Belatacept after a kidney transplant: Minor added benefit for certain patients

November 9 2012

Belatacept (trade name Nulojix) has been approved since June 2011 to prevent a rejection reaction of the body to the donor organ (transplant) in adults who have received a kidney transplant. The Institute for Quality and Efficiency in Health Care (IQWiG) has examined the added benefit of the drug pursuant to the "Act on the Reform of the Market for Medicinal Products" (AMNOG).

The assessment showed an indication of a minor added benefit of belatacept in adults with transplants from donors who had been selected according to the so-called standard criteria. Serious side effects such as urinary tract infections or pneumonia occurred less frequently in these patients and they also discontinued treatment due to side effects less often.

In patients who received transplants from donors who had been selected according to extended criteria (in this case, only deceased donors, who could also have been older and could have had certain accompanying diseases), no relevant differences could be found between the treatment with belatacept or with the comparator therapy, cyclosporine A. That means an added benefit of belatacept is not proven for these patients.

Belatacept in comparison with cyclosporine A

The immunosuppressant belatacept suppresses the immune system and thereby the natural defence reaction of the body to foreign tissue.

Immunosuppressive drugs have to be taken long-term after a transplant in order to prevent the donor kidney being rejected after transplantation.

The appropriate comparator therapy used for the early benefit assessment was cyclosporine A. Both belatacept and cyclosporine A are given in combination with corticosteroids and a mycophenolic acid. Belatacept is given as an infusion (intravenously) into the bloodstream, whereas cyclosporine A is administered as a tablet.

Different donor characteristics

In both of the studies that were part of the approval of the drug and which were included in the benefit assessment, treatment with belatacept was compared with cyclosporine A. All participants in the studies were also treated with corticosteroids, with mycophenolate mofetil and, at the start of treatment, with the antibody basiliximab.

The main difference between the two studies was in the characteristics of the donors. In Study IM103008, adults were investigated who received a kidney from a donor classified according to standard criteria (Standard Criteria Donors, SCD). Here, about half of the organs came from living donors, the other half from deceased donors (for example after a fatal accident).

In Study IM103027, the donors had been selected according to so-called extended criteria (Extended Criteria Donors, ECD) and only organs from deceased donors were transplanted. ECD means that, for example, older donors over 60 years of age or younger ones with certain accompanying diseases can also be selected. In both studies, the patients were treated for 36 months. Since treatment with belatacept is long-term, IQWiG based its assessment chiefly on the results of the entire study period.

Added benefit only for patients with transplants from donors selected according to standard criteria

No added benefit of belatacept in comparison with cyclosporine A could be derived from the study data for adult patients who received a kidney transplant from a donor selected according to extended criteria (ECD).

For adult patients with a kidney transplant from a donor selected according to standard criteria (SCD), there was in each case an indication of lesser harm from belatacept for the outcome criteria "serious adverse events" and for "treatment discontinuations due to adverse events". However, because the differences between the treatment options are small, IQWiG rates the added benefit of belatacept compared with cyclosporine A in the lower category, namely as minor.

In terms of other outcome criteria relevant to patients, such as mortality, transplant loss, cardiovascular or renal diseases, the occurrence of diabetes or a disease of the lymphatic tissue after transplantation, the development of tumours, infections as well as the quality of life, IQWiG could not identify any other advantages or disadvantages of belatacept in comparison with cyclosporine A.

G-BA decides on the extent of added benefit

The dossier assessment is part of the overall procedure for early benefit assessment conducted by the G-BA. After publication of the manufacturer's dossier and its assessment by IQWiG, the G-BA initiates a formal commenting procedure which provides further information and can result in a change to the benefit assessment. The G-BA then decides on the extent of the added benefit, thus completing the early benefit assessment.

More information: www.gesundheitsinformation.de/

Provided by Institute for Quality and Efficiency in Health Care