OPTUM™

# Infertility: Advances in evidence-based research for consumers, payers and employers

White paper

Evidence-based infertility treatment increases success rates and reduces costs.

For many couples facing infertility, their efforts to create a family are fraught with frustration, anxiety and failure. Even when they succeed, some families continue to struggle as they manage a challenging array of costly medical issues, prevalent among twins, triplets or quadruplets.

Such struggles are common. Over the past few decades, women have increasingly postponed starting a family. But as they delay, their fertility window narrows. Fertility problems affect about one-third of women older than 35.[1] Now, about one in eight couples in their childbearing years experiences infertility — the inability to conceive after one year of trying — or six months for women over age 35.[2]

But it doesn't have to be this way. When a couple is supported by a team of infertility experts practicing state-of-the-art, evidence-based medicine, the outcome is more likely to be positive and less costly.

One of the keys, studies show, is seeking the most effective infertility treatment at the right time.

## IVF versus IUI

Since the late 1970s, intrauterine insemination (IUI) and in vitro fertilization (IVF) have been used to treat infertility. Until the late 1980s, both treatments yielded similar success rates. However, since then, medical advances have improved IVF protocols and procedures, nearly doubling the success rates for women younger than 40 who undergo IVF. Meanwhile, IUI treatment methods and success rates have remained the same.[3]

Case in point: Results from the Fast Track and Standard Treatment Trial (FASTT) study, a randomized study that evaluated the effectiveness of IUI and IVF in women under 35. Couples were selected for one of two treatment tracks. One group took the more traditional, step-by-step approach of three cycles of clomiphene (an oral drug used to stimulate ovulation) and IUI, three cycles of injectable, follicle-stimulating hormone (FSH) and IUI, and up to six cycles of IVF. The other group received an accelerated treatment that omitted the three cycles of FSH/IUI. In short, the accelerated treatment group got to IVF faster.

"What they found was that pregnancy rates were actually better going straight to IVF," says Dr. Alexander Dlugi, a reproductive endocrinologist and Optum medical director of reproductive services.[4] "Time to pregnancy was shorter and the number of multiples was lower. This study changed the paradigm by getting people to IVF sooner rather than later. A follow-up study, called the FOUR-T trail, looked at women 40 and over and basically came to the same conclusion."[5]

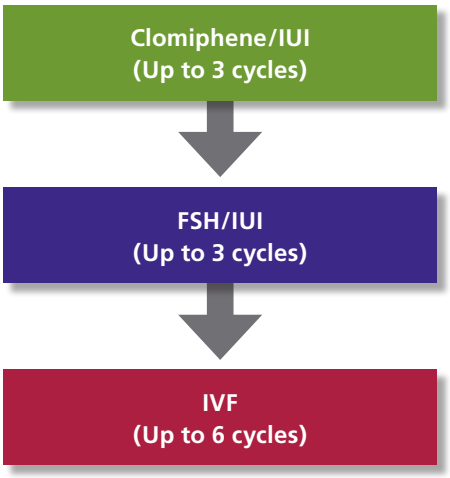
Many providers, including the Optum Centers of Excellence infertility specialists, embrace these findings as good medicine. Patients and health plans are often a bit harder to convince. "The problem is that IUI is perceived as low-tech and low cost," says Dr. Dlugi.

Patients also may harbor unrealistic hopes about the effectiveness of IUI, believing that it will help them conceive, despite conditions that suggest otherwise. And so couples undergo numerous cycles of IUI.

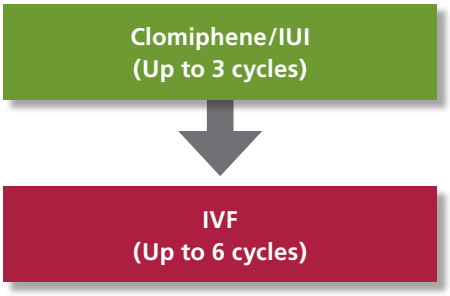
"Unfortunately, the odds are stacked against them," says Dr. Dlugi. "The data show that for a woman under 38, or over 38 after she's completed four such cycles,

### The Fast Track and Standard Treatment Trial (FASTT)[4]

**Traditional track**




**Accelerated track: Higher pregnancy rates, shorter time to pregnancy, lower risk of multiples**



the likelihood of it working starts to diminish very significantly. While someone could conceive on the twentieth IUI cycle, the likelihood is extremely low. Looking at the cost per cycle and success rate, one must conclude, as shown by the FASTT trial and the FOUR-T trial, that at some point in time, continuing with this so-called conservative treatment doesn't really make sense. IVF offers better pregnancy rates and can lower multiple births when used appropriately."

## The couple's dilemma

"Unfortunately, patients often feel they have no choice but to try IUI," says Barbara Collura, president and CEO of RESOLVE: The National Infertility Association. "They want to be a parent. They may understand that IVF is the gold standard of treatment, but they can't afford it or their insurance won't cover it." Ms. Collura says many women seek infertility treatment from their OB-GYN rather than a reproductive endocrinologist. If insurance won't cover IVF or won't cover it unless the patient tries IUI first, the OB-GYN may suggest they try IUI. The couple is going to take the treatments available to them — even if it's not the best option for them.

Clouding their decision-making are the storm of emotions associated with a diagnosis of infertility. "When a couple is told they need infertility treatment, their life plan is altered," says Ms. Collura. So in addition to managing the infertility treatments, the couple may be in emotional turmoil. "Their vision of starting a family is threatened by a diagnosis that affects couples in an intensely personal way," adds Collura. "This is why it's so hard to share their anxiety with family, friends and colleagues."

## The risks of multiple births

Once a couple begins infertility treatments, in their eagerness to have a baby they may be unaware or not fully comprehend the risks associated with multiple gestations. IUI in conjunction with ovarian stimulation is associated with an increased chance for multiple births.[6]

Yet with only limited information — and inadequate time to process and understand it — some parents may want multiple births. And they may mistakenly think they can use IVF to help create them.

"Imagine the patient who has limited resources and infertility benefits," says Dr. Dlugi. "She's going through in vitro fertilization treatments and thinking, 'I can only go through this once, maybe twice, if I'm lucky.'" Twins, even triplets, would be fine, they believe, especially for those struggling to start a family."

But the health risks with multiple births are considerable for both mother and baby. And so are the costs of treating them. (See sidebars "Multiplying health risks" at right, and "Average newborn admission cost by delivery size" on page 4.)

"As health care professionals, we need to take the time to educate and inform our patients to understand why, under appropriate clinical circumstances, the transfer of a single embryo produces the best outcome: a single, healthy baby," says Dr. Dlugi, who has more than 30 years of experience in the field. For the past four years, as medical director at Optum, he has worked with Centers of Excellence providers, health plans and would-be parents.

In fact, a recent study by researchers at the U.S. Centers for Disease Control and Prevention suggests that a substantial reduction of higher-risk, multiple births (both twin and triplet or higher order) could be achieved by greater use of single embryo transfers among favorable and average prognosis patients and surrogates under age 35.[7] There is also increasing evidence that an elective single embryo transfer is effective for older women with a favorable prognosis.

### Multiplying health risks

Being pregnant with more than one fetus increases the health risk for mothers and babies.

**Health risks for mothers:**

- Preeclampsia (pregnancy-induced high blood pressure), which can cause preterm birth, seizures and in extreme cases, death
- Gestational diabetes
- Hemorrhaging before and after delivery
- Preterm delivery

**Health risks for preterm babies:**

- Underdeveloped lungs, stomach and bowels
- Immature nervous system and delayed development
- Movement disorder and cognitive impairments
- Long-term, physical and behavioral challenges and disabilities

Source: American Society for Reproductive Medicine. Fact sheet. asrm.org/FACTSHEET_What_do_I_need_to_worry_about_with_a_multiple_pregnancy/

## The Centers of Excellence approach

At Optum, our Centers of Excellence[8] (COE) network of providers subscribes to this evidenced-based approach and adheres to our clinical guidelines. Optum COEs are carefully selected and continually evaluated, says Nancy Harrington, RNC-REIN, a specialty-certified, reproductive endocrinology and infertility nurse who serves as director of network strategy and development for Optum infertility solutions. Along with Dr. Dlugi, Harrington works closely with the providers in our COE network.

"Having over 25 years in the infertility arena has allowed me to be very familiar with the doctors who participate in our COE network," says Harrington. "We are able to meet and discuss clinical best practices with providers on a regular basis. These relationships allow us to review their clinical outcomes and have a dialogue about current clinical models and trends. The providers appreciate the opportunity to speak with clinicians who understand the technology. They are welcoming of our suggestions and feedback because we understand the science."

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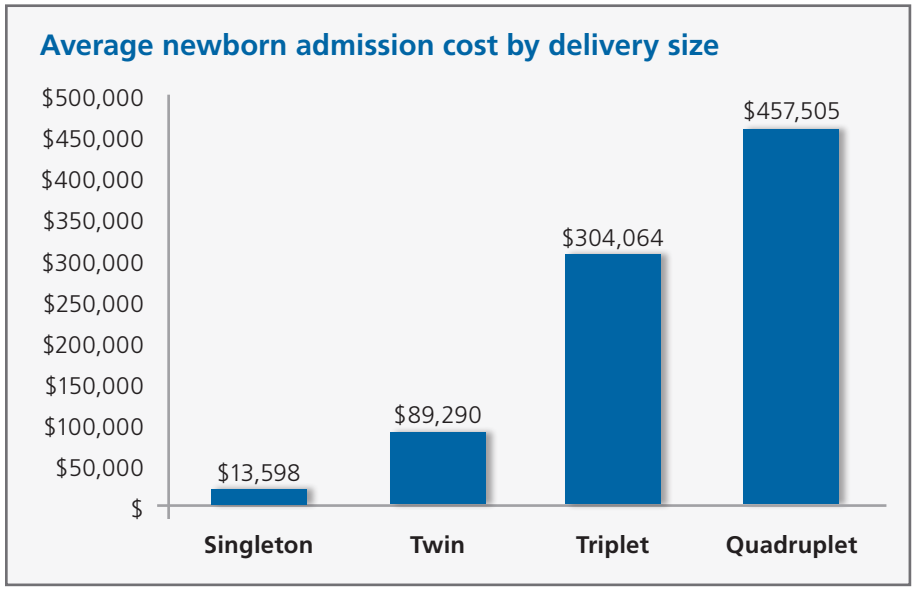
– Nancy Harrington, RNC-REIN, Optum

Suggesting that patients see COE physicians improves their chances for having a healthy baby — an outcome that benefits the baby, mother and health plan. Because they follow evidence-based clinical guidelines, our COE facilities offer higher rates of single gestation.

## Multiplying costs

"Multiples are more likely to require long stays in the neonatal intensive care unit (NICU), which increases costs. It's important for employers and health plans to connect the dots between the cost of the infertility benefit and the significant savings on the maternity and neonatal side," says Dr. Dlugi.




Source: Analysis of UHC claims data for 5,592 births 2011–2014 (3,906 IVF and 1,986 IUI), 2/20/15. Rich, 4/14/15.

## Compassion and knowledge

Optum takes the whole patient profile into consideration, says Nancy Harrington. "Some of our patients have probably already done surgery. They may have had miscarriages. They've been prescribed medications by their OB-GYN. They need so much support, so much hand holding and so much scientific knowledge. That's why I'm so passionate that they need to be with the best providers they can be with."

As part of Optum infertility solutions, patients work by phone with nurses who are former IVF coordinators. They understand the clinical terminology and evidence-based medicine, and can explain it in a way patients understand it. Harrington notes that managing infertility medications can be very complicated and confusing. "You might get a box of 14 medications, nine of which need to be injected," she says. "Our infertility nurses — along with our COE providers and backed by our medical director — are well equipped to walk patients through the process of managing these highly specialized medications and treatments."

"Combined, our nurses have 240 years of infertility nursing experience behind them," adds Dr. Dlugi. "They truly understand all of our guidelines, what they mean and how to apply them. I have seen wonderful feedback from our members about them and how truly supportive they have been in helping guide patients to the right care. I think they're awesome."

### A member's story

"Going through these infertility treatments is a major challenge … We have had our ups and downs over the years. We are about to try for our next child with IVF and my husband and I do not discuss these treatments with family or friends; we keep it very private. Speaking with the Optum infertility nurse was the first time in my life that I was able to release a lot of tension and openly talk about issues. I thank you so very much … for the wonderful comfort that I have with this program."

## Conclusion

Among large employers, 68 percent offer some type of reproductive assistance as part of their insurance plan. This may include evaluation by an infertility specialist, drug therapy, IUI and/or IVF, among other treatments. Why offer infertility benefits? The most common reasons employers cite are:

- Gain a competitive edge for talent
- Decrease the rate of multiple births and associated costs
- Support employee family building
- Promote high-quality, prenatal care[9]

In addition, 15 states mandate some form of infertility coverage. Fully insured health plans abide by state mandates; self-insured plans follow federal law and are exempt from state mandates. The problem is some state mandates may be inconsistent with the most recent evidence-based medicine. And this scenario can potentially lead to ineffective treatments, frustrated and disheartened members, higher odds of multiple gestations.

However, as employers and health plans begin to make the connection between evidence-based medicine, better outcomes and lower costs, the life-altering condition of infertility will be better managed. "Within our managed infertility program and among our Centers of Excellence, we have changed the paradigm for treatment," says Dr. Dlugi. "We've developed evidence-based clinical guidelines, we are educating consumers and the providers, and we're guiding folks to the best care in practice."

And with about 20 percent of women in the United States having their first child after age 35, the challenge is not insignificant.[10]

## Contributors

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Notes

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8. The Centers of Excellence (COE) program providers and medical centers are independent contractors who render care and treatment to health plan members. The COE program does not provide direct health care services or practice medicine, and the COE providers and medical centers are solely responsible for medical judgments and related treatments. The COE program is not liable for any act or omission, including negligence, committed by any independent contracted health care professional or medical center.
9. Mercer. National survey of employer-sponsored health plans. June 2014.
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