MINISTÈRE
DE LA SÉCURITÉ SOCIALE
Cellule d'expertise médicale

Avis 2013-08 de la Cellule d'expertise médicale

Analyse et propositions relatives à la demande concernant la prise en charge des chaussures thérapeutiques, des chaussures orthopédiques et des semelles orthopédiques pour pieds diabétiques et des semelles proprioceptives dans le cadre du traitement des problèmes neuro-musculaires

Saisine de la Commission de nomenclature (Référence CEM 2013 / 8)

Luxembourg, le 25 mars 2014

Cellule d'expertise médicale - CEM
26, rue Ste Zithe L-2763 Luxembourg
Téléphone : 2478 2478 Fax : 247-86225 E-mail : cem@igss.etat.lu

Résumé exécutif

La Cellule d'expertise médicale (CEM) a été saisie par la Commission de nomenclature d'une demande de la Fédération des Orthopédistes-Cordonniers-Bandagistes et des Cordonniers-Réparateurs visant à introduire 3 nouvelles positions dans leur nomenclature, ceci dans le cadre de la prise en charge de la prévention des troubles trophiques des pieds chez les patients diabétiques. Il s'agit des chaussures thérapeutiques pour pieds diabétiques, des chaussures orthopédiques pour pieds diabétiques ainsi que des semelles orthopédiques pour pieds diabétiques. En outre, la demande porte sur l'introduction des semelles proprioceptives sur mesure pour le traitement des problèmes neuro-musculaires.

La CEM est favorable à la proposition de la Fédération des Orthopédistes-Cordonniers-Bandagistes et des Cordonniers-Réparateurs du Grand-Duché de Luxembourg pour ce qui est de l'introduction des chaussures orthopédiques et thérapeutiques ainsi que des semelles orthopédiques pour pieds diabétiques dans le catalogue des moyens accessoires à prendre en charge par l'assurance maladie. Même si le niveau de preuve est assez faible, l'état actuel de la littérature comporte assez d'éléments indiquant que ces aides peuvent contribuer à prévenir et à réduire les ulcères existants et, de cette façon, à différer voire éviter les amputations chez des patients diabétiques.

La CEM n'est par contre pas favorable à la proposition de la Fédération des Orthopédistes-Cordonniers-Bandagistes et des Cordonniers-Réparateurs du Grand-Duché de Luxembourg à l'introduction des semelles proprioceptives dans le catalogue des moyens accessoires à prendre en charge par l'assurance maladie. L'état actuel de la littérature ne comporte pas suffisamment d'éléments sur l'efficacité des semelles proprioceptives, les indications restent imprécises et trop vastes.

Bibliographie

(1) Règlement grand-ducal modifié du 19 mars 1999 concernant la nomenclature des actes et services des maîtres mécaniciens orthopédistes-bandagistes et des maîtres orthopédistes-cordonniers pour la fourniture de prothèses, orthèses et épithèses prises en charge par l'assurance maladie, Mémorial A N°30 du 01 avril 1999.

(2) Règlement grand-ducal du 30 juillet 2011 relatif au fonctionnement de la Commission de nomenclature des actes et services pris en charge par l'assurance maladie, Mémorial A n°183 du 23 août 2011.

(3) Google. Googleplex, Mountain View, California, U.S. 1998 – Banque documentaire consultée sur la page : http://www.googlescholar.com/, octobre et décembre 2013.

(4) MedlinePlus [Internet]. Bethesda (MD): National Library of Medicine (US); [updated 2005 Aug 12; cited 2005 August 11]. Banque documentaire consultée sur la page http://www.nlm.nih.gov/medlineplus/, octobre et décembre 2013.

(5) Uccioli, L., Giacomozzi, C. (2012). The Role of Footwear in the Prevention of Diabetic Foot Problems, The Diabetic Foot. Humana Press.

(6) Owings, T.M., Apelqvist, J., Stenstrom, A., et al. (2009). Plantar pressure in diabetic patients with foot ulcers which have remained healed. *Diabet Med*, 26, 1141-6.

(7) Rizzo, L., Tedeschi, A., Fallani, E., Coppelli, A., Vallini, V., Lacopi, E., Piaggesi, A. (2012). Custom-Made Orthesis and Shoes in a Structured Follow-Up Program Reduces the Incidence of Neuropathic Ulcers in High-Risk Diabetic Foot Patients, *International Journal of Lower Extremity Wounds*, 11, 59-64.

(8) Healy, A., Naemi, R., Chockalingam, N. (2013). The effectiveness of footwear as an intervention to prevent or to reduce biomechanical risk factors associated with diabetic foot ulceration: a systematic review. *J Diabetes Complications*, 27, 391-400.

(9) Chantelau, E., Kushner, T., Spraul, M. (1990). How effective is cushioned therapeutic footwear in protecting diabetic feet: a clinical study. *Diabet Med*, 7, 355-9.

(10) Chantelau, E., Haage, P. (1994). An audit of cushioned diabetic footwear: relation to patient compliance. *Diabet Med*, 11, 114-6.

(11) Uccioli, L., Faglia, E., Monticone, G., et al. (1995). Manufactured shoes in the prevention of diabetic foot ulcers. *Diabetes Care*, 18, 1376-8.

(12) Striesow, F. (1998). Special manufactured shoes for prevention of recurrent ulcer in diabetic foot syndrome. *Med Klin* (Munich), 93, 695-700.

(13) Dargis, V., Pantelejeva, O., Jonushaite, A., Vileikyte, L., Boulton, A.J. (1999). Benefits of a multidisciplinary approach in the management of recurrent diabetic foot ulceration in Lithuania: a prospective study. *Diabetes Care*, 22, 1428-31.

(14) Reiber, G.E., Smith, D.G., Wallace, C., Sullivan, K., Hayes, S., Vath, C., Maciejewski, M.L., Yu, O., Heagerty, P.J., LeMaster, J. (2002). Effect of therapeutic footwear on foot reulceration in patients with diabetes: a randomized controlled trial. *JAMA*, 287, 25.

(15) Viswanathan, V., Madhavan, S., Gnanasundaram, S., et al. (2004). Effectiveness of different types of footwear insoles for the diabetic neuropathic foot: a follow-up study. *Diabetes Care*, 27, 474-7.

(16) Busch, K., Chantelau, E. (2003). Effectiveness of a new brand of stock 'diabetic' shoes to protect against diabetic foot ulcer relapse. A prospective cohort study. *Diabet Med*, 20, 665-9.

(17) Maciejewski, M.L., Reiber, G.E., Smith, D.G., Wallace, C., Hayes, S., Boyko, E.J. (2004). Effectiveness of diabetic therapeutic footwear in preventing reulceration. Review. *Diabetes Care*, 27, 1774-82.

(18) Bus, S.A., Waaijman, R., Arts, M., de Haart, M., Busch-Westbroek, T., Van Baal, J., Nollet, F. (2013). Effect of Custom-Made Footwear on Foot Ulcer Recurrence in Diabetes: A multicenter randomized controlled trial. *Diabetes Care*, 36 , 4109-16.

(19) Waaijman, R., Arts, M.L., Haspels, R., Busch-Westbroek, T.E., Nollet, F., Bus, S.A. (2012). Pressure-reduction and preservation in custom-made footwear of patients with diabetes and a history of plantar ulceration. *Diabet Med*, 29, 1542-9.

(20) Bus, S.A., van Deursen, R.W.M., Valk, G.D., Caravaggi, C., Armstrong, D.G., Hlavacek, P. et al. (2007). Evidence-based Guideline on Footwear and Offloading for the Diabetic Foot. International Working Group on the Diabetic Foot. Available at www.idf.org/bookshop.

(21) Knowles, E.A., Boulton, A.J.M. (1996). Do people with diabetes wear their prescribed footwear? *Diabet Med*, 13, 1064-8.

(22) McCabe, C.J., Stevenson, R.C., Dolan, A.M. (1998). Evaluation of a diabetic foot screening and protection programme. *Diabet Med*, 15, 80-4.

(23) Armstrong, D.G., Lavery, L.A., Kimbriel, H.R., Nixon, B.P., Boulton, A.J. (2003). Activity patterns of patients with diabetic foot ulceration: patients with active ulceration may not adhere to a standard pressure off-loading regimen. *Diabetes Care*, 26, 2595-7.

(24) Paton, J.S., Stenhouse, E.A., Bruce, G., Zahra, D., Jones, R.B. (2012). A comparison of customised and prefabricated insoles to reduce risk factors for neuropathic diabetic foot ulceration: a participant-blinded randomised controlled trial. *Journal of Foot and Ankle Research*, 5, 31.

(25) Waaijman, R., Keukenkamp, R., de Haart, M., Polomski, W.P., Nollet, F., Bus, S.A. (2013). Adherence to wearing prescription custom-made footwear in patients with diabetes at high risk for plantar foot ulceration. *Diabetes Care*, 36, 1613-8.

(26) Armstrong, D.G., Nguyen, H.C., Lavery, L.A., van Schie, C.H., Boulton, A.J., Harkless, L.B. (2001). Off-loading the diabetic foot wound: a randomized clinical trial. *Diabetes Care*, 24, 1019-22.

(27) Armstrong, D.G., Lavery, L.A., Wu, S., Boulton, A.J. (2005). Evaluation of removable and irremovable cast walkers in the healing of diabetic foot wounds: a randomized controlled trial. *Diabetes Care*, 28, 551-4.

(28) Hissink, R.J., Manning, H.A., van Baal, J.G. (2000). The MABAL shoe, an alternative method in contact casting for the treatment of neuropathic diabetic foot ulcers. *Foot Ankle Int*, 21, 320-3.

(29) Bus, S.A., Valk, G.D., van Deursen, R.W., Armstrong, D.G., Caravaggi, C., Hlavacek, P. et al. (2008). The effectiveness of footwear and offloading interventions to prevent and heal foot ulcers and reduce plantar pressure in diabetes: a systematic review. *Diabetes Metab Res Rev,* 24 Suppl 1, S162-S180.

(30) Katz, I.A., Harlan, A., Miranda-Palma, B., Prieto-Sanchez, L., Armstrong, D.G., Bowker, J.H., Mizel, M.S., Boulton, A.J. (2005). A randomized trial of two irremovable off-loading devices in the management of plantar neuropathic diabetic foot ulcers. *Diabetes Care*, 28, 555-9.

(31) Cavanagh, P.R., Bus, S.A. (2010). Off-loading the diabetic foot for ulcer prevention and healing. J Vasc Surg, 52(3 Suppl), 37S-43S.

(32) Ha Van, G., Siney, H., Hartmann-Heurtier, A., Jacqueminet, S., Greau, F., Grimaldi, A. (2003). Nonremovable, windowed, fiberglass cast boot in the treatment of diabetic plantar ulcers: efficacy, safety, and compliance. *Diabetes Care*, 26, 2848-52.

(33) Chantelau, E., Breuer, U., Leisch, A.C., Tanudjaja, T., Reuter, M. (1993). Outpatient treatment of unilateral diabetic foot ulcers with 'half shoes'. *Diabet Med*, 10, 267-70.

(34) Piaggesi, A., Macchiarini, S., Rizzo, L., Palumbo, F., Tedeschi, A., Nobili, L.A. et al. (2007). An off-the-shelf instant contact casting device for the management of diabetic foot ulcers: a randomized prospective trial versus traditional fiberglass cast. *Diabetes Care*, 30, 586-90.

(35) Lobmann, R., Kayser, R., Kasten, G., Kasten, U., Kluge, K., Neumann, W., Lehnert, H. (2001). Effects of preventative footwear on foot pressure as determined by pedobarography in diabetic patients: a prospective study. *Diabetic Medicine*, 18, 314-9.

(36) Bus, S.A., Ulbrecht, J.S., Cavanagh, P.R. (2004). Pressure relief and load redistribution by custom-made insoles in diabetic patients with neuropathy and foot deformity. *Clin Biomech,* 19, 629-38.

(37) Guldemond, N.A., Leffers, P., Schaper, N.C., et al. (2007). The effects of insole configuration on forefoot plantar pressure and walking convenience in diabetic patients with neuropathic feet. *Clin Biomech*, 22, 81-7.

(38) Raspovic, A., Newcombe, L., Lloyd, J., Dalton, E. (2000). Effect of customized insoles on vertical plantar pressures in sites of previous neuropathic ulceration in the diabetic foot. *Foot*, 10, 133-8.

(39) Albert, S., Rinoie, C. (1994). Effect of custom orthotics on plantar pressure distribution in the pronated diabetic foot. *J Foot Ankle Surg*, 33, 598-604.

(40) Owings, T.M., Woerner, J.L., Frampton, J.D., Cavanagh, P.R., Botek, G. (2008). Custom therapeutic insoles based on both foot shape and plantar pressure measurement provide enhanced pressure relief. *Diabetes Care*, 3, 839-44.

(41) Kato, H., Takada, T., Kawamura, T., Hotta, N., Torii, S. (1996). The reduction and redistribution of plantar pressures using foot orthoses in diabetic patients. *Diabetes Res Clin Pract*, 31, 115-8.

(42) Lavery, L.A., LaFontaine, J., Higgins, K.R., Lanctot, D.R., Constantinides, G. (2012). Shear-reducing insoles to prevent foot ulceration in high-risk diabetic patients. *Adv Skin Wound Care*, 25, 519-24.

(43) Paton, J.S., Bruce, G., Jones, R.B., Stenhouse, E. (2011). Effectiveness of insoles for the prevention of ulceration in the neuropathic diabetic foot: a systematic review. *Journal of Diabetes and its Complications*, 25, 52-62.

(44) Ragnarson Tennvall, G. & Apelqvist, J. (2004). Health-economic consequences of diabetic foot lesions. Clinical infectious diseases, 39 (S2), 132-39.

(45) Ragnarson Tennvall, G. & J. Apelqvist. (2000). Health-related quality of life in patients with diabetes mellitus and foot ulcers. *Journal of Diabetes and its Complications*, 14, 235-41.

(46) Ragnarson Tennvall, G. & Apelqvist, J. (2001). Prevention of diabetes-related foot ulcers and amputations: a cost-utility analysis based on Markov model simulations. *Diabetologia*, 44, 2077-87.

(47) Rauner, M.S., Heidenberger, K., Pesendorfer, E.-M. (2004) Using a Markov model to evaluate the cost-effectiveness of diabetic foot prevention strategies in Austria, Proceedings of the Western Multiconference, International Conference on Health Sciences Simulation, 2004, The Society of Computer Simulation International, San Diego, USA, pp. 63-8.

(48) Rizzo, L., Tedeschi, A., Fallani, E., Coppelli, A., Vallini, V., Lacopi, E., Piaggesi, A. (2012). Custom-Made Orthesis and Shoes in a Structured Follow-Up Program Reduces the Incidence

of Neuropathic Ulcers in High-Risk Diabetic Foot Patients. *International Journal of Lower Extremity Wounds March*, 11, 59-64.

(49) Chuck, A.W., Hailey, D., Jacobs, P., Perry, D.C. (2008). Cost effectiveness and budget impact of adjunctive hyperbaric oxygen therapy for diabetic foot ulcers. *Int J Technol Assess Health Care*, 24, 178-83.

(50) Morbach, S., Müller, E., Reike, H., Risse, A., Rümenapf, G., Spraul, M. (2008). Diagnostik, Therapie, Verlaufskontrolle und Prävention des diabetischen Fußsyndroms. Deutsche Diabetes Gesellschaft und Deutsche Gesellschaft für Gefäßchirurgie.

(51) Woolridge, J., Moreno, L. (1994). Evaluation of the costs to Medicare of covering therapeutic shoes for diabetic patients. *Diabetes Care*, 17, 541-8.

(52) Christovão, T.C., Neto, H.P., Grecco, L.A., Ferreira, L.A., Franco de Moura, R.C., Eliege de Souza, M., Franco de Oliveira, L.V., Oliveira, C.S. (2013). Effect of different insoles on postural balance: a systematic review. *J Phys Ther Sci*, 25, 1353-6.

(53) Alfuth, M., Rosenbaum, D. (2011). Effects of changes in plantar sensory feedback on human gait characterists: a systematic review. *Footwear Science*, 4, 1-22.

(54) Hijmans, J.M., Geertzen, J.H.B., Dijkstra, P.U., Postema, K. (2007). A systematic review of the effects of shoes and other ankle or foot appliances on balance in older people and people with peripheral nervous system disorders. *Gait & Posture*, 25, 316-23.

(55) Aminian, G., Safaeepour, Z., Farhoodi, M., Pezeshk, A.F., Majddoleslam, B. (2013). The effect of prefabricated and propriozeptive foot orthoses on plantar pressure distribution in patients with flexible flatfoot during walking. *Prosthet Orthot Int*, 37, 227-32.

(56) Ludwig, O., Quadflieg, R., Koch, R. (2013). Einfluss einer sensomotorischen Einlage auf die Aktivität des M. peroneus longus in der Standphase. *Deutsche Zeitschrift für Sportmedizin*, 64, 77-82.

(57) Kelleher, K.J. Spence, W.D., Solomonidis, S., Apatsidis, D. (2010). The effect of textured insoles on gait patterns of people with multiple sclerosis. *Gait & Posture*, 32, 67-71.

(58) Qiu, F., Cole, M.H., Davids, K.W., Hennig, E.M., Silburn, P.A., Netscher, H., Ken, G.K. (2013). Effects of Textured Insoles on Balance in People with Parkinson´s Disease. *PLOS One*, 8, e83309.

(59) Alfuth, M. & Rosenbaum, D. (2012). Effects of changes in plantar sensory feedback on human gait characteristics: a systematic review. *Footwear science*, 4, 1-22.

(60) GKV-Spitzenverband (2014). Hilfsmittelverzeichnis [Online]. Consulté le 11 février 2014 sur http://www.gkv-spitzenverband.de/krankenversicherung/hilfsmittel/hilfsmittelverzeichnis/hilfsmittelverzeichnis.jsp.

(61) Deutsche Diabetes Gesellschaft (DDG). Schuhverordnungsbogen: Anleitung zur schuhtechnischen Versorgung bei diabetischem Fußsyndrom [Online]. Site web de « AG Fuß DDG » consultée le 18 janvier sur la page: http://www.ag-fuß-ddg.de.

(62) Deutsche Diabetes Gesellschaft (DDG). Schuhkontrollbogen: Protokoll orthopädietechnische Versorgung bei Diabetes [Online]. Site web de « Arbeitsgemeinschaft Diabetologie und Endokrinologie » consultée le 18 janvier sur la page: http://www.ade-rlp.de.

(63) World Health Organisation (WHO) (2013). Diabetes mellitus: Factsheet Number 312 [Online]. Consultée sur la page: http://www.who.int/mediacentre/factsheets/fs312/en/ le 23 janvier.

Glossaire des abréviations

Classement par ordre alphabétique:

CEM	Cellule d'expertise médicale
CNS	Caisse nationale de Santé
CSS	Code de la Sécurité Sociale
Code ATC	Système de Classification Anatomique, Thérapeutique et Chimique
IGSS	Inspection générale de la sécurité sociale
GKV	Gesetzliche Krankenversicherung
RCT	randomized controlled trial - essai contrôlé randomisé
STAPS	Service Statistiques, actuariat et programmation sociale
WHO	World Health Organization
RGD	Règlement grand-ducal