Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]

Sent: Wednesday, March 22, 2006 11:51 AM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Beneficiary Advisory Panel input--Lyrica

I have been informed that the Beneficiary Advisory Panel is soliciting input on Lyrica as a formulary medication. I am an Anesthesiologist at the Pain Management Clinic at Naval Medical Center Portsmouth and currently can prescribe Lyrica only after a failure of Neurontin. I have had some significant success with this medication, most recently with a 39 yo female with chronic chest wall pain after a mastectomy 15 years ago. She noted no significant improvement with Neurontin, and was unable to tolerate a prolonged trial of Neurontin due to excessive sedation, which is seen not infrequently. After starting Lyrica, she called 4 days later to inform me how much her pain had improved with only a low dose (75mg BID) of Lyrica.

I feel this medication has some definite potential, particularly in the field of pain management, and would encourage its addition to the formulary.

T. J. Moran, D.O.

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Wednesday, March 22, 2006 12:07 PM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: beneficiary advisory (lyrica)

this email is in regard to the beneficiary advisory board dropping the medication lyrica from the formulary list.

my name is [redacted] i am a cancer survivor and a patient at the pain management clinic nav med center portsmouth in portsmouth virginia. i have been a patient for 11 years . for 11 years my doctors have tried everything to help me with my pain. my pain is due to nerve damage in my chest wall and in my right arm (brachial plexopathy). i am currently on an opiate as well as ultram. i was put on lyrica last week and noticed a dramatic improvement in my nueropathy pain..very dramatic it also has very little side effects. this is the first medicine i have taken that is for nerve pain that actually works. nerve pain is unrelenting i should know after 11 years.
PLEASE DO NOT PULL LYRICA FROM THE FORMULARY!!!!!!!!!!!!!
it is my only hope.
thank you for your attention in this matter.
sincerely,
[redacted] dep wife retired navy [redacted]

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Wednesday, March 22, 2006 12:08 PM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: DoD Formulary: Lyrica
Attachments: Lyrical Letter BAP.doc

Mr. Martel,
Attached, please find a letter in support of the addition of Lyrica to the National DoD formulary. If you have any questions, please do not hesitate to contact me.

Sincerely,
Michael Yochelson

Michael R. Yochelson, M.D.
LCDR, MC, USNR
Staff Neurologist/Physiatrist
Chairman, NNMC Pain Committee
[redacted]

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Michael R. Yochelson, M.D.
LCDR, MC, USNR
National Naval Medical Center
Department of Neurology
Bethesda, MD 20889

(301) 295-4768
FAX 295-4759

March 22, 2006

Re: Lyrica (pregabalin)

To Whom It May Concern:
It has come to my attention that in the review of medications for the DoD National Formulary that Lyrica (pregabalin) may not be approved. I would like to strongly endorse adding this medication to the formulary as it has proven to be quite beneficial in our clinic. I can site two specific examples that illustrate quite well the type of response we have been getting to the medication. I have a patient who was a young (32 years old), active duty Marine with diabetic neuropathy who was having severe pain, particularly with prolonged standing or walking. The Lyrica substantially reduced his pain (he reports 50-75% reduction). He is extremely satisfied as it has improved his overall quality of life. A second patient, a 42 year old woman with epilepsy who has been on every anticonvulsant make (except felbamate) since the age of 11, was started on Lyrica as an adjunct to her lamotrigine and has had a sharp reduction in seizure frequency.

Having spoken with other neurologists in our department as well as physicians in the Pain Clinic, I can state with confidence that this product is an excellent addition to our armamentarium in two areas of medicine (epilepsy and pain) which have a tremendous impact on patient's quality of life.

I implore you to consider the addition of Lyrica (pregabalin) to the DoD National Formulary. If you have any questions, please do not hesitate to contact me.

Sincerely,

/s/
Michael R. Yochelson, MD
Staff Neurologist
Staff Physiatrist
Chairman, NNMC Pain Committee

Martel, Richard, CTR, OASD(HA)/TMA

From: Muniz Javier A Capt 89 MDOS/SGOH [redacted]

Sent: Wednesday, March 22, 2006 1:19 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Lyrica

Mr Martel:
I would like to let you know that we are very interested in having Lyrica available for our patients. In all fairness, though it looks promising, it is a fairly new medication and we need more experience with it. Therefore I am not requesting to have it in the core formulary yet but I would like the MTFs to have the option of adding it to their formularies. Thank you.

Javier A. Muñiz, MD
Capt, USAF, MC
Chief, Addictions Services Element
Chief, Consultation/Liaison Psychiatry
Medical Director Intensive Addictions Service
[redacted]

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]

Sent: Wednesday, March 22, 2006 2:59 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Lyrica Use

Sir,

I am a pharmacist at the Naval Medical Center in Portsmouth, VA. I currently manage the Anticoagulation Clinic in the Department of Internal Medicine. A substantial part of my population suffers from chronic pain, most notably peripheral neuropathy. Some of my patients have been prescribed Lyrica by their physicians, and have benefited from therapy. Additionally, the Lyrica does not appear to affect their anticoagulation therapy. I mentioned this trend to John Tillis, our Pfizer Representative, who asked me to relay this information to you.

Thank you for your time and attention,
V/R
(Rachel) Lynn Seaman, pharmacist
Anticoagulation Clinic, Dept. of Internal Medicine
Naval Medical Center, Portsmouth
[redacted]

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]

Sent: Wednesday, March 22, 2006 4:44 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Lyrica as a formulary addition

I am a board certified Rheumatologist currently working at the Naval Medical Center Portsmouth. I have been informed that the Beneficiary Advisory Panel is currently soliciting information on Lyrica. I currently prescribed lyric out only after a failure of Neurontin. I have had some significant success with this medication and only fair success with Neurontin. My experience with Neurontin suggests that it is poorly tolerated at effective doses secondary to excessive sedation. I feel Lyrica has some definite potential particularly in the field of chronic pain management and I would encourage its addition to the formulary.

Walter M Downs
CDR MC USN
Head, Rheumatology Division

Martel, Richard, CTR, OASD(HA)/TMA

From: McVicar, Ron J. CDR[redacted]

Sent: Wednesday, March 22, 2006 5:04 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Lyrica DOD Formulary Status

From: CDR Ronald McVicar, Otolaryngology-Head & Neck Surgery, NACC Newport RI
To: Beneficiary Advisory Panel
Re: Lyrica DOD Formulary Status

As NACC Newport's otolaryngologist, I see a number of patients with trigeminal neuralgia, atypical facial pain, post-herpetic neuralgia, and otalgia of uncertain etiology. In addition, I frequently refer patients to civilian Neurology for further evaluation and treatment of these conditions. Currently, I prescribe gabapentin for treatment of neuropathic pain. I have found that patients may not demonstrate clinical improvement on gabapentin for a number of weeks. Our local neurologists have informed me that they consider pregabalin (Lyrica) the drug of choice over gabapentin (Neurontin) for treatment of neuropathic pain. They report a more rapid clinical improvement in symptoms with a lower dose compared to Neurontin. Several of the military family practitioners have expressed interest in the possible addition of pregabalin to our formulary. As NHCNE's P&T chairman, I have been asked to bring up this medication at the next NHCNE P&T Committee meeting in April.

Although I have not had the opportunity to prescribe pregabalin myself, my review of the medical literature and discussion with other medical providers suggests that there may be clinical benefit in the addition of pregabalin to the DOD formulary.

Please contact me if I can answer any questions or provide additional information.

V/R

Ronald J. McVicar, D.O.
CDR MC USN

Martel, Richard, CTR, OASD(HA)/TMA

From: Grubb, Christopher T MAJ WAMC-Ft Bragg [redacted]
Sent: Wednesday, March 22, 2006 6:34 PM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: BAP Meeting Regarding Lyrica (pregabalin)

To Whom It May Concern:

Our pain specialists at Womack Army Medical Center have recently heard that your committee will be evaluating the role of Lyrica (pregabalin) in the DoD Formulary. Our pain clinic providers would like to offer our input and experience on the drug.

We certainly are not naïve enough to believe that a particular drug is good just because it's new. In fact, none of our pain providers will prescribe a new drug until they have critically appraised the available medical literature. In the case of pregabalin, most of us anxiously awaited its FDA approval because of the promising clinical trials we had seen in our literature. We knew that the drug would have special advantages over gabapentin, especially for our active duty patients. Pregabalin does not require a slow dose titration; whereas gabapentin must be slowly increased (due to its prominent side effects), and frequently takes a month or longer for the patient to attain an effective dose (1800-3600 mg/day). Also, since gabapentin has such poor bioavailability and a short plasma half-life, it must be dosed frequently (3-5 times/day); whereas, pregabalin needs to be dosed only twice daily. Finally, our experience reflects better tolerability with pregabalin, particularly regarding somnolence, which troubles many of our active duty patients who need to be vigilant during night duty.

For neuropathic pain, the minimum effective dose of gabapentin is 1800mg/d, and most pain specialists recommend titrating up to 3600mg/d. Therefore, a cost analysis should consider the relative equipotent doses of gabapentin and pregabalin. If our patients are requiring 10-12 capsules of gabapentin per day, then the cost difference compared to pregabalin is less significant. In the case of pregabalin, all doses have been priced the same, so the daily cost of pregabalin does not increase with titration.

I hope this point of view proves useful to your committee as you evaluate the need for pregabalin on the DoD Formulary. (Ideally, we should reserve final judgment until ongoing studies comparing gabapentin and pregabalin are completed and published.)

Respectfully,

Christopher Grubb, M.D.
CPT(P), MC, US Army
Staff Anesthesiologist and Pain Management Consultant
Womack Army Medical Center
Fort Bragg, NC
(910) 907-7209

Martel, Richard, CTR, OASD(HA)/TMA

From: Strassburg Amy D Capt MIL USAF 96 MDOS/SGOMI [redacted]

Sent: Thursday, March 23, 2006 9:17 AM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: Lyrica

To Whom It May Concern:

On behalf of my patients and the internists at Eglin AFB, I would like to request that Lyrica be allowed to remain a Tier 2 drug. In this busy IM clinic with many active duty and retired diabetics, we see a significant number of patients with diabetic neuropathy. Lyrica is currently the only drug that is FDA approved for this indication. Also, in the patients that I have already begun on the medication, it provides rapid relief with very low risk of adverse events. I hope to continue to freely use this medicine, and the Tier 2 level for the drug allows easier access to our patient population.

Thank you for your consideration.

Amy Strassburg
Staff Internist
Eglin AFB

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Thursday, March 23, 2006 1:39 PM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: Lyrica testimony

Good afternoon,
I have been in the Marine Corps for more than 12 years and it has been year ago this week that I was diagnosed with Diabetes Type 1. After recovering from my hospital stay I noticed that I could not stand on my feet more than 20 minutes at a time without being in pain. On my next visit, I explained to the doctor that my feet were constantly hurting. After un dergoing some tests, I was diagnosed with clinical diabetic neuropathy. To help alleviate my painful diabetic neuropathy, I have been taking Lyrica. Lyrica has decreased my pain by 50-75%. This medication has given me the ability to stand and walk for longer periods of time. Before I started to get sick I was very active. Now, at the age of 31, I am relying on Lyrica to give me my independence back. I strongly urge the panel to continue patient access to this medication.

Respectfully,
[redacted]

New Yahoo! Messenger with Voice. Call regular phones from your PC and save big.

Martel, Richard, CTR, OASD(HA)/TMA

From: Belnap, Brian D CPT WRAMC-Wash DC [redacted]

Sent: Thursday, March 23, 2006 3:00 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Sir,

Your email address was passed on to me by one of our chief residents in Physical Medicine and Rehabilitation here at Walter Reed Army Medical Center. I understand you are involved in the decision making process to possibly add Lyrica on the national DoD formulary. It is my full time job to manage the inpatient amputee service here at WRAMC. The majority of my patients experience severe neuropathic and/or phantom limb pain. I can say unequivocally that Lyrica seems far superior to neurontin, our most commonly used neuropathic pain medicine. I have used Lyrica on approximately 20 patients now with great success in at least 75%. I consider this excellent results given that all of these patients had essentially failed the first line neuropathic pain meds such as neurontin and TCA's. We have only been able to use this medicine as a 3rd line drug as it is non-formulary. I personally feel it would be incredibly beneficial to be able to give this medication as a first line agent for our severely wounded servicemen and women.

Please call me with any questions.

Hope this is helpful.

Dr. Brian Belnap DO
PM&R Inpatient Staff
Walter Reed Army Medical Center
[redacted]

Martel, Richard, CTR, OASD(HA)/TMA

From: Marshall, Scott CPT WRAMC-Wash DC [redacted]

Sent: Thursday, March 23, 2006 5:34 PM

To: Martel, Richard, CTR, OASD(HA)/TMA

Subject: pregabalin

Sir,

I was notified by Pfizer personnel that there may be an option to have pregabalin placed on DOD formulary. I would hope that this would make this medication a more feasible therapeutic option for Neurologists in treating the ubiquitous DM associated neruopathic pain that we encounter so frequently in the clinic at WRAMC. My experience, which is limited so far to a handful of patients, has been quite good with pregabalin for this indication, most notably in it's overall effectiveness and in the onset of action quickly after starting the medication.

I would support increasing it's availability.

SCOTT MARSHALL, CPT MC
Neurology, WRAMC

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Thursday, March 23, 2006 6:11 PM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: Lyrica DoD Formulary

NHP Naval Hospital Pensacola, Florida

Department of Neurology

[redacted]

03/23/2006

Re: Lyrica DoD Formulary Review

Richard Martel:

I am the sole Neurology provider at Pensacola Navy Hospital and would like to add my comments regarding Lyrica (Pregabalin) use at this facility.

Prior to it's FDA/DEA approval many of my patients had become frustrated with the usual regimen of neuropathic pain agents including Neurontin, the TCA medications, and other antiepileptic medications. Many of them had resorted to chronic narcotic use which carried problems of dependence and tolerance.

I have started many patient's (well over 150 since 10/2005) on Lyrica for neuropathic pain from diabetic peripheral neuropathy. I have countless success stories with most of my refractory patient's reporting their first pain free response by day 2 or 3 of the medication. This is unprecedented since many of the other options to treat neuropathic pain can take months to notice an effect. The minimal side-effect profile, twice daily dosing, and absent medication interaction make it an ideal pain medication. As an example, one of my patient's noted that he began the medication on Thursday and was beginning to wonder if he ever had pain symptoms by Saturday!

I have also started Lyrica on one of my refractory post-herpetic neuralgia patients. The American Academy of Neurology has now listed Lyrica as a first-line medication for postherpetic neuralgia. This patient notes that for the first time in years, she is "pain-free" on the initial starting dose of this medication. She had failed multiple other medications in the past.

I have also used Lyrica as an adjunct in two of my refractory epilepsy patients. I can tell you that to-date they report decreased number of seizure spells while on Lyrica. These are patient's who have failed multiple other combination anti-epileptic regimens.

I highly encourage the panel to continue formulary access to Lyrica. Many of my patient's have benefited from this novel drug. Many of these same patient's have been completely refractory to exceedingly high doses of the former drug Neurontin (which acts on the same receptor). There is no comparison in my mind between these two medications as far as efficacy and compliance.

I appreciate your time and consideration. Please let me know if you need further information or have additional questions.

Very Respectfully,

Steve Steffensen, MD
LT, MC, USNR
Head, NHP Neurology
6000 West Highway 98
Pensacola, FL 32512
[redacted]

3/24/2006

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Monday, March 27, 2006 8:45 AM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: FW: lyrica formulary status

> -----Original Message-----
> From: Medeiros, Grace A. MD
> Sent: Monday, March 27, 2006 8:39 AM
> To: [redacted]
> Subject: lyrica formulary status
>
> I presently prescribe Lyrica as first line therapy for my patients
> with diabetic neuropathy and trigeminal neuralgia. I have found this
> medication to be better tolerated and clinical effects are realized at
> relatively low doses and usually within only days of treatment.
> Further benefits in prescribing this medication include minimizing
> laboratory studies (such as monitoring sodium and liver functions) and
> minimal drug interaction profile. The drug interaction profile is
> especially important in my older patients on multiple medication. I
> would hope that this medication continues on the current formulary status in order that
my patients
> maintain access to the drug.
>
> Grace Medeiros, MD
> Newport Neurology
> NHCC Medical Associates
> Newport Hospital

Martel, Richard, CTR, OASD(HA)/TMA

From: [redacted]
Sent: Monday, March 27, 2006 10:23 AM
To: Martel, Richard, CTR, OASD(HA)/TMA
Subject: Lyrica

Dear CDR Martel, (I apologize if I have mistaken your rank. There were only two R. Martels in the Global address book and only one military...a CDR),

I am a staff anesthesiology and Interventional Pain Management Clinic faculty here at NMCSD. I would like to add my input concerning Lyrica. I generally start patients with neuropathic pain on Neurontin, however, we often are referred patients who have already been started on and have failed high dose neurontin due to intolerable side effects or lack of efficacy. We generally start these patients on Lyrica. We will often write for Lyrica as the first line anticonvulsant for neuropathic pain when prescibing for Marines, Seals, sailors who are deploying to the field and have difficulty with the more complex titration schedule of Neurontin and the larger number of pills needed to maintain the typical target dose of Neurontin 900 mg to 1200 mg TID. I belive that the price of Lyrica ,(75 to 150 mg PO BID) is comparable or even better priced when compared to our typical maintenance dose of Neurontin,(900 mg to 1200 mg PO TID).
It is very difficult for us to choose only one drug due to the wide variability of response ,(side effects) among our patinets. I frequently prescribe Topomax as a first line antiseizure medication for neuropathic pain for patients who have gained a subtantial amount of weight secondary to their cronic pain and other pain and antidepressant medications. Since it has both a weight stable ,(or sumetines even a weight loss effect), as well as a mood stabilizing effect. It is very effective for a significant portion of our patients who can benefit from these effects.
Please let me know if you have any further questions. I wanted to forward this input for your consideration as you review this class of drugs. Dr Verdolin, our Pain Clinic Director, is currently writing local guidelines for the anticonvusant medications, (as used for pain managent). If you are interested, I will forward them to you when he has completed them V/R

Captain Anita H. Hickey, M.D.

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