EVALUATION OF PROGESTERONE AGENT UTILIZATION AND BIRTH OUTCOMES IN A STATE MEDICAI PLAN

BACKGROUND
- Preterm birth (PTB), or delivery before 37 weeks of gestation, is the leading cause of infant morbidity and mortality in the United States, affecting 9.6% of births.1
- History of PTB and chronic uterine shortening during pregnancy are among the strongest risk factors for PTB. Progesterone has been shown to reduce PTB rates by one-third among women at high risk.2
- The Massachusetts Medicaid Program (MassHealth) has required prior authorization (PA) for use of hydroxyprogesterone caproate injection (Makena®) and progesterone vaginal gel (Crinone®) since 2011 and 2012, respectively.

OBJECTIVE
Primary Objective:
- To report medication adherence and birth outcomes among members receiving progesterone for the prevention of PTB in a state Medicaid program.

Secondary Objectives:
- To evaluate the association between member characteristics and medication adherence and birth outcomes.
- To estimate the change in cost of care for study pregnancy compared to prior preterm pregnancy.

STUDY DESIGN
This retrospective cohort study evaluated MassHealth Primary Care Clinician (PCC) plan members who had a PA request submitted for hydroxyprogesterone caproate injection or progesterone vaginal gel for the prevention of PTB between January 1, 2011 and March 31, 2015. Data was obtained from medical claims, pharmacy claims, eligibility and enrollment records, and PA requests.

METHODS
Outcomes collected included:
- Member (age, race, gender, and age)
- Prescription details (eg, name, days supply, etc.)
- Clinical characteristics (eg, laboratory results, vital signs, etc.)
- Birth outcomes (eg, gestational age, birth weight, etc.)

RESULTS

TABLE 1: Descriptive Characteristics and Birth Outcomes

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (n=152)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age (wks)</td>
<td>31.3 (3.1)</td>
<td>0.342</td>
</tr>
<tr>
<td>Median birth weight (lbs)</td>
<td>7.3 (2.4)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Mean birth length (inches)</td>
<td>19.9 (3.2)</td>
<td>0.015</td>
</tr>
<tr>
<td>PDC category</td>
<td>Total (n=152)</td>
<td>P-value</td>
</tr>
<tr>
<td>Adherent</td>
<td>48 (34.5)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Non-Adherent</td>
<td>64 (37.9)</td>
<td></td>
</tr>
</tbody>
</table>

DISCUSSION

- Birth outcomes for members receiving progesterone for the prevention of PTB in the Massachusetts PCC plan were consistent with other clinical trials.3
- Medication adherence among MassHealth PCC plan members was similar to or lower than findings from other studies.4
- Bivariate and multivariate analyses did not identify member characteristics associated with either birth outcomes or medication adherence.
- Differences in cost of care in a prior pregnancy and current pregnancy are driven by differences in the cost of medical care between gestational ages of delivery.

LIMITATIONS
- A significant percentage of race data was reported as unknown.
- Identification of delivery and clinical comorbidities were based upon ICD-9 and ICD-10 medical claims data. It was not feasible to track all potential risk factors that are not routinely recorded in medical claims.
- The date of progesterone administration used for the PCC calculation is assumed to be the date of the paid pharmacy claim.

CONCLUSIONS
- Timely availability and access to data are important for monitoring risk factors and evaluating programs.
- Medicaid members receiving progesterone for the prevention of PTB may benefit from additional care management services, including adherence programs.

REFERENCES

ACKNOWLEDGMENTS
- The authors thank the University of Massachusetts Medical School’s Center for Community Health Improvement for their contributions to this project.
- Special thanks to Payal Kotadiya and Karen Clements for their contributions.

TABLE 2: Cost Comparison Between Prior Pregnancy and Study Pregnancy by Gestational Age

<table>
<thead>
<tr>
<th>Gestational age (wks)</th>
<th>Total cost of care</th>
<th>Difference in cost between prior and study pregnancy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior pregnancy</td>
<td>$14,561,202.15</td>
<td>$49,681.79</td>
</tr>
<tr>
<td>Study pregnancy</td>
<td>$14,521,520.36</td>
<td>$49,681.79</td>
</tr>
</tbody>
</table>

TABLE 3: Medication Adherence Analysis

<table>
<thead>
<tr>
<th>Race</th>
<th>n (%)</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Black</td>
<td>48 (34.5)</td>
<td>0.777</td>
</tr>
<tr>
<td>White</td>
<td>64 (37.9)</td>
<td></td>
</tr>
</tbody>
</table>

TABLE 4: Table 2: Birth Outcome Bivariate Analysis

<table>
<thead>
<tr>
<th>Analysis type</th>
<th>df</th>
<th>Chi-square Test</th>
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</thead>
<tbody>
<tr>
<td>Adherent vs Non-Adherent</td>
<td>1</td>
<td>0.234</td>
</tr>
</tbody>
</table>

TABLE 5: Medication Adherence Analysis

<table>
<thead>
<tr>
<th>Race</th>
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<td>White</td>
<td>64 (37.9)</td>
<td></td>
</tr>
</tbody>
</table>

FIGURE 1: Study Enrollment

FIGURE 2: Proportion of Adherent Members

N=169

M=74

N=95

n=21

n=25

n=22

n=69

n=58

n=57

n=112

n=63.3

Conclusions

- Timely availability and access to data are important for monitoring risk factors and evaluating programs.
- Medicaid members receiving progesterone for the prevention of PTB may benefit from additional care management services, including adherence programs.