



On the Bleeding EDGE

Regenerative Medicine Sparking Interest, Controversy

Cutting-edge medical treatments delivered through specialized national networks and centers of excellence can elevate both self-funded medical plans and workers' compensation programs in a multitude of ways. For starters, they present an opportunity for greater control over potentially huge catastrophic claims. But they also can improve health outcomes relative to surgical and pharmaceutical interventions, as well as save lives.

The emergence of regenerative medicine is one such promising area, with the Stem Cell Therapy Network and National Marrow Donor Program helping lead the way. Demand for cellular and platelet-rich plasma (PRP) therapies is exploding as they target a myriad of injuries. And while some people are fortunate enough to find a genetically matched donor in their family for a marrow or cord blood transplant, 70% do not and can use outside assistance.

But federal regulators, researchers, health insurers and medical providers are reacting cautiously or skeptically to this trend, which is seen as largely experimental and unproven compared to remedies in mainstream medicine. Some have even gone as far as equating it to quackery.

In spite of this reaction, several industry insiders encourage self-insured employers to take a closer look at these alternative treatment options, which they say can pay tremendous dividends down the line.

All Eyes on ROI

With these procedures considered “investigational” by health insurers, self-insured employers enjoy the freedom to decide on coverage terms without having to wait on reluctant carriers, explains Jason Hellickson, president of Harborview Healthcare and the Regenerative Orthopedic Institute, whose ROI acronym is telling.

Describing the potential ROI as being in the thousand percentiles, he notes that there’s no additional cost to these treatments. In other words, it’s all pure savings. And he says they have saved employers anywhere from 70% to 85% compared to with orthopedic surgical costs.

Another huge advantage is “substantially lower permanency ratings for work comp claims, which ultimately provides a much lower impairment for that injured employee and which means you’re getting a better result,” Hellickson adds.

These savings square with a study by the National Business Group on Health, which he says found a 50% to 80% reduction in

orthopedic costs for employers within their workers’ comp and health plans related to regenerative medicine. What’s so significant in his mind is that orthopedic costs are among the top five expenses for any large employer and generally account for 80% or more of overall workers’ comp injuries. He says these savings can quickly add up to millions each year.

Beyond the potential for significant annual savings, he also mentions better health outcomes tied to a non-invasive, less painful procedure, as well as much less downtime. “In essence,” Hellickson explains, “surgery damages tissue to repair tissue, whereas we are able to help the body heal the tissue.”

Self-insured employers that use regenerative medicine or cellular therapy can save in several ways, according to **Morgan Pile**, director of business development at the Strategic Cellular Therapy Network, a regenerative medicine consulting program, as well as founder of Arkansas Stem Cell Therapy and a global consultant at Willis Towers Watson.

One example is (PRP) therapies that return workers’ comp claimants with ligament tears to work quicker and keep them off highly addictive pain medications. He cites significant savings ranging from 70% to 90% relative to surgical procedures requiring up to six months of pain injections.

Like Hellickson, Pile is bullish on the potential for improved outcomes.

“I’ve seen hundreds and hundreds of patients with severe osteoarthritis in the knees do better, get out of wheelchairs,” he says. *“So the growth factors are very important for healing and regenerating some of these injured tissues and restoring the blood flow is the key component of what regenerative medicine is all about.”*

Pile credits Regenexx for taking the lead on helping incorporate regenerative medicine into group health plans, which can be as easy amending summary plan descriptions to allow for PRP. “It could be a covered treatment through these specific modalities,” he explains, also noting the potential to treat occupational injuries.

He knows of at least eight Regenexx cases from employers whose savings surpassed \$250,000, but believes that’s only the tip of the iceberg. For example, he notes the potential for \$34 million in first-year savings for treating state of Arkansas employees. The estimate was based on just 40% or 50% of that population using regenerative medicine instead of surgical treatments that were actually paid in 2013 for knee replacements, knee and shoulder scopes and spinal fusion.

The broad application of cellular therapy across numerous diseases means this portion of the nascent regenerative medicine market could generate anywhere from \$20 billion to \$100 billion in the next five to 10 years. The prediction was made by Michael Boo, chief strategy officer, administration and business development for Be the Match, which runs the National Marrow Donor Program. But for now, he says it’s largely confined to one or two licensed products with much left to prove in the eyes of skeptics.

“Everyone is cautious about making sure that even if the treatment works, there’s not any untoward complications as a result of that,” he explains.



Healthy Skepticism?

Stem cells have been used or considered to treat cancer, blood immune disorders, congestive heart failure, lung disease, glaucoma, muscular dystrophy, ALS, Parkinson's, Alzheimer's, multiple sclerosis, traumatic brain damage and autism. Other applications include orthopedic issues, arthritis and joint pain, as well as treatments for drug addiction, kidney function and even face-lifts and erectile dysfunction. In addition, clinical trials have shown promise for wound healing, improved heart function and scleroderma.

A bone marrow or cord blood transplant is used to treat or potential cure leukemia, lymphoma, sickle cell anemia and many other diseases. More than 25,000 people worldwide have received cord blood transplants thanks to baby umbilical cord blood donations.

But the experimental and untested nature of such treatments has

generated a tempered response among clinicians, researchers and federal regulators. The Food and Drug Administration (FDA) has proposed requiring medical clinics that use stem cell therapies to undergo a rigorous approval process that includes showing evidence of their safety and efficacy. A public hearing on the matter was scheduled for April.

Physicians and researchers alike have long pressured the FDA to rein in unproved therapies. Leigh Turner, Ph.D., a bioethicist at the University of Minnesota, is surprised clinics that use stem cells have been allowed to grow so rapidly. "If it's not safe and it's not going to help patients, it's just predatory behavior," he told STAT, a publication that examines the frontiers of health and medicine.

However, proponents of such treatments are crying foul. The federal government is overstepping its authority by potentially "interfering with the patient's right for treatment and, in the case of autologous cells, placing restrictions on a person's own healing capacity," according to Brad Fullerton, M.D., president of the American Association of Orthopedic Medicine.

David L. Harshfield, Jr., M.D., a diagnostic radiologist and adviser to the Strategic Cellular Therapy Network, noted in a recent e-mail that "there have been no serious adverse events attributed to the administration of approved cellular medicine products. This negligible complication rate speaks volumes about the safety of these procedures, particularly compared to the increasing, often devastating complications related to dangerous pharmaceuticals and surgical procedures."

Pile is mindful of the tremendous power wielded by pharmaceutical and health care lobbyists who see their businesses threatened by regenerative medicine. In contrast, he says a group like the International Cellular Medicine Society is funded

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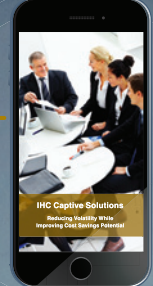
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by a handful of doctors who are trying to do the right thing. "Think about 90% of surgical treatments being eliminated because these treatments can work that well if done correctly," he observes.

Need for Early Intervention

Whatever ends up happening with regenerative medicine's place within the health care community, timing is a critical ingredient to its success. These treatments are effective only with early intervention, according to Boo.

"We've seen often where patients go through the first or second remission for their cancers without being offered a transplant," he notes. "And the science clearly shows that, in many cases, early access to transplant is good for the patient, but it's also good for the economics, because repeated rounds of chemotherapy followed by a transplant, is unsuccessful and costly for patients."

He says another key message is a need for reasonable benefits that include reimbursement of travel expenses, good access to pharmaceuticals and after-care program management following each transplant.

Be the Match's national registry includes more than 12.5 million Americans and up to 25 million worldwide who are willing to donate peripheral blood and bone marrow, as well as cord blood units, for allogeneic or non-own cell source transplantation. It also connects with registries around the world to broaden the search for a match and has banked 209,000 cord blood units. A donor's immune system is able to remain strong because just 1% to 5% of marrow is needed to save a patient's life.

Boo says outcomes data from various organ transplant centers are published

to help employers and insurers build provider networks, as well as patients compare treatment options pertaining to their specific disease.

The program arranges for transplants by paying hospitals for collection and physicians for patient physicals, as well as testing for infectious disease markers. The cost of a typical blood or marrow donation is about 15% to 20% of the total transplant cost. Network operators, such as Optum and Allianz, negotiate prices with primary or third-party insurers, or benefit managers.

Traveling for Treatment

Greater interest in regenerative medicine is expected in the years ahead. "I think there's enough demand for any one of our clinics in any city the size of Des Moines, Iowa, or bigger," Hellickson says. "But there are not enough doctors to meet that demand requirement."



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His interest in the topic began as an investor who was interested in an alternative to shoulder surgery he was facing. "I knew that it had great potential," he recalls.

Patients are showing a willing to travel for life-altering treatments, according to Pile. He mentions Gordie Howe and Bart Starr as examples of "recent celebrity athletes that went to Mexico on death's door and are now standing up and speaking at conferences again in less than a year. It's absolutely incredible and saved their lives."

Promising and affordable treatment options are now available worldwide. Thailand and Singapore are on the cutting edge of regenerative medical treatments offered at deep discounts, according to Nigel Wallbank, president of New Horizon Insurance Solutions who also chairs the Self-Insurance Educational Foundation. For example, he says a Bangkok hospital suite with 24-hour nursing is only \$350 a night "as opposed to Lord knows how high it would be here."

His knowledge of this topic dates back to the 1980s when he started an organ transplant network that became the nation's second largest at that time and was later sold to JPMorgan Chase and then Aetna. After that, he waded into the cancer arena to help combat widespread misdiagnoses and inappropriate treatments.

An aging workforce that has become increasingly savvy about its treatment options appears to be driving interest in regenerative medicine. Research suggests alarming rates of failed knee and hip replacements, as well as spinal surgeries, Pile says. And when coupled with mounting frustration over prescription drugs that simply mask the pain associated with these procedures, patients are motivated to learn about alternative options.

"The baby boomers are seeing what's going on with their parents, even with these diseases and Alzheimer's and they don't want that to happen to them," he

explains. But with only about 2% of the world's population familiar with regenerative medicine or cellular therapy, Pile says education is necessary to help advance these options.

Another challenge is dispelling myths. For example, he notes that roughly half of patient marketing materials in the U.S. portray these treatments as illegal or a threat to unborn lives as seen with discussion about removing stem cells from human embryos. When skeptics are told that regenerative medicine is simply a matter of using a person's blood and body fat to help people heal, he sees understanding taking shape. Pile would like to see a grassroots movement to educate patients about these treatment options and help the U.S. play a leading educational role. ■

Bruce Shutan is a Los Angeles freelance writer who has closely covered the employee benefits industry for 28 years.

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