DEVELOPMENT AND IMPLEMENTATION OF A SUBOXONE®/SUBUTEX® TREATMENT PROTOCOL EDIT

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BACKGROUND

Treatment guidelines call for use of Suboxone®/Subutex® (referred to as Suboxone® in poster) in an induction phase to safely suppress opioid withdrawal; a stabilization phase where the minimum dose necessary is used to keep the patient in treatment; a maintenance phase to prevent opioid withdrawal symptoms, suppress opioid cravings, and greatly attenuate the use of self-administered opioids; and a medically supervised withdrawal phase where the dose is slowly tapered. In order to promote appropriate use of Suboxone® the Mississippi Division of Medicaid implemented a treatment protocol edit.

OBJECTIVES

The major objectives of the protocol were to encourage step therapy with dose reduction over time and to limit cumulative length of time patients can remain on therapy. The new protocol was not intended to reduce access to Suboxone® therapy.

PRACTICE DESCRIPTION

Analyses conducted during development of the new treatment protocol found that only a small percentage of beneficiaries required initial daily doses greater than 24mg/day (Table 1).

Table 1: Product Dosage Strength by Starting Daily Dose
(Patients starting therapy between 10/1/2010 and 9/30/2011)

	Dosage Strength				
Starting Daily Dose	2 MG	2 - 0.5 MG	8 MG	8 - 2 MG	Total
2 mg/day	1	1	0	0	2 (1%)
4 mg/day	1	1	0	0	2 (1%)
6 mg/day	0	1	0	0	1 (0%)
8 mg/day	0	0	2	21	23 (10%)
16 mg/day	0	0	6	171	177 (74%)
24 mg/day	0	0	4	27	31 (13%)
32 mg/day	0	0	0	2	2 (1%)
Total	2 (1%)	3 (1%)	12 (5%)	221 (93%)	238

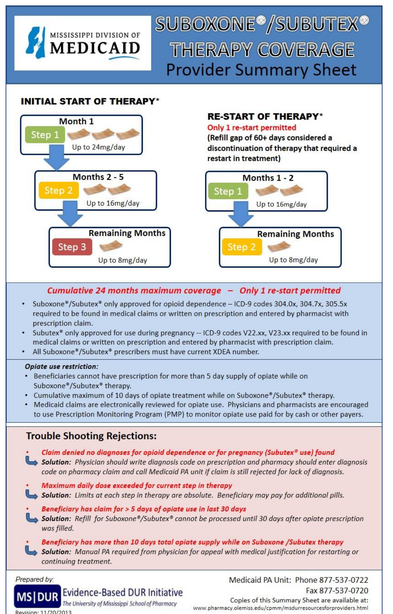
ACKNOWLEDMENTS/DISCLOSURES

The work reported was conducted by the MS-DUR program in the Center for Pharmaceutical Marketing and Management as part of the retrospective drug use analysis activities conducted under contract with the Mississippi Division of Medicaid. The views expressed are those of the authors and do not necessarily reflect those of Mississippi Division of Medicaid or the University of Mississippi.

After consultation with addictionoligists and a detailed analyses of Suboxone® treatment patterns, a new treatment protocol was developed. The key criteria include:

- Limited to treatment of opioid dependence only.
- Maximum doses for three stages of therapy are:
  - 24 mg/day for 1 month (the highest effective dose recommended in prescription information)
  - 16 mg/day for next 4 months, and
  - 8 mg/day for remainder of therapy.
- Cumulative 24 months of coverage.
- Refill gap of 60+ days is considered to be discontinuation and requires a restart.
- Beneficiaries are only allowed one restart.
- Use of opioid products is strictly limited.

MS-DUR mailed educational materials to prescribers and pharmacies explaining the new protocol and how to manage potential prior authorization issues. The protocol was implemented through the electronic prior authorization (EPA) system beginning September 1, 2012.



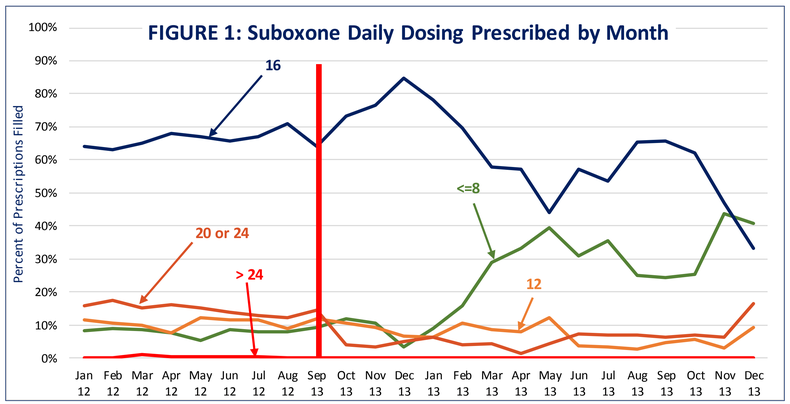
OUTCOMES

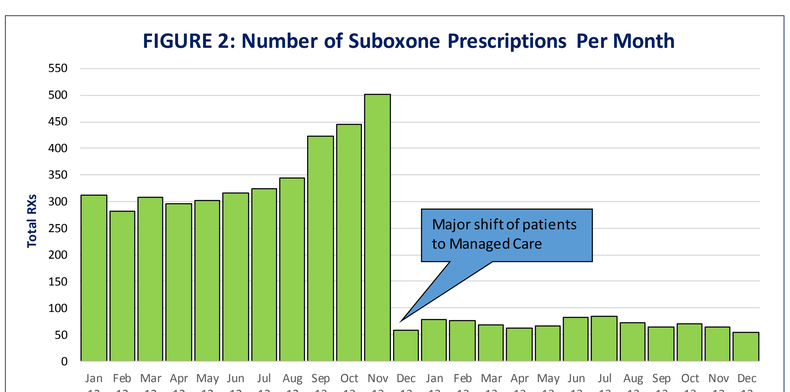
EPA denials were monitored for the first six months after implementation. Prescribers and pharmacies having repeated problems with denials were contacted for further education.

The most frequent reason for denial of claims was the absence of an appropriate diagnosis code(s) being found in prior medical claims or submitted by the pharmacy at the time of claim adjudication.

As shown in Figure 1, reduction in daily dose did occur after implementation of the new criteria. The percentage of prescriptions filled with a daily dose of 8mg/day or less significantly increased and the percentage filled with a daily dose of 16mg/day significantly decreased. Prescribing of daily doses of 20 or 24mg/day also reduced.

As shown in Figure 2, the reduction in daily dosing was achieved without reducing access to Suboxone therapy. The number of prescriptions per month actually rose in the three months after implementation of the new protocol. In December 2012, a major shift of beneficiaries to managed care took place; resulting in the majority of Suboxone® patients moving out of the FFS program. However, after this shift, the number of prescriptions per month was relatively stable, indicating access was not reduced.





CONCLUSIONS

The Suboxone® protocol implemented by DOM provided a good method for encouraging appropriate treatment patterns and appropriate utilization while not restricting access to this therapy.