

Ottobock MPKs – 12 years of health economics

Summary of 10 health economic studies from 2008 to 2020

Major Findings

Cost-effectiveness was demonstrated from payer perspective

- When comparing C-Leg with NMPKs, the value of the incremental cost-effectiveness ratio (ICER) per quality adjusted life year (QALY) was **16,123 Euros** in amputees without diabetes mellitus (DM) and **20,332 Euros** in amputees with DM in a German study ^[1], **40,155 Euros** in a recent Italian study from 2016 ^[3], **35,971 Euros** in an earlier Italian study from 2008 ^[4], and **3,128 Euros** based on data gathered from a Swedish study ^[5].
- One study compared Genium with C-Leg and obtained an ICER per QALY between **6,000 and 11,957 USD** based on an US cohort ^[7].

Cost-effectiveness was demonstrated from societal perspective

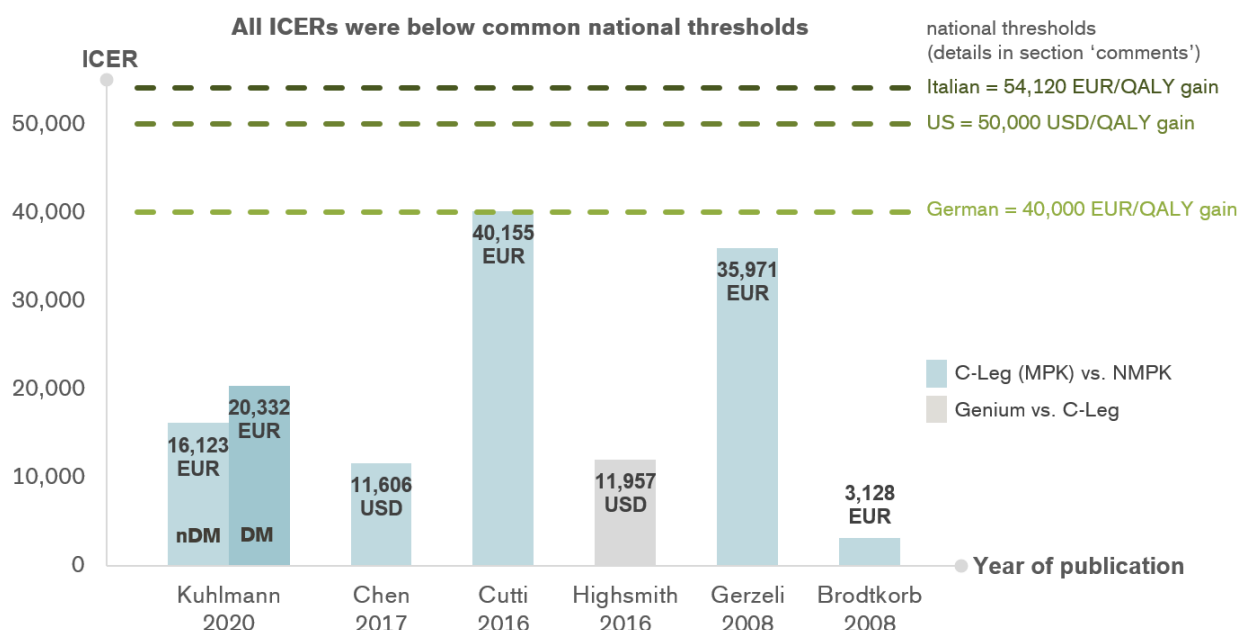
- An **ICER of 11,606 USD** for comparing C-Leg (MPKs) with NMPKs from the societal perspective was obtained in a US study ^[2].

A marginal budget impact of C-Leg in comparison to NMPKs was demonstrated in 1 study

- Over the period of 5 years, a **diminishing effect** in the size of the annual budget impact of C-Leg in comparison to NMPKs was observed ^[1].

Further important health economics findings were obtained

- A **favourable cost-benefit ratio** between C-Leg (MPKs) and NMPKs was demonstrated in a Dutch population from the societal perspective (total **costs** were **lower**, and mean **quality of life (QoL)** was **higher**)
- In 2017, for the first time, **direct medical costs of falls** were determined for adult transfemoral amputees ^[8].
- Studies before 2012 were summarized for the evaluation of past health economics finding as part of 2 review articles ^[9,10].



Clinical relevant outcomes

C-leg (MPK) compared to NMPK improved QoL in 4 studies

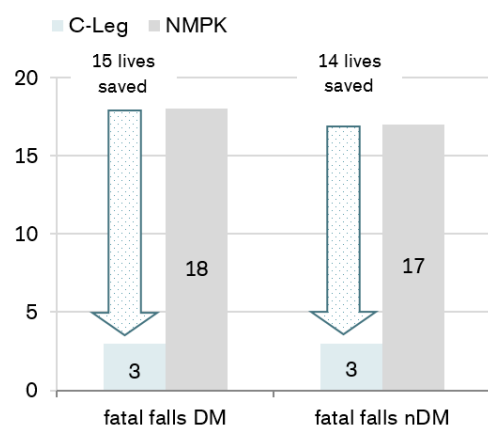
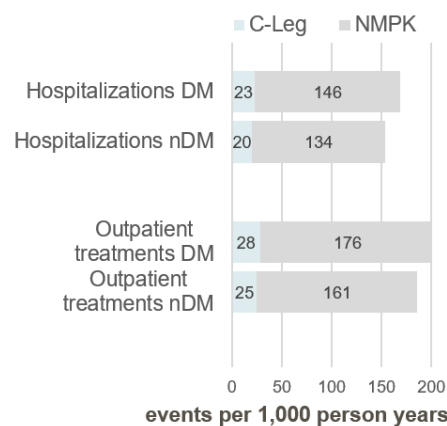
- With an **increase of 13-14 %** ^[3,4] based on EQ-5D measures in the Italian studies, **of 57 %** based on the EuroQoL VAS measure in the Swedish study ^[5] and of **18 %** based on the SF-6D measure in the Dutch study ^[6].

C-leg (MPK) compared to NMPK increased QALY in 5 studies

- With a **QALY gain of 1.74** for the non-DM and **0.92** for the DM cohort ^[1], of **0.91** within the US study ^[2], of **0.42** and **0.46** within the Italian cohorts in 2008 and 2016 ^[4,3] and of **2.38** within the Swedish study ^[5].

C-Leg (MPK) compared to NMPK improved safety - falls reduction in 2 studies

- With a **reduced rate of fall-related hospitalizations** by approximately **85 %** and **reduced rate of outpatient treatments** by approximately **84 %** ^[1].
- The **rate of fatal falls** was reduced by approximately **83 %** ^[1].



based on Germany study by Kuhlmann et.al ^[1]

- Similar results were demonstrated as part of the US study that evaluated safety within transfemoral amputees without consideration of DM as comorbidity ^[2].
- The German study showed that C-Leg users without DM **gain 1.96 life years (LYs)** and C-Leg users with DM **0.55 LYs** ^[1].
- The US study expressed this effect as lives saved, **11 lives would be saved** by C-leg (MPK) if 1,000 amputees would be observed for one year ^[2].

Further clinical relevant outcomes were demonstrated in 2 studies

- C-Leg (MPKs) resulted in **16 fewer incidences of osteoarthritis** per 100 persons ^[2].
- **Improved physical functionality of activities of daily living** of Genium compared to C-Leg was observed in one study ^[7].

Costs

- National (DRG statistics ^[1]), health insurance (Medicare ^[2], INAIL^[3,4]) and medical (Dutch rehabilitation centre^[6]) databases, literature reviews, expert panels as well as interviews with health specialists and patients were used to inform costs.
- Direct medical costs included: device acquisition, fall-related injury (hospital, inpatient, outpatient treatments e.g. for hip/femur/ankle/wrist fractures) and rehabilitation costs.
- Indirect medical costs included: lost wages, caregiving and transportation expenses (used for social perspective of studies).

Summary

- Health economics of MPKs were extensively evaluated over the last 12 years.
- Cost-effectiveness of MPKs compared to NMPKs was demonstrated.
- Individuals using an MPK benefit from improved physical functionality of activities in daily living, QoL, QALY gain, reduced number of falls and fall-related injuries.
- A negligible marginal budget impact of MPKs compared to NMPKs was demonstrated.
- These results strengthen the argumentation to provide MPKs as standard of care.

References of summarized studies

- [1] **Kuhlmann, A.**, Krüger, H., Seidinger, S. et al. Cost-effectiveness and budget impact of the microprocessor-controlled knee C-Leg in transfemoral amputees with and without diabetes mellitus. *Eur J Health Econ* (2020). <https://doi.org/10.1007/s10198-019-01138-y>
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- [10] **Highsmith, M.J.**, Kahle, J.T., Bongiorno, D.R., Sutton, B.S., Groer, S., Kaufman, K.R.: Safety, energy efficiency, and cost efficacy of the C-Leg for transfemoral amputees. A review of the literature. *Prosthet. Orthot. Int.* 34(4), 362–377 (2010). <https://doi.org/10.3109/03093646.2010.520054>

National thresholds

- **German threshold:** is equal to the German GDP per capita in 2018, which is a threshold proposed by the WHO ^[1]
- **US threshold:** corresponds to the commonly accepted threshold according to the Institute for Clinical and Economic Review in the US ^[2]
- **Italian threshold:** is equivalent to the converted upper threshold of 44,000 GBP that was reported as NICE practical acceptability threshold in the UK ^[3]

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