

Patient Agreement to Systemic Therapy: Consent Form	
Obinutuzumab-Chlorambucil	
Patient's details / addressograph:	<input type="checkbox"/> Male <input type="checkbox"/> Female
	Special requirements (e.g. other language/other communication method)
	Consultant:

Name of proposed course of treatment: Obinutuzumab-Chlorambucil**Cycle 1:**

Obinutuzumab IV infusion on Day 1, Day 2, Day 8 and Day 15, chlorambucil tablets oral once daily for 7 days

Cycle 2 and onwards:

Obinutuzumab IV infusion on Day 1, chlorambucil tablets oral once daily for 7 days

Repeated every 4 weeks for up to 6 cycles

Macmillan/CRUK/other leaflet(s) given

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

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

The intended benefits

Disease control - the aim is not to cure but to control the disease. The aim is to improve both quality of life and survival

Significant, unavoidable or frequently occurring risks:

Common side-effects: : low white blood cells (neutropenia) with risk of infection, low red blood cells (anaemia), low platelets with risk of bleeding, feeling sick (nausea) and being sick (vomiting), diarrhoea, sore mouth and ulcers, tiredness and feeling weak.

Infusion reactions related to obinutuzumab: nausea, vomiting, flu-like symptoms (high temperature, chills, muscle aches, tiredness, dizziness and headache), low blood pressure, allergic reaction (signs of which include feeling of swelling in the tongue or throat, irritation of the nasal passages, wheezing, coughing and breathlessness).

These reactions are more likely to happen with the first cycle and can be managed with medication and by slowing down the infusion

Do not take any blood pressure medication on the morning of the obinutuzumab infusion to reduce the chance of developing infusion related reactions

Less common but potentially life threatening side-effects: reduced resistance to infection which can lead to serious infections

Other less common side-effects include: Late effects include a very rare chance of a second cancer

Cancer can increase your risk of developing a blood clot (thrombosis), and having chemotherapy may increase this risk further. A blood clot may cause pain, redness and swelling in a leg, or breathlessness and chest pain - you must tell your doctor straight away if you have any of these symptoms.

Some chemotherapy drugs can damage women's ovaries and men's sperm, with risk of infertility and early menopause in women. I have warned the patient about the likelihood of:

- early menopause in women infertility (in men and in women)

Some chemotherapy drugs may damage the development of a baby in the womb (foetus), leading to the many risks associated with an abnormal pregnancy. Therefore, I have discussed the issues of protected sex. This is an issue for both men and women. The patient has been advised not to become pregnant / not to get a partner pregnant during the period of treatment, and for 12 months (women) / 6 months (men) after treatment has completed.

Any other risks:

Clinician Signature	
Signed.....	Date
Full Name (print) /	Job Title.....
(Forename)	(Surname)

Statement of patient

Patient Signature	
Please read this form carefully, which describes the benefits and risks of the proposed treatment. You have the right to change your mind at any time, including after you have signed this form.	
I agree to undergo Obinutuzumab-Chlorambucil treatment. I understand the treatment and am aware of the potential side-effects arising from this treatment.	
I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate training and experience.	
Signed.....	Name.....
Date.....	
A witness should sign below if the patient is unable to sign but has indicated his or her consent.	
Signature	Date
Name (PRINT)	

Statement of interpreter (where appropriate)

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

Signed Name (PRINT) Date.....

Confirmation of consent (to be completed by the chemotherapy nurse when the patient attends for the first cycle)

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

Signed Name (PRINT) Date.....

Copy accepted by patient: yes/no (please ring)
Copy to be retained in patient's notes

Reason for Update: N/A	Checked and approved by Consultant: Dr E Grey-Davies
Version: 1	Date: 14/12/17