

## Nivolumab - Relapsed Classical Hodgkin Lymphoma (cHL) Post-Autologous Stem Cell Transplant (ASCT) or ASCT Ineligible

This is a renamed version of *Nivolumab – Relapsed Classical Hodgkin Lymphoma (cHL) Post Autologous Stem Cell Transplant (ASCT)* policy.

(This form should be completed before the first dose is dispensed.)

### 1. Patient Profile

- \* Surname: .....
- \* Given Name: .....
- \* OHIN: ..... \* Chart Number: .....
- \* Postal Code: .....
- \* Height (cm): ..... \* Weight (kg): .....
- \* BSA (m<sup>2</sup>): ..... \* Gender:  Male  Female  Other
- \* Date of Birth: .....  
Day    Month    Year
- \* Site: .....
- \* Attending Physician (MRP- Most Responsible Physician): .....
- Requested Prior Approval  Yes \* Patient on Clinical Trial  Yes  No
- Other (specify): .....
- Specify Arm:  
 Standard of care arm  Experimental arm  
 Blinded / Unknown

### Prior Approval Request

- \* Select the appropriate prior approval scenario:

- 1-Unknown primary (submit pathology report and clinic note)
- 2-Clinical document review (identify the patient history that needs to be reviewed against eligibility criteria in Additional Comments below)
- 3-Regimen modification - schedule (complete questions a and b)
- 4-Regimen modification - drug substitutions (complete questions a and c)
- 5-Withholding a drug in combination therapy from start of treatment (complete questions d, e and f)
- 6-Maintenance therapy delay (submit clinic note)
- 7-Prior systemic therapy clinical trials (complete question g)
- 8-Modification due to supply interruption/drug shortage
- Other (specify)

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**All relevant supporting documentation must be submitted at the time of prior approval. Documentation may include a pathology report, clinic note, and/or CT scans.**

a. Co-morbidities / toxicity / justification:

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b. Intended regimen schedule: .....

c. Intended regimen: .....

d. Drug(s) to be held: .....

e. Rationale for holding drug(s): .....

f. Intention to introduce drug at a later date?  Yes

g. Prior clinical trial identifier (e.g., NCT ID, trial name) and treatment description (e.g., arm, drug/regimen): .....

h. Anticipated date of first treatment: \_\_\_\_\_  
Day    Month    Year

i. Additional comments:

\_\_\_\_\_

## 2. Eligibility Criteria

a. The patient meets the following criteria:

- For the treatment of patients with classical Hodgkin Lymphoma (cHL) who have relapsed or progressed after autologous stem cell transplantation (ASCT) and brentuximab vedotin (BV), or who are not candidates for ASCT and have failed BV.  Yes

## 3. Baseline Information

a. ECOG Performance Status at the time of enrolment  0     1     2

## 4. Funded Dose

Nivolumab 3 mg/kg IV, up to a maximum of 240 mg, every two weeks as an intravenous (IV) infusion, or nivolumab 6 mg/kg IV, up to a maximum of 480 mg, every four weeks as an IV infusion.

Treatment should continue until confirmed disease progression or unacceptable toxicity.

[ST-QBP regimen code: NIVL]

## 5. Notes

1. Patients will be eligible for either pembrolizumab or nivolumab for refractory or relapsed classical Hodgkin lymphoma (cHL), but not both.
2. For patients stopping nivolumab without disease progression, resumption of treatment will be funded provided no other treatment is given in between.
3. Nivolumab is not funded for patients who have confirmed disease progression while receiving a prior anti-PD-1 inhibitor.

## 6. FAQs

**i. My patient is currently receiving nivolumab through non-publicly funded means for relapsed cHL. Can my patient be transitioned over to receive funding through the New Drug Funding Program (NDFP)?**

Provided the funding criteria were met at the time of treatment initiation and the patient's disease has not progressed, your patient may be eligible for continued coverage of nivolumab through NDFP.

**ii. My patient with relapsed/refractory classical Hodgkin lymphoma (cHL) is not a candidate for an autologous stem cell transplant (ASCT). Would they be eligible for nivolumab?**

Patients with relapsed/refractory cHL who are not candidates for an ASCT would be eligible for nivolumab after failure of prior brentuximab vedotin.

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## **7. Supporting Documents**

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None required at time of enrolment.

In the event of an audit, the following should be available to document eligibility:

- Clinic notes indicating treatment history including the date of the ASCT (if eligible).
- CT scans every 3 to 6 months (or as clinically appropriate), along with clinic notes indicating no disease progression.
- In instances where there is pseudoprogression,
  - a clinic note documenting the assessment and decision to continue, AND
  - a confirmatory scan conducted preferably at 6 to 8 weeks but no later than 12 weeks after the initial disease progression to confirm the absence of true progression.

Signature of Attending Physician (MRP- Most Responsible Physician): .....

.....  
Day      Month      Year