NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Health Technology Appraisal

Mogamulizumab for treated mycosis fungoides or Sézary syndrome T-cell lymphoma ID1405

Draft scope

Remit/appraisal objective

To appraise the clinical and cost effectiveness of mogamulizumab within its marketing authorisation for treated mycosis fungoides or Sézary syndrome 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 a number of 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). 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 adult patients with treated mycosis fungoides or Sézary syndrome T-cell lymphoma.

Intervention(s)	Mogamulizumab
Population(s)	Adults with mycosis fungoides or Sézary syndrome 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 • 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. 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	Appraisals in development: Brentuximab vedotin for treating CD30-positive cutaneous T-cell lymphoma. NICE technology appraisals guidance [ID1190]. Publication expected May 2019. 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

Questions for consultation

Have all relevant comparators for mogamulizumab been included in the scope?

Which treatments are considered to be established clinical practice in the NHS for treated mycosis fungoides or Sézary syndrome T-cell lymphoma? How should established clinical management be defined?

Are the outcomes listed appropriate?

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

Where do you consider mogamulizumab will fit into the existing NICE pathway, non-Hodgkin's lymphoma?

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the proposed remit and scope may need changing in order to meet these aims. In particular, please tell us if the proposed remit and scope:

- could exclude from full consideration any people protected by the equality legislation who fall within the patient population for which mogamulizumab will be licensed;
- could lead to recommendations that have a different impact on people protected by the equality legislation than on the wider population, e.g. by making it more difficult in practice for a specific group to access the technology;
- could have any adverse impact on people with a particular disability or disabilities.

Please tell us what evidence should be obtained to enable the committee to identify and consider such impacts.

Do you consider mogamulizumab to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?

Do you consider that the use of mogamulizumab can result in any potential significant and substantial health-related benefits that are unlikely to be included in the QALY calculation?

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

To help NICE prioritise topics for additional adoption support, do you consider that there will be any barriers to adoption of this technology into practice? If yes, please describe briefly.

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/article/pmg19/chapter/1-Introduction).

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

