# DOSTARLIMAB (Jemperli)

## INDICATION (ICD10) C54

*Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required. (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/)* (DOS1)

1. Dostarlimab monotherapy for patients with microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) recurrent or locally advanced or metastatic endometrial carcinoma with progressive disease after prior platinum-based chemotherapy. No symptomatic brain or leptomeningeal metastases. PS 0 or 1.

## REGIMEN

**Cycles 1 and 2**

| | | | | |
|---|---|---|---|---|
| Days 1 and 22 | **DOSTARLIMAB** | 500mg | IV infusion | #ml sodium chloride 0.9% over 30 minutes |

**Cycle 3 onwards**

| | | | | |
|---|---|---|---|---|
| Day 1 | **DOSTARLIMAB** | 1000mg | IV infusion | #ml sodium chloride 0.9% over 30 minutes |

# diluent volume for dose prescribed as per national standardised product specification

## CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 42 days until disease progression.
A formal medical review as to whether treatment with dostarlimab should continue will occur at least by the end of the 2nd 3-weekly cycle of treatment.
NB once dostarlimab is stopped for disease progression or unacceptable toxicity or withdrawal of patient consent, dostarlimab cannot be re-started.

## ANTI-EMETICS

None required

## CONCURRENT MEDICATION REQUIRED

None required

## EXTRAVASATION AND TYPE OF LINE / FILTERS

Dostarlimab - neutral

Administer dostarlimab via a 0.2 or 0.22micron in-line polyethersulfone (PES) filter
Peripheral line

## INVESTIGATIONS

Blood results required before SACT administration

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| FBC, U&E including $Mg^{++}$ (>0.4) and LFTs<br>Neutrophils x $10^9$/L ≥1.0 provided patient is well<br>Platelets ≥100x$10^9$/L | baseline and every cycle |
| Thyroid function | baseline and every cycle |
| Random cortisol | baseline and every cycle |
| Random glucose | baseline and every cycle |
| Virology | before cycle 1 if not previously checked |
| Weight | baseline and every cycle |

## MAIN TOXICITES AND ADVERSE REACTIONS

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|---|---|
| Dostarlimab | Immune related toxicities - pneumonitis, colitis or hepatitis etc |

## INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
**(not exhaustive list check SPC)**

| | |
|---|---|
| Dostarlimab | - |

## DOSE MODIFICATIONS
### Non-haematological
Dostarlimab
Immune-related adverse reactions - refer to TV immune-oncology agent immune related adverse event clinical guideline

Recurrence of immune-related adverse reactions after resolution to ≤grade 1 (except for pneumonitis)

| | |
|---|---|
| Grade 3 to 4 | Permanently discontinue. |

Colitis

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|---|---|
| Grade 2 to 3 | Withhold dose. Restart dosing when toxicity resolves to grade 0-1. |
| Grade 4 | Permanently discontinue. |

Hepatitis

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| Grade 2 with AST or ALT >3 and up to 5×ULN or total bilirubin >1.5 and up to 3×ULN | Withhold dose. Restart dosing when toxicity resolves to grade 0 to 1. |
| Grade ≥3 with AST or ALT >5×ULN or total bilirubin >3×ULN | Permanently discontinue. For patients with liver metastases who begin treatment with grade 2 increase of AST or ALT, if AST or ALT increases by ≥50 % relative to baseline and lasts for at least 1 week, then treatment should be discontinued. |

Hypophysitis or adrenal insufficiency

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|---|---|
| Grade 2 to 4 | Withhold dose. Restart dosing when toxicity resolves to grade 0 to 1. Permanently discontinue for recurrence or worsening while on adequate hormonal therapy. |

Hypothyroidism or hyperthyroidism

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| Grade 3 to 4 | Withhold dose. Restart dosing when toxicity resolves to grade 0 to 1. |

Infusion-related reactions

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|---|---|
| Grade 2 | Withhold dose. If resolved within 1 hour of stopping, may be restarted at 50% of the original infusion rate, or restart when symptoms resolve with pre-medication. If grade 2 recurs with adequate premedication, permanently discontinue. |
| Grade 3 to 4 | Permanently discontinue. |

Nephritis

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|---|---|
| Grade 2 | Withhold dose. Restart dosing when toxicity resolves to grade 0-1. |
| Grade 3 to 4 | Permanently discontinue. |

Pneumonitis

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|---|---|
| Grade 2 | Withhold dose. Restart dosing when toxicity resolves to grade 0-1. If grade 2 recurs, permanently discontinue. |
| Grade 3 to 4 | Permanently discontinue. |

Immune-mediated rash

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|---|---|
| Grade 3 | Withhold dose. Restart dosing when toxicity resolves to grade 0-1. |
| Grade 4 | Permanently discontinue. |

Other immune-related adverse reactions (including but not limited to myositis, myocarditis, encephalitis, demyelinating neuropathy including Guillain Barré syndrome, sarcoidosis, autoimmune haemolytic anaemia, pancreatitis, iridocyclitis, uveitis, diabetic ketoacidosis, arthralgia, solid organ transplant rejection, graft-versus-host disease)

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|---|---|
| Grade 3 | Withhold dose. Restart dosing when toxicity resolves to grade 0-1. |
| Grade 4 | Permanently discontinue. |

Type 1 diabetes mellitus (T1DM)

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| Grade 3 to 4 (hyperglycaemia) | Withhold dose. Restart dosing in appropriately managed, clinically and metabolically stable patients. |

**Hepatic impairment**

Dostarlimab

No dose adjustment is recommended for patients with mild hepatic impairment. There are limited data in patients with moderate hepatic impairment and no data in patients with severe hepatic impairment.

**Renal impairment**

Dostarlimab

No dose adjustment is recommended for patients with mild or moderate renal impairment. There are limited data in patients with severe renal impairment or end-stage renal disease undergoing dialysis.

**REFERENCES**

1. SPC 2024

Assessments

| | Pre | Cycle 1 | Cycle 2 | Cycle 3 | Cycle 4 | Ongoing |
|---|---|---|---|---|---|---|
| Clinical assessment | X | | Pre cycle | | Pre cycle | Every cycle |
| SACT assessment (PS and toxicities) | X | X | X | X | X | Every cycle |
| FBC | X | X | X | X | X | Every SACT |
| U&E, calcium, magnesium & LFT | X | X | X | X | X | Every cycle |
| CT scan | X | | | | | At cycle 6, Inform consultant team if not booked |
| Informed consent | X | | | | | Verbal each cycle |
| Height | X | | | | | |
| Weight recorded | X | X | X | X | X | Every cycle |