regimen.

Next review date: September 2027

References: a full reference list is available on request.

This document includes evidence published since the last review or full assessment of this medicine for the indication under consideration. It does not replace the original full evidence status report. Any previous reviews and the original full evidence status report are available on request by email to AWTTC@wales.nhs.uk.

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