Cancer Care Ontario
Action Cancer Ontario

eClaims

Eligibility Form

Durvalumab - In Combination with Etoposide and Platinum for Extensive-Stage Small Cell Lung Cancer

(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^2): ..... * 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:

.....

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

The patient must meet the following criteria:

Durvalumab is used in combination with etoposide and platinum (EP) chemotherapy (cisplatin or carboplatin), for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) who have not received previous treatment for ES-SCLC, and have good performance status upon treatment initiation with durvalumab. ☐ Yes

3. Baseline Information

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

b. Is the patient transitioning from a private pay or compassionate program? ○ Yes ○ No

c. If yes to 3b, has the patient started maintenance durvalumab? ○ Yes ○ No

d. If no to 3c, how many cycles of durvalumab (in combination with EP) have been given?
○ 1 ○ 2 ○ 3 ○ 4

4. Funded Dose

Durvalumab 1500mg* intravenously (IV), once every 3 weeks (in combination with etoposide and platinum (carboplatin or cisplatin)) for 4 cycles, followed by durvalumab 1500mg once every 4 weeks as monotherapy until disease progression or unacceptable toxicity.

*For patients weighing less than or equal to 30kg, a weight-based durvalumab dose of 20mg/kg is used until weight increases to greater than 30kg.

[ST-QBP regimen code: Either one of CISPETOP+DURV, or CISPETOP(PO)+DURV, or CRBPETOP+DURV, or CRBPETOP(PO)+DURV, followed by DURV(MNT) for use as monotherapy]

5. Notes

1. Durvalumab must be used in combination with etoposide and platinum chemotherapy, followed by durvalumab maintenance.

2. Ontario Health (Cancer Care Ontario) will fund one of atezolizumab <u>or</u> durvalumab, in combination with platinum-etoposide followed by maintenance, for ES-SCLC.

6. FAQs

i. **My patient is currently receiving durvalumab through non-publicly funded means for ES-SCLC. 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 durvalumab through NDFP. Please submit as a prior approval request including the most recent clinic note documenting the response to treatment.

ii. **Will durvalumab be funded if an alternative chemotherapy is given for the first line treatment of ES-SCLC?**

Durvalumab is only funded if used in combination with etoposide and platinum chemotherapy.

iii. **My patient has recently completed EP chemotherapy for the first line treatment of ES-SCLC. Is my patient eligible for durvalumab?**

Patients who have completed EP chemotherapy are not eligible for durvalumab funding.

iv. **My patient had to stop durvalumab due to an adverse event. Will NDFP fund a restart of durvalumab?**

If durvalumab was stopped due to an adverse event, NDFP will fund the restart of durvalumab provided that no systemic treatment is given in between.

Supporting Documents

None required at the time of enrolment.

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

- Clinic note indicating that durvalumab is used with etoposide and platinum for the first line treatment of extensive-stage small cell lung cancer.
- Pathology report demonstrating histologically or cytologically confirmed ES-SCLC.
- CT scans every 3 to 6 months, along with clinic notes indicating no disease progression.
- If there is radiographic progression, a clinic note must be provided confirming that there is no clinical disease progression and that the patient may continue to experience clinical benefit.

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

....
Day Month Year

Form 1002