Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 11-18-2016.

Submission # 2

This request has not been approved for oral testimony (10/25/16).

Gennrich, Jane

From: Eide, Tamara J.
Sent: Monday, October 24, 2016 11:23 AM
To: Gennrich, Jane
Subject: FW: Requested Medical Information Regarding APTIOM - Case Number 2016-005782
Attachments: Aptiom Package Insert.pdf; Medical Information Letter.pdf

Tami Eide, Pharm.D., BCPS
Medicaid Pharmacy Program Manager
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From: Sunovion Med Info [mailto:sunovionmedinfo@irmsonline.net]
Sent: Monday, October 24, 2016 10:55 AM
To: Eide, Tamara J.
Cc: Kimberly.Laubmeier@sunovion.com
Subject: Requested Medical Information Regarding APTIOM - Case Number 2016-005782

Dear Dr. Eide:

The enclosed information is being provided by Sunovion Pharmaceuticals Inc. on APTIOM® (eslicarbazepine acetate) for the Idaho Medicaid Pharmacy & Therapeutics Committee Review on November 18, 2016.

Should you have questions or need additional information, please contact us directly at 1-800-739-0565, email us at minfo@sunovion.com, or visit us at www.SunovionMedical.com.

Sincerely,
Sunovion Medical Information

October 24, 2016

Tami Eide, PharmD
3232 Elder Street
Boise, ID 83705

Dear Idaho Medicaid Pharmacy and Therapeutics Committee:

Thank you for your interest in APTIOM® (eslicarbazepine acetate) Tablets. The enclosed information is in response to your request prepared for the Idaho Medicaid Pharmacy and Therapeutics Committee Review on November 18th, 2016. This was forwarded by your Health Economics and Outcomes Research Liaison, Kimberly Laubmeier, regarding:

• Aptiom Tablets – HEOR Responsive Testimony for Idaho Medicaid

APTIOM is indicated for the treatment of partial-onset seizures as monotherapy or adjunctive therapy.

Please see the attached package insert for important safety information.

The enclosed information is provided as a professional courtesy in response to your unsolicited request for information. This information is intended to provide pertinent data that may assist you in forming your own conclusions and making your own decisions based on your professional judgment. This information is not intended to advocate any indication, dosage, or other claim that is not covered in the enclosed package insert.

Should you have any questions or need additional information, please contact us directly at 1-800-739-0565, email us at minfo@sunovion.com, or visit our Medical Information website at www.sunovionmedical.com.

Thank you again for your interest in APTIOM.

Sincerely,

Sunovion Pharmaceuticals Inc.
Medical Information Department

Sunovion Pharmaceuticals Inc. (Sunovion) is a wholly-owned U.S. subsidiary of Sumitomo Dainippon Pharma Co., Ltd.

2016-005782

APTIOM (eslicarbazepine acetate) HEOR Responsive Testimony for Idaho Medicaid
November 18, 2016

Hello everyone. My name is Dr. Kim Laubmeier, and I am a Director of Health Economics and Outcomes Research with Sunovion Pharmaceuticals Inc. Thank you for the opportunity to present today regarding the clinical and pharmacoeconomic profile of eslicarbazepine acetate, commercially known as APTIOM*.

Epilepsy is a serious, and potentially fatal, neurological condition, characterized by unpredictable seizures, which can be difficult to manage.[1] In a seminal case study, 36% of patients with epilepsy continued to experience seizures despite adequate trials of 1 or more AEDs.[2] Indeed, many patients require switching to a different medication, or a combination of medications, due to lack of efficacy or intolerable side effects.[2] And, for these reasons, the American Epilepsy Society has stated that "people with epilepsy must have access to, and insurance coverage for, all AEDs in all their formulations without formulary restrictions".[3]

APTIOM was first approved by the FDA for adjunctive treatment of partial-onset seizures in adults on November 8, 2013.[4,5] And, on August 27, 2015, APTIOM received the additional indication for use as monotherapy treatment of partial-onset seizures in adults.[4,5] Patients included in these trials generally had a longstanding history of refractory epilepsy.[4,5]

APTIOM is not a controlled substance, is dosed once daily, and may be taken crushed or whole, with or without food.[4,5] I refer you to the full prescribing information for a complete list of warnings, precautions and adverse events.[4]

While there are no direct, head-to-head comparisons between different branded AEDs, cost-effectiveness modeling based on network meta-analyses of phase 3 clinical trials has been performed.[5]

For adjunctive therapy, APTIOM resulted in an additional 22.2 seizures avoided over a 3-year time horizon compared to placebo.[5] And, APTIOM was dominant (meaning lower cost and higher effectiveness) versus Vimpat® (lacosamide) and Oxtellar XR® (oxcarbazepine).[5]

For monotherapy, APTIOM resulted in an additional 34.5 seizures avoided compared to placebo over a 3-year time horizon.[5] And, APTIOM was dominant in cost effectiveness versus Lamictal XR (lamotrigine).[5]

Looking at number needed to treat (or NNT) and number needed to harm (or NNH) outcomes, based on an endpoint of 50% response rate in Phase 3 clinical trials for adjunctive therapy, APTIOM's single-digit NNT [=7] reaches the predefined threshold of clinically meaningful benefits.[6] And, based on the endpoint of all-cause discontinuations, APTIOM's double-digit NNH [=11] does not reach the predefined threshold for clinically meaningful harms.[6] These NNT and NNH outcomes are more favorable for APTIOM than for Oxtellar XR®.[6]

Finally, budget impact modeling for APTIOM use suggests that the addition of APTIOM results in a minimal to neutral impact on the formulary budget.[5]

In closing, clinical and health outcomes data have shown that APTIOM provides a treatment option with high potential value in terms of efficacy and cost effectiveness, and helps address important unmet needs in patients with partial-onset seizures. Thus, on behalf of Sunovion Pharmaceuticals Inc., I respectfully request that APTIOM be retained on the preferred drug list for the Medicaid beneficiaries in the state of Idaho. I am happy to address any questions you may have.

References

1. National Institutes of Health. Epilepsy Fact Sheet. http://report.nih.gov/nihfactsheets/Pdfs/Epilepsy (NINDS).pdf. Accessed May, 15, 2014.
2. Kwan P, et al. Early identification of refractory epilepsy. *N Engl J Med*. 2000;342(5):314-319.
3. American Epilepsy Society (AES). Position Statement on Access to Epilepsy Care. Available at: https://www.aesnet.org/about_aes/position_statements/american%20epilepsy%20society%20position%20on%20access%20to%20epilepsy%20care.
4. APTIOM (Eslicarbazepine acetate) tablets [package insert]. Marlborough, MA: Sunovion Pharmaceuticals Inc.
5. APTIOM (Eslicarbazepine acetate) tablets [Formulary Submission Dossier]. Marlborough, MA: Sunovion Pharmaceuticals Inc. 2015.
6. Data on File, Sunovion Pharmaceuticals Inc.

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