

Request for permission for oral testimony at Idaho
Medicaid's P&T Committee meeting on 04-20-2012

Submission # 5

As of April 10, 2012, this request has been:

- Approved
- Denied

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Friday, March 30, 2012 11:36 AM
To: Gennrich, Jane - Medicaid
Subject: FW: Idaho Medicaid P&T Committee 4/20/12
Attachments: Vesicare (Astellas) Idaho P&T April 20, 2012.docx

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From: Shull, Toni [<mailto:Toni.Shull@us.astellas.com>]
Sent: Friday, March 30, 2012 10:56 AM
To: Eide, Tamara J. - Medicaid
Cc: Case, David; Henrich, Christin
Subject: Idaho Medicaid P&T Committee 4/20/12

Dear Dr. Eide,

I hope this finds you well! I have attached proposed testimony for Vesicare which includes new data only as per committee requirements. I am sending the hard copy of the testimony to you via Fed-Ex which will arrive on Monday 4/2.

Thank you,

Toni

Toni Shull, RN
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"Linking People, Science, Products"

VESicare (solifenacin succinate)
Idaho Medicaid Pharmacy and Therapeutics Committee Meeting
Preferred Drug List
April 20, 2012

This presentation is in response to an unsolicited request for scientific data. The information provided is for scientific exchange and is not intended to recommend administration of VESicare in a manner inconsistent with approved labeling.

- VESicare tablets are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency¹.
- The recommended dose of VESicare is 5 mg once daily. If the 5mg dose is well tolerated, the dose may be increased to 10 mg once daily
- VESicare has been evaluated in four Ph 3a and several Ph 3b/4 randomized control trials (RCT) and open-label trials investigating efficacy regarding key OAB symptoms and patient-reported outcomes.

Brand vs. Generic

An open label study of 156 patients with OAB compared the efficacy, tolerability and safety of name brand to generic medications for 8 weeks². Patients were receiving Detrol LA, VESicare, Enablex or Sanctura XR. When switched to oxybutynin IR by their primary care prescriber or prescription benefit provider, women and men, respectively experienced more frequency (2.1 to 2.4 episodes) more nocturia (1.2 to 1.4 episodes) and more urinary incontinence (40 to 46%). In addition, there were increased side effects in both genders (dry mouth +14 to 23%) and constipation (+32 to 34%). Switching from VESicare and another brand competitor to generic oxybutynin resulted in the greatest changes in safety and efficacy. There is also a wide variability in generic preparations of oxybutynin.

Vector

The VECTOR study (randomized, double-blind, double-dummy, 8 week trial with 132 subjects) compared the tolerability (primary) and efficacy (secondary) of 5 mg solifenacin once daily and 5 mg oxybutynin IR three times daily³.

- Solifenacin treatment was associated with significantly fewer dry mouth episodes and significantly less dry mouth severity, as compared to oxybutynin IR. Solifenacin was also associated with lower rates of adverse events and lower severity overall.
- Adverse events in patients taking solifenacin and oxybutynin included dry mouth (35%, 83%), constipation (13%, 6%), and nasal dryness (0%, 14%), respectively. Both solifenacin and oxybutynin IR significantly reduced symptoms and improved patient-reported outcomes.

Solifenacin/Tolterodine Comparison

A prospective, randomized, open label study compared the efficacy and safety of solifenacin 5 mg a day (n = 39) to tolterodine 4 mg daily (n = 36) in a Taiwanese population⁴.

- At week 12, solifenacin and tolterodine demonstrated equal efficacy in reducing the number of micturitions (p= 0.58), urgency (p= 0.37) and incontinence (p=0.28) episodes per 24 hours.
- The authors conclude that both medications are comparably effective and safe, with the most common adverse events being dry mouth and constipation.

Urodynamic Effects

A subanalysis of a post-marketing study evaluated the urodynamic effects, therapeutic efficacy and safety of solifenacin 5 mg daily (n = 26) versus tolterodine 4 mg daily (n =22) in Taiwanese women⁵.

- Both solifenacin and tolterodine had similar urodynamic effects, therapeutic efficacy and adverse events in treating women with overactive bladder syndrome, however, tolterodine had a greater effect in increasing heart rate at week 12 (increase of 1.5 bpm vs 3.5 bpm, p= 0.0004) rate than solifenacin.

Please refer to PI for complete safety information

References

1. VESIcare (solifenacin succinate) Prescribing Information; Astellas Pharma US, Inc. Deerfield, IL
2. Kaplan S, Safety and Efficacy Concerns in Switching Patients with Overactive Bladder (OAB) Symptoms from Branded to Generic Anticholinergic Medications. Presented AUA Annual Meeting, Chicago, Sept 29, 2009 #1870
3. Herschorn S, Stothers S,, Carlson K, Egerdie B, Kitchener, Gajewski J, , Pommerville P, Schulz J, et. Al. Tolerability of Solifenacin 5 mg Once Daily Versus Oxybutynin IR 5 mg Three Times Daily: Results of the VECTOR Trial *J Urol.* 2010; 183:1892-1898.
4. Ho CH, Chang TC, Lin HH et al. Solifenacin and Tolterodine are Equally Effective in the Treatment of Overactive Bladder. *J Formos Med Assoc* 2010; 109:702-708
5. Hsiao SM, Chang TC, Wu WY et al. Comparisons of urodynamic effects, therapeutic efficacy and safety of solifenacin versus tolterodine for female overactive bladder syndrome. *J Obstet Gynaecol Res.* 2011;37:1084-1091