

Nivolumab Monotherapy 240mg-14 days

This regimen supersedes NCCP Regimen 00349 Nivolumab Monotherapy as of May 2018 and Regimen 00573 as of Nov-2019 due to a change in the licensed dosing posology.

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
As monotherapy for the treatment of advanced (unresectable or metastatic) melanoma in adults.	C43	00483a	ODMS 09/10/2017
As monotherapy for the treatment of advanced renal cell carcinoma (RCC) after prior therapy in adults.	C64	00483b	ODMS 09/10/2017
As monotherapy is indicated for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) after autologous stem cell transplant (ASCT) and treatment with brentuximab vedotin.	C81	00483c	ODMS 09/10/2017
As monotherapy for the treatment of squamous cell cancer of the head and neck in adults progressing on or after platinum-based therapy.	C00-C14, C30-C32, C76	00483d	ODMS 01/05/2018
As monotherapy for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy in adults.	C34	00483e	ODMS 03/09/2018
As monotherapy for the adjuvant treatment of adults with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.	C43	00483f	ODMS 01/02/2021
As monotherapy for the adjuvant treatment of adult patients with oesophageal or gastro-oesophageal junction (GEJ) cancer who have residual pathologic disease following prior neo-adjuvant chemo-radiotherapy.	C15/C16	00483g	ODMS 01/09/2023
As monotherapy for the adjuvant treatment of adults with muscle invasive urothelial carcinoma (MIUC) with tumour cell PD-L1 expression $\geq 1\%$, who are at high risk of recurrence after undergoing radical resection of MIUC, providing patients are unsuitable for adjuvant treatment with platinum based chemotherapy.	C65, C66, C67, C68	00483h	ODMS 01/12/2024

* This is for post 2012 indications only.

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

For adjuvant melanoma and muscle invasive urothelial carcinoma (MIUC), nivolumab is administered once every 14 days for the maximum treatment duration of **12 months (26 cycles)**.

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Tumour Group: Genitourinary/Lymphoma/ Melanoma/Head & Neck /Lung/Gastrointestinal NCCP Regimen Code: 000483	IHS/ISMO Contributor: Prof. G. Gullo, Dr. D. O'Mahony, Dr. R. Bambury, Dr. L. Bacon, Dr E. Hanrahan, Dr. S. Cuffe, Prof. M. Keane, Prof. F. Kelleher, Dr D. O'Donnell	Page 1 of 10
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For adjuvant oesophageal or gastro-oesophageal junction (GEJ) cancer, nivolumab is administered at a dose of 240mg once every 14 days or 480mg once every 28 days for the first 16 weeks, followed by nivolumab 480mg every 28 days, beginning at week 17 for a **total duration of 12 months**. Please refer to [NCCP Regimen 00484 - Nivolumab Monotherapy 480mg-28 days](#).

For all other indications nivolumab is administered once every 14 days until disease progression or unacceptable toxicity develops.

Patients should be monitored continuously (at least up to 5 months after the last dose) as an adverse reaction with nivolumab may occur at any time during or after discontinuation of therapy.

If melanoma, RCC, oesophageal cancer, GEJ cancer or MIUC (adjuvant treatment) patients need to be switched from the 240mg every 2 weeks schedule to the 480mg every 4 weeks schedule (See [NCCP Regimen 00484 - Nivolumab Monotherapy 480mg-28 days](#)), the first 480mg dose should be administered two weeks after the last 240mg dose.

Facilities to treat anaphylaxis MUST be present when nivolumab is administered.

Drug	Dose	Route	Diluent & Rate	Cycle
Nivolumab	240mg	IV infusion	Infuse over 30 minutes through a sterile, non-pyrogenic, low protein binding in-line filter with a pore size of 0.2-1.2 µm	Ongoing every 14 days to progression or toxicity
Nivolumab must not be administered as an intravenous push or bolus injection.				
Nivolumab can be infused directly as a 10mg/mL solution or can be diluted to as low as 1mg/mL with sodium chloride 9mg/mL (0.9%) solution for injection or glucose 50mg/mL (5%) solution for injection.				

Note: Administration volumes and fluids have been standardised to facilitate electronic prescribing system builds.

ELIGIBILITY:

- Indications as above
- ECOG status
 - **Advanced melanoma and RCC:** 0-2
 - **cHL:** 0-1
 - **Head and Neck:** 0-1
 - **NSCLC:** 0-1
 - **Adjuvant melanoma:** 0-1
 - **Adjuvant oesophageal / GEJ:** 0-1
 - **Adjuvant MIUC:** 0-1
- Aged 18 years or above
- Adequate haematological, hepatic and renal function
- Nivolumab is not recommended during pregnancy and in women of childbearing potential not using effective contraception unless prescribing consultant deems clinical benefit outweighs the

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potential risk. Effective contraception should be used for at least 5 months following the last dose of nivolumab

- **Renal cell carcinoma**
 - Histologic confirmation of advanced or metastatic renal-cell carcinoma.
 - Have received one or more prior lines of systemic therapy including at least one prior anti-angiogenic tyrosine kinase inhibitor
- **Head and Neck**
 - Histologically confirmed recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) (oral cavity, pharynx, larynx), that is not amenable to local therapy with curative intent (surgery or radiation therapy with or without chemotherapy)
 - Tumour progression or recurrence within 6 months of last dose of platinum-based therapy in the adjuvant (i.e. with radiation after surgery), primary (i.e. with radiation), recurrent, or metastatic setting
- **Non-small cell lung cancer (NSCLC)**
 - Subjects must have experienced disease recurrence or progression during or after one prior platinum-containing doublet chemotherapy regimen for advanced or metastatic disease
- **Adjuvant melanoma**
 - Stage III or completely resected Stage IV Melanoma
- **Adjuvant oesophageal / GEJ:**
 - Stage II or Stage III carcinoma of the oesophagus or GEJ and histologically confirmed predominant adenocarcinoma or squamous cell carcinoma
 - Have completed neo-adjuvant platinum-based chemo-radiotherapy followed by surgery (nivolumab should commence within 16 weeks post-surgery)
- **Adjuvant MIUC:**
 - Radical surgical resection within 4 months of the start date for adjuvant nivolumab therapy
 - MIUC at high risk of recurrence, as defined by either:
 - a. pathological stage pT3-pT4a or pT0/x-pT4a/N+ for patients not eligible/declined adjuvant cisplatin-based chemotherapy or
 - b. pathological stage pT2-pT4a or pT0/xpT4a/N+ for patients who received neoadjuvant cisplatin
 - Confirmation of PD-L1 expression on $\geq 1\%$ of tumour cells as demonstrated by a validated test method on the tumour tissue
 - Disease free status as determined by imaging within 4 weeks of expected date of start date for adjuvant nivolumab therapy

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CAUTION:

Use with caution in:

- Patients with clinically significant autoimmune disease
- Symptomatic CNS metastases
- Immunosuppressive doses of systemic corticosteroids or other immunosuppressive medication(s) (defined as >10mg prednisolone/daily (or steroid equivalent, excluding inhaled or topical steroids)
- Any active clinically significant infection requiring therapy

EXCLUSIONS:

- Hypersensitivity to nivolumab or any of the excipients
- Information regarding prior therapy with an anti PD-1 or anti PD-L1 antibody is [Available on the NCCP website](#)
- Symptomatic interstitial lung disease
- **Head and neck:**
 - Patients with carcinoma of the nasopharynx or salivary gland as primary tumour site.
- **Adjuvant melanoma:**
 - Uveal melanoma
- **MIUC:**
 - Partial cystectomy or partial nephrectomy
 - Adjuvant systemic or radiation therapy for MIUC following radical surgery

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist or by a Consultant Haematologist working in the area of haematological malignancies.

TESTS:

Baseline tests:

- Blood, renal and liver profile
- Blood glucose
- TFTs
- Hepatitis B (HBV sAg) and Hepatitis C (HCV RNA)
- Serum cortisol (ideally a morning sample)

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Disease specific baseline test:

- **Adjuvant and advanced Melanoma:** Determination of BRAF status
- **MIUC:** PD-L1 testing with the DAKO autostainer using the 28-8 Pharm DX antibody on the request of a Consultant Medical Oncologist or following a tumour conference recommendation where there is an intention to treat with nivolumab in line with this licensed indication

Regular tests:

- FBC, renal, liver profile and blood glucose prior to each cycle
- TFTs once a month and as indicated based on clinical evaluation

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

NSCLC

- Patients should be assessed for progression prior to commencing their 8th cycle

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant
- Dose escalation or reduction is not recommended. Any dose modification should be discussed with a Consultant
- Management of immune-related adverse reactions may require withholding of a dose or permanent discontinuation of nivolumab therapy and institution of systemic high-dose corticosteroid
- If immunosuppression with corticosteroids is used to treat an adverse reaction, a taper of at least 1 month duration should be initiated upon improvement. Rapid tapering may lead to worsening or recurrence of the adverse reaction. Non-corticosteroid immunosuppressive therapy should be added if there is worsening or no improvement despite corticosteroid use. Nivolumab should not be resumed while the patient is receiving immunosuppressive doses of corticosteroids or other immunosuppressive therapy
- Guidelines for withholding of doses or permanent discontinuation are described in Table 1 below

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Table 1: Recommended Treatment Modifications for Nivolumab

Immune-related adverse reaction	Severity	Treatment Modification
Immune-related pneumonitis	Grade 2 pneumonitis	Withhold dose(s) until symptoms resolve, radiographic abnormalities improve, and management with corticosteroids is complete
	Grade 3 or 4 pneumonitis	Permanently discontinue treatment
Immune-related colitis	Grade 2 diarrhoea or colitis	Withhold dose(s) until symptoms resolve and management with corticosteroids, if needed, is complete
	Grade 3 diarrhoea or colitis	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete
	Grade 4 diarrhoea or colitis	Permanently discontinue treatment
Immune-related hepatitis	Grade 2 elevation in aspartate aminotransferase (AST), alanine aminotransferase (ALT), or total bilirubin	Withhold dose(s) until laboratory values return to baseline and management with corticosteroids, if needed, is complete
	Grade 3 or 4 elevation in AST, ALT, or total bilirubin	Permanently discontinue treatment
Immune-related nephritis and renal dysfunction	Grade 2 or 3 creatinine elevation	Withhold dose(s) until creatinine returns to baseline and management with corticosteroids is complete
	Grade 4 creatinine elevation	Permanently discontinue treatment
Immune-related endocrinopathies	Symptomatic Grade 2 or 3 hypothyroidism, hyperthyroidism, hypophysitis, Grade 2 adrenal insufficiency, Grade 3 diabetes	Withhold dose(s) until symptoms resolve and management with corticosteroids (if needed for symptoms of acute inflammation) is complete. Treatment should be continued in the presence of hormone replacement therapy as long as no symptoms are present
	Grade 4 hypothyroidism Grade 4 hyperthyroidism Grade 4 hypophysitis Grade 3 or 4 adrenal insufficiency Grade 4 diabetes	Permanently discontinue treatment

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Immune-related skin adverse reactions	Grade 3 rash	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete
	Grade 4 rash	Permanently discontinue treatment
	Stevens-Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN)	Permanently discontinue treatment
Immune-related myocarditis	Grade 2 myocarditis	Withhold dose(s) until symptoms resolve and management with corticosteroids is complete
	Grade 3 or 4 myocarditis	Permanently discontinue treatment
Other immune-related adverse reactions	Grade 3 (first occurrence)	Withhold dose(s)
	Grade 4 or recurrent Grade 3 ; persistent Grade 2 or 3 despite treatment modification ; inability to reduce corticosteroid dose to 10mg prednisone or equivalent per day	Permanently discontinue treatment

Toxicity grades are in accordance with National Cancer Institute Common Terminology Criteria for Adverse Events Version 4.0 (NCI-CTCAE v4).

Renal and Hepatic Impairment:

Table 2: Dose modification of nivolumab in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
No dose adjustment is needed		Mild/moderate	No dose adjustment is needed
Haemodialysis	No need for dose adjustment is expected	Severe	No need for dose adjustment is expected
Renal and hepatic dose modifications as per Giraud et al, 2023.			

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SUPPORTIVE CARE:

EMETOGENIC POTENTIAL:

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting - [Available on the NCCP website](#)

Minimal (**Refer to local policy**).

For information:

Within NCIS regimens, antiemetics have been standardised by Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - [Available on the NCCP website](#)
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - [Available on the NCCP website](#)

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE: No specific recommendations

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for information.

COMPANY SUPPORT RESOURCES/Useful Links:

Please note that this is for information only and does not constitute endorsement by the NCCP

Patient Alert Card:

<https://www.hpra.ie/img/uploaded/swedocuments/c02753be-51a5-44fd-8117-123823bdcff8.pdf>

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17. Nivolumab (OPDIVO®) Summary of Product Characteristics EMA. Last updated: 28/03/2023. Accessed June 2023. Available at: https://www.ema.europa.eu/en/documents/product-information/opdivo-epar-product-information_en.pdf
18. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V5 2023. Available at: <https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf>

Version	Date	Amendment	Approved By
1	21/05/2018		Prof. G. Gullo, Dr. D. O'Mahony, Dr. R. Bambury, Dr. L. Bacon, Dr E Hanrahan, Prof. F Kelleher
2	27/08/2018	Inclusion of indication for second line treatment of non small cell lung cancer	Dr. D. O'Mahony, Dr. S. Cuffe.
3	05/02/2019	Updated thyroid function testing	Prof Maccon Keane
4	24/04/2019	Inclusion of caution for use in patients with clinically significant history of auto-immune disease	Dr Deirdre O'Mahony Dr. S. Cuffe. Dr E Hanrahan
5	09/10/2019	Updated adverse effects/regimen specific complications section as per SmPC update regarding CMV infection/reactivation	Prof Maccon Keane
6	06/11/2019	Inclusion of adjuvant melanoma indication.	Prof Maccon Keane
7	23/09/2020	Updated eligibility criteria for adjuvant melanoma indication	Prof Maccon Keane
8	01/02/2021	Updated reimbursement status	Prof Maccon Keane
9	12/10/2022	Reviewed. Updated dose modifications section	Prof Maccon Keane
10	01/09/2023	Addition of new indication for adjuvant oesophageal / gastro-oesophageal junction (GEJ) cancer (00483g)	Prof Maccon Keane
11	25/11/2024	Addition of new indication for MIUC. Updated Treatment, Eligibility, Exclusions and Baseline testing sections. Updated dose modifications in renal and hepatic impairment to align with Giraud et al. Updated Emetogenic potential, Adverse effects, Regimen specific complications and Drug interactions sections to align with NCCP standardisation.	Dr Dearbhaile O' Donnell
11a	28/11/2024	Update to HSE reimbursement status of 00483h	NCCP
11b	08/05/2025	Update ICD-10 code.	NCCP

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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Tumour Group: Genitourinary/Lymphoma/ Melanoma/Head & Neck /Lung/Gastrointestinal NCCP Regimen Code: 000483	IHS/ISMO Contributor: Prof. G. Gullo, Dr. D. O'Mahony, Dr. R. Bambury, Dr. L. Bacon, Dr E. Hanrahan, Dr. S. Cuffe, Prof. M. Keane, Prof. F. Kelleher, Dr D. O'Donnell	Page 10 of 10
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