Plan Summary

Nivolumab 28 day v= V2.0

Overview

Unlicensed indication, temporary change to increase cycle length, as interim COVID -19 mitigation

Indications:
The treatment of recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy where all the following crtieria are met:
2. As the prescribing clinician I am fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis.
3. The patient has a histologically or cytologically confirmed diagnosis of squamous cell carcinoma of the head and neck.
4. The patient has recurrent or metastatic head and neck cancer that is not amenable to local therapy with curative intent (surgery and/or radiation therapy with or without chemotherapy)
5. The patient's disease has progressed or recurred during or within 6 months of the last dose of previously received platinum-based chemotherapy. Please indicate whether this previous platinum-based chemotherapy was given as: adjuvant chemotherapy; neo-adjuvant chemotherapy; concurrent with radiotherapy; or palliative chemotherapy for recurrent or metastatic disease.Note: Patients progressing more than 6 months after completing platinum-based chemotherapy are not eligible for nivolumab.
6. The patient has an ECOG performance status of 0 or 1 and would otherwise be potentially fit for docetaxel-based or methotrexate-based 2nd line chemotherapy.
7. The patient has not received prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.
8. Every effort has been made for the patient to have PD-L1 testing with an approved and validated test to determine the Tumour Proportion Score (TPS). Please document the TPS results below:- TPS (if negative enter zero): OR- Please enter 'yes', if the TPS cannot be quantified OR- Please enter 'yes', if PD-L1 testing was not possible as the pathologist has documented that these was insufficient tissue
9. Nivolumab will be administered as monotherapy.
10. The patient has no symptomatically active brain metastases or leptomeningeal metastases.
11. Nivolumab will be stopped on disease progression* or unacceptable toxicity or patient choice to discontinue treatment, whichever occurs first.*Atypical responses (i.e., an initial transient increase in tumour size or small new lesions within the first few months followed by tumour shrinkage) have been observed. It is recommended to continue treatment for clinically stable patients with initial evidence of disease progression until further disease progression is confirmed.
12. The patient will receive a maximum treatment duration of 2 years of uninterrupted treatment or 52 administrations (where administered every 2 weeks) or 26 administrations (where administered every 4 weeks) with nivolumab, whichever is later*.*Where treatment is interrupted any restart and continuation of drug must be in line with the treatment break policy outlined in Specialised Services Circular (SSC) 1918.
13. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC) with the exception of criterion 12.

The treatment of relapsed or refractory classical Hodgkin Lymphoma in ADULT patients where all the following criteria are met:
2. The prescribing clinician is aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis
3. The patient has a histologically confirmed diagnosis of classical Hodgkin's Lymphoma
4. The patient has relapsed or refractory disease
5. The patient has received prior high-dose conditioning chemotherapy followed by autologous stem cell transplant (ASCT) as part of previous therapy for classical Hodgkin's Lymphoma
6. The patient has had prior treatment with brentuximab vedotin
7. The patient has an ECOG performance status (PS) 0-1
8. The patient is an adult.
9. Nivolumab will be given as monotherapy.
10. The patient has no known central nervous system lymphoma.
11. The patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless received as part of the nivolumab EAMS programme for this indication and meeting all other criteria listed.
12. The patient will receive a maximum treatment duration of 2 years of uninterrupted treatment or 52 administrations (where administered every 2 weeks) or 26 administrations (where administered every 4 weeks) with nivolumab, whichever is later*. *Where treatment is interrupted any restart and continuation of drug must be in line with the treatment break policy outlined in Specialised Services

continuation of drug must be in line with the treatment break policy outlined in Specialised Services Circular (SSC) 1918.
13. Nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC)**
Nivolumab can also be administered as 480mg every 4 weeks

Nivolumab for the treatment of relapsed or refractory classical Hodgkin lymphoma in adults following treatment with brentuximab and with no previous stem cell transplantation
1. I understand that this application is for an interim version of the usual treatment criteria for this drug/regimen as an option so as to reduce the risk to patients and alleviate the impact on service capacity during the COVID19 pandemic.
If the patient is still suitable for the standard regimen of nivolumab following transplantation, please use form NIV2.
2. I confirm that this application is being made by and the first cycle of systemic anti-cancer therapy with nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.
3. I confirm that as the prescribing clinician I am fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis.
4. I confirm that the patient has a histologically confirmed diagnosis of classical Hodgkin's Lymphoma.
5. I confirm that the patient has relapsed or refractory disease.
6. I confirm that the patient has had prior treatment with at least 1 line of cytotoxic chemotherapy and also with brentuximab vedotin for relapsed/refractory disease.
7. I confirm that the patient has not been treated with high dose chemotherapy and stem cell transplantation.
8. I confirm that the patient has an ECOG performance status (PS) 0-1.
9. I confirm that the patient is an adult*
10. I confirm that nivolumab will be given as monotherapy and preferably at a dose of 480mg every 4 weeks.
11. I confirm that Trust policy regarding the use of unlicensed treatments has been followed as the use of nivolumab pre stem cell transplantation and the dose (480mg) and frequency of administration (every 4 weeks) are not licensed in this indication.
12. I confirm that the patient has no known central nervous system lymphoma.
13. I confirm that the patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody unless received as part of the nivolumab EAMS programme for this indication and meeting all other criteria listed.
14. I confirm the patient will receive a maximum treatment duration of 2 years of uninterrupted treatment or 52 administrations (when administered every 2 weeks) or 26 administrations (when administered every 4 weeks) with nivolumab, whichever is later*.
15. I confirm that where a treatment break of more than 12 weeks beyond the expected cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.
16. I confirm that I have fully discussed with the patient as to the risks/benefits of giving this regimen including the discussion as to likely clinical benefit and toxicities of the modified regimen compared with the standard funded regimen.
17. I confirm that nivolumab will otherwise be used as set out in its Summary of Product Characteristics (SPC), except criterion 10 and 14.

Nivolumab for treating metastatic colorectal cancer for patients with high microsatellite instability (MSI-H) or mismatch repair deficiency (dMMR)
1. I understand that this application is for interim access to this drug/regimen so as to provide an option to reduce the risk to patients and alleviate the impact on service capacity during the COVID19 pandemic.
2. I confirm that this application is being made by and the first cycle of systemic anti -cancer therapy with nivolumab will be prescribed by a consultant specialist specifically trained and accredited in the use of systemic anti-cancer therapy.
3. I confirm that as the prescribing clinician I am fully aware of the management of and the treatment modifications that may be required for immune-related adverse reactions due to anti-PD-L1 treatments including pneumonitis, colitis, nephritis, endocrinopathies and hepatitis.
4. I confirm that the patient has metastatic colorectal carcinoma
5. I confirm that the patient has a documented presence of high microsatellite instability (MSI-H) or the presence of DNA mismatch repair deficiency (dMMR) confirmed by validated testing.
6. I confirm that the patient has either not received previous systemic therapy for colorectal cancer (prior adjuvant chemotherapy for colorectal cancer therapy is allowed as long as therapy was completed at least 6 months prior to the diagnosis of metastatic disease) or the patient has previously received chemotherapy for metastatic colorectal cancer.
Please mark below which clinical scenario applies to this patient:

Please mark below which clinical scenario applies to this patient:
no previous systemic therapy for metastatic colorectal cancer and no previous adjuvant chemotherapy

no previous systemic therapy for metastatic colorectal cancer and previous adjuvant chemotherapy
previous systemic therapy for metastatic colorectal cancer.
7. I confirm that the patient has an ECOG performance status (PS) of 0 or 1
8. I confirm that the patient has no symptomatic brain or leptomeningeal metastases.
9. I confirm that the patient has not received prior treatment with an anti-PD-1, anti-PD-L2, anti-CD137, or anti-Cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4) antibody.
10. I confirm that Trust policy regarding the use of unlicensed treatments has been followed as 1st or subsequent line nivolumab monotherapy in patients with high microsatellite instability (MSI-H) or the presence of DNA mismatch repair deficiency (dMMR) is not licensed in this indication.

11. I confirm that nivolumab will be administered as monotherapy as either 2-weekly cycles of nivolumab at a dose of 240mg (or if the patient is stable and well, 4-weekly cycles of nivolumab monotherapy 480mg).
12. I confirm that nivolumab will be stopped on disease progression or unacceptable toxicity, whichever occurs first.
13. I confirm that a formal medical review as to whether treatment with nivolumab should continue will occur at least by the end of the 2nd month of treatment.
14. I confirm that where a treatment break of more than 12 weeks beyond the expected 2 or 4-weekly cycle length is needed, I will complete a treatment break approval form to restart treatment, including indicating as appropriate if the patient had an extended break because of COVID 19.
15. I confirm that I have fully discussed with the patient as to the risks/benefits of giving this regimen including the discussion as to likely clinical benefit and toxicities of the modified regimen compared with the standard funded regimen.
16. I confirm that nivolumab will be otherwise used as set out in its Summary of Product Characteristics (SPC).

Blueteq form (CV form) needs to be completed for all patients.

DRUG REGIMEN
Nivolumab 480mg in 100ml* sodium chloride 0.9% IV infusion over 60 minutes
via 0.2/0.22micron in-line filter.
*doses 58mg to 110mg in 50ml sodium chloride 0.9%

every 4 weeks until progression or intolerance (up to total maximum 2 years)

EXPANDED ACCESS GUIDANCE DOCUMENT CA209254
Version of 03 July 2014
Nivolumab SPC Ref 3677021
SPC April 2018

TVCN protocol: CDF list, temporary changes

Plan Summary

Nivolumab 28 day v= V2.0

Chemo Order Instructions

ANTIEMETIC POLICY:
None needed

CONCURRENT MEDICATION
None required

INVESTIGATIONS
U&Es, LFTs, FBC
Endocrine profile including cortisol and glucose

DOSE MODIFICATIONS
See OPDIVO (nivolumab) SPC

ADVERSE REACTIONS
See Immuno-oncology adverse event management guidelines
Involve consultant in all grade 2 or higher toxicities.
CMV related colitis

Amendment Summary

Direct copy of nivolumab 28 day metastatic
Name changed to relapsed/metastatic.
Disease sites and categories amended to temporary indications
S Coutts
6/4/2020

Colorectal disease sites added and indication
S Coutts 28/4/2020