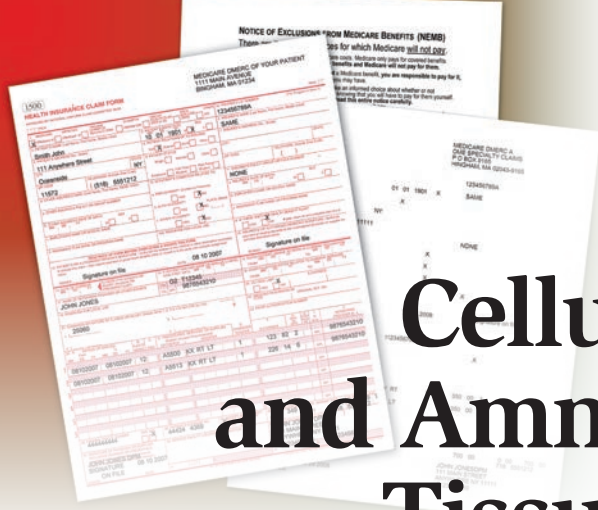

Cellular Tissue and Amniotic/Placental Tissue Products

Medicare no longer covers these for musculoskeletal conditions.

BY PAUL KESSELMAN, DPM

Over the last few years, there has been an explosion of use of cellular tissue and amniotic/placental tissue products for a myriad of conditions. Many of the successful applications (before the CMS committee responsible for approving new HCPCS codes) are for these "biologic" products. The acquisition costs and reimbursement for many of these are significant, making the denial of or post-payment recoupment of one claim a significant economic impact on your practice. This month's column will summarize the recent experiences of amniotic/placental products for musculoskeletal conditions.

Whether used for wounds or musculoskeletal (MSK) conditions, amniotic/placental products clearly have the potential to reshape medicine in ways that are still not well understood.

Preliminary studies a decade or so ago provided evidence that amniotic/placental tissue products afforded wound closure rates not achievable with standard or advanced wound care techniques. Many colleagues also began using embryonic products for MSK conditions that often did not respond to other traditional therapies such as PT, orthotics, NSAIDs, and steroid injections. For both wound care and MSK conditions, the results for many were astounding, and so began the expansion (and in the eyes of some insurance companies the abuse) of the use of these products.

In addition to podiatry, other specialties using amniotic/placental tissue include but are not limited to oncology, GI, neurology, immunology, pain management and orthopedics.

Many Medicare and third-party carriers initially embraced these products and afforded assurances of coverage of these products, either based on medical necessity or written into the LCD (the latter exclusively for wound care) or local coverage articles. Verbal and written assurances were received from certain carriers and offered to many providers that coverage for MSK conditions were also covered for routine MSK conditions such as plantar fasciitis, bursitis, etc. that had not responded to the usual potpourri of traditional medicinal therapies. Despite acquisition costs exceeding one thousand dollars, practitioners saw reimbursements often exceeding twice their costs.

Many in the insurance industry saw the use of these products for wounds, while expensive, still effective deterrents to more expensive limb amputation.

Because the use of embryonic placental-based products was not written into the LCD for treatment of a variety of MSK conditions and with carriers' costs skyrocketing, a variety of Medicare contractors initiated post-payment HCPCS-based recoupment demands. As with DME services, many providers did not adequately document the failure of other treatments. Others who did still face recoupments with the potential to bankrupt a practice because carriers decided amniotic/placental tissue injections were investigational.

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Due to the sheer numbers or providers (not just podiatrists) subject to these post-payment recoupments, as well as due to the previous assurances by carriers, an eventual agreement was reached with CMS (and other carriers) not to universally or automatically recoup money based solely on the pricing or HCPCS code. However, CMS (and others) insisted that they retained the right to pursue

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post-payment recoupment based on a claim-by-claim chart analysis.

Currently, providers who are subject to recoupments for the use of amniotic/placental products (almost exclusively prior to 2022) have only to meet reasonable and necessary requirements to document medical necessity for their use for MSK conditions (see below).

Richard Silverstein, DPM did have such documentation and successfully appealed against pre-payment denials at the third level of appeal, the Administrative Law Judge (ALJ). This practitioner provided written documentation proving he had worked with policy writers at their carrier to substantiate the use of embryonic and placental tissue injections as reasonable and necessary. This is a requirement for substantiating coverage when neither an LCD nor NCD is in place. That is, the procedure is: safe and effective, not experimental, or investigational and appropriate for Medicare patients.

Most practices may not have been as successful because they lacked the above documentation from a carrier official, did not possess the supportive literature or the skills necessary to navigate through the appeals process, and/or failed to obtain professional assistance with their appeals.

As with all third-party pre- or post-payment audits, practitioners should seek out professional assistance from medical and legal experts in the field. This is often available through the practitioner's professional liability carrier which offers Administrative Defense Coverage.

Effective April 30 2023, CMS instituted an LCD (L39128) which can be found through the MCR LCD National Database at:

https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39128&ver=7.

This policy currently excludes coverage for amniotic and placental derived product injections for MSK non-wound conditions effective April 30, 2023.

Thus, it is imperative to understand that those providers wishing to continue to provide embryonic and placental derived product injections for MSK conditions must educate their patients about non-coverage and self-pay. That is, patients must understand they are fully financially responsible for payment for any injection of amniotic/placental tissue grafts for MSK conditions.

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To comply with proper notification of non-coverage and self-pay requirements for insured patients, the following documentation requirements are suggested:

1) When treating a fee-for-service Medicare patient, obtain a properly executed Advanced Beneficiary Notification (ABN). Cite the LCD39128 and be very specific with your verbiage.

2) For Medicare Advantage and commercial insured patients, denial of prior authorization or denial of pre-determination of benefits needs to be documented. Provide patients with such documentation and require them to sign a financial statement of responsibility.

3) Because of the uncertainty as to whether embryonic or placental tissue products are FDA-indicated for the MSK condition being treated, an off-label consent may be warranted. Consult your professional liability carrier as they may have this form in their resource library.

4) Cite failed previous treatments provided and your rationale for use of amniotic or placental-based tissue products.

Summary

Amniotic/placental-based tissue products offer an additional option for many MSK conditions which are otherwise refractory to traditional therapies. However, due to both their high acquisition costs and reimbursements, Medicare as well as other third-party payers have conducted post-payment audits for dates of service prior to 2022. This has successfully resulted in large recoupments, with some practices facing potential bankruptcy. Widescale retribution for successfully appealing lower-level adverse outcomes is largely unheard of.

In the absence of an LCD, proper documentation of reasonable and necessary, and correspondence with your third-party payer confirming coverage, is suggested to successfully defend against future recoupments. As of April 30, 2023, Medicare has an LCD excluding coverage for amniotic/placental tissues for MSK conditions. When either an NCD or LCD excludes coverage, further steps documenting patient financial responsibility is essential. **PM**

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Dr. Kesselman is board certified by ABFAS and ABMSP. He is a member of the Medicare Jurisdictional Council for the DME MACs' NSC and provider portal subcommittees. He is a noted expert on durable medical equipment (DME) and an expert for Codingline.com and many third-party payers. Dr. Kesselman is also a medical advisor and consultant to many medical manufacturers and compliance organizations.