Request for permission for oral testimony at Idaho Medicaid's P&T Committee meeting on 11-16-2012

Submission # 1

As of November 5, 2012, this request has been APPROVED.

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Tuesday, October 30, 2012 2:02 PM
To: Gennrich, Jane - Medicaid
Subject: FW: Pharmacy & Therapeutics Committee meeting Nov 19
Attachments: Idaho Medicaid Presentation on Lyrica 10_25.docx; Idaho Medicaid Presentation on Celebrex 10_25.docx

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From: Palmer, Roy [mailto:Roy.Palmer@pfizer.com]
Sent: Friday, October 26, 2012 1:45 PM
To: Eide, Tamara J. - Medicaid
Cc: Heineman, Susan M
Subject: Pharmacy & Therapeutics Committee meeting Nov 19

Dear Dr. Eide,

I would like to request permission for oral testimony of Lyrica and Celebrex at the November 19th Idaho Medicaid P&T meeting. The Provider Synergies' Therapeutics Class Reviews have not yet been posted on the P&T Website, however the attached documents contain recent data for Lyrica and Celebrex.

Thank you for your consideration.

Sincerely,

Roy Palmer

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Idaho Medicaid Presentation on Lyrica (pregabalin)

1) Data supporting the new indication for the treatment of neuropathic pain (NeP) associated with spinal cord injury (SCI)

In June of 2012 Lyrica received the indication for the treatment of neuropathic pain (NeP) associated with spinal cord injury based upon data from 2 pivotal double-blind, placebo controlled, multi-center clinical trials. This makes Lyrica the first and only medication to receive such an indication in this relatively small but important patient population. I would like to present the data which supported the indication.

SCI is relatively uncommon, but can cause permanent disability and pain

- There are approximately 270,000 persons in the US with traumatic SCI. (2)
- Neuropathic pain is quite common in SCI and when present, the pain can be severe.
- In a prospective longitudinal study of 73 adults with traumatic SCI followed for 5 years, 40% of SCI patients had neuropathic pain. The pain was described as excruciating or severe in 60% of persons with at level NeP and 48% of persons with below level NeP. (3)

The efficacy of Lyrica for management of NeP associated with SCI was established in two pivotal double-blind, placebo controlled, multi-center studies. Patients were enrolled with neuropathic pain associated with spinal cord injury that persisted continuously for at least three months. The baseline mean pain scores across the two studies ranged from 6.5 to 6.7 on an 11-point numerical pain rating scale. Patients were allowed to take opioids, non-opioid analgesics, antiepileptic drugs, muscle relaxants, and antidepressant drugs if the dose was stable for 30 days prior to screening. Patients were allowed to take acetaminophen and nonsteroidal anti-inflammatory drugs during the studies. (9)

- The first 12 week study enrolled 137 adult patients with neuropathic pain associated with traumatic Spinal Cord Injury. Patients received either matched placebo or escalating doses of pregabalin 150-600 mg/day given in 2 divided doses, which were adjusted over three weeks based on subject response and tolerability. (7)
  - Endpoint weekly mean pain score was statistically significantly improved for the pregabalin group compared to the placebo group. (9)
  - The proportion of patients with at least a 30% and 50% reduction in their pain scores from baseline were statistically significantly increased in the pregabalin group compared to placebo. (9)

- The second 16-week study enrolled 219 adult patients with neuropathic pain associated with traumatic and non-traumatic Spinal Cord Injury. Patients received either matched placebo or escalating doses of pregabalin 150-600 mg/day given in 2 divided doses, which were adjusted over 4 weeks based on subject response and tolerability. (8)
  - Endpoint weekly mean pain score was statistically significantly improved for the pregabalin group compared to the placebo group. (9)
  - The proportion of patients with at least a 30% and 50% reduction in their pain scores from baseline were statistically significantly increased in the pregabalin group compared to placebo. (9)

Pregabalin Safety Profile

In clinical trials of patients with NeP associated with SCI, 13% of patients treated with pregabalin and 10% of patients treated with placebo discontinued prematurely due to adverse events. (9)

- In the pregabalin group the most common reasons for discontinuation due to adverse reactions were somnolence (3%) and edema (2%). In comparison, none of the placebo treated patients withdrew due to somnolence or edema. (9)
- Other reasons for discontinuation from the trials, occurring in greater frequency in the PGB treatment group than in the placebo treatment group, were fatigue and balance disorder. Each of these adverse reactions led to withdrawal in less than 2% of patients. (9)
- The most common adverse reactions across all LYRICA clinical trials are dizziness, somnolence, dry mouth, edema, blurred vision, weight gain, constipation, euphoric mood, balance disorder, increased appetite, and thinking abnormal (primarily difficulty with concentration/attention). (9)

Medicaid patients with neuropathic pain associated with SCI have significantly higher health resource utilization (HRU) and costs than SCI patients without neuropathic pain. (6)

- A retrospective longitudinal cohort study used Medicaid medical and pharmacy claims data from 2005-2010 in 12 geographically dispersed states. Healthcare resource utilization and costs in the one year period following a first diagnosis of SCI with neuropathic pain were compared to SCI patients without neuropathic pain.
- Sample selection identified 162 adult SCI patients with NeP and 1,918 adult SCI patients without evidence of NeP.
- The SCI patients with NeP had statistically significantly higher baseline comorbidity rates thank the SCI patients without NeP during the 12-month baseline period prior to the first diagnosis of SCI with NeP Costs were adjusted due to differences in baseline risk using an ordinary least squares model.
- HRU was significantly higher (all $p < 0.001$) among the SCI patients with NeP than the SCI patient without NeP for inpatient admission, emergency department visits, physician office visits, and pain intervention procedures, for the first year after diagnosis of SCI with NeP.
- The adjusted cost in the first year after diagnosis of SCI with NeP is $43,587 compared to $16,210 in SCI without NeP. The difference of $27,376 (SE $6,084; 95% Confidence Interval $15,970, $40,477) represents the estimated incremental cost burden associated with presence of NeP among adult SCI patients in the US Medicaid population.
- Pain medication usage was dominated by short-acting opioids, which was used by 96% of SCI patients with NeP.

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