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Coding and Justification for the User-Adjustable, Mechanical, Residual Limb Volume Management System feature.

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The “Boa Fit Dial System” that is fabricated into the Varos socket allows the user to adjust and manage limb volume variations.

Additional Coding (U.S.) to describe the Varos’ User Adjustable Volume Management System

L5783 ADDITION TO LOWER EXTREMITY, USER ADJUSTABLE, MECHANICAL, RESIDUAL LIMB VOLUME MANAGEMENT SYSTEM

Justification for User Adjustability

The general justification for the adjustable, mechanical, residual limb volume management system of the Varos is to provide the user the ability to adjust the internal volume of their socket to maintain proper fit, function, and comfort of their prosthesis. Patients with transfemoral amputation experience daily changes to their residual limb volume because the structures which facilitate normal fluid movement throughout the body have been disrupted. Fluid movement and accumulation varies daily with activity and other factors such as hydration. Residual limb volumes also change over time due to changes in body composition including muscular atrophy and weight gain or loss. In response, the user must adjust the internal volume of their socket to maintain an intimate prosthetic fit. Loss of an intimate fit between the user and socket results in excessive movement of the prosthesis which reduces function and stability of attached components. The excessive shear forces associated with excess motion also cause skin irritation which leads to discomfort, and, eventually to open residual limb wounds and ulcers. These factors reduce the ability of the user to complete activities of daily living and participate in their community.

Management of residual limb volume with socket fit by the user is further complicated by the presence of common comorbidities which may cause edema including diabetes mellitus, chronic venous insufficiency, renal disease, and lymphedema. Diabetes often results in peripheral arterial disease due to atherosclerosis which reduces circulation. Chronic venous insufficiency occurs when circulation back to the heart is disturbed which causes edema. The ability of the patient to remove excessive fluid from the body is reduced with renal disease. Patients who require dialysis to remove this fluid experience massive fluctuations in fluid volumes during their sessions, typically two to three times weekly. Patients who require chemotherapy for treatment of cancer often incur damage to the lymphatic system in the treatment area which reduces bodily drainage and causes lymphedema. The Varos enables the user to mechanically manage their residual limb volume and maintain prosthetic fit through adjustment of the two Boa™ dials integrated into the socket.

A second justification applies to patients with recent amputation where rapid volume loss is expected for 6-12 months following surgery. Maintaining an intimate fit between the prosthetic socket and user is especially important for these patients who are less proficient at walking and more prone to falling than experienced users. The Varos provides users with the ability to reduce the internal volume of their socket on demand during this period to maintain fit as long as possible.

An additional justification is comfort in sitting when users can reduce mechanical tension of the Varos on their residual limb. This method allows fluid to return to the limb during sitting thereby improving fit when the user stands and tightens the socket again. The mechanical loosening also allows the socket to deform with the thigh in sitting which improves comfort and allows the user to keep the prosthesis on longer throughout the day than traditional sockets.

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