NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

Proposed Health Technology Appraisal

Pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma

Draft scope (Pre-referral)

Draft remit/appraisal objective

To appraise the clinical and cost effectiveness of pralatrexate within its licensed indication for the treatment of relapsed or refractory peripheral T-cell lymphoma.

Background

Lymphomas are cancers of the lymphatic system, which are broadly described as either Hodgkin's lymphoma or non-Hodgkin's lymphoma (NHL). Peripheral T-cell lymphoma (PTCL) comprises a group of rare and aggressive non-Hodgkin lymphomas that develop from T-cells in different stages of maturity.

In 2006, there were approximately 9400 new cases of NHL diagnosed in England and Wales. It is estimated that around 10% of NHL is classified as PTCL. It generally affects people over 60 years of age and is diagnosed in slightly more men than women. People with PTCL usually develop lumps, which may grow quite rapidly. Although these lumps most often form in the neck (nodal PTCL), they can occur in other body sites (extranodal PTCL), including the stomach, skin and small intestine. By the time the condition is diagnosed, most people have widespread disease, with fever, fatigue, weight loss and night sweats, and will require aggressive treatment to manage their condition.

In 2007, there were 4533 deaths due to NHL in the UK. Only 25% of people with aggressive PTCL will survive for five years after first-line therapy.

Combination chemotherapy with a CHOP-based regimen (cyclophosphamide, doxorubicin, vincristine, prednisolone) is often used for the first-line treatment of PTCL. People with relapsed or refractory PTCL are treated with best supportive care.

The technology

Pralatrexate (Folotyn, Allos Therapeutics) is a folate analogue that inhibits the activity of the enzyme dihydrofolate reductase, which is necessary for cell growth and multiplication. It is administered by intravenous infusion.

Pralatrexate does not have a UK marketing authorisation for the treatment of peripheral T-cell lymphoma. It has been studied in single-arm clinical trials in people with relapsed or refractory peripheral T-cell lymphoma in combination

with vitamin B12 and folic acid supplementation. People were considered to have relapsed or refractory disease if they had no response to their most recent treatment or to any prior therapies, including CHOP-based chemotherapy and other multi-agent chemotherapy regimens.

Intervention(s)	Pralatrexate
Population(s)	People with relapsed or refractory peripheral T-cell lymphoma
Comparators	Best supportive care
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rate • duration of response • adverse effects of treatment • health-related quality of life
Economic analysis	The reference case stipulates that the cost effectiveness of treatments should be expressed in terms of incremental cost per quality-adjusted life year. The reference case stipulates that the time horizon for estimating clinical and cost effectiveness should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared. Costs will be considered from an NHS and Personal Social Services perspective.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation.
Related NICE recommendations	Related Guidelines: Cancer Service Guidance, Oct 2003, 'Improving outcomes in haematological cancers – the manual'.

Questions for consultation

How is relapsed or refractory peripheral T-cell lymphoma currently managed in clinical practice?

- Have the most appropriate comparators for the treatment of relapsed or refractory peripheral T-cell lymphoma been included in the scope?

- What does best supportive care consist of?

Are there any subgroups of patients in whom the technology is expected to be more clinically effective and cost effective or other groups that should be examined separately?

Are there any issues that require special attention in light of the duty to have due regard to the need to eliminate unlawful discrimination and promote equality?

What do you consider to be the relevant clinical outcomes and other potential health related benefits of pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma, particularly when compared with currently used treatment options?

Please identify the nature of the data which you understand to be available to enable the Appraisal Committee to take account of these benefits.

NICE intends to appraise this technology through its Single Technology Appraisal (STA) Process. We welcome comments on the appropriateness of appraising this topic through this process. (Information on the Institute's Technology Appraisal processes is available at http://www.nice.org.uk/aboutnice/howwework/devnicetech/technologyappraisalprocessguides/technology_appraisal_process_guides.jsp)