



Medicine: daratumumab (brand name: Darzalex®)

Janssen-Cilag Ltd

The Scottish Medicines Consortium (SMC) has assessed daratumumab for the treatment of adults with light chain (AL) amyloidosis (a rare condition where deposits of proteins called amyloid build up and cause damage to tissues and organs). Daratumumab is used together with cyclophosphamide, bortezomib and dexamethasone to treat newly diagnosed patients. This document summarises the SMC decision and what it means for patients.

What has SMC said?

After careful consideration, SMC has accepted daratumumab for treating light chain amyloidosis, as described above.

This SMC advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of daratumumab. In addition, SMC was able to apply a more [flexible approach*](#) in the assessment, as it is for a rare condition.

What does SMC's decision mean for patients?

If your healthcare professional thinks that daratumumab for use as described above is the right medicine for you, you should be able to have the treatment on the NHS in Scotland.



What is daratumumab used for?

Daratumumab is used to treat adults with AL amyloidosis. In AL amyloidosis cells in the bone marrow called plasma cells (which normally produce antibody proteins), produce abnormal proteins which clump together and form fibrils called amyloid. Over time, these amyloid fibrils build up in the blood, tissues and organs e.g. the heart and kidneys, causing life-threatening conditions such as congestive heart failure and renal failure which can lead to death. Daratumumab is used together with cyclophosphamide, bortezomib and dexamethasone to treat patients who are newly diagnosed with AL amyloidosis.

How does daratumumab work?

Daratumumab is a type of medicine called a monoclonal antibody. It binds to a protein called CD38 which is on the surface of the faulty plasma cells. By binding to CD38 daratumumab activates the patient's immune system to destroy the faulty plasma cells that are making the amyloid proteins.

*<https://www.scottishmedicines.org.uk/how-we-decide/pace/>

How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC considers the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- Information from patient groups about the potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not only those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of daratumumab by looking at the SMC Detailed Advice Document (SMC2447).

More information

The organisation below can provide more information and support for people with light chain (AL) amyloidosis and their families. SMC is not responsible for the content of any information provided by external organisations.

Myeloma UK



<https://www.myeloma.org.uk>



0800 980 3332

You can find out more about daratumumab (Darzalex®) in the Patient Leaflet by searching for the medicine name on the electronic medicines compendium (EMC) website.



<https://www.medicines.org.uk/emc/>