

**Guidance on
the use of
fludarabine as
second line
therapy for
B-cell chronic
lymphocytic
leukaemia**

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because it was causing side effects or their disease had progressed), may be treated with fludarabine tablets.

Fludarabine may be introduced at the stage where people with CLL might have previously been offered one of the following combination treatments:

- cyclophosphamide, doxorubicin, vincristine and prednisolone (CHOP)
- cyclophosphamide, doxorubicin and prednisolone (CAP), or
- cyclophosphamide, vincristine and prednisolone (CVP)

People with CLL should only be given fludarabine by a drip when their condition is such that they are unable to take the tablets.

If you, or someone you care for, has CLL then you may wish discuss this advice with the doctor or nurse at your next appointment.

Will NICE review its Guidance?

Further Information

Yes. The guidance will be reviewed August 2004.

Further information on NICE, and the full guidance issued to the NHS is available on the NICE web site (www.nice.org.uk).

The guidance can also be requested from 0870 1555 455, quoting reference N0025.

If you have access to the Internet and would like to find out more about cancer visit the NHS Direct website: www.nhsdirect.nhs.uk. If you would like to speak to NHS direct please call them on 08 45 46 47.

This leaflet is also available in Welsh, (Ref no. N0028).

Mae'r daflen hon hefyd ar gael yn Gymraeg (rhif cyfeirnod N0028).

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What is NICE Guidance?

The National Institute for Clinical Excellence (NICE) is a part of the NHS. It produces guidance for both the NHS and patients on medicines, medical equipment, diagnostic tests and clinical and surgical procedures, and how and when they should be used.

When the Institute evaluates these things, it is called an appraisal. Each appraisal takes around 12 months to complete and involves the manufacturers of the drug or device, the professional organisations and the groups who represent patients and their carers.

NICE was asked to look at the available evidence on fludarabine and provide guidance that would help the NHS in England and Wales decide where it should be used in the management of B-cell chronic lymphocytic lymphoma.

Cancer is a disease of the body's cells. Normally, all cells divide and reproduce themselves in an orderly and controlled manner. In cancer, cells multiply without proper control. Chronic lymphocytic

leukaemia (CLL) is cancer of the white blood cells (lymphocytes). People with CLL have abnormal white blood cells that prevent the red blood cells, the normal white blood cells and the platelets (particles that have a role in the clotting of blood) from working properly. This can stop the blood from clotting, cause anemia (lack of iron in the blood) and expose people with CLL to infections.

CLL is the most common form of leukaemia. It affects mainly older people - about 7 out of 10 people diagnosed with CLL are over the age of 60. Twice as many men as women are affected. The length of time people live with CLL depends on how far the disease has progressed when it is first diagnosed.

The type of treatment given for a cancer depends on many factors. These include:

- the type of cancer
- where in the body it started
- what the cancer cells look like under the microscope

- how far they have spread, if at all
- the general health of the patient

Treatments for CLL vary depending on the stage of the disease. For people at an early stage, there is no evidence that treatment with drugs has any benefits, rather, it may cause harm. Initial treatment is usually 'watchful waiting', during which the condition is carefully monitored for any change. If the disease progresses, or if diagnosis is made at a later stage, a series of treatments using combinations of chemotherapy drugs are available. Chemotherapy drugs are anti-cancer drugs that are used to destroy cancer cells. These treatments can themselves sometimes cause harm to the person taking them. Doctors and patients will therefore want to discuss the benefits and the possible disadvantages of treatment before starting.

What is fludarabine?

Fludarabine is a chemotherapy drug. It works by preventing cancer cells reproducing and can therefore slow down the progression of the disease. It can be given either by a drip into a blood vessel or by tablet. This treatment is given every day for 5 days and is called a 'treatment cycle'. The treatment cycle is then repeated every 28 days for up to 6 cycles. If the drug is given by a drip, then the person with CLL usually has to visit hospital on each day of the cycle. If it is given as a tablet then the person with CLL may need to visit the hospital less often.

Side effects of fludarabine include nausea (feeling sick), vomiting and hair loss. There can also be some more severe long-term side effects relating to the blood and ability to fight infection.

NICE has recommended to the NHS that:

People with B-cell chronic lymphocytic leukaemia (CLL) who have had to stop their first chemotherapy treatment (for example

What is chronic lymphocytic leukaemia?