MODEL APPEAL LETTER – LYRICA (PREGABELIN)

Today's date

Plan Name
Plan Address
Plan Address

Re: Patient's Name or Insurance ID #

To Whom it May Concern:

This is a request for ***(pre-authorization, appeal of your denial, request for formulary exception)*** for pregabelin (lyrica) for my patient ***(_patient's name _____)*** who suffers from pain related to multiple sclerosis.

As described in the enclosed publication of the National Multiple Sclerosis Society (NMSS), pain in MS is poorly recognized and often under-treated. It can also be more difficult to treat successfully than other symptoms of the disease.
Yet a growing body of evidence supports the use of anti-epileptic agents, including pregablin (lyrica), for the treatment of various pain syndromes associated with MS.

In addition to the 40+ citations supporting the NMSS Clinical Bulletin on MS-related pain, O'Connor and Dworkin's 2009 review sites calcium channel alpha (2)-delta ligands (i.e., gabepengtin and pregabalin) as recommended for first line treatment of neuropathic pain supported by randomized clinical trials.[i] Additionally, Pollman and Feneberg's 2008 review of the current management of pain in MS highlights the use of these same agents in a variety of MS-related pain symdromes. [ii]

(If applicable, describe other treatments this patient has tried for pain and results here.)

Thank you for your consideration.

Sincerely,

Your name, MD
Affiliation

[i] O'Connor AB, Dworkin RH, *Treatment of neuropathic pain: an overview of recent Guidelines,* Am J Med2009 Oct;122(10 Suppl):S22-32.

[ii] Pöllmann W, Feneberg W, *Current management of pain associated with multiple sclerosi,* CNS Drugs. 2008;22(4):291-324 .

Abstract #1 Lyrica (regabelin)

Am J Med. 2009 Oct;122(10 Suppl):S22-32.

Treatment of neuropathic pain: an overview of recent guidelines.

O'Connor AB, Dworkin RH.

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A number of different treatments for neuropathic pain have been studied, but the literature is sizable, rapidly evolving, and lacks important information about practical aspects of patient management. Under the auspices of the International Association for the Study of Pain (IASP) Neuropathic Pain Special Interest Group (NeuPSIG), a consensus process was used to develop evidence-based guidelines for the pharmacologic management of neuropathic pain that take into account clinical efficacy, adverse effects, impact on health-related quality of life, convenience, and costs. On the basis of randomized clinical trials, medications recommended as first-line treatments for neuropathic pain included certain antidepressants (i.e., tricyclic antidepressants and dual reuptake inhibitors of both serotonin and norepinephrine), calcium channel alpha(2)-delta ligands (i.e., gabapentin and pregabalin), and topical lidocaine. Opioid analgesics and tramadol were recommended as second-line treatments that can be considered for first-line use in selected clinical circumstances. Other medications that generally would be used as third-line treatments include certain other antidepressant and antiepileptic medications, topical capsaicin, mexiletine, and N-methyl-d-aspartate receptor antagonists. Two other national and international associations recently published pharmacologic treatment guidelines for neuropathic pain, which are summarized and contrasted with the NeuPSIG recommendations. Recent guidelines for the use of neurostimulation for the treatment of neuropathic pain also are summarized. For all treatments for neuropathic pain, long-term studies, head-to-head comparisons, and studies of treatment combinations are a priority for future research.

Abstract #2 Lyrica (regabelin)

CNS Drugs. 2008;22(4):291-324.

Current management of pain associated with multiple sclerosis.

Pöllmann W, Feneberg W.

Marianne-Strauss-Klinik, Berg, Germany. walter.poellmann@ms-klinik.info

While pain is a common problem in patients with multiple sclerosis (MS), it is not frequently mentioned by patients and a more direct approach is required in order to obtain information about pain from patients. Many patients with MS experience more than one pain syndrome; combinations of dysaesthesia, headaches and/or back or muscle and joint pain are frequent. For each pain syndrome a clear diagnosis and therapeutic concept needs to be established. Pain in MS can be classified into four diagnostically and therapeutically relevant categories: (i) neuropathic pain due to MS (pain directly related to MS); (ii) pain indirectly related to MS; (iii) MS treatment-related pain; and (iv) pain unrelated to MS. Painful paroxysmal symptoms such as trigeminal neuralgia (TN), or painful tonic spasms are treated with antiepileptics as first choice, e.g. carbamazepine, oxcarbazepine, lamotrigine, gabapentin, pregabalin, etc. Painful 'burning' dysaesthesias, the most frequent chronic pain syndrome, are treated with TCAs such as amitriptyline, or antiepileptics such as gabapentin, pregabalin, lamotrigine, etc. Combinations of drugs with different modes of action can be particularly useful for reducing adverse effects. While escalation therapy may require opioids, there are encouraging results from studies regarding cannabinoids, but their future role in the treatment of MS-related pain has still to be determined. Pain related to spasticity often improves with adequate physiotherapy. Drug treatment includes antispastic agents such as baclofen or tizanidine and in patients with phasic spasticity, gabapentin or levetiracetam are administered. In patients with severe spasticity, botulinum toxin injections or intrathecal baclofen merit consideration. While physiotherapy may ameliorate malposition-induced joint and muscle pain, additional drug treatment with paracetamol (acetaminophen) or NSAIDs may be useful. Moreover, painful pressure lesions should be avoided by using optimally adjusted aids. Treatment-related pain

associated with MS can occur with subcutaneous injections of interferon-beta or glatiramer acetate, and may be reduced by optimizing the injection technique and by local cooling. Systemic (particularly 'flu-like') adverse effects of interferons, e.g. myalgias, can be reduced by administering paracetamol, ibuprofen or naproxen. A potential increase in the frequency of pre-existing headaches after starting treatment with interferons may require optimization of headache attack therapy or even prophylactic treatment. Pain unrelated to MS, such as back pain or headache, is common in patients with MS and may deteriorate as a result of the disease. In summary, a careful analysis of each pain syndrome will allow the design of the appropriate treatment plan using various medical and nonmedical options (multimodal therapy), and will thus help to improve the quality of life (QOL) of the patients.

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