Patient details Patient agreement to Patient's surname/family name: systemic anti-cancer therapy (SACT) Patient's first name(s): **Durvalumab** with Carboplatin and Date of birth: Paclitaxel (+/- Olaparib) NHS number: (or other identifier) Hospital/NHS Trust/NHS Board: Special requirements: (eg other language/other communication method) **Responsible Consultant:** Name: Job title: ____ Name of proposed course of treatment (include brief explanation if medical term not clear) Durvalumab with Carboplatin and Paclitaxel +/- Olaparib* (*delete if not needed) for the treatment of endometrial cancer. Durvalumab, Carboplatin and Paclitaxel given intravenously on day 1 every 21 days up to 6 cycles. Following 6 cycles, ONLY Durvalumab is given intravenously as maintenance every 28 days up to a maximum of 3 years or until disease progression or unacceptable side effects. Where will I have treatment? ☐ Outpatient ☐ Day unit/case ☐ Inpatient Other: Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy) Tick all relevant boxes ☐ I confirm the patient has capacity to give consent. I have explained the course of treatment and intended benefit to the patient. **The intended benefits** (there are no guarantees about outcome) Curative – to give you the best possible chance of being cured. Disease control or palliative – the aim is not to cure, but to control or shrink the disease and improve both quality of life and survival.

Adjuvant – therapy given after surgery or radiotherapy to reduce the risk of the cancer coming back. Neo-adjuvant – therapy given before surgery or radiotherapy to shrink the cancer, allow treatment and

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reduce the risk of the cancer coming back

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Durvalumab with Carboplatin and Paclitaxel (+/- Olaparib)

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Statement of health professional

You may have one or more of the side effects listed

Common side effects: Affecting more than 10 in every 100 (>10%) people	Occasional side effects continued: Heart and blood vessel problems including risk of
 An increased risk of getting an infection from a drop in white blood cells – it is harder to fight infections and you can become very ill. If you have a severe infection this can be 	stroke, low or high heart rate. Paclitaxel may cause an allergic reaction. You will have medicines before to prevent this. Reactions with Carboplatin are less common.
life-threatening. Contact your doctor or hospital straight away if: • your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team • you suddenly feel unwell (even with a normal temperature) Feeling sick (nausea), being sick (vomiting), sore mouth/ulcers, reduced appetite, taste changes, tummy pain, diarrhoea, tiredness and feeling weak (fatigue). Thinning of the hair or sometimes complete hair loss (occasionally permanent), skin changes (rash, itch, colour changes). Muscle and joint aches and pain (may be severe), dizziness, headache. Numbness or tingling in the hands/feet (may be temporary or permanent). Watery and sore eyes, fluid build-up in arms and legs, low blood pressure during treatment. Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets). Electrolyte changes (low sodium, potassium, calcium and magensium levels) – monitored with blood tests. Changes in kidney and liver function (monitored).	 Durvalumab side effects: □ This treatment acts on your immune system and can cause inflammation in parts of the body. This can cause severe side effects that can be life threatening. It's important to treat side effects quickly to stop them getting worse. Some side effects can begin during treatment or months after. □ Commonly, inflammation of: Hormone glands (thyroid, pituitary, adrenal, pancreas): high or low thyroid hormone levels, headache, tiredness, irritation, blurred or double vision, forgetfulness, high blood sugars (rarely diabetes) Brain or nerves: confusion, memory problems, seizures, numbness, tingling, weakness □ Occasionally, inflammation of: Stomach or intestine: tummy pain, diarrhoea, mucus or blood in the stools Lungs: breathlessness, cough, hoarse voice Skin: rash, itch, redness, colour loss (severe reactions causing blistering, peeling, sores, ulcers are rare) Bladder: frequent or painful urination, blood in the urine
Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people	Uncommonly, inflammation of:Heart muscle: chest pain, palpitations, irregular
Nail changes (brittle nails, change in colour), nail loss is temporary. Dry mouth, indigestion, constipation. Hearing changes (ringing in the ears, changes in hearing and uncommonly high frequency hearing loss which may be permanent, ringing in ears), eye problems (vision changes). Low mood, feeling nervous, difficulty sleeping, bone/back pain, leg cramps. Pain when passing urine, nose bleed. Pain, swelling, inflammation at injection site. Changes in the lungs (scarring) causing cough, chest pain, shortness of breath. Tell your doctor if you have symptoms at rest or with gentle activity.	 rhythm, changes in heart function Liver: yellowing of the skin or eyes, dark urine, tummy pain Joints and muscles: stiffness, aches, pain, arthritis Kidneys: changes in how they work, which are monitored Pancreas: tummy pain, feeling or being sick Eyes: dry, itchy, watery eyes, pain, vision changes Rarely, the immune system may attack groups of blood cells and cause other blood conditions Continue on to the next page
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Statement of health professional

Other risks:
Side effects may need treatment with steroids, hormones or medicines to suppress the immune system. They may be permanent and need long term treatment. These medicines have side effects that are sometimes severe.
With Olaparib, a blood disorder which causes a drop in normal cell numbers (myelodysplastic syndrome) or blood cancers (acute myeloid leukaemia) can occur. If you have low blood counts, your doctor may arrange to test your bone marrow to check.
Cancer and this treatment can increase the risk of a blood clot (thrombosis) causing pain, skin colour changes, swelling in an arm or leg, breathlessness, chest pain. Tell your doctor straight away if you have symptoms.
All intravenous drugs may leak out of the vein while it is being given (extravasation) and can damage the tissue around the vein. Tell the nurse straight away if you have any stinging, pain, colour changes or swelling around the vein. It's uncommon but important to deal with quickly.
Paclitaxel contains alcohol. This may affect your ability to drive or operate machinery.
Side effects with the anti-sickness medication may include: constipation, headaches, indigestion, difficulty sleeping and agitation.
Steroids can raise your blood sugar. If you have diabetes, please monitor your blood sugar levels.
Before treatment, you might have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV or more unusual infections. This treatment may weaken your natural defence (immune) system, so infections like this could worsen or become active again if you've had them in the past. You may have medicines to prevent or treat infection.
Changes in your memory, concentration, or ability to think clearly. There can be many

Other risks continued:

ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).
Some anti-cancer medicines may damage the development of a baby in the womb. It is important not to become pregnant during treatment and for 6 months afterwards. Use effective contraception.
Complications of treatment can very occasionally be life-threatening and may result in death. The risks are different for every individual. Potentially life-threatening complications include those listed on this form, but other exceedingly rare side effects may also be life-threatening.

both.

causes including your treatment, diagnosis or

Statement of health professional

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Any other risks and information:		
☐ I have discussed the intended benefit and risks of alternative treatments (including no treatment).	the recommended treatment, and of any available	
☐ I have discussed the side effects of the recommer straight away or in the future, and that there may rare or have not yet been reported. Each patient r	be some side effects not listed because they are	
☐ I have discussed what the treatment is likely to invitiming of the treatment, blood and any additional t	•	
☐ I have explained to the patient, that they have the contact the responsible consultant or team if they	right to stop this treatment at any time and should wish to do so.	
☐ I have discussed concerns of particular importance	e to the patient in regard to treatment	
(please write details here):		
Clinical management guideline/Protocol co	mpliant (please tick):	
Yes No Not available If No please	e document reason here:	
The following written information has been provided:	Health professional details:	
Information leaflets for Durvalumab with Carboplatin and Paclitaxel (+/- Olaparib)	Signed:	
24 hour alert card or SACT advice service contact details	Name (PRINT):	
SACT treatment record (cruk.org/treatment-record)	Job title:	
Other, please state:		
Statement of interpreter (where applicable):	opropriate)	
I have interpreted the information above to the patient believe they can understand.	t to the best of my ability and in a way in which I	
Signed:	Date:	
Name (PRINT):	Job title:	

Statement of patient

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your own copy of the form which describes the be	nas been planned in advance, you should already have enefits and risks of the proposed treatment. If not, you will estions, do ask – we are here to help you. You have the fter you have signed this form.	
☐ I have had enough time to consider my option	ns and make a decision about treatment.	
I agree to the course of treatment described of	on this form.	
A witness should sign below if the patient is unable parental responsibility will be asked to sign for you	e to sign but has indicated their consent. A person with ung people under the age of 16 years.	
Patient's signature:		
Name (PRINT):	Date:	
Person with parental responsibility/witness' signat	ure:	
Name (PRINT):	(PRINT): Date:	
Copy accepted by patient: yes / no (please circle)		
Confirmation of consent	Further information for	
(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)	patients	
	Contact details (if patient wishes to discuss	

On behalf of the team treating the patient, I have confirmed that the nationt has no

further questions and wishes the course of treatment/procedures to go ahead.
Signed:
Date:
Name (PRINT):
Job title:
Important notes: (tick if applicable)
See also advance decision to refuse treatment
Patient has withdrawn consent (ask patient to sign and date here)
Signed:

options later):

Contact your hospital team if you have any questions about cancer and its treatment.

Cancer Research UK can also help answer your questions about cancer and treatment. If you want to talk in confidence, call our information nurses on freephone 0808 800 4040, Monday to Friday, 9am to 5pm. Alternatively visit cruk.org for more information.

These forms have been produced by Guy's and St. Thomas' NHS Foundation Trust as part of a national project to support clinicians in ensuring all patients are fully informed when consenting to SACT.

The project is supported by Cancer Research UK. This does not mean you are taking part in a clinical trial.



Date:

Guidance for health professionals

(to be read in conjunction with the hospital's consent policy)

Patient identifier/label

What a consent form is for

This form documents the patient's agreement to go ahead with the treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an aide-memoir to health professionals and patients, by providing a checklist of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent

See the following publications for a comprehensive summary of the law on consent. Consent: Patients and doctors making decisions together, GMC 2020 (gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (doh.gov.uk).

Who can give consent

Everyone aged 16 or over is presumed to have the capacity to give consent for themselves, unless the opposite is demonstrated. For young people, it is good practice to involve those with parental responsibility in the consent discussions, unless specifically asked not to. A person with parental responsibility must sign this form for a child or young person under the age of 16. Such patients should be given the opportunity to 'assent' to treatment if they wish. If a patient has the capacity to give consent but is physically unable to sign a form, you should complete this form as usual and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form

If the patient lacks the capacity to give consent, you should use an alternative form available for this purpose (dependent on patient age). A patient lacks capacity if they have an impairment or disturbance of the brain, affecting the way their mind works. For example, if they cannot do one of the following:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh this information as a part of their decision making process, or

communicate their decision (by talking, using sign language or any other means)

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives cannot be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court deputy.

Information

Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'significant, unavoidable or frequently occurring' risks. If patients make clear they have particular concerns about certain kinds of risk, you should ensure that they are informed about these risks, even if very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on the consent form or in the patient's notes.

NHS Scotland

NHS Scotland staff should refer to Healthcare Improvement Scotland, Guidance on consent for SACT and local NHS Board guidance on consent aligned to the Scottish legal framework.

References

- 1. Summary of Product Characteristics for individual drugs: medicines.org.uk/emc
- 2. Cancer Research UK: cruk.org/aboutcancer/treatment/drugs
- 3. Macmillan Cancer Support: macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

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