Billing and Coding: Skin Substitute Grafts/Cellular and/or Tissue-Based Products

CGS, FCSO AND NOVITAS CTP LCD CHANGES

CGS, First Coast Service Option (FCSO) and Novitas all issued their final CTP LCDs on 8/3/23. These policies will go into effect **on September 17**.

Below is a summary. Notable changes in the policies are as follows:

1. Any product designated as a wound cover will not be covered. The LCD as well as the Article spend a lot of time discussing FDA pathways as well as designation of HCT/P products. All LCDs do not cover products that are designated as a wound cover or surgical dressing.

2. Many products were added to or kept on the Group 3 Non-Covered list. Please see approved products in Group 2.

3. The LCDs states, 4 applications over a 12-week period permitted under the coverage policy. A product may be changed during treatment if it is not working but there is still a cumulative application limitation of 4 - the number of applications will not restart because a new product is being used.

4. Application of a skin substitute graft/CTP beyond the 12-week episode of skin replacement surgery will be denied.

5. The MACs have used the term ulcer management method rather than advanced therapy to describe CTPs.

6. Conservative wound care measures have been replaced in the document with the term standards of care treatment

7. CTPs will **NOT** be considered medically reasonable and necessary under the following conditions:

- Application of skin substitute grafts/CTPs in patients with inadequate control of underlying conditions or exacerbating factors, or other contraindications (e.g., uncontrolled diabetes, active infection, active Charcot arthropathy of the ulcer extremity, active vasculitis).
- Use of surgical preparation services (for example, debridement), in conjunction with routine, simple and/or repeat skin replacement surgery with a skin substitute graft/CTP.
- All liquid skin substitute products/CTPs for ulcer care.

8. The medical record must clearly document that the criteria listed in the LCD has been met, as well as the appropriate diagnosis and response to treatment. Description of the ulcer(s) must be documented at baseline (prior to beginning standard of care treatment) relative to size, location, stage, duration, and presence of infection, in addition to the type of standard of care treatment given and the response. This information must be updated in the medical record throughout the patient's treatment. It

is expected that the response of the ulcer to treatment will be documented in the medical record at least once every 30 days. The ulcer description must also be documented pre- and post- treatment with the skin substitute graft/CTP being used. The reason(s) for any repeat application should be specifically addressed in the medical record.

9. EVERY page of the medical record must be legible

10. Manufacturers are required to obtain a Tissue Reference Group (TRG) letter from CMS and provide it to the MACs to be considered for inclusion in the Group 2 covered product list.

11. Still requiring that the JZ or JW modifiers be used