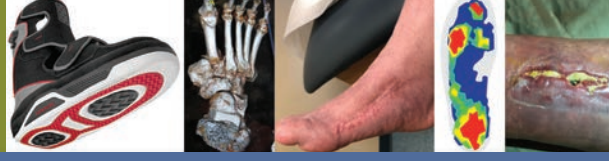

CMS' Challenge to Cellular Tissue Products

Proposals to cut reimbursements threaten wound care.

BY PAUL KESSELMAN, DPM

In late July 2022, CMS published for comment the preliminary Medicare Physicians Fee Schedule for 2023. Along with a proposal to drastically reduce the conversion factor for 2023, thereby reducing reimbursements, Medicare is now proposing a significant shift in how cellular tissue products are to be covered starting in 2024. This article will provide a brief overview of how these products are reimbursed today and Medicare's proposal for their reimbursement in the future.

Presently, Medicare and most third-party payers reimburse office-based providers for cellular tissue products based on a complex formula of allowances, known as the ASP (average sale price) which is updated quarterly. Medicare allows a 6% markup on the ASP. Each FDA-approved and HCPCS granted product is typically billed on a unit basis (per cm) and is billed with the appropriate "Q" code. Additionally, the following modifiers are amended to the designated "Q" code: (KX) meets the LCD requirements, JC (material applied as a graft), and JW (amount discarded). The number of units is billed separately for the JC and JW amended claim line. Providers are allowed approximately a 1 cm border on all sides of the wound and are instructed to order the smallest possible material-sized graft to minimize wastage.

Hospital and outpatient departments which purchase these products currently do not have the luxury of billing in this fashion and are pigeonholed into a low or high-cost bracket depending on the product purchased. Additionally, in either scenario the surgeon bills for the application based on two factors, the site and size of the wound, which is reflected by a myriad of CPT codes.

The frequency of application is usually set by the LCD and attached policy articles depending on the specific cellular tissue product. Presently, cellular tissue products have their own designation which is not shared by surgical dressings, standard surgical supplies used in wound care, or NPWT soft goods. All of these are designated into their own separate categories.

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The preliminary 2023 Medicare Physicians Fee Schedule proposes to change much of the above for the office-based physician. Starting in 2024, the proposed changes include:

1) All of the above noted wound care products will now be referred to as wound care management products. This proposal would now place all products no matter their expense or sophistication into the same product category. That is, surgical dressings and cellular tissue products would be considered in the same product category.

2) A Diagnosis Related Group (DRG) effect will be employed to pay a single lump sum for management of a wound with currently employed "Q" codes products, having their designations changed to an "A" code.

3) The effect of changing products from a "Q" to an "A" code is to change the payment from the current ASP based policy to the product being included in with the CPT application code. That is, the product(s) will become incident to the service (application) and not separately reimbursable (as they currently are).

4) The intent is not for providers to have to shell out thousands of dollars for the materials with no reimbursement, but to load the cost of the materials in with the application. The effect would be to pay a flat fee no matter the brand nor the

Continued on page 130

Cellular Tissue *(from page 129)*

size of the product ordered (applied + wastage). Thus, large wounds would no longer be profitable to treat with CTP since there would be a fixed reimbursement for the materials no matter the size of the materials ordered.

5) Higher cost items may suffer as they will no longer be competitive, while lower cost products would become more competitive, with product efficacy now an afterthought.

6) A severe frequency limit would be imposed under the title "episode of care" with Medicare only paying for one application of a CTP per episode of care, no matter how many wounds and without regard to the patient's response. Exactly what defines an episode of care for diabetic patients with multiple wounds in various stages (or even recurrent wounds) remains unclear.

The rationale for these proposals lies in the fact that many of the CTPs currently on the market have poorly based studies. There also has been a significant uptick in their use combined with many successful post-payment recoupments by payers and the Recovery Audit Contractor (RAC). Most often cited deficiencies include an inconsistency between the wound size and amount of product ordered (applied + discarded). Also, often deficient are proper wound measurement (Length x Width x Depth) and adequate documentation of adequate vascularization, previous debridement, removal of biofilm, drainage quality, and adherence to other LCD requirements.

If the 2024 proposal creates concern about the potential effects this may have on your wound care patients, you are not alone. APMA and many other medical associations representing wound care providers, and industry and individual providers have submitted lengthy and detailed letters opposing the implementation of such draconian measures. The expression "Throwing the baby out with the bathwater" comes to mind and the current proposals are far too overreaching and are unlikely going to do anything about reducing abuse.

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Some providers have offered a pre-authorization proposal, similar to the newly-imposed program for certain spinal and knee orthotics. This would subject claims to chart review prior to application within a limited time frame (not more than two weeks) prior to the application. Since most of these procedures are scheduled and not urgently or emergently required, this is ample time frame for submission, review, and approval by CMS contractors. The use of the ST modifier in the rare case a CTP is emergently or urgently required would subject the claim to a pre-payment review. This system has worked well in the noted cases of certain spinal and knee orthoses, and it should also work well with CTP.

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Other concerns with the proposal are to stifle innovation of future generations of CTP, which may be high cost but more efficacious, requiring fewer applications. Payment of a low global sum, while meeting the costs of low-cost products, will still not result in adequate reimbursement for office-based applications.

The epidemic of diabetes plus the cause and effect of delayed care created by the Covid-19 pandemic has resulted in a higher demand for all wound care services, including CTP use, and has strained CMS resources. It is understandable that CMS has seen the need to "stem the tide" of payments for every healthcare service. But at what cost to our patients and what will be the result? Many who oppose the proposal believe amputation rates will soar, with costs actually escalating rather than decreasing.

By the time you read this article, the proposed 2023 Medicare Physicians Fee Schedule will be finalized and the Conversion Factor issue hopefully will be resolved for 2023 by an act of Congress. However, the debate over the 2024 proposals is likely to continue for some time. At this time (late Summer 2022), exactly how the "grass roots" and patient advocate associations are to be involved is uncertain. As with many healthcare policy proposals, hopefully this one will be significantly modified due to comments offered by professional associations before it comes close to implementation. **PM**

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.