

Alliance Summary- Hospital Outpatient PPS Proposed Rule July 15 2022

Moments ago CMS issued the much anticipated proposed hospital outpatient PPS regulation. We have not read the regulation yet, but only turned to the section addressing Cellular and/or Tissue Based Products for Skin Wounds (CTPs). A more detailed summary of the proposed rule will follow. In the meantime, below are highlights of the CTP proposed provisions.

1. CMS for the time being has not changed the payment methodology for CTPs in CY2023 UNLESS the provisions impacting ASP reporting in the physician fee schedule are finalized.
This means:
 - CMS will continue to determine the high cost/low cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold.
 - Proposed CY 2023 MUC threshold is \$47 per cm² (rounded to the nearest \$1) and the proposed CY 2023 PDC threshold is \$837 (rounded to the nearest \$1)
 - If the elimination of ASP reporting is finalized, then CMS will continue to place products in the high low threshold in CY 2023 using AWP or WAC. (specific language in the proposed rule: *There is a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies. If this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in CY 2023; and we would no longer be able to use ASP+6 percent pricing for a graft skin substitute product to determine whether the product should be assigned to the high cost group or the low cost group. However, manufacturers would continue to report WAC and AWP pricing information for skin substitute products through pricing compendia. Having WAC and AWP pricing will allow us to continue to use our alternative process to assign graft skin substitute products to the high cost group when cost data for a product is not available*)
2. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.
3. Retirement of C1849. Rationale according to CMS - While graft synthetic skin substitute products are described by HCPCS code C1849, FDA 510(k)-cleared biological products are not. Since CMS is moving to codes for product-specific HCPCS A-codes for synthetic graft skin substitute products and for unclassified synthetic graft skin substitute products and other unclassified FDA 510(k)-cleared products identified by HCPCS code A4100, HCPCS code C1849 is no longer necessary to bill for these products when they are used in the hospital outpatient department with graft skin substitute application procedures.

4. Any graft skin substitute product that is currently assigned a product-specific code in the HCPCS A2XXX series and is appropriately described by HCPCS code C1849 or is assigned a product-specific code in the HCPCS A2XXX series in the future and is appropriately described by HCPCS code C1849 will be assigned to the high cost skin substitute group.
5. HCPCS code A4100 (Skin substitute, fda cleared as a device, not otherwise specified) will be assigned to the low cost skin substitute group.
6. Changing nomenclature from skin substitutes to wound care management products.
7. CMS will use 1-5 years to phase in changes
8. CMS is looking for feedback on their objectives in making changes in this space. Their objectives include:
 - Ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting;
 - Ensuring that all skin substitute products are assigned an appropriate HCPCS code;
 - Using a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so we can incorporate payment methodologies that are more consistent; and
 - Maintaining clarity for interested parties on CMS skin substitutes policies and procedures