National Institute for Health and Clinical Excellence

Single Technology Appraisal (STA)

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

Response to consultee and commentator comments on the draft scope

Section	Consultees	Comments	Action
Background information	Royal College of Pathologists and BSH	Accurate	Comment noted.
The technology/ intervention	Royal College of Pathologists and BSH	Yes	Comment noted.
Population	Royal College of Pathologists and BSH	Yes	Comment noted.
Comparators	Lymphoma Association	There are no direct comparator studies and no standard treatment for this group of patients.	Comment noted.
	Royal College of Pathologists and BSH	In a subgroup of patients, namely those with AILT, Thalidomide and dexamethasone could be considered as a comparator.	We do not believe the suggested combination is precluded by the existing comparator definition, and do not believe it is necessary to specify it separately.
Outcomes	Royal College of Pathologists and BSH	Yes	Comment noted.
Economic analysis	Lymphoma Association	As there are no effective alternatives for these patients, it is desirable, assuming UK marketing authorisation is approved, that this technology should be made available as soon as possible.	Comment noted. NICE aims to publish technology appraisal guidance within six months of product launch.

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Equality	Lymphoma Association	Peripheral T-cell lymphoma has a higher prevalence in Asian and Afro-Caribbean populations. This was particularly noted in an assessment of incidence and outcomes in the US, published in 2008 (Abouyabis,A., et al, Leukemia and Lymphoma, volume 49, Issue 11 November 2008, pages 2099-2107).	Comments noted. It was noted at the scoping workshop that, in the UK, one subtype of PTCL (adult T-cell leukaemia/lymphoma) occurs almost exclusively in people of African–Caribbean family origin. However, the clinical specialists present advised that they were not aware of any evidence of systematically differing prognosis or access to treatment amongst different racial groups. Evidence will be sought and considered on this issue throughout the appraisal.
Questions for consultation	Lymphoma Association	We consider this to be an innovative technology as this patient group has a poor prognosis, responding extremely poorly to salvage chemotherapy. Due to its rarity there is no universal standard of care in the management of relapsed disease. The results of the PROPEL study (O'Connor O et al, JCO Vol 27, No 26, Sept 10 2009 pp 4357 – 4363) demonstrate that pralatrexate has high levels of activity in this population, offering salvage therapy worth considering for a group of patients with few therapeutic alternatives. The PROPEL study demonstrated response rates of 27% in heavily pre-treated patients. Toxicity was manageable. Achieving remission would mean that some patients were offered further curative therapy with stem cell transplant.	Comments noted. As part of its appraisal, the Committee will review evidence on the extent to which pralatrexate may be considered an innovative technology. It will give consideration to whether factors such as those listed constitute significant and substantial health-related benefits that are unlikely to be included in the QALY calculation.
	Royal College of Pathologists and BSH	The technology is a development rather than a step change compared to currently available treatments for this disease. Its potential value is twofold Selected responding patients may be eligible for allogeneic bone marrow transplantation which is a	Comments noted. As part of its appraisal, the Committee will review evidence on the extent to which pralatrexate may be considered an innovative technology. It will give consideration to whether factors such as those listed constitute significant and substantial health-related benefits

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		potentially curative therapy Alternative therapies such as platinum based salvage regimens require significant time as a hospital inpatient and are associated with substantial haematological and non-haematological toxicity. In a predominantly palliative setting such as this, avoidance of hospital admission and toxicity are particularly valuable	that are unlikely to be included in the QALY calculation.

The following consultees/commentators indicated that they had no comments on the draft scope

Allos Therapeutics Inc.
Department of Health
NHS Quality Improvement Scotland
Public Health Wales NHS Trust
Royal College of Nursing
Welsh Assembly Government