Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

One Wales Medicines Assessment Group Recommendation
Nivolumab (Opdivo®) concentrate for solution for infusion (OW28)

Date of advice: July 2024
Date of last review: October 2025
AWTTC reference number: OW28

It is the view of the One Wales Medicines Assessment Group (OWMAG) that nivolumab (Opdivo®) should not be supported within NHS Wales for monotherapy as a first-line treatment for patients with metastatic or locally advanced and unresectable, deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) oesophageal and gastric cancer.

Individual Patient Funding Request (IPFR) consideration remains appropriate for those patients who are likely to obtain significantly more clinical benefit from the intervention than would normally be expected at a reasonable value for money.

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

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

One Wales advice assists consistency of access across NHS Wales.

AWTTC
All Wales Therapeutics & Toxicology Centre
Canolfan Therapiwteg a Thocsicoleg Cymru Gyfan

This is a summary of any new evidence available since the One Wales decision July 2024.

Background: Oesophageal cancer, mainly squamous cell carcinoma or adenocarcinoma, and stomach cancer, primarily gastric adenocarcinoma, causes symptoms such as swallowing difficulties, nausea, and indigestion. Despite slight improvements in survival rates in the UK, prognosis remains poor due to late diagnosis. The five-year survival rate in Wales is around 17% for oesophageal and 21% for stomach cancer, and metastatic disease has a very low survival rate.

Nivolumab monotherapy was previously available under National Institute for Health and Care Excellence (NICE) interim guideline NG161 as an option to treat MSI-H upper gastrointestinal cancers, serving as an alternative to first-line chemotherapy via the Cancer Drugs Fund (CDF). Access in Wales ended in March 2023 after NG161 was withdrawn and nivolumab was removed from the CDF. Patients with dMMR/MSI-H upper gastrointestinal cancers often respond poorly to chemotherapy but show better outcomes with immunotherapy. Nivolumab, a PD-1 blocking antibody, boosts the immune response against tumours, which are more likely to respond due to their high mutational burden and neoantigen load compared to microsatellite stable tumours.

Clinicians in Wales consider there is an unmet need and identified a cohort of patients who could benefit from this treatment, nivolumab was therefore considered suitable for assessment through the One Wales medicines process. In June 2024 the One Wales Medicines Assessment Group considered the evidence for nivolumab in treatment of metastatic or locally advanced and unresectable, dMMR / MSI-H oesophageal and gastric cancer. The group considered that the level of evidence was insufficient to establish the magnitude of effect of nivolumab for this indication and that it was unlikely to be cost effective.

Current One Wales Decision: Not supported for use via the One Wales Medicines process

Licence status: Nivolumab is not licensed as monotherapy for the first-line treatment of patients with metastatic or locally advanced and unresectable oesophageal and gastric cancer with deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H); its use for this indication is off-label.

Guidelines: There have been no relevant updates to existing guidelines identified.

Licensed alternative medicines or Health Technology Assessment advice for alternative medicines: No new medicines or Health Technology Assessment advice reported.

Effectiveness: AWTTC conducted a literature search in July 2025 to find new evidence for the use of nivolumab monotherapy in the first-line treatment of

dMMR/MSI-H upper gastrointestinal cancers. The search excluded articles published before 2024, articles that reviewed evidence previously presented in AWTTC's first Evidence Summary Report, and conference abstracts.

No additional systematic reviews, clinical trials, retrospective studies, or case reports were found to supplement the existing evidence base.

Safety: No relevant safety analyses identified in the repeat literature search.

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

Budget impact: Due to the non-recommendation of nivolumab monotherapy for this indication, a budget impact review is not required.

Impact on health and social care services: Not applicable, as nivolumab monotherapy is not recommended for this indication.

Patient outcome data: As nivolumab monotherapy was not recommended for this indication, no patient outcome data have been collected. At the time of writing, AWTTC is not aware of any Individual Patient Funding Requests (IPFRs) submitted since the original report.

Next review date: October 2026

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.

Information presented in this document can be reproduced using the following citation: All Wales Therapeutics & Toxicology Centre. Evidence Review. Nivolumab (Opdivo®). Deficient mismatch repair (dMMR) / high microsatellite instability (MSI-H) oesophageal and gastric cancer. Reference number: (OW28). 2025.

References: a full reference list is available on request.