Strange Science - New, Unorthodox & Odd Treatments Seen by Claims Professionals

Amanda Waltemath, PharmD, MPH

The Clinical Services department is here to help and encourages claims professionals and case managers to contact us with questions. From time to time, we are asked about new, somewhat unorthodox and sometimes zany treatments purporting claims of efficacy that seem too good to be true. If it sounds too good to be true, it probably is.

Here are some highlights of recent inquiries along with our research findings on what works, what doesn’t – and what’s so odd it often leaves us scratching our heads.

**AmnioFix for Musculoskeletal Injury**

**Treatment Claim:** Advertised to reduce inflammation in tendon and soft tissue caused by injury.

**About the Therapy:** AmnioFix is an injectable human amniotic membrane created by MiMedx, who claims it decreases inflammation and reduces the formation of scar tissue. The product is processed from human tissue and is not regulated by the FDA.

**Treating Opioid-Induced Constipation**

Constipation is a common side effect of taking opioid pain medication. It can become a serious problem if not treated immediately. An appropriate daily bowel regimen should be included as a preventive measure when opioids are prescribed, but it should be noted that they are not always effective.

- The recommended preventive treatments are inexpensive, over-the-counter products including senna or bisacodyl tablets.
- Including a stool softener with the stimulant laxatives is often useful.
- Docusate is the most commonly used agent.
- Bisacodyl suppositories, polyethylene glycol, sorbitol and lactulose may also be used.
- If constipation develops, there are several prescription choices, including methylnaltrexone (Relistor®), administered as a subcutaneous injection, and lubiprostone (Amitiza®), available as an oral capsule. Naloxegol is now in clinical trials to treat constipation in patients using opioids. Its benefit is that it can be taken with the patient’s current opioid therapy because it selectively blocks the opioid stomach receptors but not the body’s opioid pain receptors. This means that patients can experience pain relief and avoid the constipating side effects of opioids.
Data: No data exist to support efficacy. The manufacturer cites articles related to dental and ophthalmic use but offers none related to musculoskeletal injuries. The references reviewed were either small animal studies or case reports; no valid studies have been done.\(^2,^4\)

Standard Therapy: NSAIDs, acetaminophen and other analgesics are most commonly prescribed for musculoskeletal injuries accompanied by neuropathic co-analgesics in some cases.

Recommendation: Stick with standard therapy

**Platelet-Rich Plasma for Wound Healing Post Orthopedic Surgery**

Treatment Claim: Platelet-Rich Plasma (PRP) injections have been investigated and used as a clinical tool for treating nerve injury, tendinitis, osteoarthritis, cardiac muscle injury, bone repair and regeneration, plastic surgery, oral surgery and sports injuries in professional athletes.

About the Therapy: Professional athletes are the best known users of platelet-rich plasma (PRP). Once banned by the World Anti-Doping Agency, PRP was removed from the ‘prohibited’ list in January 2011 due to lack of evidence that it enhanced performance.\(^5\) The treatment involves concentrating the patient’s own platelets and injecting the enriched plasma at the site of injury. Activation releases growth factors with demonstrated wound-healing properties. The theory is that a higher platelet count will speed recovery and tissue repair.

Data: While the use of platelet-rich plasma may be trending upwards, it is not based on strong evidence. Studies demonstrated that use of platelet-rich plasma carries no clinical benefit over placebo.\(^6\)

Standard Therapy: NSAIDs, acetaminophen and other analgesics are most commonly prescribed for musculoskeletal injuries accompanied by neuropathic co-analgesics in some cases.

Recommendation: Stick with standard therapy

**Autologous Serum Eye Drops for Corneal Damage and Dry Eye**

Treatment Claim: The clear fluid part of a patient’s blood, called serum, is thought to replicate the biochemistry of natural tears. It contains components not found in artificial tear products that protect against infection, fight bacteria, support growth and boost the immune system. Claims professionals have seen these eye drops prescribed for corneal damage and dry eye.

About the Therapy: Autologous serum eye drops are made by diluting a patient’s serum with a sterile salt or other solution.

Data: This is not FDA approved. The solutions used to dilute the serum differ, and studies reviewed did not compare the use of other preparations with the autologous drops.\(^7,^8,^9\) There appears to be some clinical evidence to support the efficacious use in this instance, however it is still considered an investigational use.

Standard Therapy: Artificial tear drops
Recommendation: Caution is advised when using any compounded product. Scrutiny of the facility and compounding procedures is strongly recommended as eye drops must be sterile and there have been many instances where patient harm has occurred with contaminated compounded products.

Fecal Transplant to Treat \textit{C. difficile}

Treatment Claim: Fecal microbial transplant (FMT) — more commonly known as fecal transplant — has been used to treat antibiotic-resistant \textit{C. difficile} infections (\textit{C. diff}). While this is rarely seen in workers' compensation, the increasing prevalence of \textit{C. diff} infection puts hospital patients and healthcare workers at risk.

About the Therapy: Healthy stool is extracted from a donor and screened for HIV, hepatitis and other communicable diseases and the presence of pathogenic bacteria or parasites. The donor stool is transmitted to the recipient via enema, nasogastric tube or colonoscopy. To eliminate the awkward process of finding a donor, physicians in Canada developed synthetic stool. The synthetic product is called \textit{RePOOPulate}\footnote{honest!}.

Data: Studies have demonstrated that FMT is extremely effective at treating \textit{C. difficile} infections.\footnote{11} The success of FMT comes with a new focus on the regulations surrounding it. The Center for Biologics Evaluation and Research recently determined that fecal microbiota is considered a biologic product and falls under FDA regulation.

Recommendation: Since FMT is not approved for any indication – and will require clinical trials to gain such approval – any use requires a physician to submit an investigational new drug application, significantly restricting patient access.\footnote{12}

References:


References for Treating Opioid-Induced Constipation:


The contents of this document are for informational purposes only. It is not a substitute for a medical exam, nor does it replace the need for services provided by a medical professional. The information provided in this document is not intended to diagnose, treat or cure. Every effort has been made to provide accurate, up-to-date and complete information, but no warranty or guarantee is made to that effect. Healthesystems is not liable for any direct, indirect, consequential, special, exemplary, or other damages arising from the use or misuse of any material or information provided in this document.

This document contains proprietary and confidential information of Healthesystems. Such proprietary information may not be used, reproduced, or disclosed to any other parties for any other purpose without the express written permission of Healthesystems.

©2012 Produced by the Healthesystems Clinical Services Group. A product of the Healthesystems Vigilant Rx clinical program.