

# Biologics, Cell Therapy and Regenerative Medicine

There has been a lot of public interest in various medical treatments known by many names; stem cell, mesenchymal cell and embryonic cell therapies. A recent national oversight committee decided to refer to all these therapies as “cell therapy”. These therapies are based on the possibility that these more immature cells can work to improve or heal certain conditions such as arthritis, tendonitis, muscle injuries or tendon tears.

Solid proof of the effectiveness of these therapies is limited. Many of these therapies are being offered based on potential rather than proven effectiveness. The FDA has given approval to certain of these therapies from a safety standpoint.

These cells typically come from the patient’s own blood, bone marrow or fatty tissues. Other donor tissues (amniotic products) are also used. These cells can then be minimally manipulated to enhance their properties. These manipulated cells are then injected into the target area, hopefully enhancing the healing response. The risks of bleeding, infection, nerve damage or increased pain is small. Safety data at this point shows no increased risk of cancer or other diseases from cell therapy.

Since insurance carriers still consider these therapies as experimental, there is no insurance coverage. Patients will be expected to cover the cost out of their pocket. The OrthoCarolina price is designed to cover our costs. These costs include those associated with a study trying to answer the question of the effectiveness of the treatment.

OrthoCarolina wants to offer these new therapies in a responsible manner. Our hope is that this type of treatment may help certain select patients with certain orthopedic problems. The more selective we are in offering these therapies, the more likely the therapy is to be successful. OrthoCarolina is focused on value based health care. This means that we weigh the costs and risks of a treatment against the likelihood of success, to decide on the appropriateness of a treatment. OrthoCarolina utilizes medical studies which are of the highest quality to determine if a therapy might be of benefit to our patients.

OrthoCarolina is also participating in its own studies to help answer the question of cell therapy effectiveness. OrthoCarolina has developed a patient registry to follow you during your regenerative medicine process and to assist in collecting information on how you are feeling. The registry will communicate with patients through email. The information will be kept private and only used for OrthoCarolina research. It is important for patients to complete the emailed questions/forms BEFORE and AFTER your regenerative medicine injection. There will be periodic emails with questions after your injection.

If the patient has a history of bone marrow derived cancer (lymphoma), blood derived cancer (leukemia) or non-bone marrow cancer or metastatic disease, the patient should discuss the proposed injection with their oncologist. An active infection is a contraindication for cell therapy treatment.

Regenerative Medicine is a promising, yet still evolving field. Your OrthoCarolina provider cannot guarantee success with any cell therapy. It will be important for you to discuss with your OrthoCarolina provider if a cell therapy may be appropriate for you.

**YOU. IMPROVED.**

OrthoCarolina