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THE PRESCRIBER e-LETTER

MassHealth PHARMACY PROGRAM

Smoking Cessation Initiatives

In the United States, cigarette smoking is estimated to result in more than 400,000 deaths annually. More than 70% of smokers see a physician yearly and more than 70% of smokers actively want to quit. This creates an important opportunity for clinical interventions. Pharmacological and behavior therapy have been shown to be the most effective treatment. The pharmacological agents are described below.

7 FDA-Approved Products

2 Non-nicotine Products

- varenicline (Chantix)
- bupropion SR (Zyban)

5 Nicotine Replacement Products

- nicotine inhaler (Nicotrol)
- nicotine nasal spray (Nicotrol)
- nicotine gum
- nicotine lozenges (Commit)
- transdermal nicotine systems

MassHealth has determined that the first 24-week course of Chantix and treatment courses of less than 90 days with nicotine gum, patches, and lozenges do not require prior authorization. Generic OTC and prescription versions of nicotine patches are available for use without prior authorization. All of the nicotine replacement products have equivalent efficacy. Increased adverse events are seen when Chantix is used with nicotine replacement products, and therefore this combination is not recommended and requires prior authorization. Zyban is a brand-name drug with an FDA "A"- rated generic.

Drug Name	PA Status	Ave. cost /month
bupropion sustained-release (Zyban)	Brand name = PA	$18
nicotine inhaler (Nicotrol)	PA	$984-2,624
nicotine nasal spray (Nicotrol)	PA	$164-329
nicotine gum	PA > 90 days' treatment PA > 2 treatments/year	$72
nicotine lozenges (Commit)	PA > 90 days' treatment PA > 2 treatments/year	$135
transdermal nicotine systems	PA > 90 days' treatment PA > 2 treatments/year	$59
varenicline (Chantix)	PA > 24 weeks/year	$110-120

Chantix in the News

Chantix, the commonly prescribed smoking cessation medication, has been in the news recently due to safety concerns regarding an increase in reports of psychiatric adverse events. On February 1, 2008, the FDA issued an alert to highlight revisions to the prescribing information for Chantix. The new warning states the following.

> "Serious neuropsychiatric symptoms have occurred in patients being treated with Chantix. Some cases may have been complicated by the symptoms of nicotine withdrawal in patients who stopped smoking; however, some of these symptoms have occurred in patients who continue to smoke. All patients being treated with Chantix should be observed for neuropsychiatric symptoms including changes in behavior, agitation, depressed mood, suicidal ideation, and suicidal behavior. These symptoms, as well as worsening of pre-existing psychiatric illness, have been reported in patients attempting to quit smoking while taking Chantix in the post-marketing experience. Patients with serious psychiatric illness such as schizophrenia, bipolar disorder, and major depressive disorder did not participate in the pre-marketing studies of Chantix and the safety and efficacy of Chantix in such patients has not been established. Patients attempting to quit smoking with Chantix and their families and caregivers should be alerted about the need to monitor for these symptoms and to report such symptoms immediately to the patient's healthcare provider."[1]

Pros[2]

- Reduces withdrawal symptoms
- Blocks the positive effects associated with smoking
- Treatment for up to 24 weeks increases continuous abstinence rates
- Safety alone has been studied for up to 52 weeks of continuous treatment
- Patients can continue smoking for the first week of treatment
- No meaningful drug interactions
- Once daily dosing
- No dose adjustments are necessary for light smokers

Cons[2]

- Case reports of serious neuropsychiatric symptoms that are likely associated with its use
- Symptoms can develop upon initiating treatment, after several weeks of treatment, or after discontinuation of treatment
- Patients need to be observed for emotional and behavioral changes
- Safety was not studied in patients with preexisting psychiatric illnesses
- Requires renal monitoring and dose adjustments
- Adverse events:
  - Insomnia 18-19 %
  - Abnormal dreams 9-13%
  - Nausea 16-40%

References:
[1] Chantix (varencline) [package insert]. Pfizer Labs. NY, NY. January 2008
[2] A clinical practice guideline for treating tobacco use and dependence: 2008 update: A U.S. public health service report. Am J Prev Med. 2008 8;35(2):158-76.

The Prescriber e-Letter is an update designed to enhance the transparency and efficiency of the MassHealth drug prior-authorization (PA) process and the MassHealth Drug List. Each issue will **highlight** key clinical **information and updates** to the **MassHealth Drug List**. The Prescriber E-Letter was prepared by the MassHealth Drug Utilization Review Program and the MassHealth Pharmacy Program.

Recent MassHealth Drug List Updates

Drug/Drug Class	Addition/Deletion/Change	Rationale
alvimopan (Enterg)	Addition; does not require PA	Alvimopan is available only in an inpatient hospital setting. MassHealth does not pay for this drug to be dispensed through a retail pharmacy or physician's office.
antipyrine /benzocaine (Auralgan)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
carbenicillin (Geocillin)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
castor oil/peru balsam/trypsin (Granul-derm, Granulex), trypsin/balsam peru/castor oil (TBC)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
ciclesonide (Alvesco)	Addition; does not require PA	Ciclesonide is indicated for the treatment to control persistent asthma in adults and adolescents (12 years or older).
difluprednate (Durezol)	Addition; **requires PA**	Difluprednate is indicated for the treatment of inflammation and pain associated with ocular surgery. There are more cost-effective alternatives available for the management of the same clinical conditions including Acular 0.5%, dexamethasone 0.1%, diclofenac 0.1%, flurbiprofen 0.03%, flurometholone 0.1%, Lotemax 0.5%, and prednisolone (acetate 1%, sodium 1%).
doxycycline (Doryx)	Change in PA status; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical conditions.
gabapentin (Neurontin)	Change in PA status; does not require PA	Due to findings from a recent quality assurance analysis, the PA requirement has been removed.
granisetron transdermal system (Sancuso)	Addition; **requires PA**	There are more cost-effective alternatives available for the management of the same clinical conditions. MassHealth has determined that 5-HT3 antagonists require PA when certain quantity limitations are exceeded.
hydrocortisone/aloe vera (Nucort)	Addition; **requires PA**	There are more cost-effective alternatives available for management of the same clinical condition. Other low potency topical corticosteroids that do not require PA include alclometasone dipropionate 0.05%, desonide 0.05%, fluocinolone acetonide 0.01%, and hydrocortisone 0.5%, 1%, and 2.5%.

Recent MassHealth Drug List Updates continued on next page

Recent MassHealth Drug List Updates (cont.)

Drug/Drug Class	Addition/Deletion/Change	Rationale
L-glutamine (NutreStore)	Addition; **requires PA**	There is inconsistent data regarding the efficacy of L-glutamine. Therefore, prior authorization is required.
levetiracetam extended release (Keppra XR)	Addition; **requires PA**	There are more cost-effective alternatives available for management of the same clinical condition. Immediate-release levetiractem is available without prior authorization.
levoleucovorin (Fusilev)	Addition; **requires PA**	There are more cost-effective alternatives available for management of the same clinical condition. Leucovorin is available without prior authorization.
lidocaine ophthalmic gel (Akten)	Addition; does not require PA	Lidocaine ophthalmic gel is a local anesthetic indicated for ocular surface anesthesia during ophthalmologic procedures
papain/urea (Accuzyme, Ethezyme, Kovia), papain/urea/ chlorophyllin/copper complex (Panafil), papain/urea/ chlorophyllin (Ziox)	Deletion; no longer on MassHealth Drug List	MassHealth does not pay for drug products (including identical, similar, or related drug products) that the U.S. Food and Drug Administration has proposed, in a Notice of Opportunity for Hearing (NOOH), to withdraw from the market because they lack substantial evidence of effectiveness for all labeled indications.
prednisolone (Veripred)	Addition; **requires PA**	There are more cost-effective alternatives available for management of the same clinical condition. Prednisolone solution is available without prior authorization
romiplostim (Nplate)	Addition; **requires PA**	Romiplostim is indicated for the treatment of refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP). Standard practice for ITP has been to initiate treatment with glucocorticosteroids. Romiplostim is considered a second line therapy, therefore, prior authorization will be required.
salsalate (Disalcid)	Deletion; no longer on MassHealth Drug List	This product has been removed from the MassHealth Drug List because it has been discontinued by the manufacturer.
venlafaxine extended-release tablet	Addition; does not require PA	Venlafaxine extended-release tablet is indicated for the treatment of generalized anxiety disorder, major depressive disorder, and social phobia.

Please send any **suggestions** or **comments** to: **PrescriberELetter@state.ma.us.**