Medical Xpress

First device approved for dialysis-related amyloidosis

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(HealthDay)—The U.S. Food and Drug Administration has approved the first device to treat dialysis-related amyloidosis (DRA), a complication of dialysis used to treat kidney failure.

DRA is a rare, yet chronic, condition caused by blood buildup of a protein called beta 2-microglobulin. It occurs most often among people aged 60 or older who have been on dialysis for more than five years, the FDA said in a news release. Symptoms if the protein spreads to the bones may include painful and stiff joints, bone cysts and torn tendons and ligaments.

The newly approved device, the Lixelle Beta 2-microglobulin Apheresis Column, removes the protein from the blood using porous cellulose beads. It was evaluated among 100 clinical trial patients in Japan.

The most common side effects noted were temporary low blood pressure and a drop in red blood cell count.

The FDA ordered Japanese device maker Kaneka Corp. to conduct a post-approval study of the device's benefits, risks and side effects among users in the United States, the FDA said.

More information: The FDA has more about this approval.