Drug Use Research & Management Program
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Drug Policy Evaluation (Brief): Buprenorphine

Background:

In August of 2023, the DURM conducted a policy evaluation on quantity limits on buprenorphine products. The policy evaluation recommended raising the quantity limit of 24mg per day on buprenorphine products to 32mg per day. The goal of this change was to provide access to higher dose for members with Opioid Use Disorder (OUD) who might benefit for the higher dose. Those recommendations were implemented in August of 2023.

Research Questions:

1. Was there an increase in the number of members with a single prescription with a daily dose over 24mg
2. Was there an increase in the number of members with multiple prescriptions with a daily dose totally over 24mg
3. Was there an increase in the total units (aka tablets) per day
4. Was there a decrease in the proportion of members with a diagnosis of OUD before or after treatment (i.e., was buprenorphine being used more frequently for the treatment of pain vs. OUD).

Conclusions:

There was a small increase in members receiving over 24mg per day of buprenorphine (12.2%, p=0.0019), suggesting the policy had the desired impact to provide access to higher doses for the minority of members who would benefit from a higher dose. There was a decrease in the proportion of members without an OUD diagnosis during the baseline period, but the small magnitude of this change does not warrant a policy change. No other meaningful changes in healthcare resource utilization were observed. The policy change to raise the daily quantity limit from 24mg to 32 mg per day on buprenorphine products appears to have had the desired outcome without introducing unexpected increases in utilization. There may be dose consolidation opportunities, in particular for claims for 2mg tablets with quantities of 4 units per day and higher.

Recommendations:

No policy changes recommended.

Methods:

Claims were evaluated from 10/21/2020 to 12/31/2024. The index date was defined as the first buprenorphine claim for a member. Members were included in the study if the index date fell within one of 2 distinct periods: before the policy change 1/1/2021-9/30/2022, and after the policy change 10/1/2023-9/30/2024. The baseline period was the 9 months prior to the index date. The follow up period was 90 days beginning at the index date. Members were excluded if they had

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other primary insurance coverage, non-continuous Medicaid FFS eligibility during the baseline or the follow up period, or were not between 18 and 65 years old as of the index date.

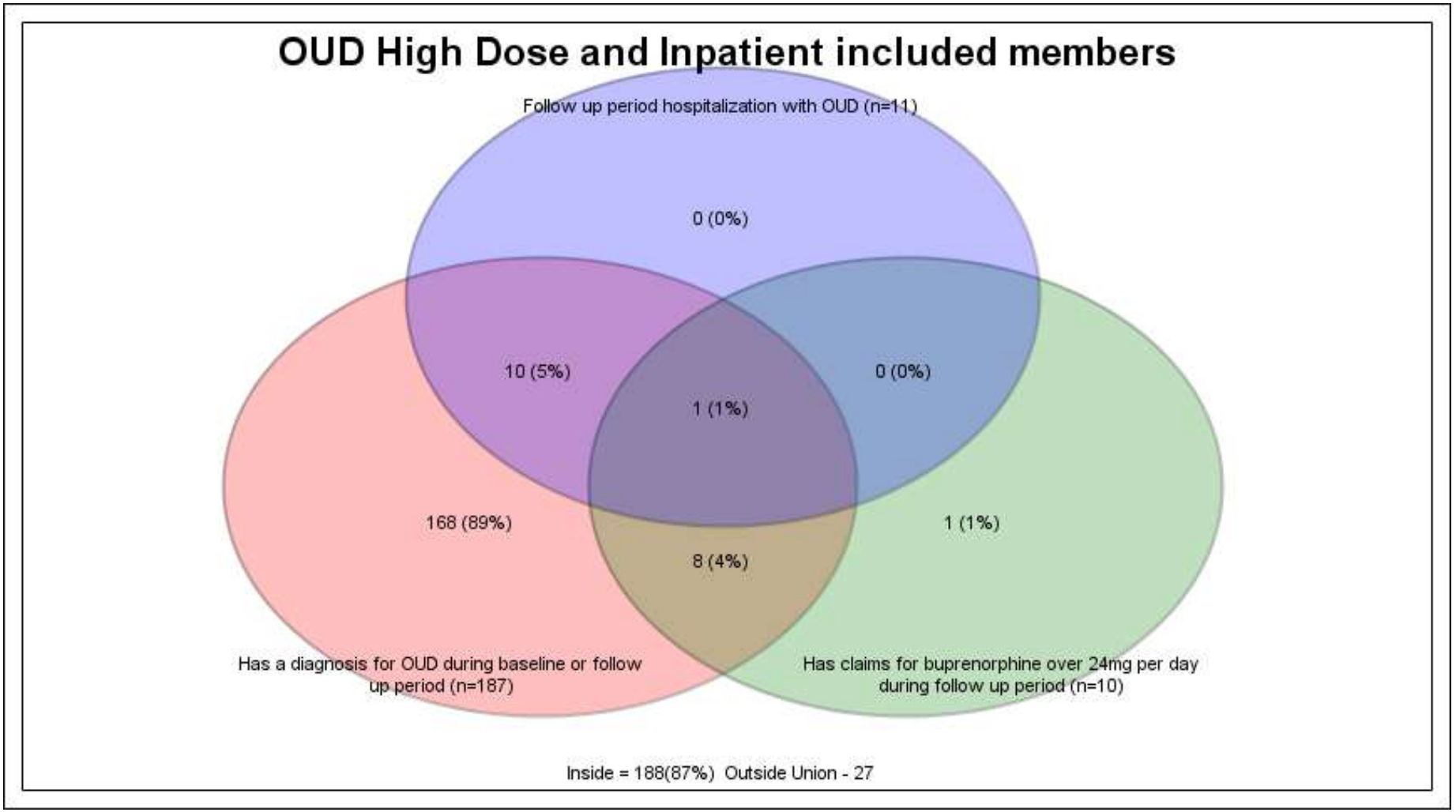
Results:
In total, 215 members were included in the study, with 133 included in the before policy change group and 82 in the after policy change group. There were no significant differences in age or gender between the two groups. A small but significant reduction in the proportion of members with baseline OUD was observed from before to after the policy change (86.47% vs. 75.61%, p = 0.0427). After the policy change, 87.80% of members continued to have claims for 24mg/day or less, while 12.2% of new starts included doses exceeding 24mg per day (p=0.0019). There was no significant difference in the proportion of members with claims for multiple strengths. The average number of units per day remained unchanged. There was no significant difference in the proportion of members with a claim with an OUD diagnosis during the follow-up period.

As part of an *ad hoc* analysis, no differences were observed in the proportion of members receiving buprenorphine in the inpatient setting, receiving naltrexone microspheres, or hospitalizations with a diagnosis of OUD. Additionally, there appears to be opportunities for dose consolidation for several strength and units per day combination:

A. 2mg x 12 units per day => 12mg x 2 units per day
B. 2mg x 8 units per day => 8mg x 2 units per day
C. 2mg x 6 units per day => 6mg x 2 units per day
D. 2mg x 4 units per day => 4mg x 2 units per day or 8mg once daily

Full study results and details are available by request to DURM.

Additional Venn diagram: OUD Hospitalizations, OUD Diagnosis, and buprenorphine claims over 24mg per day



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Buprenorphine and Buprenorphine/Naloxone

Goals:

- Prevent use of high-dose transmucosal buprenorphine products for off-label indications.

Length of Authorization:

- Up to 6 months

Requires PA:

- Transmucosal buprenorphine products that exceed an average daily dose of 32 mg per day

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. Is the prescription for opioid use disorder (opioid dependence or addiction)?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness
2. Is the prescription for a transmucosal formulation of buprenorphine (film, tablet) with an average daily dose of more than 32 mg (e.g., >32 mg/day or >64 mg every other day)?	**Yes:** Go to #3	**No:** Go to #7
3. Is there documentation of inadequate symptom improvement with 32 mg daily?	**Yes:** Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Is there recent documentation (within past month) from a urine drug screen indicating that buprenorphine is being taken?	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
5. Has the prescriber evaluated the PDMP in the past 3 months?	**Yes:** Go to #6	**No:** Pass to RPh. Deny; medical appropriateness
6. Does the member have access to naloxone?	**Yes:** Approve for 30 days. Subsequent requests for continuation of therapy will require documentation of objective clinical benefit with higher doses (e.g. improved management of OUD), documentation of a comprehensive treatment plan for OUD, and ongoing monitoring plan for safety risks.	**No:** Pass to RPh. Deny; medical appropriateness
7. Is the requested medication a preferred agent?	**Yes:** Approve for 6 months. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.	**No:** Go to #8
8. Will the prescriber switch to a preferred product? Note: Preferred products are reviewed for comparative safety and efficacy by the Oregon Pharmacy and Therapeutics Committee.	**Yes:** Inform prescriber of covered alternatives in class.	**No:** Approve for 6 months. Note: Notify prescriber concomitant naloxone is recommended if not present in claims history.

P&T/DUR Review: *8/25 (TW); 10/23; 8/23 (SS); 2/23; 12/22; 12/20;11/19; 1/19; 1/17; 9/16; 1/15; 9/09; 5/09*
Implementation: *9/1/23; 1/1/2020; 3/1/2019; 4/1/2017; 9/1/13; 1/1/10*

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