Brentuximab vedotin

This information is about brentuximab vedotin, a targeted drug used in the treatment of certain types of lymphoma.

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What is brentuximab vedotin?

Brentuximab vedotin (Adcetris®) is an antibody-drug conjugate. This type of targeted treatment consists of an antibody joined to a chemotherapy drug. Brentuximab vedotin includes:

- a CD30 **monoclonal antibody** – an antibody that binds (sticks) to a protein called ‘CD30’, which is found on the abnormal cells in some types of lymphoma
- the **chemotherapy** drug monomethyl auristatin E (MMAE).

The antibody binds (sticks) to lymphoma cells that have the CD30 protein, delivering the chemotherapy directly to the lymphoma cells.

The chemotherapy drugs used in this type of treatment are good at killing lymphoma cells but can’t be given into the bloodstream on their own because they are too toxic.
Who can have it?

Brentuximab vedotin is approved in Europe for three types of lymphoma – classical Hodgkin lymphoma, systemic anaplastic large cell lymphoma and cutaneous (skin) T-cell lymphoma. This treatment can only be used if your lymphoma cells have the CD30 protein. Cells from your biopsy sample might be tested for CD30 before you can have brentuximab vedotin.

Classical Hodgkin lymphoma

- For people whose lymphoma has relapsed (come back) after an autologous stem cell transplant (using their own stem cells), or who didn’t respond to a stem cell transplant.
- For people who are not able to have a stem cell transplant or a combination of chemotherapy drugs and have had at least two other types of treatment.
- For people at high risk of their lymphoma coming back or getting worse after an autologous stem cell transplant.

Systemic anaplastic large cell lymphoma (ALCL)

- For people whose lymphoma has relapsed or has not responded to previous treatment.

Cutaneous (skin) T-cell lymphoma (CTCL)

- For people who have already received at least one other course of systemic (whole-body) drug treatment.

Brentuximab vedotin is still being tested in further clinical trials in people with these types of lymphoma, for example as a first-line treatment and in combination with other treatments. It is also being tested in other types of lymphoma. Use our searchable database to see if there’s a clinical trial that might be suitable for you at Lymphoma TrialsLink.

Is it available on the NHS in the UK?

Brentuximab vedotin has been assessed by health authorities for some uses on the NHS in the UK. Its availability on the NHS may vary for different parts of the UK.

In England, Wales and Scotland, brentuximab vedotin is available on the NHS for:

- people with relapsed or refractory classical Hodgkin lymphoma who have had an autologous stem cell transplant, or who are not able to have a stem cell transplant or a combination of chemotherapy drugs and have had at least two other types of treatment
• people with advanced primary cutaneous anaplastic large cell lymphoma, mycosis fungoides or Sézary syndrome who have had at least one previous systemic (whole body) treatment.

In England and Wales brentuximab vedotin is also available on the NHS for:

• people with relapsed or refractory ALCL who are fit enough to have it.

Brentuximab vedotin is also being assessed for other uses, for example in combination with different treatments for certain types of lymphoma.

Northern Ireland usually follows NICE recommendations.

What can I do if brentuximab vedotin isn’t funded for me?

If brentuximab vedotin is approved for use in your situation but isn’t currently funded by the NHS, your doctor may be able to make an individual funding request in exceptional cases. Discuss this with your doctor if you think that this might apply to you.

If you have private medical insurance, ask your provider if you are covered for treatment with brentuximab vedotin.

Some people might be able to enter a clinical trial of brentuximab vedotin. Ask your doctor if there is a clinical trial suitable for you or search for a trial at Lymphoma TrialsLink.

Benefits

The main trials that led to approval of brentuximab vedotin are briefly described below.

Benefits in classical Hodgkin lymphoma

Many people with Hodgkin lymphoma are treated successfully with their first course (line) of treatment. Sometimes, classical Hodgkin lymphoma can be difficult to treat and may need more chemotherapy (second line, or salvage treatment) and an autologous stem cell transplant. There are few treatment options if classical Hodgkin lymphoma relapses again or does not respond to a stem cell transplant. The main study in this area showed that three-quarters of 102 people treated with brentuximab vedotin responded to the treatment (their lymphoma shrank or disappeared – a partial or complete remission, respectively).
People who have had at least two other courses (lines) of treatment but are not suitable for a stem cell transplant or chemotherapy with a combination of drugs might also benefit from brentuximab vedotin. In a study of 40 people with classical Hodgkin lymphoma, just over half responded to brentuximab vedotin.

Brentuximab vedotin could also help to keep classical Hodgkin lymphoma under control for longer in people who have had a stem cell transplant but who are at high risk of their lymphoma coming back. In a study of 329 people, lymphoma stayed under control for nearly twice as long in people treated with brentuximab vedotin compared with people who received a placebo (dummy treatment).

**Benefits in systemic ALCL**

ALCL can be difficult to treat if it comes back or doesn’t respond to treatment. In a study of 58 people with relapsed or refractory ALCL, 50 people responded to treatment with brentuximab vedotin.

**Benefits in CTCL**

CTCL is rare and usually requires a range of different treatments during the course of the disease. In a trial of 128 people with relapsed or refractory CTCL, more than half of people responded to treatment with brentuximab vedotin, compared with around 1 in 10 of those given other treatments.

**How is it given?**

You have brentuximab vedotin as an intravenous infusion (into a vein) over 30 minutes. You usually have the treatment once every 3 weeks, where each 3-week period is a ‘cycle’ of treatment. Most people can have the treatment in hospital as an outpatient, but some people might need to stay overnight for monitoring. On average, a response to brentuximab vedotin is seen after 4 or 5 cycles of treatment. The number of cycles of brentuximab vedotin you have depends on how you respond, how the treatment affects you and whether or not you go on to have a stem cell transplant. If brentuximab vedotin is controlling your lymphoma, you can have up to 16 cycles (1 year) of treatment. If your lymphoma stops responding or you develop side effects, you might stop treatment earlier.

**Possible side effects**

All medicines can cause side effects (unwanted effects of treatment). As brentuximab vedotin is a new treatment, more information about possible side effects is still being gathered.
The most common side effects of brentuximab vedotin, which can affect more than 1 in 10 people, are:

- infusion-related reactions (occurring while the treatment is given or shortly afterwards) such as shivers, fevers, and other flu-like symptoms
- gastrointestinal problems, such as nausea, vomiting, diarrhoea, constipation, abdominal (tummy) pain and weight loss
- fatigue (extreme tiredness)
- itching and rashes
- hair loss
- muscle and joint pain
- peripheral neuropathy (nerve damage that can cause problems such as pins and needles)
- infections (for example colds) and neutropenia (a drop in the number of neutrophils you have, a type of white blood cell that fights infection)
- cough and shortness of breath.

Serious complications are less common but could include:

- serious infections like pneumonia and, very rarely, progressive multifocal leukoencephalopathy (a viral brain infection, which can be fatal)
- problems with the lungs or liver, or gastrointestinal complications
- tumour lysis syndrome (complications caused by the rapid breakdown of lymphoma cells)
- demyelinating polyneuropathy (a neurological disorder characterized by slowly progressive weakness and a loss of sensation in the legs and arms)
- Stevens-Johnson syndrome (a life-threatening allergic reaction affecting the skin and mucous membranes)
- pancreatitis (inflammation of the pancreas).

This is not a complete list of side effects that have been reported. Ask your medical team for the most up-to-date information about possible side effects. Ask all the questions you have. You also need to tell your medical team about any other conditions you have and any medicines, supplements or complementary therapies you are taking before you start any new treatment.

Your medical team monitor you closely for side effects during treatment. They can tell you what to look out for and who to contact if you have any problems.
Precautions

Some people will not be able to have brentuximab vedotin because they are taking other medications or have other conditions. **Make sure you tell your doctor about any medical conditions and any medicines you are taking.** Your doctor may reduce your dose and monitor you more closely or recommend that you do not take brentuximab vedotin if you have certain other conditions. These include liver problems and kidney problems. Your doctor might also change your dose if you experience troublesome side effects.

Brentuximab vedotin has not been approved for use in people under 18.

People who are pregnant should not usually have brentuximab vedotin during their pregnancy in case it could harm the unborn baby. You must use at least two effective measures of contraception to prevent pregnancy for at least 6 months after treatment and you should not breastfeed for the same period. Discuss your treatment options with your doctor if you think you might be pregnant.

References

The full list of references is available on request. Please email publications@lymphoma-action.org.uk or call 01296 619409 if you would like a copy.

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