Request# 20.054

Topic/Issue:

Request to establish a new Level II HCPCS code to identify a Wharton's jelly-derived human tissue allograft.

Trade name: CoreText/ProText

Applicant's suggested language: CoreText, ProText, per cc

Applicant's Summary

Regenative Labs requests a new Level II HCPCS code for CoreText/ProText.

CoreText and ProText are regulated by the FDA as a human tissue product subject to Section 361 of the Public Service Act and 21 CFR 1271. The products are very similar. Wharton's jelly products have been shown to reduce scarring, fibrosis and adhesions in surgical and wound sites. The difference between ProText and CoreText is that the cell sorter used in the preparation of Protext is 300 um mesh and for CoreText is 200um. Thus the particle fiber size is larger for ProText. Both the products are intended to provide the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for the repair of damaged tissue. They are typically used for muscle and cartilage tears and help to repair damaged tissue. The products are used for wounds and tissue defects and is applied directly to the defect using a syringe. The amount used depends on the size of the defect and the clinicians' discretion. As per applicant, each human tissue based product distributed by Regenative Labs is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a cryogenic primary tissue container, which contains a product label that includes the product details such as unique product number, storage requirements and volumes. Contents are aseptically processed and are not considered sterile.

According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific, therefore there isn't a code that can presently be used to identify the products.

CMS Decision

Establish a new Level II HCPCS code Q4246 "Coretext or Protext, per cc."

Effective: 07/01/2020

Request# 20.055

Topic/Issue:

Request to establish a new Level II HCPCS code for Amniotext patch.

Applicant's suggested language: Amniotext patch, per square centimeter.

Applicant's Summary

Regenative Labs requests a new Level II HCPCS code for Amniotext patch.

Amniotext patches are minimally manipulated, amniotic membrane-derived, human tissue allografts. The product serves as wound covering. It is typically used for chronic non-healing wounds such as diabetic foot ulcers and venous leg ulcers. It provides the extracellular matrix needed for the infiltration, attachment and proliferation of cells required for repair of damaged tissue. The graft is applied directly to the wound bed and is available in various sizes, the size used matches the wound defect. As per applicant, each human tissue based product distributed by Regenative Labs is identified by its own unique serial number. The product is packaged in a transport protective pouch. The product is contained in a dual package tissue container system, in which the outermost ploy-foil pouch contains a product label that includes the product details such as unique product number, storage requirements and size. Contents are aseptically processed and sterilized, and are considered sterile.

According to the applicant, currently available HCPCS codes for skin substitutes are product and brand specific, therefore, there is no code that can presently be used to identify the product.

CMS Decision

Establish a new Level II HCPCS code Q4247 "Amniotext patch, per square centimeter."

Effective: 07/01/2020