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Medicaid Director

See also the Preferred buprenorphine/naloxone product letter of January 2016

Subject: buprenorphine/naloxone tablets

March 2013

Dear Prescriber,

This is a follow-up to our December 2012 letter that highlighted Reckitt Benckiser's planned withdrawal of Suboxone® sublingual tablets due to concerns of a greater unintentional exposure risk in children younger than 6 years of age, compared to the sublingual film formulation. As you may know, Reckitt Benckiser has announced in a press release that, effective March 18, 2013, it is ceasing the sale and distribution of Suboxone® sublingual tablets.

Since our December 2012 letter, there have been further new developments. On February 22, 2013, the FDA approved generic buprenorphine/naloxone sublingual tablets manufactured by Amneal Pharmaceuticals and Actavis Elizabeth. This decision came after the FDA denied Reckitt Benckiser's Citizen's Petition, which recommended that the FDA adopt more stringent packaging standards and increased educational interventions to help reduce the number of children exposed to buprenorphine-containing products. ***The bioequivalent 2 mg/0.5 mg and 8 mg/2 mg generic sublingual tablets are currently available at pharmacies.*** As a result of these recent developments, MassHealth is advising you of changes to MassHealth's prior-authorization policy pertaining to the available formulations of these drugs.

Effective for dates of service on or after March 8, 2013, MassHealth will require prior authorization for all prescriptions of brand Suboxone® sublingual film.[1] No prior authorization will be required for prescriptions of generic buprenorphine/naloxone sublingual tablets that meet the following dose and quantity limits.

- Doses ≤ 16 mg/day
- Doses > 16 mg/day but ≤ 24 mg/day with a duration of ≤ 180 days
- Doses > 24 mg/day but ≤ 32 mg/day with a duration of ≤ 90 days

Please note that active prescriptions for a member who had previously obtained prior authorization for Suboxone® Film, or had prescriptions for Suboxone® Film covered by MassHealth due to the lack of tablet availability will continue to be honored for the duration of the prior authorization or life of the prescription (for those without prior authorization). Upon expiration of the prior authorization or prescription, as the case may be, MassHealth will require use of the generically available tablets unless the member demonstrates that use of the brand Suboxone® Film is medically necessary through the prior-authorization process. In addition, all

[1] Prior authorization will also be required for brand Suboxone® sublingual tables for as long as they are in distribution.

members who were approved for Suboxone® Film because they reside in a household with a child under 6 years old will continue to be authorized.

Further information on buprenorphine and buprenorphine/naloxone treatment is set forth in the MassHealth Drug List (see Table 36 and the related Evaluation Criteria). Please note that the changes referenced in this letter will be reflected in the next published update to the MassHealth Drug List. The MassHealth Drug List and other information can be found on the MassHealth Pharmacy web page at www.mass.gov/masshealth/pharmacy.

We appreciate your continued support and dedication to providing care to MassHealth members.

Sincerely,

Paul L. Jeffrey, PharmD
Pharmacy Director
MassHealth