Patient agreement to systemic anti-cancer therapy (SACT)

Peri-operative Pembrolizumab with Radiotherapy +/- Cisplatin

Hospital/NHS Trust/NHS Board:

_____

_____

Responsible Consultant:

Name: _____

Job title: _____

Patient details

Patient's surname/family name:

_____

Patient's first name(s): _____

_____

Date of birth: _____

NHS number: _____
(or other identifier)

Special requirements:
(e.g. other language/other communication method)

_____

_____

_____

_____

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

☐ Peri-operative Pembrolizumab with RT (+/- Cisplatin) for the treatment of non-metastatic, resectable squamous cell carcinoma of the head and neck. A separate consent form must be completed for radiotherapy.

☐ Before surgery (Neoadjuvant): Pembrolizumab is given intravenously* or subcutaneously* on day 1 every 3 weeks* (for 2 cycles) OR on day 1 (for 1 cycle) (*delete as appropriate).

☐ After surgery (Adjuvant): Cisplatin given intravenously on day 1 every 3 weeks (for 3 cycles) * OR weekly for 6 weeks*; Pembrolizumab given intravenously* or subcutaneously* on day 1 every 3 weeks* (for 15 cycles) OR on day 1 every 6 weeks* (for 8 cycles), or until disease progression or unacceptable side effects, whichever occurs first (*delete as appropriate).

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 reduce the risk of the cancer coming back

Statement of health professional

Patient identifier/label

You may have one or more of the side effects listed

Common side effects:

Affecting more than 10 in every 100 (>10%) people

☐ Pembrolizumab acts on the immune system and can cause inflammation in parts of the body. It can cause severe side effects that can be life-threatening. It's important to treat side effects quickly to stop them getting worse. Side effects may begin during treatment, or months after.

☐ Pembrolizumab commonly causes 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
- Heart muscle: chest pain, palpitations, irregular rhythm, changes in heart function
- Lungs: breathlessness, cough
- Stomach or intestine: tummy pain, diarrhoea, mucus or blood in the stools
- Skin: rash, itch, colour loss in patches (severe reactions causing blistering, peeling, sores, ulcers are rare)
- Joints or muscles: stiffness, aches, pain, arthritis
- Liver: yellowing of the skin or eyes, dark urine, tummy pain

☐ 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:**

- **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), reduced appetite, taste changes, constipation, tummy pain.

☐ Tiredness and feeling weak (fatigue), fluid build-up in arms and legs.

☐ Hearing changes (ringing in the ears and uncommonly high frequency hearing loss which may be permanent).

☐ Headache.

☐ Anaemia (due to low red blood cells), bruising or bleeding (low platelets).

Common side effects continued:

☐ Changes in electrolyte levels such as sodium, potassium, magnesium and calcium levels (monitored with blood tests).

☐ Changes in kidney and liver function (monitored with blood tests).

Occasional side effects:

Affecting between 1-10 in every 100 (1-10%) people

☐ During and within 24 hours of Pembrolizumab infusion, common reactions can include allergic reactions, flu-like symptoms, blood pressure changes, flushing, shortness of breath, rapid heart rate, and injection site pain.

☐ Pembrolizumab occasionally causes inflammation of:

- Eyes: dry, itchy, watery eyes, pain, vision changes
- Pancreas: tummy pain, feeling or being sick
- Kidneys: changes in how well the kidneys work (monitored with blood tests)
- Bladder: frequent or painful urination, blood in the urine
- Rarely, the immune system may attack groups of blood cells and cause other blood conditions

☐ Dry mouth.

☐ Difficulty sleeping.

☐ Dizziness.

☐ Hair thinning or loss.

☐ Changes in heart rhythm, low or high heart rate.

☐ High blood pressure.

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.

☐ 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.

☐ Subcutaneously, Pembrolizumab may cause reactions such as soreness, rash, swelling, itchiness at the injection site.

☐ Side effects of radiotherapy may be temporarily increased when given alongside chemotherapy.

☐ Side effects with the anti-sickness medication may include constipation, headaches, indigestion, difficulty sleeping and agitation.

Continue to the next page

Statement of health professional

Patient identifier/label

Other risks continued:

- ☐ Before treatment, you might have blood tests to check for viruses such as Hepatitis B, Hepatitis C, HIV or more unusual infections. 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.
- ☐ Cancer and its treatment can increase your risk of developing a blood clot (thrombosis), causing pain, skin colour changes and swelling in an arm or leg, breathlessness, chest pain or stroke. Tell your doctor straight away if you have any symptoms.
- ☐ Changes in your memory, concentration, ability to think clearly. There can be many causes of this including your treatment, diagnosis or both.
- ☐ Some anti-cancer medicines can damage ovaries and sperm leading to infertility/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 or make someone pregnant during treatment and for 6 months after. Use effective contraception throughout.
- ☐ 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

Any other risks and information:

_____

_____

☐ I have discussed the intended benefit and risks of the recommended treatment, and of any available alternative treatments (including no treatment).

☐ I have discussed the side effects of the recommended treatment, which could affect the patient straight away or in the future, and that there may be some side effects not listed because they are rare or have not yet been reported. Each patient may experience side effects differently.

☐ I have discussed what the treatment is likely to involve (including inpatient/outpatient treatment, timing of the treatment, blood and any additional tests, follow-up appointments etc) and location.

☐ I have explained to the patient, that they have the right to stop this treatment at any time and should contact the responsible consultant or team if they wish to do so.

☐ I have discussed concerns of particular importance to the patient in regard to treatment

(please write details here): _____

_____

Clinical management guideline/Protocol compliant (please tick):

☐ Yes ☐ No ☐ Not available If No please document reason here:

_____

The following written information has been provided:

☐ Information leaflet for Pembrolizumab with Radiotherapy (+/- Cisplatin)

☐ 24 hour alert card or SACT advice service contact details

☐ SACT treatment record (cruk.org/treatment-record)

☐ Other, please state: _____

_____

Health professional details:

Signed: _____

Date: _____

Name (PRINT): _____

_____

Job title: _____

_____

Statement of interpreter **(where appropriate)**

Interpreter booking reference (if applicable):

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe they can understand.

Statement of patient

Signed: _____

Name (PRINT): _____

Date: _____

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: _____

Person with parental responsibility/witness' signature: _____

Name (PRINT): _____ 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.

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: _____

Date: _____

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.

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/about-cancer/treatment/drugs
3) Macmillan Cancer Support: macmillan.org.uk/cancer-information-and-support/treatments-and-drugs
4) Guy's and St. Thomas' NHS Foundation Trust, Chemotherapy consent form