

Anomalous Spending for Skin Substitutes

Overview

- ACOs have noticed significant increases in billings for skin substitutes since 2023. Upon review of patient medical records, ACOs are finding that use of skin substitutes does not align with clinical need.
 - Using skin substitute products in patients without control of underlying conditions or exacerbating factors. Members have reported that skin substitutes have been provided to patients who are poor candidates for specialty wound care, including hospice patients receiving significant wound care in the last 3 days of life, patients with inability to off-load pressure or transport without force, and patients who are unable to maintain adequate nutrition.
 - Exceeding recommended treatment minimums and continuing to treat wounds that are not improving. Members have reported that the number of units are increasing over time, indicating that the wound is not healing. Additionally, there is lack of use of the JW modifier indicating the number of discarded units, this would assume that the number of units are billed perfectly.
- Medicare payments for skin grafts rose from \$1.6 billion in 2022 to \$3.9 billion in 2023 and \$6.9 billion in the first three quarters of 2024.
 - These increases are driven by use of new and expensive skin graft products.
 - Increased spending is driven by a few providers. A few of the providers with the highest growth in skin graft billing have had actions taken against them by the Department of Justice.
 - There is wide geographic variation in spending increases, some states have more than a 400% increase in spending while others have less than a 100% increase in spending between 2022 and 2024.
 - The Institute for Accountable Care [analysis](#) provides additional detail and is available for NAACOS members.
- ACOs have limited ability to proactively address clinical appropriateness due to poorly defined fee-for-service (FFS) coverage guidance.
 - Medicare Administrative Contractors (MACs) have proposed Local Coverage Determinations (LCDs) for skin substitutes for lower extremity treatment of diabetic foot ulcers and venous leg ulcers.
 - The effective dates of the LCDs have been rolled back multiple times.
- ACOs are often held accountable for fraudulent spending and have limited opportunity to work with CMS and other agencies to address potential fraud.

- The increased spending for skin substitutes will be determinantal to ACOs' ability to meet benchmarks.
- ACOs are required to report suspected fraud to CMS and the HHS Office of Inspector General (OIG).
 - Frequently, ACOs report fraud and do not hear anything until months or years later when the fraudulent activity makes headlines.
 - Often, ACOs remain accountable for fraudulent spending that they reported.
 - The OIG has noted that CMS should provide a heightened level of attention to ACOs reporting fraud.
- In 2024, following ACO identification of significant widespread catheter fraud, CMS implemented policies to remove instances of significant, anomalous, and highly suspect (SAHS) billings in ACOs.
 - [Under § 425.672](#), CMS gives itself the sole discretion to identify SAHS billings that would warrant removing anomalous billings from ACO financial calculations, including performance year expenditures, trend factor updates, and benchmarks.
 - CMS established broad criteria for making SAHS determinations:
 - The billings have national or regional impact or significance;
 - Inaction would create an imbalance between ACO performance and historic benchmark expenditures;
 - The billings could result in significantly inaccurate and inequitable payment determinations that are outside of an ACO's control; or
 - The claims may disproportionately represent Medicare providers or suppliers whose Medicare enrollment status has been revoked.
 - While ACO REACH does not have a standing policy, CMS has indicated that it will apply similar approaches across MSSP and REACH.

NAACOS Recommendations

- Ensure ACOs are held harmless for any fraudulent spending for skin substitutes outside of their control.
 - The existing SAHS policies are insufficient for addressing skin substitutes and other potential areas of suspected fraud, waste, and abuse.
 - The criteria rely on significant national or regional impact; however, historically fraud, waste, and abuse has been highly localized.
 - The policy would apply to all ACOs when only a subset of impacted ACOs may need relief.
 - CMS should modify its criteria for SAHS to include:
 - Claims representing a significant volume increase in a particular billing code for a particular ACO compared to historical use (as evidenced by the claims history utilized for developing the ACO benchmark);
 - Claims for which CMS payment is paid into escrow or a "holding" account while examined for SAHS and/or fraud;
 - Claims submitted by a provider under indictment or investigation by a federal agency;

- Claims for DMEPOS that are not supported by a referral from a treating provider or by a corresponding office visit as evidenced from reliable sources such as CCLF6 (Part B DMEPOS File);
 - Claims from any DMEPOS supplier for which CMS has reversed a threshold of the claims for a performance year; and
 - Any claims for billing codes previously deemed SAHS in prior years.
 - A materiality threshold across all criteria:
 - Claims must represent a minimum percent (e.g., 0.5%) of the ACO's benchmark for the applicable performance year; and
 - Claims must be for services not provided by an ACO participant.
- Address payment challenges with skin substitutes.
 - Explore other approaches for paying for skin substitutes, such as treating skin substitutes as supplies to a physician service.
 - When implemented, the current LCD will be insufficient as ACOs have identified egregious use of skin substitutes beyond the indicated conditions. A national coverage determination approach will ease provider burden and better assist all ACOs in ensuring patients receive clinically appropriate care.
- Improve approaches for ACOs to coordinate with the government to prevent fraud, waste, and abuse.
 - CMS should establish a streamlined reporting mechanism for ACOs to report suspected fraud, waste, and abuse to CMS and OIG.
 - ACOs are a great steward of the Medicare program, regularly identifying instances of suspected fraud, waste, and abuse as part of their ongoing efforts to reduce costs and improve patient care.