NHS England South West

Subject: Specialised Services Circular (SSC)
Sent on behalf of: Chair of the SW Specialised Service Circular Group

Dear Colleagues,

Please find attached the following Specialised Services Circular(s):

SSC Number	SSC Title	Trusts approved to prescribe in accordance with the SSC, providing appropriate internal governance arrangements are in place
2840	**New Subcutaneous (SC) formulation for nivolumab 600mg/5ml (Opdivo®): Implications for currently funded indications**	All South West Acute Trusts

Is an implementation plan required from all SW trusts (regardless of commissioned status) for this SSC? No

For all other South West region trusts this is for information only.

Trusts should ensure that use is registered on the Blueteq system (if appropriate).

Treatment will only be funded where the drugs minimum dataset is fully and accurately populated.

Please direct any queries to: england.speccomm-southwest@nhs.net

Note: Outsourcing Subcutaneous Nivolumab - NHSE specialised commissioning will **not** reimburse providers for the costs of outsourcing the preparation of subcutaneous Nivolumab for use in a hospital setting. Subcutaneous nivolumab can be prepared outside of a pharmacy aseptic unit and therefore it is not necessary to outsource their preparation. If any costs associated with the subcutaneous preparation of Nivolumab used in a hospital setting are identified, these will be challenged.

All Chief Executives

All Medical Directors

All Chief Pharmacists

Specialised Commissioning
South West
NHS England
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BS1 6AG
Email: england.speccomm-southwest@nhs.net

13 June 2025

Dear Colleagues,

Re: New Subcutaneous (SC) formulation for nivolumab 600mg/5ml (Opdivo®): Implications for currently funded indications.

I am writing to advise you of the funding position for nivolumab (Opdivo®) following licensing of a subcutaneous (SC) version of the product. A new Summary of Product Characteristics (SmPC) for nivolumab 600mg/5ml solution for injection is available at: https://products.mhra.gov.uk/product/?product=OPDIVO%20600%20MG%20SOLUTION%20FOR%20INJECTION

NHS England can confirm that the new SC nivolumab product will be funded within the NHS from the date of this letter provided it remains a cost neutral alternative to the IV formulation.

The new SC product has a recommended dose of 600mg or 1,200mg (depending on frequency of administration) of nivolumab solution for subcutaneous injection. New patients may be initiated on the SC version as an alternative to the IV formulation following discussion between the individual patient and their clinical team. Patients currently receiving IV nivolumab can be switched to SC nivolumab after discussion with their clinical team.

The SC nivolumab formulation is licensed/available for the following indications:

- NIV1 – Nivolumab for previously treated advanced renal cell carcinoma (TA417)
- NIV5 – Nivolumab monotherapy for the treatment of squamous locally advanced or metastatic non-small cell lung cancer after chemotherapy (TA655)
- NIV6 – Nivolumab for the treatment of recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy (TA736)
- NIV7 – Nivolumab for the adjuvant treatment of newly diagnosed and completely resected stage III or completely resected stage IV malignant melanoma (TA684)
- NIV8a – Nivolumab monotherapy (with or without initial combination treatment with ipilimumab) for treating unresectable or advanced malignant melanoma (TA384/TA400)
- NIV9 – Nivolumab with ipilimumab for the 1st line treatment of intermediate or

poor risk advanced renal cell carcinoma (TA780)

- NIV10 – Nivolumab with ipilimumab for the treatment of patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) metastatic or locally advanced and inoperable colorectal cancer after prior fluoropyrimidine-based chemotherapy for metastatic disease (TA716)
- NIV15 – Nivolumab For the treatment of adult patients with unresectable locally advanced or recurrent or metastatic squamous cell carcinoma of the oesophagus previously treated with a fluoropyrimidine and platinum-based combination chemotherapy (TA707)
- NIV17 – Nivolumab as adjuvant monotherapy for the treatment of completely resected oesophageal or gastro-oesophageal carcinoma who have residual pathological disease at surgery following prior neoadjuvant chemoradiotherapy (TA746)
- NIV18 – Nivolumab with ipilimumab for treating advanced melanoma (TA400)
- NIV19 – Nivolumab monotherapy for adjuvant treatment after complete tumour resection in adult patients with high-risk muscle invasive urothelial cancer with tumour cell PD-L1 expression of ≥1% and in whom adjuvant treatment with platinum-based chemotherapy is unsuitable (TA817)
- NIV21 – Nivolumab in combination with platinum and fluoropyrimidine-based chemotherapy for previously untreated unresectable advanced or recurrent or metastatic squamous cell carcinoma of the oesophagus with a tumour cell PD-L1 expression of 1% or more and a PD-L1 combined positive score of <10 (TA865)
- NIV22 - Nivolumab in combination with platinum and fluoropyrimidine-based chemotherapy for previously untreated advanced or metastatic HER-2 negative adenocarcinomas of the stomach, gastrooesophageal junction or oesophagus which express PD-L1 with a combined positive score of 5 or more (TA857)
- CABNIV1 – Cabozantinib in combination with nivolumab for use in treatment-naïve patients with intermediate or poor risk advanced renal cell carcinoma for whom combination treatment with either nivolumab plus ipilimumab or lenvatinib plus pembrolizumab would otherwise be suitable (TA964)

Please refer to the individual forms either on Blueteq or via the CDF web list, or the nivolumab SmPC for **specific details regarding the point in the regimen that SC nivolumab is licensed for use.**

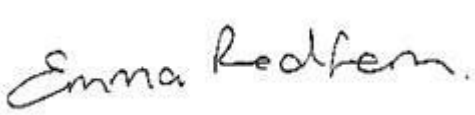
In addition:

- Trusts must ensure that they are purchasing nivolumab at the agreed proposed patient access scheme (PAS) discounted price. This discounted price will be applied automatically at point of invoice and applies to all indications. Trusts should refer to the CAP portal for further information on the PAS price. The CAP portal is available at https://nhsengland.sharefile.eu/Authentication/Login
- Trusts must ensure that charges are submitted to the correct commissioner for validation.
- In line with the terms and conditions included in the NHS Standard Contract and as per the agreement that Cancer Services are commissioned with Trusts, Schedule 6a Reporting Requirements for drugs will apply. Payment of Trust invoices will be contingent on the completion of the MDS record and this information being made available in a timely way.

- Trusts must ensure they are registering nivolumab use on SACT. The SACT dataset is a mandated dataset as part of the Health and Social Care Information Standards. This is listed as a Schedule 6 national information requirement within the NHS Standard Contract.
- All new patients must be registered via Blueteq and meet the clinical criteria on the registration form.
- Patients who started on the IV formulation and switched to SC nivolumab **do not** need to re-register on Blueteq when switching to SC nivolumab. Note: the relevant nivolumab Blueteq forms have been updated to include SC administration as an option.
- **Payment of Trust invoices will be contingent on Blueteq registration, the full SACT and CDF MDS record applicable to the drug being completed and this information being made available in timely way.**
- Trusts must ensure that local governance aspects (e.g. technical issues, education & training, patient information) have been identified and addressed for all staff groups (as appropriate) in order to permit the safe delivery of this therapy.

I would be grateful if you could cascade this information to relevant clinical teams within your organisation to support the consistent adoption of the policy nationally.

With best wishes,



Emma Redfern
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Tracey Williams
Principal Pharmacist