NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Mogamulizumab for treated mycosis fungoides or Sézary syndrome cutaneous T-cell lymphoma

Final scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of mogamulizumab within its marketing authorisation for treated mycosis fungoides or Sézary syndrome cutaneous T-cell lymphoma.

Background

Lymphomas are cancers of the lymphatic system. They are broadly divided into Hodgkin's and non-Hodgkin's lymphomas. Cutaneous T-cell lymphoma is a rare type of non-Hodgkin's lymphoma that affects the skin. It is caused by the uncontrolled growth of T-lymphocytes within the skin. Many types of cutaneous T-cell lymphoma start as flat red patches or plaques on the skin, which progress to skin tumours, and may be itchy and sometimes painful. Some people with cutaneous T-cell lymphoma experience swelling of the lymph nodes.

Within the group of cutaneous T-cell lymphoma, distinct subtypes can be distinguished. Mycosis fungoides is the most common type of cutaneous T-cell lymphoma. Sézary syndrome is closely related to mycosis fungoides and refers to a condition when cancerous T-cells (called Sézary cells) are found in the blood as well as the lymph nodes.

Between 2009 and 2013, 1,659 people were newly diagnosed with cutaneous T-cell lymphomas of which around 55% were mycosis fungoides[1]. The overall incidence of cutaneous T-cell lymphomas in 2013 was around 0.75 per 100,000 (England), and it was more common in men than women (ratio around 1.6:1)[1]. The majority of people diagnosed with cutaneous T-cell lymphoma are over the age of 50 but it can also affect young people[1,2].

Treatment options depend on several factors, including how much of the skin is involved, the nature of the disease (aggressive or slow growing), the type of lesion and whether the cutaneous T-cell lymphoma has spread to lymph nodes or other organs. Current management of cutaneous T-cell lymphoma consists of skin directed therapies and systemic therapies. Skin directed therapies are aimed primarily at the skin and include photo therapy (such as psoralen and ultraviolet A treatment - PUVA, narrow band ultraviolet B treatment); radiotherapy; total skin electron beam therapy (TSEBT); and topical chemotherapy agents, topical corticosteroids and topical retinoids. Systemic therapies are aimed at treating the skin and/or internal organs

affected or at risk, and include chemotherapy (such as methotrexate, gemcitabine, liposomal doxorubicin or multi-agent chemotherapy–cyclophosphamide, doxorubicin, vincristine, and prednisone), and immunotherapy (such as bexarotene, interferon alpha, or extracorporeal photopheresis - ECP). NICE technology appraisal 577 recommends brentuximab vedotin as an option for treating CD30-positive cutaneous T-cell lymphoma (CTCL) after at least one systemic therapy in adults, only if they have mycosis fungoides stage IIB or over, primary cutaneous anaplastic large cell lymphoma or Sézary syndrome. Stem cell or bone marrow transplant (such as allogeneic stem cell transplant) may also be a treatment option for some people (for example those with advanced disease, a poor response to systemic therapy, multiple relapses or a short remission). Treatment options for cutaneous T-cell lymphoma can be used either alone or in combination. People may have multiple sequential treatments and remain on maintenance therapy with palliative intent although there is no established standard of care.

The technology

Mogamulizumab (Poteligeo, Kyowa Kirin) is a humanised anti-CC chemokine receptor type 4 (CCR4) monoclonal antibody. It inhibits T cells that express CCR4, with indirect anti-tumour effects. It is administered by intravenous infusion.

Mogamulizumab has a UK marketing authorisation for treating cutaneous T-cell lymphoma. It is indicated for the treatment of adults with mycosis fungoides or Sézary syndrome who have received at least one prior systemic therapy.

Intervention(s)	Mogamulizumab
Population(s)	Adults with mycosis fungoides or Sézary syndrome cutaneous T-cell lymphoma following at least one prior systemic therapy.
Comparators	Established clinical management without mogamulizumab.
Outcomes	The outcome measures to be considered include: • overall survival • progression-free survival • response rates • time to next treatment • 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. The availability of any commercial arrangements for the intervention, comparator and subsequent treatment technologies will be taken into account.
Other considerations	Guidance will only be issued in accordance with the marketing authorisation. Where the wording of the therapeutic indication does not include specific treatment combinations, guidance will be issued only in the context of the evidence that has underpinned the marketing authorisation granted by the regulator.
Related NICE recommendations and NICE Pathways	Related technology appraisals: Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma. NICE technology appraisals guidance [TA577]. Published April 2019. Appraisals in development: Mogamulizumab for previously treated T-cell leukaemia-lymphoma. NICE technology appraisals guidance [ID1390]. Publication date to be confirmed. Related Guidelines: Non-Hodgkin's lymphoma: diagnosis and management (2016) NICE guideline 52. Haematological cancers: improving outcomes (2016) NICE guideline 47 Improving outcomes for people with skin tumours including melanoma (2006) NICE cancer service guideline 8 Non-Hodgkin's lymphoma: rituximab subcutaneous injection (2014) NICE evidence summary 46 Related Quality Standards: Haematological cancers (2017) NICE quality standard QS150

	Related NICE Pathways: Non-Hodgkin's lymphoma (2018) NICE Pathway
Related National Policy	The NHS Long Term Plan, 2019. NHS Long Term Plan NHS England (2018/2019) Manual for Prescribed Specialised Services 2018/19. Chapter 105. Department of Health and Social Care, NHS Outcomes Framework 2016-2017 (published 2016): Domain 1

References

1. Public Health England (2016) Registration of Cutaneous T-Cell Lymphoma (CTCL) in England. National Cancer Registration and Analysis Services Short Report 2016397

2. Abbott, R.A., Aldridge, C., Dojcinov, S. and Piguet, V. (2013), Incidence of primary cutaneous T-cell lymphoma in Wales. Br J Dermatol 169: 1366–1367