Belfast Health and Social Care Trust
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FOI/36168

30 April 2026

Patients Treated with a Regimen of Lenvatinib and Prembrolizumab for Metastatic Papillary Kidney Cancer

Information Request 1

a. Between 2022 to the present – have any patients who are/were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic papillary (or other non-clear renal cell) kidney cancer, received MORE THAN 17 CYCLES of Prembrolizumab within the BHSCT?

No

b. If so, how many?

None

No patients in Northern Ireland have received more than 24 months of Prembrolizumab, as this is outwith the current evidence base for this regimen in advanced renal cell carcinoma of any subtype.

Information Request 2

a. Between 2022 to the present – have any patients who are/were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic clear renal cell kidney cancer, received MORE THAN 17 CYCLES of Prembrolizumab within the BHSCT?

No

b. If so, how many?

None

No patients in Northern Ireland have received more than 24 months of Pembrolizumab, as this is outwith the current evidence base for this regimen in advanced renal cell carcinoma of any subtype.

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Information Request 3

a. Between 2022 to the present – how many patients who were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic papillary (or other non-clear renal cell) kidney cancer have had their Prembrolizumab therapy WITHDRAWN at 17 CYCLES solely because of perceived stipulations around the regimen LICENCE DURATION (i.e., while the regimen was still working, evidenced in stable scans; and while toxicity was within tolerable limits)?

In Belfast Trust, <5 patients with non-clear cell renal pathology have received Lenvatinib and Pembrolizumab. No patients to date fall into the above-described category.

Use of <5 (less than five): We are unable to provide an exact figure - exempt from release under Section 40(2) of the Freedom of Information Act - Personal Information relating to a third party, as the small numbers involved could make patients personally identifiable. Disclosure would constitute a breach of the principles of the General Data Protection Regulation 2018.

All patients receiving Lenvatinib / Pembrolizumab are prescribed up to a maximum of 2 years of Pembrolizumab, in keeping with the clinical trial evidence base for advanced renal cell carcinoma and associated NICE approval. Whilst the recommendations in NICE TA 858 do not explicitly state that Pembrolizumab should be limited to 2 years, the Committee clearly state later in the document that the use of Pembrolizumab should be limited to 2 years in line with available evidence.

b. In these cases, does (did) the consulting oncologist have any clinical discretion in the application of the regimen licence stipulations?

As above, the treating Consultant Oncologists prescribe up to 24 months of Pembrolizumab, which is the accepted standard of care for this regimen in advanced renal cell carcinoma and reflects the phase 3 clinical trial evidence. Pembrolizumab is stopped after 2 years for all patients, including all subtypes of advanced Renal Cell Carcinoma (RCC).

As previously stated, the consultant team adhere to the clinical trial evidence, licence and NICE approval and do not extend Pembrolizumab beyond the standard 2 years of treatment, as there is currently no strong evidence that benefits would outweigh risks of doing so.

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Information Request 4

a. Between 2022 to the present – how many patients who were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic clear renal cell kidney cancer have had their Prembrolizumab therapy WITHDRAWN at 17 CYCLES solely because of perceived stipulations around the regimen LICENCE DURATION (i.e., while the regimen was still working, evidenced in stable scans; and while toxicity was within tolerable limits)?

Ten patients with clear cell renal pathology have received Lenvatinib and Pembrolizumab. To date, <5 patients have completed 2 years of Pembrolizumab.

As outlined in Request 3, we are unable to provide an exact figure - exempt from release under Section 40(2) of the Freedom of Information Act - Personal Information relating to a third party.

b. In these cases, does (did) the consulting oncologist have any clinical discretion in the application of the regimen licence stipulations?

The same answer applies as for Request 3, as the same approach is taken for all RCC patients (clear cell and non-clear cell pathologies) with this systemic anti-cancer treatment regimen.

As previously stated the consultant team adhere to the clinical trial evidence, licence and NICE approval and do not extend Pembrolizumab beyond the standard 2 years of treatment, as there is currently no strong evidence that benefits would outweigh risks of doing so.

Information Request 5

a. Between 2022 to the present – how many patients who were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic papillary (or other non-clear renal cell) kidney cancer have had their Prembrolizumab therapy WITHDRAWN at 23 MONTHS (first to last cycle) solely because of perceived stipulations around the regimen LICENCE DURATION (i.e., while the regimen was still working, evidenced in stable scans; and while toxicity was within tolerable limits)?

No patient cases have been identified as described above. Pembrolizumab would be discontinued prior to 24 months if risks such as toxicity, poor tolerability, and impact on quality of life were felt to outweigh benefits of continuing. Both agents would be discontinued prior to 24 months in the event of cancer progression indicating lack of a beneficial effect of treatment.

A decision to stop Pembrolizumab prior to the 24 months is made on an individual case basis by the treating Consultant Oncology Team, taking into consideration the clinical effectiveness of the regimen, the toxicity issues being encountered and the overall fitness of the patient and current quality of life.

b. In these cases, does (did) the consulting oncologist have any clinical discretion in the application of the regimen licence stipulations?

Not applicable

Information Request 6

a. Between 2022 to the present – how many patients who were being treated with a regimen of Lenvatinib and Prembrolizumab for metastatic clear renal cell kidney cancer have had their Prembrolizumab therapy WITHDRAWN at 23 MONTHS (first to last cycle) solely because of perceived stipulations around the regimen LICENCE DURATION, (i.e., while the regimen was still working, evidenced in stable scans; and while toxicity was within tolerable limits)?

No patient cases have been identified as described above for the reasons provided in Request 5.

The same answer applies as for Request 5 as the same approach is taken for all RCC patients (clear cell and non-clear cell pathologies) with this systemic anti-cancer treatment regimen.

b. **In these cases, does (did) the consulting oncologist have any clinical discretion in the application of the regimen licence stipulations?**

Not applicable