

PRESS RELEASE

NICE publishes guidance on three cancer drugs

The National Institute for Health and Clinical Excellence (NICE) has today (27 October) published three separate pieces of guidance for the NHS on the use of the cancer drugs ofatumumab (Arzerra, GlaxoSmithKline), temsirolimus (Torisel, Pfizer) and bendamustine (Levact, Napp Pharmaceuticals).

The new NHS guidance for ofatumumab does not recommend the drug as a treatment for chronic lymphocytic leukaemia that is refractory (does not respond) to the drugs fludarabine and alemtuzumab, because the benefit it offers over and above current NHS treatments does not justify its cost.

NICE has also published advice on the use of temsirolimus for the treatment of mantle cell lymphoma. This follows the termination of the appraisal because the manufacturer did not submit any evidence of the drug's effectiveness. This means that NICE cannot evaluate whether temsirolimus is useful for this type of lymphoma and, as a result, is unable to recommend the drug.

NICE is also unable to recommend bendamustine for use in the NHS for the treatment of low grade non-Hodgkin's lymphoma that is refractory to rituximab or a rituximab-containing regimen. Again, this is because the manufacturer did not submit any evidence and the appraisal has now been terminated.

Sir Andrew Dillon, NICE Chief Executive, said: "The aim of our guidance is to provide clear recommendations to the NHS following a thorough evaluation of all available evidence, including research data from the manufacturer and expert opinion from clinical specialists and patient representatives. In the case of ofatumumab, the Appraisal Committee did not consider the evidence to be sufficiently robust and concluded that the benefit that ofatumumab might offer patients, compared with currently available treatment does not justify its high cost.

“We are disappointed to have to terminate the two appraisals involving temsirolimus and bendamustine but NICE is left with little choice if manufacturers choose not to submit any evidence. The guidance that we have produced about these two drugs informs the NHS that NICE is unable to recommend each treatment, includes an explanation from the relevant manufacturer as to why they did not submit evidence and advice on what to do next. Of course, if manufacturers decide to submit the evidence in the future, NICE will then take the opportunity to review our advice to the NHS.”

For more information, please visit the NICE website: www.nice.org.uk

Ends

Notes to Editors

About the ofatumumab guidance

- The guidance is available to view at: <http://guidance.nice.org.uk/TA202> (from Wednesday 27 October 2010).
- According to the guidance, ofatumumab is not recommended for the treatment of chronic lymphocytic leukaemia that is refractory to fludarabine and alemtuzumab. It also states that people currently receiving ofatumumab for the treatment of chronic lymphocytic leukaemia that is refractory to fludarabine and alemtuzumab should have the option to continue treatment until they and their doctor consider it appropriate to stop.
- Cost-effectiveness is the additional cost of one year of healthy life (expressed as the cost per quality adjusted life year, or QALY, gained). The committee considered the best available estimate for the base case ICER is between more than £60,500 and more than £81,500 per QALY gained.
- According to the manufacturer, ofatumumab costs £182.00 per 100 mg vial, excluding VAT. The manufacturer of ofatumumab, GlaxoSmithKline, did agree a patient access scheme (PAS) with the Department of Health, in which ofatumumab will be made available to the NHS at a discounted price. However, even with this in place, ofatumumab was judged to be too costly for the uncertain benefit it may offer patients.
- Nearly 2,000 people were diagnosed with chronic lymphocytic leukaemia in England in 2004¹. It affects the body's immune system by encouraging a type of white blood cell called B lymphocytes to grow abnormally, causing anaemia and an increased susceptibility to infection. The condition is termed 'refractory' if it does not respond to treatment. This can happen either at the beginning of, or during, treatment.

About the temsirolimus guidance

- The guidance for the terminated appraisal of temsirolimus for the treatment of mantle cell lymphoma can be viewed here: <http://guidance.nice.org.uk/TA207> (from Wednesday 27 October 2010)
- The guidance states that “given the rarity of the condition, the complex clinical management of mantle cell lymphoma and the large number of comparator regimens used in the single randomised clinical trial, the manufacturer did not believe that an adequate assessment of the clinical and cost effectiveness of temsirolimus would be possible.”

- The advice states that NHS organisations should take into account the reasons why no evidence of temsirolimus' clinical and cost-effectiveness was submitted when considering their local use of the drug.
- Mantle cell lymphoma is a rare type of non-Hodgkins lymphoma, which is a cancer of the lymphatic system. This system is spread throughout the body and helps to circulate white blood cells (lymphocytes). Mantle cell lymphoma specifically targets B-cell lymphocytes, making them grow and divide abnormally, creating tumours and weakening the immune system.

About the bendamustine guidance

- The guidance for the terminated appraisal of bendamustine for the treatment of indolent (low grade) non Hodgkins lymphoma that is refractory to rituximab or a rituximab-containing regimen can be viewed here: <http://guidance.nice.org.uk/TA206> (from Wednesday 27 October 2010)
- The manufacturer of bendamustine was invited to submit evidence for this appraisal but informed NICE that it would not be doing so because it was “unable to identify relevant sources of clinical evidence suitable for a NICE appraisal in people with rituximab refractory disease. The manufacturer indicated that further research was ongoing but data would not be available in a time frame that would allow NICE to produce timely guidance.”
- The advice states that NHS organisations should take into account the reasons why no evidence of bendamustine's clinical and cost-effectiveness was submitted when considering their local use of the drug.
- Non-Hodgkins lymphoma is a cancer of the lymphatic system. This system is spread throughout the body and helps to circulate white blood cells (lymphocytes). There are several different types of non Hodgkin's lymphoma but they all affect the body's white blood cells.

About NICE

1. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance and standards on the promotion of good health and the prevention and treatment of ill health
2. NICE produces guidance in three areas of health:
 - **public health** – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector
 - **health technologies** – guidance on the use of new and existing medicines, treatments, medical technologies (including devices and diagnostics) and procedures within the NHS
 - **clinical practice** – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
3. NICE produces standards for patient care:
 - **quality standards** – these reflect the very best in high quality patient care, to help healthcare practitioners and commissioners of care deliver excellent services
 - **Quality and Outcomes Framework** – NICE develops the clinical and health improvement indicators in the QOF, the Department of Health scheme which rewards GPs for how well they care for patients
4. NICE provides advice and support on putting NICE guidance and standards into practice through its **implementation programme**, and it collates and accredits high quality health guidance, research and information to help health professionals deliver the best patient care through **NHS Evidence**.

¹ Office of National Statistics, Cancer Statistics series MB1 no. 35. <http://www.statistics.gov.uk>