FARMACI CON USO CONSOLIDATO NEL TRATTAMENTO DI PATOLOGIE NEUROLOGICHE PER INDICAZIONI ANCHE DIFFERENTI DA QUELLE PREVISTE DAL PROVVEDIMENTO DI AUTORIZZAZIONE ALL'IMMISSIONE IN COMMERCIO

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
Amantadina	**Fatica nella sclerosi multipla** (Prescrizione specialistica: Neurologi) Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 941-942 Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 420 Multiple Sclerosis. Mc Alpine's. Fourth Edition. Churchill Livingstone Elsevier. 2006 pp 717-718
Azatioprina	**Malattie autoimmuni a carattere neurologico** Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 941 (sclerosi multipla); pp 1486-1487 (miastenia grave) Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 419 (sclerosi multipla); pp 533 (miastenia grave)
Carbamazepina	**Dolore neuropatico** (Prescrizione specialistica: neurologo, terapista del dolore) Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 147-151 Le basi farmacologiche della terapia. Goodman and Gilman. Decima edizione. Edited by Mc Graw Hill, New York. 2003 pp 511-512 Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 50 Wiffen PJ, et al. Carbamazepine for acute and chronic pain in adults. Cochrane Database Syst Rev. 2011 Jan 19; (1): CD005451. doi: 10.1002/14651858.CD005451.pub2.

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
Ciclofosfamide	**Malattie autoimmuni a carattere neurologico** (Prescrizione specialistica: Neurologo) Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 941 (sclerosi multipla) Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 419 (sclerosi multipla); pp 533 (miastenia grave). Hart IK, Sathasivam S, Sharshar T. Immunosuppressive agents for myasthenia gravis. Cochrane Database Syst Rev. 2007 Oct 17;(4):CD005224. Review. PubMed PMID: 17943844. Kuitwaard K, van Doorn PA. Newer therapeutic options for chronic inflammatory demyelinating polyradiculoneuropathy. Drugs. 2009 May 29;69(8):987-1001. 10.2165/00003495-200969080-00004. Review. PubMed PMID: 19496628. McDaneld LM, Fields JD, Bourdette DN, Bhardwaj A. Immunomodulatory therapies in neurologic critical care. Neurocrit Care. 2010 Feb;12(1):132-43. doi: European Federation of Neurological Societies; Peripheral Nerve Society, van Schaik IN, Bouche P, Illa I, Léger JM, Van den Bergh P, Cornblath DR, Evers EM, Hadden RD, Hughes RA, Koski CL, Nobile-Orazio E, Pollard J, Sommer C, van Doorn PA. European Federation of Neurological Societies/Peripheral Nerve Society guideline on management of multifocal motor neuropathy. Eur J Neurol. 2006 Aug;13(8):802-8.
Clonidina	**Tics** **RCT positivi:** - Leckman JF, Hardin MT, Riddle MA, Stevenson J, Ort SI, Cohen DJ (1991) Clonidine treatment of Gilles de la Tourette's syndrome. Arch Gen Psychiatry 48:324–328 - Leckman JF, Hardin MT, Riddle MA, Stevenson J, Ort SI, Cohen DJ (1991) Clonidine treatment of Gilles de la Tourette's syndrome. Arch Gen Psychiatry 48:324–328

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	RCT negativi: - Goetz CG, Tanner CM, Wilson RS, Carroll VS, Como PG, Shannon KM (1987) Clonidine and Gilles de la Tourette's syndrome: double-blind study using objective rating methods. Ann Neurol 21:307–310 **Linee guida:** - Roessner V, Plessen KJ, Rothenberger A, Ludolph AG, Rizzo R, Skov L, et al. ESSTS Guidelines Group. European clinical guidelines for Tourette syndrome and other tic disorders. Part II: pharmacological treatment. Eur Child Adolesc Psychiatry 2011;20:173e96. - Pringsheim T, Doja A, Gorman D, McKinlay D, Day L, Billinghurst L, Carroll A, Dion Y, Luscombe S, Steeves T, Sandor P. Canadian guidelines for the evidence-based treatment of tic disorders: pharmacotherapy. Can J Psychiatry. 2012 Mar;57(3):133-43. Manuali: Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 312-313
Deflazacort	**Trattamento della distrofia muscolare di Duchenne** Bushby K, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93; Henricson EK et al. The cooperative international neuromuscular research group Duchenne natural history study: glucocorticoid treatment preserves clinically meaningful functional milestones and reduces rate of disease progression as measured by manualmuscle testing and other commonly used clinical trial outcome measures. Muscle Nerve. 2013;48(1):55-67 Marika Pane et al. Benefits of glucocorticoids in non-ambulant boys/men with Duchenne muscular dystrophy: A multicentric longitudinal study using the Performance of Upper Limb test. Neuromuscular Disorders 2015;25(10):749-53;

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	Mercuri E. Registries versus tertiary care centers: How do we measure standards of care in Duchenne muscular dystrophy? Neuromuscul Disord. 2016;26(4-5):261-3.
Fenobarbital	**Tremore essenziale** (Prescrizione specialistica: Neurologi) Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 100 Harrison's Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 308 Deuschl G, Raethjen J, Hellriegel H, Elble R. Treatment of patients with essential tremor. Lancet Neurol. 2011 Feb;10(2):148-61; Zesiewicz TA, Elble R, Louis ED, et al. Practice parameter: therapies for essential tremor: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2005; 64: 2008–20.
Immunoglobuline (uso endovenoso)	• **Crisi miastenica, in alternativa alla plasmaferesi.** • **Forme di miastenia gravis rapidamente ingravescenti e nelle fasi di riacutizzazione della malattia, quando è necessario un miglioramento rapido della forza muscolare per ridurre al minimo il rischio di paralisi bulbare o di insufficienza respiratoria.** • **Nelle fasi iniziali della miastenia gravis, in attesa dell'effetto della terapia cortisonica e/o immunosoppressiva.** • **Come preparazione alla timectomia, nei pazienti affetti da miastenia gravis non sufficientemente compensati dalle terapie specifiche di base.** • **In pazienti affetti da miastenia gravis non responsivi alle terapia farmacologiche steroideo e/o immunosoppressiva oppure aventi controindicazioni al loro utilizzo.** Gajdos P, Chevret S, Toyka KV. Intravenous immunoglobulin for myasthenia gravis. Cochrane

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	Database Syst Rev. 2012; 12:CD002277. Wolfe GI et al. Randomized Trial of Thymectomy in Myasthenia Gravis. N Engl J Med. 2016; 375(6): 511-22. Sanders DB et al. International consensus guidance for management of myasthenia gravis: Executive summary. Neurology. 2016; 87(4):419-25.
Natalizumab	**Trattamento della sclerosi multipla recidivante-remittente grave ad evoluzione rapida, definita da due o più recidive disabilitanti in un anno, e con 1 o più lesioni captanti gadolinio alla RM cerebrale o con un aumento significativo del carico lesionale in T2 rispetto ad una precedente RM effettuata di recente, nei pazienti adolescenti di età compresa fra i 12 ed i 18 anni:** • **che sono in trattamento con il farmaco e hanno mostrano una risposta clinica soddisfacente;** • **nei quali l'uso di Fingolimod sia controindicato, non sia stato tollerato o non si sia mostrato efficace.** (prescrizione da parte di medici appartenenti a strutture ospedaliere e sanitarie territoriali espressamente autorizzate dalla Regione di rispettiva pertinenza (Centri specialistici sclerosi multipla), mediante l'impiego della scheda cartacea per la prescrizione dei farmaci disease modifying per la sclerosi multipla, per linee di trattamento successive alla prima) Banwell B et al. Therapies for multiple sclerosis: considerations in the pediatric patient Nat. Rev. Neurol. 2010 Consensus Statement :Evaluation of new and existing therapeutics for pediatric MS: International Pediatric MS Study Group (IPMSSG) Jan 2011 Ghezzi A. et al. Natalizumab therapy of multiple sclerosis: recommendations of the Multiple Sclerosis Study Group-Italian Neurological Society Published online Neurol Sci 2011 Ghezzi A et al. The management of multiple sclerosis in children: a European view Mult Scler published online 4 August 2010

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	Ghezzi et al. Safety and efficacy of natalizumab in children with multiple sclerosis Neurology 2010 Ghezzi a Therapeutic strategies in childhood multiple sclerosis Ther Adv Neurol Disord 2010
Ossigeno	**Trattamento della cefalea a grappolo nella fase acuta** Kudrow L. Response of cluster headache attacks to oxygen inhalation. Headache 1981; 21: 1–4. Fogan L. Treatment of cluster headache. A double-blind comparison of oxygen v air inhalation. Arch Neurol 1985; 42: 362–363. Rozen TD. High oxygen flow rates for cluster headache. Neurology 2004; 63: 593. Cohen AS, Burns B and Goadsby PJ. High-flow oxygen for treatment of cluster headache: A randomized trial. JAMA 2009; 302: 2451–2457. Rozen TD and Fishman RS. Demand valve oxygen: A promising new oxygen delivery system for the acute treatment of cluster headache. Pain Med 2013; 14: 455–459. A. May et al. EFNS guidelines on the treatment of cluster headache and other trigeminalautonomic. European Journal of Neurology 2006, 13: 1066–1077. Sarchielli P et al. Italian guidelines for primary headaches:2012 revised version. J Headache Pain (2012) 13 (suppl 2):S31-S70.
Prendisone	**Trattamento della distrofia muscolare di Duchenne** Bushby K, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93; Henricson EK et al. The cooperative international neuromuscular research group Duchenne natural history study: glucocorticoid treatment preserves clinically meaningful functional milestones and reduces rate of disease progression as measured by manualmuscle testing and other commonly used clinical trial outcome measures. Muscle Nerve. 2013;48(1):55-67

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	Marika Pane et al. Benefits of glucocorticoids in non-ambulant boys/men with Duchenne muscular dystrophy: A multicentric longitudinal study using the Performance of Upper Limb test. Neuromuscular Disorders 2015;25(10):749-53; Mercuri E. Registries versus tertiary care centers: How do we measure standards of care in Duchenne muscular dystrophy? Neuromuscul Disord. 2016;26(4-5):261-3
Prednisolone	**Trattamento della distrofia muscolare di Duchenne** Bushby K, et al. Diagnosis and management of Duchenne muscular dystrophy, part 1: diagnosis, and pharmacological and psychosocial management. Lancet Neurol. 2010;9(1):77-93; Henricson EK et al. The cooperative international neuromuscular research group Duchenne natural history study: glucocorticoid treatment preserves clinically meaningful functional milestones and reduces rate of disease progression as measured by manualmuscle testing and other commonly used clinical trial outcome measures. Muscle Nerve. 2013;48(1):55-67 Marika Pane et al. Benefits of glucocorticoids in non-ambulant boys/men with Duchenne muscular dystrophy: A multicentric longitudinal study using the Performance of Upper Limb test. Neuromuscular Disorders 2015;25(10):749-53; Mercuri E. Registries versus tertiary care centers: How do we measure standards of care in Duchenne muscular dystrophy? Neuromuscul Disord. 2016;26(4-5):261-3
Primidone	**Tremore essenziale** (Prescrizione specialistica: Neurologi) Principi di neurologia. Adams and Victor. Edited by Mc Graw Hill. 2002 pp 100 Harrison’s Neurology in Clinical Medicine. Edited by Stephen L. Hauser, Scott Andrew, Josephson, Joey, D. English and John W. Engstrom. 2006 pp 308 Deuschl G, Raethjen J, Hellriegel H, Elble R. Treatment of patients with essential tremor. Lancet Neurol. 2011 Feb;10(2):148-61. Review

Nome composto	**Estensione di indicazione relative ad usi consolidati sulla base di evidenze scientifiche presenti in letteratura.**
	Zesiewicz TA, Elble R, Louis ED, et al. Practice parameter: therapies for essential tremor: report of the Quality Standards Subcommittee of the American Academy of Neurology. Neurology 2005; 64: 2008–20
Tossina botulinica di tipo A	**Trattamento delle forme di scialorrea severa e invalidante che non rispondono alle terapie alternative.** (La prescrizione del medicinale deve essere effettuata dal neurologo) Lagalla, G., Millevolte, M., Capecci, M., Provinciali, L., Ceravolo, M.G., 2006. Botulinum toxin type A for drooling in Parkinson's disease: a double-blind, randomized, placebo-controlled study. Mov. Disord. 2006; 21 (5): 704-7. Lakraj AA, Moghimi N, Jabbari B. Sialorrhea: anatomy, pathophysiology and treatment with emphasis on the role of botulinum toxins. Toxins. 2013; 5 (5):1010-31. Lipp, A., Trottenberg, T., Schink, T., Kupsch, A., Arnold, G., 2003. A randomized trial of botulinum toxin A for treatment of drooling. Neurology . 2003; 61 (9): 1279-81. Mancini, F., Zangaglia, R., Cristina, S., et al., 2003. Double-blind, placebo-controlled study to evaluate the efficacy and safety of botulinum toxin type A in the treatment of drooling in parkinsonism. Mov. Disord. 2003; 18 (6): 685-8. Mazlan M, Rajasegaran S, Engkasan JP, Nawawi O, Goh KJ, Freddy SJ. A Double-Blind Randomized Controlled Trial Investigating the Most Efficacious Dose of Botulinum Toxin-A for Sialorrhea Treatment in Asian Adults with Neurological Diseases. Toxins (Basel). 2015; 7 (9):3758-70. Restivo DA, Panebianco M, Casabona A, Lanza S, Marchese-Ragona R, Patti F, Masiero S, Biondi A, Quartarone A. Botulinum Toxin A for Sialorrhoea Associated with Neurological Disorders: Evaluation of the Relationship between Effect of Treatment and the Number of Glands Treated. Toxins (Basel). 2018; 10(2). Vashishta R, Nguyen SA, White DR, Gillespie MB. Botulinum toxin for the treatment of sialorrhea: a meta-analysis. Otolaryngol Head Neck Surg. 2013; 148 (2):191-6.