Patient agreement to systemic anti-cancer therapy (SACT) Niraparib

Hospital/NHS Trust/NHS Board: Responsible consultant: Name: Job title:

Patient details	
Patient's su	urname/family name:
Patient's fir	est name(s):
Date of birt	h:
NHS numb (or other ide	
Special req (eg other la method)	uirements: anguage/other communication

side effects. Treatment is supplied every 28 days (one cycle). Where will I have treatment?

Name of proposed course of treatment (include brief explanation if medical term not clear)

□ Niraparib is taken orally once a day continuously as first line maintenance treatment up to 3 years OR
 □ Taken orally once a day continuously in subsequent lines until disease progression or unacceptable

☐ Niraparib for the treatment of ovarian* / fallopian tube* / primary peritoneal cancer*(*delete as

Statement of health professional

☐ Outpatient ☐ Day unit/case ☐ Inpatient

(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in the hospital/Trust/NHS board's consent policy)

Other:

\checkmark	Tick	all	relevant	boxes
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appropriate).

☐ 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)

Maintenance – therapy given on continuing basis, aiming to prevent disease flaring up and to control the symptoms.

Statement of health professional

Patient	identifier/label	
ationit	1001101/10001	

You may have one or more of the side effects listed

Common side effects:	Other risks:		
Affecting more than 10 in every 100 (>10%) people	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		
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 life- threatening. Contact your doctor or hospital straight away if:	may arrange to test your bone marrow to check. A very rare side effect includes posterior reversible encephalopathy syndrome (PRES)		
 your temperature goes over 37.5°C or over 38°C, depending on the advice given by your chemotherapy team 	causing seizures, headaches, change in mental status, visual disturbances. Before treatment you may have blood tests to		
	check for viruses (Hepatitis B or C, HIV, or		
 you suddenly feel unwell (even with a normal temperature) 	unusual infections). Treatment may weaken your		
Anaemia (due to low red blood cells), bruising or bleeding (due to low platelets), increase risk of urinary tract infections.	natural defence (immune) system so infections like this may worsen or become active if you've had them before. You may have medicines to prevent or treat infection.		
Reduced appetite, feeling sick (nausea) and being sick (vomiting), indigestion, tummy (abdominal) pain, diarrhoea, constipation.	Changes in your memory, concentration or ability to think clearly. There can be many causes including your treatment, diagnosis, or both.		
Shortness of breath, cough, palpitations, stuffy and/or runny nose, feeling tired and weak (fatigue), dizziness, difficulty sleeping.	Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, redness and swelling in an arm or leg,		
High blood pressure (rare cases can be severe), back pain, pain in the joints, headache.	breathlessness, chest pain. Tell your doctor straight away if you have any symptoms.		
Occasional side effects: Affecting between 1-10 in every 100 (1-10%) people	Some anti-cancer medicines can damage ovaries and sperm. This may lead to infertility and/or early menopause (hot flushes, vaginal dryness).		
Red or pink eye (conjunctivitis), nose bleed, dry mouth, sore mouth and ulcers, muscle pain.	Some anti-cancer medicines may damage the development of a baby in the womb. It is		
Skin sensitivity to light causing rash, fluid build-up in legs, ankles.	important not to become pregnant during treatment and for 6 months afterwards. Use		
Low potassium levels, changes in liver and kidney function (picked up in blood tests).	effective contraception. Niraparib may affect how well hormonal contraceptives work. Speak to		
Feeling anxious and/or depressed, memory problems, taste changes, increase in heart rate.	your doctor or nurse. 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.		

Statement of health professional

	Patient identifier/label	
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Any other risks and information:		
☐ I have discussed the intended benefit and risks alternative treatments (including no treatment).	of the recommended treatment, and of any available	
	nended treatment, which could affect the patient straight me side effects not listed because they are rare or have ence side effects differently.	
☐ I have discussed what the treatment is likely to of the treatment, blood and any additional tests	involve (including inpatient/outpatient treatment, timing , follow-up appointments etc) and location.	
☐ I have explained to the patient, that they have t contact the responsible consultant or team if the	he right to stop this treatment at any time and should ey wish to do so.	
☐ I have discussed concerns of particular importation (please write details here):		
Clinical management guideline/Protocol co	e document reason here:	
The following written information has been provided:	Health professional details: Signed:	
☐ Information leaflet for Niraparib	Date:	
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 Interpreter booking reference (if applicable):		
I have interpreted the information above to the pati believe they can understand.	ent to the best of my ability and in a way in which I	
Signed:	Date:	
Name (PRINT):	Job title:	

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of the form which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I have had enough time to consider my options and make a decision about treatment.

I agree to the course of treatment described on this form.

A witness should sign below if the patient is unable to sign but has indicated their consent. A person with parental responsibility will be asked to sign for young people under the age of 16 years.

Patient's signature:

Name (PRINT):

Date:

Date:

Date:

Copy accepted by patient: yes / no (please circle)

Confirmation of consent

(health professional to complete when the patient attends for treatment, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed that the patient has no further questions and wishes the course of treatment/procedures to go ahead.

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)

Further information for patients

Contact details (if patient wishes to discuss 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 aidememoir 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 (www.gmc-uk.org/guidance). Reference guide to consent for examination or treatment, Department of Health, 2nd edition 2009 (www.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: www.medicines.org.uk/emc
- Cancer Research UK: www.cancerresearchuk.org/aboutcancer/treatment/drugs
- Macmillan Cancer Support: www.macmillan.org.uk/cancer-information-andsupport/treatments-and-drugs
- 4. Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form

To be retained in patient notes
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Date of issue: Nov-24; Version 4; Review date: Nov-27 Approved by: Janine Mansi UK SACT Board Check cruk.org/sact_consent for latest version Niraparib