

Request for permission for pharmaceutical industry oral testimony at Idaho Medicaid's P&T Committee meeting on 5-20-2016.

Submission # 7

This submission was received after the deadline for review so it will not be reviewed or accepted for oral presentation at the meeting.

Gennrich, Jane - Medicaid

From: Eide, Tamara J. - Medicaid
Sent: Thursday, May 12, 2016 3:19 PM
To: Gennrich, Jane - Medicaid
Subject: FW: Public Comment for May 20th
Attachments: Pharmacy and Therapeutics Committee.doc

Tami Eide, Pharm.D., BCPS

Medicaid Pharmacy Program Supervisor/Manager
Idaho Department of Health and Welfare
eidet@dhw.idaho.gov
3232 Elder St.
Boise, ID 83705
208-364-1829
800-327-5541 fax

From: Mullen, William [<mailto:William.Mullen@Indivior.com>]
Sent: Thursday, May 05, 2016 11:21 AM
To: Eide, Tamara J. - Medicaid
Subject: Public Comment for May 20th

Hello Dr. Eide.

I would like to request the opportunity to present during the P&T on May 20th 2016, on behalf of Indivior, the Manufacturer of Suboxone Film. I was notified the class of Opioid Dependent Medication was being reviewed on May 20th P&T.

My information is:
William Mullen PA-C, MPH
Medical Affairs Clinical Advisor
Indivior Pharma
Cell: 862-596-7779
Email: William.mullen@indivior.com

Attached is the written document of my oral presentation.

Thank you for your time and consideration.

-Will Mullen

William Mullen PA-C, MPH
Managed Care Clinical Advisor
Medical Affairs, North America
Cell: 862-596-7779

Indivior Inc.
10710 Midlothian Turnpike

Suite 430
Richmond, VA 23235
Indivior.com



Please Consider the Environment before printing this Email

This email was sent from within Indivior PLC. Indivior PLC is registered in the United Kingdom. Registered office: 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom. Registration information is available at www.indivior.com.

This email, and any attachments or hyperlinks within, may contain information that is confidential, proprietary, legally privileged, or otherwise protected from disclosure. If you are not the intended recipient, you are not entitled to use, disclose, distribute, copy, search, print, disseminate this email or its contents, or rely on this email in any way. If you have received this email in error, please notify the sender immediately by telephone or email and destroy it, and all copies of it.

We have taken steps to ensure that this email and any attachments are free from computer viruses, malware, or other disabling code. However, it is the recipient's responsibility to ensure that it is actually free of viruses, malware or other disabling code.

Any emails that you send to us may be monitored for the purposes of ascertaining whether the communication complies with the law and our policies.

Dear members of the Pharmacy & Therapeutics (P&T) Committee,

Thank you for your time in allowing me to come speak on behalf of Indivior Inc. and SUBOXONE® (buprenorphine and naloxone) Sublingual Film, for sublingual or buccal use (CIII) in order to provide you with a clinical update. My name is William Mullen and I am a member of Indivior's Medical Affairs team.

SUBOXONE Sublingual Film was first FDA approved in 2010 for the maintenance treatment of opioid dependence.¹ In April of 2014, the FDA approved an indication labeling revision. Currently, SUBOXONE Sublingual Film is indicated for the treatment of opioid dependence.¹

In September of 2015, the FDA approved a labelling revision to section 2.3 of the SUBOXONE Sublingual Film Package Insert. Section 2.3 relates to the dosage and administration, method of administration of SUBOXONE Sublingual Film. There are now two methods to administer SUBOXONE Sublingual Film: sublingual administration, and buccal administration. For the new method, buccal administration, a patient should be instructed to place one film on the inside of the right or left cheek. If an additional film is necessary to achieve the prescribed dose, place an additional film on the inside of the opposite cheek. The film must be kept on the inside of the cheek until the film is completely dissolved. If a third film is necessary to achieve the prescribed dose, place it on the inside of the right or left cheek after the first two films have dissolved.¹

SUBOXONE Sublingual Film contains buprenorphine and naloxone. Buprenorphine is a partial agonist at the mu-opioid receptor and an antagonist at the kappa-opioid receptor. Naloxone is a potent antagonist at mu-opioid receptors and produces opioid withdrawal signs and symptoms in individuals physically dependent on full opioid agonists when administered parenterally.¹

SUBOXONE Sublingual Film should be used as part of a complete treatment plan to include counseling and psychosocial support. Treatment should only be initiated under the direction of a physician qualified under the Drug Addiction Treatment Act (DATA 2000).¹

Abuse and diversion of buprenorphine containing products has been a concern of P&T committees nationwide. Two recent publications have shown that abuse and diversion of buprenorphine tablets, with or without naloxone, have been shown to exceed those of SUBOXONE Sublingual Film. Data on the rates for abuse and diversion with other branded or generic combination sublingual tablet formulations versus SUBOXONE Sublingual Film are not available.

The first publication, titled, "Abuse and Diversion of Buprenorphine Sublingual Tablets and Film" was published in 2014 in the *Journal of Substance Abuse Treatment* by Lavonas, et al. Data from the Researched Abuse, Diversion and Addiction-Related Surveillance (RADARS®) System showed that single ingredient tablets had the greatest rates of abuse and diversion in 3 programs (OTP, SKIP, College Survey), while the SUBOXONE Sublingual Tablet formulation had the greatest rates in the Poison Center Program. In all programs, rates of abuse and diversion for combination film were significantly less than rates for either tablet formulation. Geographic patterns were not apparent.²

A second publication, titled, "The Diversion and Injection of a Buprenorphine-Naloxone Soluble Film Formulation" was published in 2014 in *Drug and Alcohol Dependence* by Larance et al. A 2014 Australian Postmarketing Surveillance Survey showed that SUBOXONE Sublingual Film had a lower rate of injection compared with SUBOXONE Sublingual Tablet formulation and that the prevalence of weekly injection drug use among patients receiving SUBOXONE Sublingual Film was decreased compared to those receiving the tablet formulation (3% vs 9% respectively).² Please consult the package insert for SUBOXONE Sublingual Film to obtain full safety and prescribing information.

If the committee has any questions for me at this time, I would be happy to answer them. Thank you.

William Mullen PA-C, MPH
Indivior Inc.
10710 Midlothian Turnpike
Suite 430
Richmond, VA 23235
T 1-877-782-6966 indivior.com

Publication references:

1. SUBOXONE Sublingual Film [package insert]. Richmond, VA: Indivior inc.; September 2015.
2. Lavonas EJ, Severtson SG, Martinez EM, Bucher-Bartelson B, Le Lait M-C, Green JL, Murrelle L, Cicero TJ, Kurtz SP, Rosenblum A, Surratt HL, Dart RC. Abuse and diversion of buprenorphine sublingual tablets and film. *J Subst Abuse Treat* 2014; 47(1):27-34.
3. Larance B, Lintzeris N, Ali R, Dietz P, Mattick R, Jenkinson R, White N, Dagenhardt. The diversion and injection of a buprenorphine-naloxone soluble film formulation. *Drug and Alcohol Dependence* 136 (2014) 21–2.

