Impact of 17P Usage on NICU Admissions In a Managed Medicaid Population — A Five-Year Review

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ABSTRACT

Objective. To evaluate whether providing 17 alpha-hydroxyprogesterone caproate (17P) to high-risk pregnant women who have a history of preterm delivery in a Medicaid managed care population reduces the rate of recurrent preterm delivery and neonatal intensive care unit (NICU) admissions.

Study design. A 2004–2009 longitudinal review of birth outcomes in 193 singleton pregnant women with a history of spontaneous preterm delivery that were treated with 17P versus a control group.

Methodology. Intervention included offering 17P as a benefit to pregnant women who had a history of spontaneous preterm delivery and who were deemed to be appropriate candidates by their doctor. Members for this study were identified by claims review and obstetrical (OB) case managers in the health plans.

A process of early identification, using a variety of data sources, was established along with an educational program aimed at physicians, their office staff, and plan members in order to increase 17P utilization in appropriate candidates.

Results. Deliveries with a gestational age of less than 35 weeks decreased significantly from 41.67% in the control group to 26.42% in the 17P group when 17P was initiated by 28 weeks of gestation. The NICU admission rate decreased from 45% in the control group to 33.68% in this 17P group, and was nearly significant.

Conclusion. Offering 17P as a benefit does have a positive effect on reducing the rate of recurrent preterm delivery and rate of NICU admission in a managed Medicaid population. There was no decrease in effectiveness with delay in initiation of 17P as long as it was started by 28 weeks of gestation.

Key words: Managed Medicaid, preterm birth, 17P

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INTRODUCTION

Preterm delivery, defined as a delivery before 37 weeks, and the resulting high dollar NICU claims represents a large portion of a managed Medicaid company's medical expenses.

After a 36% increase in the national preterm birth rate since the 1980s, the preterm birth rate declined slightly in 2007 to 12.7% from 12.8% in 2006 (March of Dimes 2008). While this small, but statistically significant decrease is promising, the complex, ongoing health issues — behavioral, learning, development, and adult disease — associated with the more than 540,000 infants born prematurely in the United States accounts for more than $26 billion annually and continues to strain our health care system. The average medical costs for a premature baby are over ten times those of a term baby for the first year of life.

The pathophysiological events that trigger preterm labor are for the most part not known, but a history of spontaneous preterm delivery is one of the strongest risk factors for preterm birth in a subsequent pregnancy (Mercer 1999).

Progestins have been known to have an important role in the maintenance of pregnancy for some time. In the 1930s, George Corner, MD, and Willard Allen, MD, isolated and named progesterone. Possibilities were first realized when they used isolated corpus luteum extract to obtain secretary endometrium in a rabbit uterus. Subsequently, they isolated progesterone and showed that it proliferated endometrium and maintained pregnancy.

Progestins have been difficult to give in an effective, convenient fashion. If natural progesterone is given orally, it is rapidly metabolized in the liver. If synthetic progesterone is given and not rapidly metabolized it carries androgenic effects. Two safe progestins in pregnancy are natural progesterone cream, and synthetic caproate ester of naturally occurring 17 alpha-hydroxyprogesterone (17P).

A multicenter randomized con-

trolled trial by the National Institute of Child Health and Human Development, published in the *New England Journal of Medicine*, showed a significant reduction in preterm labor and delivery for high-risk women with a history of spontaneous preterm delivery. The study enrolled 463 women with a prior history of preterm birth in 19 clinical trial centers. Patients were enrolled at 16 to 21 weeks of gestation and randomly assigned to receive weekly injections of 17P or placebo until delivery or 37 weeks of gestation. Treatment with 17P resulted in an overall reduction in the preterm birth rate of 34% and a reduction of 42% in the rate of preterm births prior to 32 weeks. In addition, infants born to women treated with 17P had significantly lower rates of serious complications such as necrotizing enterocolitis, intraventricular hemorrhage, use of supplemental oxygen, and mean number of days of respiratory therapy.

The Meis/National Institute of Child Health and Human Development (NICHHD) study is considered the landmark study that moved progesterone therapy for the prevention of preterm birth back into modern obstetrics. Another study of note is a meta-analysis published in *Obstetrics and Gynecology* in 2005. The authors looked at ten studies that used 17P in women with an increased risk for premature birth. Using rigid study criteria, they searched randomized controlled trials that used a variety of progesterones for treatment of these patients. The outcomes they sought in these studies were delivery before 37 weeks, threatened preterm labor, birth weight less than 2500 g, perinatal mortality, or respiratory distress syndrome. Eight of the qualifying studies used 17P for treatment, one used progesterone 100 mg intramuscular (IM) injection, and one used medroxyprogesterone. The conclusion was that progesterational agents "convincingly" reduce the occurrence of preterm birth in patients at elevated risk. The study also showed a lower rate of hospital admission for preterm labor and a lower rate of deliveries of less than 2500 grams (Sanchez-Ramos 2005). Tita et al in the March 2009 edition of *American Journal of Obstetrics & Gynecology* reviewed literature since 2000 on progesterone for prevention of preterm births. The review concluded overall there was significant reduction in preterm birth and low birth weight, and less conclusive benefit in reduction of neonatal morbidity and mortality.

Members in managed Medicaid often have unique issues and barriers that must be addressed in a treatment plan, especially one addressing premature birth prevention and 17P. Issues include compliance with weekly injections, late initiation of prenatal care, and lack of social or financial resources. A longitudinal review of birth outcomes in 24 pregnant women with a history of preterm birth in a managed Medicaid plan showed a significant decrease in NICU admissions as well as NICU length of stay resulting in cost savings (Mason 2005). Additionally, an observational, causal comparative study reviewed birth outcome in 104 pregnant managed Medicaid women with a confirmed history of preterm delivery. Women whose 17P treatment was initiated during the recommended time frame of 16–21 weeks of gestation were compared with those whose treatment was initiated after 21 weeks of gestation. No significant changes in birth outcomes were noted when comparing those members whose treatment was initiated during the recommended time frame of 16 to 21 weeks versus those whose treatment began after 21 weeks of gestation. Members who received therapy of at least five injections of 17P, as opposed to those receiving fewer than five injections, experienced a statistically significant reduction in NICU admissions and in preterm birth at less than 37 weeks and at fewer than 32 weeks (Mason 2007).

The goal of this study is to look at the five-year 17P experience of a managed Medicaid plan to determine if 17P impacts the rate of recurrent preterm birth and rate of NICU admission in a Medicaid population despite delays in initiation of treatment and problems with compliance.

WHAT IS 17P?

A naturally occurring metabolite of progesterone, produced during human pregnancy, 17P is used for recurrent miscarriages and various menstrual disorders. This hormone has been indicated for amenorrhea, endometrial carcinoma, and uterine corpus adenocarcinoma. It has no androgenic activity and animal studies show no teratogenic or virilizing effects. Clinical studies support 17P safety in pregnancy.

Use of 17P in women who have had a previous premature birth (<37 weeks) has been endorsed by the American College of Obstetricians and Gynecologists (2003). In 2008, ACOG reaffirmed this position.

> Progesterone supplementation for the prevention of recurrent preterm birth should be offered to women with a singleton pregnancy and a prior spontaneous preterm birth due to spontaneous preterm labor or premature rupture of membranes.

In 2006, the Reproductive Health Drugs Advisory Committee to the U.S. Food and Drug Administration (FDA) recommended by a majority vote that the data presented by Adeza in its new drug application (NDA) for Gestiva support efficacy in preventing preterm birth prior to 35 weeks and that overall safety data are adequate and sufficiently reassuring to support marketing approval in women with a history of preterm delivery. The FDA ruled that the drug was "approvable" but that additional tests were required. FDA approval is anticipated in the near future.

HOW DOES 17P WORK?

In animal models, progesterone appears to be responsible primarily for maintaining uterine quiescence during pregnancy. A drop in progesterone levels normally occurs at the initiation of labor at term. However, the mechanism is not the same for preterm labor or preterm rupture of the membranes; evidence suggests this is the result of an inappropriate, inflammatory response. Weekly injections of 17P starting at 16 to 21 weeks until 35 weeks of gestation may suppress this pathological labor (Mercer 1999).

The quantities of 17P produced naturally during pregnancy, predominately by the placenta, far exceeds the recommended dose of 250 mg weekly by intramuscular injection during the last half of pregnancy. Based on the several animal and clinical studies that support the safety of 17P in pregnancy and the fact that large quantities are naturally produced by the body during pregnancy, one would not expect any serious side effects from 17P. Reprotox (1997), an online reproductive toxicology database, states "there is no available evidence that the administration of this agent (17P) during pregnancy is harmful."

METHODS

Environment

Centene Corporation provides programs and related services to individuals receiving benefits under Medicaid, including Supplemental Security Income (SSI) and the State Children's Health Insurance Program (SCHIP). Centene currently serves over 1.4 million members in managed Medicaid and low income programs in eleven states, including more than 70,000 pregnant members a year.

Because many of our members are from lower socioeconomic groups, much attention is focused on preventing poor birth outcomes and NICU admissions. Start Smart for Your Baby is our prenatal program that expands into the first year of life of the child. The Start Smart for Your Baby program includes dedicated obstetric nurse case managers and social workers who provide support for pregnant mothers who are identified as being at high risk for complications during pregnancy. There are educational materials at the fifth grade reading level that address health literacy and foreign language needs. Incentive programs are developed to encourage members to seek prenatal and postpartum care, and clinical programs are aimed at increasing HEDIS scores as well as documentation of clinical outcomes of the mother and baby.

A pregnancy notification system helps our plans to identify 17P candidates as early as possible in their pregnancy. Because of a number of factors, including not accessing care in a timely manner, state eligibility processes, and noncompliance, patients who are candidates for 17P can present to the physician late in pregnancy.

Availability

In 2004–2009, 17P was not offered as a benefit in the fee-for-service Medicaid plan in any of our plans' states — Arizona, Florida, Georgia, Indiana, Massachusetts, New Jersey, Ohio, South Carolina, Texas, and Wisconsin. The fee-for-service Medicaid program is prohibited from paying for any drug product for which a rebate agreement has not been signed. However, our contracts with the states allow Centene and its health plans to provide 17P as a benefit.

The use of 17P treatment is voluntary, and physicians have adopted its use at different rates.

Identification of high-risk members

For this review, members who received 17P during their pregnancy were identified by claims review and data collection from the OB case managers in the health plans. Those who were deemed appropriate candidates by their doctor also needed to meet the eligibility requirements that were used in the 2003 Meis/NICHHD study. There were two additional allowances for eligibility outside of these "Meis criteria." If the previous spontaneous preterm delivery was in a twin gestation the patient was allowed 17P therapy. Also, if the patient's eligibility was not noted until later in pregnancy she was allowed 17P therapy. Initiation of therapy was allowed up to 28 and 6/7 weeks.

There is a clear set of criteria that defines these patients. Physician offices and clinics are not able to identify and counsel every eligible patient in a timely fashion. Centene has developed unique ways to identify and track members who are pregnant and eligible for 17P therapy.

Our *Potential 17P Candidate Report* is a list of currently pregnant members who may be candidates for 17P. The *17P Assessment* guides the case manager and member through a series of medical questions to decide if the member is truly a candidate. If she is a candidate, she remains on the report until she begins 17P or until she or her physician decides not to treat with 17P. Members receiving 17P are tracked through their pregnancy and pertinent information is logged in the *17P Journal*. All members with a 17P journal are listed in the *17P Utilization Report*. This report tracks all members who received 17P. Information about members who were eligible for 17P, but did not receive the treatment is also found in the report.

Providing the 17P benefit

Once a physician prescribes 17P, arrangements to administer the injections in the physician office or through home health are made by the health plan. Frequent contact with the health plan's OB case manager provides the member education and

support in order to ensure compliance with treatment.

OUTCOMES

Statistical test

A *chi-square* analysis (2 × 2 contingency table), commonly used when comparing the number of occurrences between two groups or time frames, was conducted to determine statistical significance.

RESULTS

The measurement of the 17P program's effectiveness is the NICU admission rate and preterm delivery rate (at less than 37, 35, and 32 weeks of gestation) for women enrolled in the program (17P group) compared to women not enrolled in the program with similar risk factors but who did not receive treatment (the control group).

The control group consisted of 60 identified members who did not receive 17P treatment during their recent pregnancy and who had a history of pre-term delivery within the last 36 months. Twenty-five percent of these members were enrolled in OB case management.

The intervention group consisted of 193 identified members who received 17P injections during their pregnancy. The majority of the members who received 17P treatment were also enrolled in OB case management (93.78%) and were monitored for treatment compliance.

The table below illustrates a breakdown of statistics between the two study groups and the Meis study control group.

NICU admissions

The control group had 45% NICU admission rate, while the intervention group had 33.68% NICU admission rate, a 25.20% difference in NICU admissions between the two groups, and was nearly statistically significant ($p = 0.095$).

Preterm delivery rate

The control group had a preterm delivery rate at less than 35 weeks of gestation of 41.67%, while the intervention group had a preterm delivery rate at less than 35 weeks of 26.42%. The difference between the two groups was statistically significant ($p = 0.024$).

Initiation of 17P treatment

In a comparison of members who initiated 17P treatment prior to 21 weeks of gestation with members who initiated 17P treatment prior to 28 weeks of gestation, there was no significant difference in NICU/Special Care Nursery (SCN) admissions or in preterm delivery rates at less than 37 weeks, 35 weeks, or 32 weeks of gestation.

TABLE

A comparison of patients who received 17P treatment with those who did not

Name of group	17P group injections initiated ≤28 weeks gestation	17P group injections initiated ≤21 weeks gestation	Meis 17P group	Centene control group	Meis control group
Number of members	193	132	306	60	153
Range of gestational age at 17P initiation	14–28 weeks	14–21 weeks	16–20 weeks	NA	NA
% having more than 1 previous preterm term delivery	32.64%	34.09%	27.7%	unknown	41.2%
Range of number of previous preterm deliveries	1 to 4	1 to 4	unknown	unknown	unknown
Average number previous preterm deliveries	1.43	1.45	1.4	unknown	1.6
Average gestational age of previous preterm delivery	30.02	30.24	30.6	30.33	31.3
% in case management	93.78%	94.70%	unknown	25%	unknown
% delivered < 37 weeks	46.63%	46.21%	36.3%	51.67%	54.9%
% delivered < 35 weeks	26.42%	23.48%	20.6%	41.67%	30.7%
% delivered < 32 weeks	13.47%	14.39%	11.4%	21.67%	19.6%
Number with confirmed weight	191	131	unknown	60	unknown
% delivered < 2500 g	37.70%	37.40%	27.2%	48.33%	41.1%
% delivered < 1500 g	12.57%	12.98%	8.6%	13.33%	13.9%
% delivered < 1000 g	4.71%	6.87%	unknown	5.00%	unknown
% delivered < 37 weeks and < 2500 g	34.03%	32.06%	unknown	43.33%	unknown
% in neonatal intensive care unit or special care nursery	33.68%	33.33%	unknown	45.00%	unknown
Known members' confirmed hospital stay	54	36	unknown	60	unknown
Average confirmed hospital length of stay	28.35	30.58	unknown	29.30	unknown

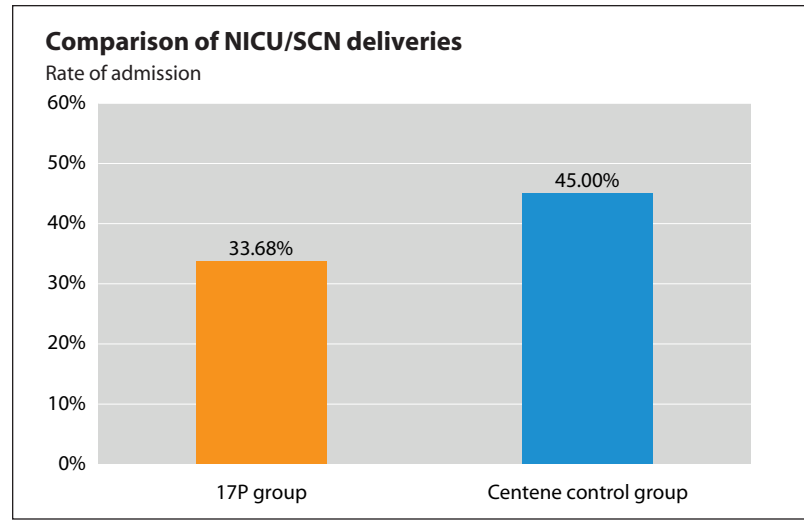
DISCUSSION

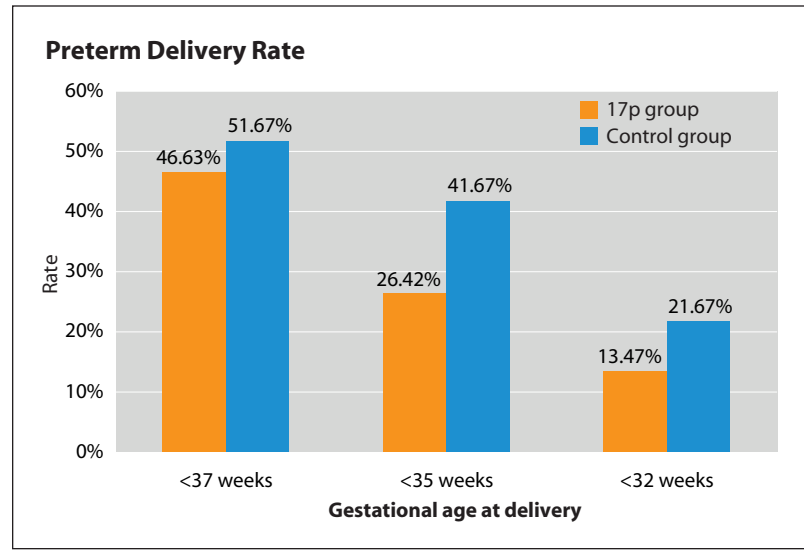
This study reconfirms that 17P can be successfully used in a managed Medicaid population to reduce the rate of recurrent preterm delivery and the rate of NICU admission. Our five year experience shows that 17P can result in positive birth outcomes despite issues of delay in the first prenatal visit, delay in initiation of 17P, compliance issues and social barriers that are common in the Medicaid population.

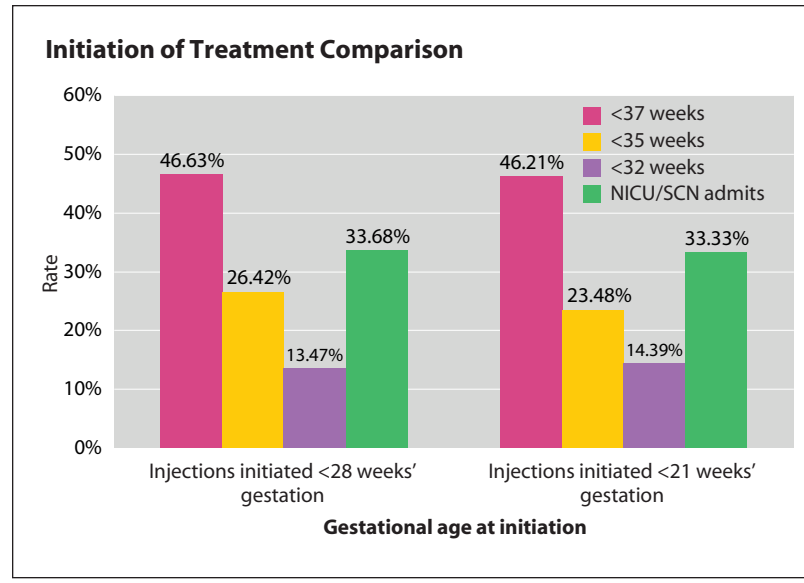
The strengths of this study are its design, which includes patients who are typical candidates in a managed Medicaid population. The results are statistically significant for the reduction in the rate of deliveries prior to 35 weeks and nearly significant for the rate of NICU admissions despite the small sample size.

A limitation of our study involves the fact that we had difficulty finding an adequate control group for comparison. We gathered our Medicaid control group by looking at historical claims data. We were unable to determine by claims whether a preterm birth was spontaneous or indicated (i.e., the provider decided it was in the best interest for the mother or the baby to proceed with delivery before the baby was full term). We were also unable to assess the number of prior preterm deliveries in this group.

Because of this, we also did a comparison to the Meis study control group. We felt that the characteristics of our 17P group were similar to this group with respect to the number of prior preterm deliveries and the average gestational age of prior preterm deliveries. One significant difference, however, is that 36.8% of our members began 17P after 21 weeks of gestation. It was 0% in the Meis group. Because of delays in access to care, accurate pregnancy dating is often difficult in our members. External factors that can affect prematurity and low birth weight such as substance abuse and social stressors are prevalent in a Medicaid popula-







tion. This highlights the challenges faced in the Medicaid population with respect to accessing care in a timely manner.

Compliance with injections was also an issue among some in our 17P group. Of the members whom we could verify compliance, 39% (34/88) showed noncompliance. There was 92% compliance in the Meis group. This may explain why we did not see the same decrease in preterm delivery rate that was demonstrated in the Meis study. However, when comparing to our own Medicaid member data, we observed a statistically significant decrease in rate of delivery at < 35 weeks and nearly significant decrease in NICU or SCN admission indicating that 17P does work in this population.

We did not note any statistically significant difference between outcomes of members who initiated treatment by 28 weeks versus members who initiated treatment by 21 weeks. Late initiation of treatment (up to 28 weeks) does not appear to diminish the effect of 17P. Other than offering 17P as a benefit, we are not aware of any external reasons that would have caused decreases in preterm delivery rate and NICU admission rate such as coding changes, changes in NICU admission or discharge criteria, or new interventions that decrease preterm birth. However, the majority of our 17P group members were case managed by a nurse (93.78%). The effect of OB case management is not addressed in this study.

Doctors continue to see declining reimbursement. They are seeing more patients in an hour, which means that there is less time available for education. This affects the adoption of new, important technology like 17P. Ideally, this counseling will occur early in pregnancy and again at 16 to 20 weeks. The window of opportunity for discussing and beginning 17P therapy might be missed, as there are other important antepartum events at this time (detailed ultrasounds of fetal anatomy and serum testing for chromosomal disorders). This early period is also at a time when a patient and her doctor may not be thinking about preterm labor and delivery. Most patients at risk will be asymptomatic. These are all additional reasons for a Medicaid patient to miss the opportunity to begin 17P therapy.

Interestingly, despite 17P being endorsed by ACOG in 2003 and 2008 for use in women who have had a previous premature birth (<37 weeks), we continue to see members who would benefit from 17P who were not offered this treatment by their physician. Despite educational efforts by our health plans and specialized reports that help to alert case managers and physicians about women who are potential candidates for 17P, utilization of 17P has not been maximized. The reasons for this lack of identification of potential candidates and initiation of treatment are not clear and need to be further explored.

CONCLUSION

Our five-year longitudinal review of birth outcomes in 193 pregnant women who had a history of preterm delivery and who were prescribed 17P, compared with a control group, showed a significant decrease in preterm deliveries and nearly significant decrease in NICU admissions for a managed Medicaid plan. The evidence provided by these results is consistent with those of the double-blind, randomized, placebo-controlled trial by Meis and colleagues (2003).

The use of 17P on a broader scale should be a strong consideration in treating high-risk pregnant women with a history of preterm delivery. Consistent, early identification and treatment of all potential candidates who could benefit from 17P pose a challenge despite overwhelming acceptance by ACOG.

Take-away points

17P is an important option for preterm birth prevention in women with history of spontaneous premature birth.This study shows the following:

- 17P can be successfully used in a managed Medicaid population despite issues with noncompliance, late initiation of treatment, and social barriers.
- As long as treatment can be initiated by 28 weeks, there does not appear to be a decrease in the effect of 17P.
- Active case management of members to help mitigate the barriers they face is important.
- Not all physicians are prescribing 17P despite the endorsement for use with premature birth prevention by ACOG.
- Consistent, early identification and treatment of all potential candidates who could benefit from 17P pose a challenge.
- We anticipate that in the future the office processes needed to identify and properly counsel 17P eligible patients will be as important as those that currently address abnormal Pap smears and mammograms.

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