

Lancashire & South Cumbria Cancer Network Systemic Anticancer Treatment Protocol

DRUG REGIMEN

Durvalumab

Indication for use

Locally advanced unresectable Stage III non-small cell lung cancer (NSCLC) who did not have disease progression after two or more cycles of platinum-based chemoradiotherapy

Regimen

Durvalumab 10 mg/kg in 100ml 0.9% sodium chloride administered as an intravenous infusion over 60 minutes every 2 weeks until disease progression, unacceptable toxicity, or a maximum of 12 months

***Under NICE COVID19 amendments, durvalumab may be given at a dose of 1500mg every 4 weeks**

In the event of a complete response (based upon Immune-Related Response Criteria) it is at the discretion of the consultant to keep a patient on treatment or to discontinue treatment. This decision will be based on the consultant's judgment of a patient's overall clinical condition, including performance status, clinical symptoms, and laboratory data.

If the treatment is tolerated tumour response should be assessed every 12 weeks or as clinically indicated.

Investigation prior to initiating treatment

FBC, U&Es incl bicarbonate, LFTs, LDH, Ca, glucose, TFTs
Serum samples for HIV, hep C antibody and HBsAg if risk factors.
Pregnancy test (if applicable)
Weight, vital signs, ECOG performance status

Investigations and consultations prior to each cycle

ECOG performance status
FBC, U&Es, LFTs
TFTs – alternate doses or if abnormal at each cycle

Cautions

Patients should be on the lowest clinically effective dose of systemic steroids.

Administration Guidelines

Administer the drug solution over 60 minutes using a volumetric pump through an in-line 0.2µm or 1.2µm polyethersulfone or 0.2µm positively charged nylon filter

DOSE MODIFICATIONS

For information on treatment of Immune related side effects see:

<https://www.nwscsenate.nhs.uk/strategic-clinical-network/our-networks/cancer/lancs-south-cumbria-chemotherapy-protocols/lsc-immune-related-toxicity-management-guidelines/>

Dose Modifications/Discontinuation Criteria

Durvalumab will be withheld for a drug-related non-hematological toxicity \geq Grade 2 (excluding fatigue).

Once the patient has recovered to Grade 0-1 the drug can be continued

Durvalumab will be permanently discontinued for any Grade 3-4, severe or life-threatening adverse reaction.

For rash / dermatitis reactions permanently discontinue only if Grade 4.

For any endocrinopathy treatment can be resumed once clinically stable.

Drug does NOT need to be delayed or discontinued for controlled endocrinopathies.

Grade 1: No action. Provide symptomatic treatment

Grade 2: May withhold durvalumab. Consider systemic corticosteroids in addition to appropriate symptomatic treatment

Grade 3 and Grade 4: Withhold durvalumab. Discontinue if unable to reduce corticosteroid dose to < 10 mg per day prednisolone equivalent within 12 weeks of toxicity. Systemic corticosteroids are indicated in addition to appropriate symptomatic treatment. May utilize 1 to 2 mg/kg prednisolone or equivalent per day. Steroid taper should be considered once symptoms improve to Grade 1 or less and tapered over at least 4 weeks.

THIS PROTOCOL HAS BEEN DIRECTED BY DR A. MIRZA, CLINICIAN FOR LUNG CANCER

RESPONSIBILITY FOR THIS PROTOCOL LIES WITH THE HEAD OF SERVICE

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