

Fludarabine monotherapy for the first line treatment of chronic lymphocytic leukaemia

Cancerbackup welcomes the opportunity to contribute to the appraisal of fludarabine monotherapy for the first line treatment of chronic lymphocytic leukaemia (CLL). As the leading specialist provider of independent information on all types of cancer, Cancerbackup has regular contact with people living with CLL and those caring for them.

Last year Cancerbackup received over 1,036 telephone enquiries about leukaemia over 26,000 visitors to our website pages on CLL.

Cancerbackup believes that everyone with cancer should be offered the most effective and appropriate treatment, based on the available evidence and the patient's own wishes and preferences. We believe that:

- Patients should have access to the most effective treatments appropriate to them as individuals;
- Patients should be able to choose – in partnership with their oncologist – the treatment that is likely to suit them best in terms of relative benefits and side-effects;
- The impact of treatments on patient's quality of life, as well as length of life, should be given full consideration by the Appraisal Committee.

Cancerbackup is disappointed that the ACD does not recommend the use of fludarabine monotherapy for the first line treatment of chronic lymphocytic leukaemia and urges NICE to reconsider and approve this technology.

Living with Chronic Lymphocytic Leukaemia (CLL)

At the moment, CLL is not regarded as curable. However, treatments are very successful in getting most people into remission, which can last for a number of years. The aim of treatments is to allow patients with CLL to have a normal life for as long as possible with no symptoms.

Fludarabine Monotherapy

As the ACD notes early results from the CLL4 trial show clear benefits for patients in the use of fludarabine monotherapy compared to chlorambucil with response rates of 77% for fludarabine monotherapy and 69% for chlorambucil; and 3 year progression free survival of 31% for fludarabine monotherapy and 23% for chlorambucil.

Patients receiving fludarabine may experience side effects including; a lowered resistance to infection, bruising or bleeding, anaemia, loss of appetite, fever, chills and joint pain and tiredness and a general feeling of weakness.

Scope of Appraisal

Whilst we understand NICE can only appraise treatments for their licensed indications we are disappointed that NICE do not appear to acknowledge the affect that rejecting fludarabine as a monotherapy will have on patients whose clinicians have recommend fludarabine in combination with cyclophosphamide (FC). The CLL4 study clearly shows higher response rates (90%) and higher 3 year progression free survival rates (62%) than fludarabine monotherapy. FC is widely used as a treatment for patients with CLL and we are seriously concerned that negative NICE guidance on fludarabine as a monotherapy will prevent the use of FC.

Final Appraisal Determination

Cancerbackup argues that NICE should recommend that fludarabine monotherapy is available on the NHS for the first line treatment of patients with chronic lymphocytic leukaemia.

Fludarabine is an important treatment for patients with CLL and must be available as a treatment option where patients and clinicians agree it is the best option. Cancerbackup believes that people with cancer should have the right to make an informed choice about their own care and treatment. NICE's final guidance should reflect the right of patients to make decisions, in consultation with their clinicians, about their treatment.

Crucially, if the Appraisal Committee decides to uphold the negative guidance given in the ACD, NICE must ensure that:

1. Patients currently being given fludarabine should have the option to continue their treatment

The Appraisal Consultation Document fails to note that this technology is already being prescribed. If fludarabine monotherapy is not recommended for use then the Final Appraisal Determination (FAD) must specify that those patients currently being given fludarabine for first line treatment of chronic lymphocytic leukaemia should have the option to continue their treatment. Otherwise, there is a risk that these patients will have treatment withdrawn.

2. The FAD clearly relates only to the use of fludarabine as a monotherapy

As described above we are seriously concerned that negative NICE guidance on fludarabine as a monotherapy will prevent the use of FC. The FAD must not prohibit the use of fludarabine in combination use, and must clearly state that this is the case.

3. NICE should recommend the use of fludarabine in further clinical trials

Further trials are needed to further determine the effectiveness of fludarabine in treating chronic lymphocytic leukaemia.

Declaration of interest

Cancerbackup has received sponsorship for several publications and projects from Schering Health Care Ltd, the manufacturer of fludarabine.

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