

Drotrecogin alfa (activated) for severe sepsis

Understanding NICE guidance –
information for the families and carers of
people with severe sepsis, and the public

September 2004



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What is NICE guidance?

The National Institute for Clinical Excellence (NICE) is part of the NHS. It produces guidance (recommendations) on the use of medicines, medical equipment, diagnostic tests, and clinical and surgical procedures within the NHS in England and Wales.

To produce this guidance, NICE looks at how well the medicine, equipment or procedure works and also how well it works in relation to how much it costs. This process is called an appraisal. The appraisal process involves the manufacturer of the medicine or equipment for which guidance is being produced and the organisations that represent the healthcare professionals, patients and carers who will be affected by the guidance.

NICE was asked to look at the available evidence on the use of drotrecogin alfa (activated) for severe sepsis. NICE was asked to provide guidance that will help the NHS in England and Wales decide when drotrecogin alfa (activated) should be used.

What is severe sepsis?

Sepsis is a response of the body to infection. When sepsis is severe it can cause the blood pressure to drop and clotting of the blood in the smallest blood vessels, which can interfere with normal blood circulation and damage organs such as the kidneys, heart and lungs. When these organs stop working properly, this is known as organ failure – when more than one organ stops working properly it is called 'multiple organ failure'.

Severe sepsis can be fatal or can cause permanent damage to organs or tissues, which may result in long-term poor health or disabilities.

People who develop severe sepsis are usually cared for in an intensive care unit.

What is drotrecogin alfa (activated)?

Drotrecogin alfa (activated) is a treatment for patients with severe sepsis. Drotrecogin alfa (activated) is also known as Xigris (its trade name) or recombinant human activated protein C.

Activated protein C is a protein molecule that is normally found in the body. It helps to reduce blood clotting and inflammation, which can be caused by severe sepsis. Patients with sepsis have low levels of protein C and a reduced ability to produce activated protein C.

Drotrecogin alfa (activated) is a genetically engineered form of activated protein C that has the same effects as the natural protein in the body. It seems to work by helping the body to overcome some of the effects of severe sepsis.

However, drotrecogin alfa (activated) may increase bleeding, and so it cannot be given to some patients, including those who have internal bleeding or long-term severe liver disease.

What has NICE recommended on drotrecogin alfa (activated) for severe sepsis?

During the appraisal, NICE's Appraisal Committee read and heard evidence from:

- good-quality studies (randomised clinical trials) of drotrecogin alfa (activated)
- doctors with specialist knowledge of severe sepsis and its treatment
- individuals with specialist knowledge of the issues affecting people who have had severe sepsis
- organisations representing the views of people who will be affected by the guidance (for example, because they work in the NHS and are involved in providing care for people with the condition)
- the manufacturer of drotrecogin alfa (activated).

The evidence is summarised in the full guidance (see page 10 for details). More information about the studies is provided in the assessment report for this appraisal (see page 10 for details).

NICE has made the following recommendations about the use of drotrecogin alfa (activated) to treat severe sepsis within the NHS in England and Wales.

Drotrecogin alfa (activated) is recommended for adult patients who

- have severe sepsis that has resulted in multiple organ failure (two or more major organs are not working properly)

and

- are being given the most appropriate intensive care support for their condition.

The use of drotrecogin alfa (activated) should be started and supervised by a specialist consultant with skills in intensive care and experience in the care of patients with sepsis.

What should I do next?

If you think this guidance may apply to someone in your family who is in hospital or somebody you care for who is in hospital, you should discuss this guidance with their specialist consultant.

Will NICE review its guidance?

Yes. The guidance will be reviewed in September 2007.

Further information

The NICE website (www.nice.org.uk) has further information about NICE and the full guidance on drotrecogin alfa (activated) for severe sepsis that has been issued to the NHS. The assessment report, which contains details of the studies that were looked at, is also available from the NICE website. A short version of the guidance (a 'quick reference guide') is available on the website and from the NHS Response Line (phone 0870 1555 455 and quote reference N0713).



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