Healthcare Improvement Scotland | SMC Advice on new medicines

SMC2953

dostarlimab concentrate for solution for infusion (Jemperli®)

GlaxoSmithKline UK Ltd

10 July 2026

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and advises NHS Boards and Area Drug and Therapeutic Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following a resubmission assessed under the end of life and orphan equivalent medicine process

dostarlimab (Jemperli®) is accepted for use within NHSScotland.

Indication under review: in combination with platinum-containing chemotherapy for the treatment of adult patients with primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.

In a phase III study, dostarlimab compared with placebo, numerically improved progression-free survival in adults with primary advanced or first recurrence of endometrial cancer who had proficient mismatch repair (pMMR)/microsatellite stable (MSS) disease.

This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower.

This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting.

SMC has previously accepted dostarlimab for use in combination with platinum-containing chemotherapy for the treatment of adult patients with mismatch repair deficient (dMMR)/microsatellite instability-high (MSI-H) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy (SMC2635). This advice remains valid.

Chair
Scottish Medicine Consortium

1. Clinical Context

1.1. Medicine background

Dostarlimab is a monoclonal antibody that binds to the programmed cell death protein 1 (PD-1) receptor and blocks its interaction with ligands PD-L1 and PD-L2, thereby enhancing T-cell anti-tumour responses. In the indication under review, it is given by intravenous (IV) infusion, 500 mg every three weeks, in combination with platinum-containing chemotherapy, for six cycles and then 1,000 mg every six weeks for up to three years. For the dose of concomitant chemotherapeutic agents, refer to their SPC.[1]

1.2. Disease background

Endometrial cancer is the fourth most common cancer in women in the UK. The incidence of endometrial cancer increases with age and is highest between the ages of 75 to 79 years in the UK. Risk factors include obesity, hypertension, hyperinsulinaemia and prolonged exposure to unopposed oestrogen. Endometrial cancer is confined to the uterus at diagnosis in about 80% of cases and often detected by post-menopausal bleeding. Survival rates are high for localised disease that is surgically removed, but poor for distant disease, with estimated survival between 18% to 25% at five years. About 70% to 75% of endometrial cancers are pMMR.[2-4]

1.3. Company proposed position

For use in combination with platinum-containing chemotherapy for the treatment of adult patients with proficient mismatch repair (pMMR)/microsatellite stable (MSS) primary advanced or recurrent endometrial cancer and who are candidates for systemic therapy.

1.4. Treatment pathway and relevant comparators

The 2021 British Gynaecological Cancer Society (BGCS) uterine cancer guidelines recommend carboplatin plus paclitaxel as standard first-line chemotherapy for the treatment of advanced or recurrent endometrial cancer.(2) Pembrolizumab (PD-1 receptor inhibitor) and durvalumab (PD-L1 inhibitor) have been recently accepted by SMC in July and October 2025 (SMC2767 and SMC2797, respectively) for first-line use in combination with platinum-based chemotherapy for treatment of advanced or recurrent endometrial cancer that is pMMR/MSS, with durvalumab maintenance therapy in combination with olaparib.[5,6] The timing of SMC advice for these medicines precludes them being relevant comparators in this submission. Cancer Medicines Outcome Programme Public Health Scotland (CMOP-PHS) data confirmed that the majority of patients in NHSScotland receiving first-line systemic anti-cancer therapy for advanced endometrial cancer received carboplatin plus paclitaxel or one of these medicines alone, while a smaller proportion received both in combination with dostarlimab, which would be given for the previously licensed indication in patients with deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease.[1,7]

1.5. Category for decision-making process

Eligibility for interim acceptance decision option

Dostarlimab has received an Innovation Passport allowing entry into the Innovative Licensing and Access Pathway.

Eligibility for a PACE meeting

Dostarlimab meets SMC orphan equivalent and end of life criteria for this indication.

2. Summary of Clinical Evidence

2.1. Evidence for the licensed indication under review

Evidence is from Part 1 of the RUBY study (RUBY-1), as detailed in Table 2.1.[8-11]

Table 2.1. Overview of relevant study.[8,9]

Criteria	RUBY-1
Study design	Double-blind, phase III study.
Eligible patients	Adults, ≥18 years old, with primary advanced (Stage III or IV) or first recurrent endometrial cancer with low potential for cure with surgery and/or radiotherapy. Patients were naïve to or had a recurrence at least 6 months after (neo)adjuvant systemic anticancer therapy. They had ECOG performance status of 0 or 1.
Treatments	All patients received IV infusions of carboplatin (AUC 5 mg/mL/min) and paclitaxel (175 mg/m^2) every three weeks for six cycles. Patients were equally assigned to IV infusions of placebo or dostarlimab 500 mg every three weeks for six cycles then 1,000 mg every six weeks till disease progression, unacceptable toxicity or 3 years.
Randomisation	Randomisation was stratified by MMR/MSI status (dMMR/MSI-H or pMMR/MSS), prior external pelvic radiation (yes or no) and disease status (recurrent, primary stage III or primary stage IV).
Co-primary outcomes	1. PFS, defined as time from randomisation to investigator-assessed progression on RECISTv1.1, or death from any cause in (a) dMMR and (b) overall populations. 2. OS, defined as time from randomisation to all cause death in overall population.
Secondary outcomes	ORR, DOR, analyses in pMMR population.
Statistical analysis	The co-primary outcomes were included in a testing hierarchy. Analyses in the pMMR population were additional and, in common with other non-primary outcomes, were not formally assessed or controlled for multiplicity.

Abbreviations: AUC = area under the curve; dMMR/MSI-H = deficient mismatch repair/microsatellite instability-high; DOR = duration of response; ECOG = Eastern Co-operative Oncology Group; HR = hazard ratio; IV = intravenous; KM = Kaplan-Meier estimate; MMR/MSI = mismatch repair/microsatellite instability; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; pMMR/MSS proficient mismatch repair/microsatellite stable; RECISTv1.1 = Response Evaluation Criteria in Solid Tumors version 1.1.

At the first interim analysis (28 September 2022), dostarlimab (plus carboplatin and paclitaxel) compared with placebo (plus carboplatin and paclitaxel) significantly improved one of the co-primary outcomes, investigator-assessed progression-free survival (PFS) on Response Evaluation Criteria in Solid Tumors version 1.1 (RECISTv1.1), in both the dMMR and overall study population and there was no further testing of this outcome. The other co-primary outcome, overall survival (OS) in the overall population, did not reach statistical significance but at the planned second interim analysis (22 September 2023), it was significantly greater with dostarlimab (plus carboplatin and paclitaxel) compared with placebo (plus carboplatin and paclitaxel).[8,9] Results are detailed in Table 2.2. The study is ongoing for final assessment of OS.

Table 2.2: Results of RUBY-1 study.[8,9]

	Overall		dMMR		pMMR	
	Dostarlimab	**Placebo**	**Dostarlimab**	**Placebo**	**Dostarlimab**	**Placebo**
	N=245	**N=249**	**N=53**	**N=65**	**N=192**	**N=184**
Progression-free survival by investigator on RECISTv1.1 at 28 September 2022						
Events	135	177	19	47	116	130
Median, months	11.8	7.9	NR	7.7	9.9	7.9
HR (95% CI)	0.64 (0.51 to 0.80)[A]		0.28 (0.16 to 0.50)[A]		0.76 (0.59 to 0.98)[D]	
KM PFS at 2 years	36%	18%	61%	16%	28%	19%
Overall survival at 22 September 2023						
Deaths	109	144	12	35	97	109
Median, months	44.6	28.2	NR	31.4	34.0	27.0
HR (95% CI)	0.69 (0.54 to 0.89)[B]		0.32 (0.17 to 0.63)[C]		0.79 (0.60 to 1.04)[E]	
KM OS at 2 years	70%	54%	83%	54%	66%	53%
Objective response in evaluable patients by investigator on RECISTv1.1 at 28 September 2022						
ORR, % (n/N)	70% (149/212)	65% (142/219)	78% (38/49)	69% (40/58)	68% (111/163)	63% (102/161)
Median DOR, months	10.6	6.2	NR	5.4	8.6	6.3

Abbreviations: A = p<0.001; B = p=0.002; C = nominal p<0.001; D = nominal p=0.0177; E = nominal p=0.0493.
CI = confidence interval; DOR = duration of response; HR = hazard ratio; KM = Kaplan-Meier estimate; ORR = objective response rate; OS = overall survival; PFS = progression-free survival; RECISTv1.1 = Response Evaluation Criteria in Solid Tumors version 1.1.

2.2. Evidence to support the positioning proposed by the submitting company

Additional analyses, not included in the formal testing hierarchy, provide evidence for the new indication in the pMMR/MSS group. This indicated numerical improvements with dostarlimab in PFS (28 September 2022) and in OS (22 September 2023) that were smaller than those seen in the dMMR/MSI-H subgroup but considered relevant in a regulatory review. Results are detailed in Table 2.1 above.[8,9]

2.3. Health-related quality of life outcomes

Health-related quality of life outcomes included the EuroQol five-dimensions five levels (EQ-5D-5L) visual analogue scale (VAS), the European Organisation for the Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC-QLQ-C30) and the EORTC-QLQ-Endometrial Cancer (EN24). These instruments were used at baseline and at every cycle of treatment; results were not statistically tested and are descriptive only. The mean change from baseline in EORTC-QLQ-C30 and EN24 and EQ-5D-5L were similar between the treatment groups.[8,9]

3. Summary of Safety Evidence

A regulatory review noted that the adverse events observed in RUBY-1 corresponds with the established safety profile of dostarlimab and no new issues were identified. The adverse event rate is greater with dostarlimab plus platinum-containing chemotherapy than with chemotherapy alone.

In the RUBY-1 study at the second interim analysis (data cut-off 22 September 2023), median duration of treatment in the dostarlimab and placebo group was 43 and 36 weeks, respectively, (39 and 36 weeks in the pMMR/MSS population). All patients experienced at least one adverse event, with 98% (236/241) and 99% (243/246) having a treatment-related adverse event (97% and 98% in pMMR/MSS). Adverse events considered related only to dostarlimab or placebo were reported by 61% and 42% (58% and 44% in pMMR/MSS) and these were at least grade 3 severity in 22% and 9.8% (20% and 11% in pMMR/MSS). Serious adverse events related only to dostarlimab or placebo occurred in 6.6% and 3.3% (5.8% and 3.3% in pMMR/MSS). Adverse events that led to discontinuation of dostarlimab or placebo were reported by 19% and 8.1% (20% and 8.3% in pMMR/MSS).[8]

Immune adverse events considered related only to dostarlimab or placebo were reported by 41% and 16% and included hypothyroidism (12% versus 2.8%), rash (7.1% versus 2.0%), arthralgia (6.6% versus 6.5%) and increased alanine aminotransferase (6.2% versus 1.2%). Adverse event of grade ≥3 severity considered related to these medicines included anaemia (13% and 13%), neutropenia (9.5% and 8.9%), neutrophil count decreased (7.5% and 14%), lymphocyte count decreased (4.1% and 4.9%), decreased white cell count (5.8% versus 4.9%), rash (4.1% and 1.2%) and hypertension (2.1% versus 0).[8]

4. Summary of Clinical Effectiveness Considerations

4.1. Key strengths

- In a double-blind phase III study dostarlimab compared with placebo (in combination with carboplatin and paclitaxel), numerically improved PFS and OS in the pMMR/MSS group, with increases in the medians of about 2 and 7 months, respectively.[8-11]
- Dostarlimab adds to the number of checkpoint inhibitor medicines that are licensed for the treatment of pMMR/MSS primary advanced or first recurrence of endometrial cancer.[1,5,6]

4.2. Key uncertainties

- The benefits in terms of PFS and OS in the pMMR/MSS patients were from additional analyses of a subgroup (comprising 76% of the study population) that were not formally tested or controlled for multiplicity. The study was not powered to assess PFS and OS in this subgroup and this may impact interpretation of these results.[8,9]
- The magnitude of benefit in pMMR/MSS patients was smaller than in dMMR/MSI-H patients. A regulatory authority noted that although the benefit in PFS and OS in the overall population is driven by the dMMR/MSI-H subgroup, the pMMR/MSS subgroup also obtain benefit from dostarlimab.[8,9]
- The dostarlimab group, compared with placebo, had lower rates of subsequent anti-cancer therapies, 49% and 70% (55% and 73% in pMMR/MSS), particularly immunotherapy, 17% and 38% (18% and 37% in pMMR/MSS), but similar rates of chemotherapy, hormonal therapy and radiation therapy across the treatment groups.[8,11] This may confound OS analyses but may be representative of practice.

- CMOP-PHS data suggests that patients in RUBY-1 were less representative of those treated in NHSScotland in terms of Eastern Cooperative Oncology Group (ECOG) performance status.[7,8]

4.3. Clinical expert input

Clinical experts consulted by SMC noted that dostarlimab in this indication does not fulfil an unmet need as there are other medicines in the same therapeutic class licensed for treatment of primary advanced for first recurrent endometrial cancer with pMMR/MSS disease.

5. Patient and clinician engagement (PACE)

A patient and clinician engagement (PACE) meeting with patient group representatives and clinical specialists was held to consider the added value of dostarlimab, as an orphan equivalent and end of life medicine, in the context of treatments currently available in NHSScotland.

The key points expressed by the group were:

- Advanced or recurrent endometrial cancer that is pMMR/MSS is an incurable, life-limiting disease with debilitating symptoms, including pain, fatigue, abdominal swelling, nausea, and urinary incontinence, that limit the patient's ability to care for themselves and work or care for family. It has a substantial psychological impact on the patient and their family, who may suffer anxiety, fear of disease recurrence and uncertainty around their future.
- The standard of care platinum-based chemotherapy is associated with a poor prognosis, and there is an unmet need for more effective therapies with acceptable tolerability. Expanding access to innovative treatments may help reduce inequalities.
- Addition of dostarlimab to platinum-based chemotherapy prolongs the time that the patient's disease is well controlled and they can lead a more meaningful life with a reduced need for support from their family. It can provide reassurance that they are receiving optimal treatment and give patients hope that they will see family milestones and allow them to plan for future events. It may give patients the hope that they may maintain their health to a point where they can potentially access other new treatments in the future. Overall, it may reduce the emotional impact of the disease on the patient and their family.
- Patients advise that they are happy to risk the side-effects of immunotherapy to access the benefits of dostarlimab in progression-free and overall survival. Expert clinicians advise that side-effects can be effectively managed. They note that dostarlimab would be used in line with its licence and the proposed positioning.

Additional Patient and Carer Involvement

We received a patient group submission from Peaches Womb Cancer Trust, which is a registered charity. Peaches Womb Cancer trust has received 26.2% pharmaceutical company funding in the past two years, including from the submitting company. A representative from Peaches Womb Cancer Trust participated in the PACE meeting. The key points of their submission have been included in the full PACE statement considered by SMC.

6. Summary of Comparative Health Economic Evidence

6.1. Economic case

An economic case was presented and is summarised in Table 6.1.

Table 6.1 Description of economic analysis

Criteria	Overview
Analysis type	Cost-utility analysis
Time horizon	Lifetime
Population	In combination with platinum-containing chemotherapy for the treatment of adult patients with pMMR/MSS primary advanced or recurrent endometrial cancer who are candidates for systemic therapy.
Comparators	Carboplatin plus paclitaxel (CP)
Model description	A cohort based partitioned survival model was used with three health states: progression-free (PF), progressed disease (PD) and death.
Clinical data	Data on PFS, OS, time to treatment discontinuation (TTD), baseline patient characteristics and adverse events (AEs) for dostarlimab in combination with CP and CP alone were from the respective arms of the RUBY-1 study.
Extrapolation	The company extrapolated long-term PFS and OS for dostarlimab in combination with CP and CP alone for use in the economic model using parametric survival modelling. Curve selection was based on goodness of fit statistics, the hazard profile in the observed study data and clinical expert opinion. Curve selection for the CP arm was also validated by a comparison to external data sources. For PFS, the company selected independently fitted flexible spline models based on inspection of non-proportional and monotonic hazards. This resulted in an odds 3 knots model for dostarlimab in combination with CP and a normal 2 knots model for CP alone. For OS, the company selected independently fitted standard parametric models based on non-proportional hazards. This resulted in the lognormal model for dostarlimab in combination with CP and the loglogistic model for CP alone.
Quality of life	EQ-5D data from RUBY-1 were used to derive utility values for use in the economic model for the PF and PD health states. AE disutilities from the literature were applied according to rates observed in the respective treatment arms of RUBY-1.
Costs and resource use	Costs included in the model were for medicine acquisition, administration, ongoing disease management, subsequent treatments, management of AEs and terminal care costs. Treatment duration was used directly from RUBY-1 up to a maximum of 3 years with dostarlimab, in line with its stopping rule, and 6-cycles with CP. Treatment duration was adjusted in the first 6 treatment cycles according to completion rates observed in RUBY-1 for dostarlimab and CP, and a relative dose intensity was applied to dostarlimab thereafter. The distribution of patients receiving subsequent treatments were according to those observed in the respective treatment arms of RUBY-1 adjusted based on patients who received dostarlimab in the model would not receive a subsequent immunotherapy upon progression. Subsequent treatment costs were adjusted according to the proportion of PFS events that were fatal in RUBY-1 across treatment arms.
PAS/contract price	A patient access scheme (PAS) was submitted by the company and assessed by the Patient Access Scheme Assessment Group (PASAG) as acceptable for implementation in NHSScotland. Under the PAS a discount was offered on the list price. PAS discounts are in place for paclitaxel, which was a combination and comparator medicine, and for pembrolizumab and lenvatinib, which were subsequent treatments. These were included in the results used for decision-making by using estimates of the PAS prices.

6.2. Results

This resubmission has been assessed under the fast track resubmission process.

The company presented results comparing dostarlimab in combination with carboplatin plus paclitaxel to carboplatin plus paclitaxel alone. The key cost drivers were medicine acquisition costs and subsequent treatment costs; key drivers of the QALY gain were pre- and post-progression survival.

The results of this analysis are presented in Table 6.2. SMC considered results for decision-making that took into account all relevant PAS. SMC is unable to present these results due to competition law issues.

Table 6.2: Base case results

Technologies	Total costs (£)	Total LYG	Total QALYs	Incr. costs (£)	Incr. LYG	Incr. QALYs	ICER (£/QALY)
Dostarlimab + carboplatin + paclitaxel	CIC	CIC	CIC	-	-	-	-
Carboplatin + paclitaxel	CIC	CIC	CIC	CIC	CIC	0.753	CIC

Abbreviations: CIC = commercial in confidence, ICER = incremental cost-effectiveness ratio, Incr. = incremental, LYG = life years gained, QALY = quality adjusted life year.

*Other data were also assessed but remain confidential.**

6.3. Sensitivity analyses

A range of sensitivity and scenario analysis were considered and descriptions of these key scenarios are provided in Table 6.3.

Table 6.3: Key scenario analyses

	Parameter	Base Case	Scenario	Incr. cost	Incr. QALY	ICER (£/QALY)
1a	Time horizon	Lifetime	25	CIC	0.529	CIC
1b			15	CIC	0.319	CIC
1c			10	CIC	0.213	CIC
2a	PFS extrapolation	Dostarlimab = odds k=3, CP = normal k=2	Dostarlimab = lognormal, CP = loglogistic	CIC	0.743	CIC
2b			Dostarlimab = normal 1 knot, CP = odds 1 knot	CIC	0.739	CIC
3a	OS extrapolation	Dostarlimab = lognormal, CP = loglogistic	CP = lognormal	CIC	0.718	CIC
3b			Dostarlimab = loglogistic	CIC	0.648	CIC

3c			CP = lognormal, Dostarlimab = loglogistic	CIC	0.613	CIC
3d			Dostarlimab = generalised gamma	CIC	0.344	CIC
3e			Dostarlimab = generalised gamma, CP = exponential	CIC	0.497	CIC
4	Comparative efficacy OS	Independently fitted parametric curves to RUBY-1 KM data	OS HR = 1	CIC	0.027	CIC
5	Treatment waning	Excluded	Included	CIC	0.711	CIC
6	TTD completion rates	Included	Excluded	CIC	0.753	CIC
7a	Subsequent treatment assumptions	Ruby-1 data used with adjustment for no subsequent IO in dostarlimab arm	Proportion receiving 'no subsequent treatment' assumed to the same across treatment arms	CIC	0.753	CIC
7b			RUBY-1 subsequent treatment proportions including subsequent IO for dostarlimab arm	CIC	0.753	CIC
7c		Proportion of RUBY-1 deaths from PF state excluded from subsequent treatment costs	All PFS events accrue subsequent treatment costs	CIC	0.753	CIC
8a	Health state utilities	RUBY-1 pMMR subgroup	RUBY-1 ITT population	CIC	0.750	CIC
8b			SMC2797	CIC	CIC	CIC
8c			SMC2767	CIC	CIC	CIC
C1	Combined scenarios	4c + 12a (OS extrapolations: dostarlimab + CP = loglogistic, CP = lognormal + % receiving no subsequent treatment set equal across both arms)		CIC	CIC	CIC
C2		4e + 12a (OS extrapolations: dostarlimab + CP = gen. gamma, CP = exponential + % receiving no subsequent treatment set equal across both arms)		CIC	0.497	CIC

Abbreviations: AEs = adverse events, CIC = commercial in confidence, CP = carboplatin + paclitaxel, ICER= incremental cost-effectiveness ratio, incr. = incremental, IO = immunotherapy, ITT = intention to treat, k = knots, KM = Kaplan-Meier, LEN = lenvatinib, pMMR = mismatch repair proficient, OS = overall survival, PD = progressed disease, PEM = pembrolizumab, PF = progression-free, PFS = progression-free survival, TTD = time to treatment discontinuation, QALY = quality adjusted life year

*Other data were also assessed but remain confidential.**

6.4. Key strengths

- The choice of comparator was appropriate.
- The modelling approach was reasonable and similar to other HTA submissions for related indications.
- Quality of life data were from the central clinical study and appeared to align reasonably well with external sources.

6.5. Key uncertainties

- As OS and PFS were key parameters in the economic analysis, the lack of statistical significance for a benefit with dostarlimab in terms of these outcomes added uncertainty to the results of the cost-effectiveness analysis.
- There was uncertainty around the long-term OS benefit with dostarlimab compared with carboplatin plus paclitaxel. The results of the economic analysis depended on extensive extrapolation of RUBY-1 OS data which demonstrated a numerical benefit but lacked statistical significance yet resulted in sustained and significant survival benefit over the model time horizon. A range of alternative extrapolations were explored to understand their impact on the cost-effectiveness results. The loglogistic distribution for dostarlimab closely aligned with the expectations of one clinical expert consulted by the company and resulted in higher estimates of cost-effectiveness when explored in a scenario (Scenario 3b). The impact on estimates of cost-effectiveness was greater when combined with the more optimistic curve selection for carboplatin plus paclitaxel OS (lognormal, see Scenario 3c). The generalised gamma curve for dostarlimab may also be plausible as it resulted in a benefit with dostarlimab compared with carboplatin plus paclitaxel up to 15-years (Scenario 3d); the exponential curve for carboplatin plus paclitaxel was also explored simultaneously to maintain a benefit with dostarlimab over the entire modelled time horizon (Scenario 3e).
- More patients in the dostarlimab arm of RUBY-1 received no subsequent treatment than patients in the chemotherapy arm. The company suggested that this was because of prior immunotherapy in the dostarlimab arm of RUBY-1 which led to fewer treatment options for these patients upon disease progression. This seemed to imply that post progression treatment was determined by prior treatment, whereas the company noted that subsequent treatment upon progression was not guided by prior therapy as blinding was maintained beyond disease progression. When the proportion of patients who did not receive a subsequent treatment was held equal across the treatment arms in the model, this resulted in only a small change in the estimate of cost effectiveness (Scenario 7a) as only patients in the chemotherapy arm could receive immunotherapy as a subsequent treatment.

7. Conclusion

The Committee considered the benefits of dostarlimab in the context of the SMC decision modifiers that can be applied when encountering high cost-effectiveness ratios and agreed that as

dostarlimab is an orphan equivalent medicine, SMC can accept greater uncertainty in the economic case.

After considering all the available evidence and the output from the PACE process, the Committee accepted dostarlimab for use in NHSScotland.

8. Guidelines and Protocols

In November 2021, the British Gynaecological Cancer Society (BGCS) published 'Uterine cancer guidelines: recommendations for practice.'(2)

In June 2022, the European Society for Medical Oncology (ESMO) published 'Guidelines on the diagnosis, treatment and follow-up of endometrial cancer.'(3)

In August 2025, the British Gynaecological Cancer Society (BGCS) published 'ESGO–ESTRO–ESP guidelines for the management of patients with endometrial carcinoma: update 2025.'(12)

9. Additional Information

9.1. Product availability date

13 December 2024

Table 9.1 List price of medicine under review

Medicine	Dose regimen	Cost per year (£)
Dostarlimab Carboplatin Paclitaxel	500 mg IV every 3 weeks for 6 doses then 1,000 mg every six weeks for up to 3 years AUC 5 mg/mL/minute IV every 3 weeks for 6 doses 175 mg/m^2 IV every 3 weeks for 6 doses	101,262 (110,427 in year 1)

AUC = area under the curve; Costs based on body surface area of 1.8 m^2. Costs from BNF online on 1 October 2025. Costs calculated using the full cost of vials/ampoules assuming wastage.

10. Company Estimate of Eligible Population and Estimated Budget Impact

The submitting company estimated there would be 134 patients eligible for treatment with dostarlimab in year 1 rising to 135 in year 3. SMC is unable to publish the with PAS budget impact due to commercial in confidence issues. A budget impact template is provided in confidence to NHS health boards to enable them to estimate the predicted budget with the PAS. This template does not incorporate any PAS discounts associated with comparator medicines or PAS associated with medicines used in a combination regimen.

*Other data were also assessed but remain confidential.**

References

1. GlaxoSmithKline. Dostarlimab concentrate for solution for infusion (Jemperli®) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/ Last updated 27 June 2025
2. Morrison J, Balega J, Buckley L, et al. British Gynaecological Cancer Society (BGCS) uterine cancer guidelines: Recommendations for practice. European journal of obstetrics, gynecology, and reproductive biology 2022; 270: 50-89.
3. Oaknin A, Bosse TJ, Creutzberg CL, et al. Endometrial cancer: ESMO Clinical Practice Guideline for diagnosis, treatment and follow-up. Ann Oncol 2022; 33(9): 860-77.
4. Corr BR, Erickson BK, Barber EL, et al. Advances in the management of endometrial cancer. BMJ 2025; 388: e080978.
5. Merck Sharp and Dohme. Pembrolizumab (Keytruda®) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/ Last updated 5 August 2025.
6. AstraZeneca. Durvalumab (Imfinzi®) Summary of Product Characteristics. Electronic Medicines Compendium www.medicines.org.uk/emc/ Last updated 22 August 2025.
7. Public Health Scotland. Cancer Medicines Outcome Programme (CMOP) report, first-line treatment for primary advanced or recurrent endometrial cancer, 29 April 2025.
8. European Medicines Agency (EMA). European public assessment report for dostarlimab (Jemperli®), EMEA/H/C/005204/II/0032, 12 December 2024.
9. European Medicines Agency (EMA). European public assessment report for dostarlimab (Jemperli®), EMEA/H/C/005204/II/0023, 12 October 2023.
10. Mirza MR, Chase DM, Slomovitz BM, et al. Dostarlimab for primary advanced or recurrent endometrial cancer. N Engl J Med 2023; 388: 2145-58.
11. Powell MA, Bjorge L, Willmott L, et al. Overall survival in patients with endometrial cancer treated with dostarlimab plus carboplatin-paclitaxel in the randomized ENGOT-EN6/GOG-3031/RUBY trial. Ann Oncol 2024; 35: 728-38.
12. Concin N, Matias-Guiu X, Cibula D, et al. ESGO-ESTRO-ESP guidelines for the management of patients with endometrial carcinoma: update 2025. Lancet Oncol 2025; 26: e423-35.

This assessment is based on data submitted by the applicant company up to and including 19 June 2026.

**Agreement between the Association of the British Pharmaceutical Industry (ABPI) and the SMC on guidelines for the release of company data into the public domain during a health technology appraisal:*https://www.scottishmedicines.org.uk/about-us/policies-publications/

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC includes Scottish national contract prices in its decision-making. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document.

Patient Access Schemes (PAS): A PAS is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. The Patient Access Scheme Assessment Group (PASAG), established under the auspices of Public Services Delivery Scotland, reviews and advises NHS Scotland on the feasibility and acceptability on implementing proposed schemes. PASAG operates separately from SMC to maintain the integrity and independence of the assessment process of the SMC. When SMC accepts a medicine for use in NHS Scotland on the basis of a PAS that has been considered acceptable for implementation by PASAG, a set of guidance notes on the operation of

the scheme will be circulated to health boards' Area Drugs and Therapeutics Committees prior to publication of SMC advice.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after careful consideration and evaluation of the available evidence. It is provided to inform the considerations of Area Drug and Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.