



December 3rd, 2015
CYBERDYNE Inc.

**Application for national health insurance coverage for
HAL for Medical Use (Lower Limb Type)
submitted to the Ministry of Health, Labour and Welfare**

CYBERDYNE Inc. (2-2-1, Gakuen-Minami, Tsukuba, Ibaraki) submitted an application for the coverage of HAL for Medical Use (Lower Limb Type) (medical device approval number: 22700BZX00366000; hereinafter referred as “HAL for Medical Use”) under national health insurance to the Ministry of Health, Labour, and Welfare on December 3, 2015.

Having received the approval for manufacture and distribution of HAL for Medical Use (Lower Limb Type) as a medical device on November 25, 2015^{*1}, this signifies the progression to the next step of obtaining insurance coverage for its treatments.

Discussions and deliberations related to the insurance coverage of treatments using HAL for Medical Use by the Central Social Insurance Medical Council and a group of experts on insurance and medical supplies will be scheduled next. If the insurance coverage is approved, its application in healthcare will be permitted. For the application classification of this medical device, there are four months in the year when its insurance listing can take place, and CYBERDYNE Inc. is aiming for insurance coverage by April 2016.

HAL for Medical Use is the world’s first robot therapeutic device that outputs a motor force according to bioelectric signals (“BES”) measured from the surface of the skin in order to assist the patient’s movements. By moving in unison with the patient, the device improves the patient’s ambulatory function through repeated assistance of their lower limb walking movements. In Germany, the application for public health insurance coverage was submitted in October 2015^{*2}.

The device’s safety and efficacy of slowing down the advancement of disease for patients with slowly progressing neuromuscular diseases^{*3} were recognized through clinical tests, and the device received its regulatory approval as Japan’s first robot therapeutic device.

*1 News release for the approval for medical device manufacture and distribution:
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=3749

*2 News release for the application for Germany’s public health insurance coverage:
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=3641
http://www.cyberdyne.jp/english/company/PressReleases_detail.html?id=3686



*3 Target Diseases:

amyotrophic lateral sclerosis (ALS)
spinal muscular atrophy (SMA)
spinal and bulbar muscular atrophy (SBMA)
Charcot-Marie-Tooth disease (CMT)
muscular dystrophy
distal myopathy
congenital myopathy
inclusion body myositis (IBM)

Company Profile:

Company Name CYBERDYNE Inc.
Headquarters 2-2-1, Gakuen-Minami, Tsukuba,
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Capital Stock JPY 16.511 Billion
Founded June 24th, 2004
Business Robot suit development, manufacture,
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Stock Code 7779

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