

# NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

## Single Technology Appraisal

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

#### Final scope

#### Remit/appraisal objective

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

#### Background

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

In 2008, approximately 10,000 people were diagnosed with non-Hodgkin's lymphoma in England and Wales. It is estimated that around 10% of non-Hodgkin's lymphoma is classified as PTCL. It generally affects people over 60 years of age and incidence is slightly higher in men than in women. People with PTCL usually develop lumps, which may grow quite rapidly. Although these lumps most often form in the lymph nodes (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, and experience fever, fatigue, weight loss and night sweats, and will require aggressive treatment to manage their condition.

In 2009, there were 3,993 deaths from non-Hodgkin's lymphoma in England and Wales, which included 252 deaths from peripheral and cutaneous T-cell lymphomas. The estimated five year survival rate for people with aggressive PTCL after first-line therapy is 30%.

Combination chemotherapy with a CHOP-based regimen (cyclophosphamide, doxorubicin, vincristine and prednisolone) is often used for the first-line treatment of PTCL. People with relapsed or refractory PTCL receive a variety of second-line and subsequent treatments, most commonly multi-agent chemotherapy that may be platinum based. If disease is unresponsive to therapy, best supportive care (which may include single-agent chemotherapy for symptomatic relief) is provided.

## The technology

Romidepsin (Istodax, Celgene) is a histone deacetylase inhibitor. It catalyses the removal of acetyl groups from histone proteins resulting in impaired DNA functions and cell death. It is administered by intravenous infusion.

Romidepsin 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 adults with relapsed or refractory peripheral T-cell lymphoma, and whose disease has not responded to at least one prior treatment.

<b>Intervention(s)</b>	Romidepsin
<b>Population(s)</b>	Adults with relapsed or refractory peripheral T-cell lymphoma after at least one prior treatment.
<b>Comparators</b>	Single and combination treatment regimens that may include platinum-based chemotherapy (such as carboplatin or cisplatin) and/or other chemotherapeutic agents (such as cytarabine, epirubicin, etoposide, fludarabine, gemcitabine, ifosamide or lomustine) and/or corticosteroids
<b>Outcomes</b>	The outcome measures to be considered include: <ul style="list-style-type: none"><li>• overall survival</li><li>• progression-free survival</li><li>• response rate</li><li>• duration of response</li><li>• time to response</li><li>• adverse effects of treatment</li><li>• health-related quality of life.</li></ul>
<b>Economic analysis</b>	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.
<b>Other considerations</b>	Guidance will only be issued in accordance with the marketing authorisation.

<b>Related NICE recommendations</b>	Related Technology Appraisals: Suspended Technology Appraisal, 'Pralatrexate for the treatment of relapsed or refractory peripheral T-cell lymphoma'. Related Guidelines: Cancer Service Guidance, Oct 2003, 'Improving outcomes in haematological cancers – the manual'.
-------------------------------------	--